CONTENTS June 2011

I. EXECUTIVE ORDER

BJ 11-08 Executive Branch—DOTD Guidelines for Vehicles, Trucks and Loads Which Haul Hay from Louisiana to Texas 1477
BJ 11-09 Merit Increase Freeze 1477
BJ 11-10 Flags at Half Staff 1478

II. EMERGENCY RULES

Governor

Coastal Protection and Restoration Authority—Prohibition of Activities on Levees and Flood Control Structures (LAC 4:VII.2795) 1479

Health and Hospitals

Bureau of Health Services Financing—Disproportionate Share Hospital Payments (LAC 50.V.2501, 2701, 2705, and 2707) 1481
Federally Qualified Health Centers—Diabetes Self-Management Training (LAC 50:XI.Chapters 103-105 and 10701) 1483
Home and Community-Based Services Waivers—Adult Day Health Care (LAC 50:XXI.2103, 2107, 2301, 2501, 2503, 2701, 2901-2905 and 2915) 1485
Home and Community-Based Services Waivers—Elderly and Disabled Adult Waiver—Emergency Opportunities and Reimbursement Methodology (LAC 50:XXI.8105, 9101, 9107-9121) 1490
Home and Community-Based Service Providers—Minimum Licensing Standards (LAC 48:I.Chapter 50) 1500
Inpatient Hospital Services—Major Teaching Hospitals—Supplemental Payments (LAC 50:V.1333) 1532
Inpatient Hospital Services—Major Teaching Hospitals—Qualifying Criteria (LAC 50:V.1301-1309) 1533
Inpatient Hospital Services—Neonatal and Pediatric Intensive Care Units and Outlier Payment Methodologies (LAC 50:V.953-954 and 967) 1535
Intermediate Care Facilities for Persons with Developmental Disabilities—Public Facilities Reimbursement Methodology (LAC 50:VII.32965-32969) 1538
Medical Transportation Program—Emergency Ambulance Services—Supplemental Payments (LAC 50:XXVII.327) 1539
Nursing Facilities—Minimum Licensing Standards—Approval of Facility Plans (LAC 48:I.9707) 1541
Nursing Facilities—Reimbursement Methodology—Direct Care Multiplier and Fair Rental Value Component (LAC 50:II.20005) 1541
Outpatient Hospital Services—Diabetes Self-Management Training (LAC 50:V.Chapter 63) 1542
Professional Services Program—Diabetes Self-Management Training (LAC 50:IX.Chapter 7 and 15103) 1543
Professional Services Program—Reimbursement Methodology—Supplemental Payments (LAC 50:IX.15151 and 15153) 1544
Rural Health Clinics—Diabetes Self-Management Training (LAC 50:XI.Chapters 163-165 and 16701) 1546

Natural Resources

Office of Conservation—Statewide Orders No. 29-B and 29-B-a (LAC 43:XIX.Chapters 2 and 11) 1547

Wildlife and Fisheries

Office of the Secretary—Atchafalaya Basin Closure Continuation 1559
Atchafalaya Basin Flooding Closure 1559
Wildlife and Fisheries Commission—Oyster Bedding Season—CSA 1 1560

III. RULES

Education

Board of Elementary and Secondary Education—Bulletin 746—Louisiana Standards for State Certification of School Personnel—Requirements to Add Early Childhood (Grades PK-3)(LAC 28:CXXXI.605) 1561
Student Financial Assistance Commission, Office of Student Financial Assistance—Scholarship/Grant Programs—Academic Year (LAC 28:IV.301) 1561
Scholarship/Grant Programs—Tuition (LAC 28:IV.301) 1562

This public document was published at a total cost of $5,580. Five hundred copies of this public document were published in this monthly printing at a cost of $5,580. The total cost of all printings of this document including reprints is $5,580. This document was published by Moran Printing, Inc. 5425 Florida Boulevard, Baton Rouge, LA 70806, as a service to the state agencies in keeping them cognizant of the new rules and regulations under the authority of R.S. 49:950-971 and R.S. 49:981-999. This material was printed in accordance with standards for printing by state agencies established pursuant to R.S. 43:31. Printing of this material was purchased in accordance with the provisions of Title 43 of the Louisiana Revised Statutes.

The Office of the State Register provides auxiliary aids for the *Louisiana Register* for visually impaired individuals. By appointment, oral presentation of the *Register* is available at the Office of the State Register, or an audiocassette tape of requested sections of the *Register* can be provided for the cost incurred by the Office of the State Register in producing such a tape. For more information contact the Office of the State Register.

Environmental Quality
Office of the Secretary—Emergency Response for Solid Waste Facilities (LAC 33:VII.115, 513, 521, 711, 713, 715, 717, 721, 723 and 725)(SW054) ... 1563
$PM_{2.5}$ NSR Implementation (LAC 33:III.504 and 509)(AQ318) ... 1568
Health and Hospitals
Board of Veterinary Medicine—Prescribing and Dispensing Drugs—Preceptorship Program (LAC 46:LXXXV.705 and 1105) ... 1571
Bureau of Health Services Financing—All Inclusive Care for the Elderly—Reimbursement Rate Reduction (LAC 50:XXIII.1301) ... 1572
Ambulatory Surgical Centers—Reimbursement Rate Reduction (LAC 50:XI.7503) ... 1572
Coordinated Care Network (LAC 50:I.Chapters 31-40) ... 1573
Early and Periodic Screening, Diagnosis and Treatment—Dental Program—Covered Services and Reimbursement Rate Reduction (LAC 50:XV.6903 and 6905) ... 1598
Early and Periodic Screening, Diagnosis and Treatment—Health Services—EarlySteps Reimbursement Rate Reduction (LAC 50:XV.7107) ... 1599
End Stage Renal Disease Facilities—Reimbursement Rate Reduction (LAC 50:XI.6901 and 6903) ... 1599
Family Planning Clinics—Reimbursement Rate Reduction (LAC 50:XI.3501) ... 1600
Outpatient Hospital Services—Duration of Outpatient Status (LAC 50:V.5107) ... 1600
Prosthetics and Orthotics—Osteogenic Bone Growth Stimulators (LAC 50:XVII.10501-10505) ... 1600
Licensed Professional Counselors Board of Examiners—License of Title for Marriage and Family Therapy (LAC 46:LX. 3303, 3305, 3309 and 3311) ... 1601
Office of Aging and Adult Services—All Inclusive Care for the Elderly—Reimbursement Rate Reduction (LAC 50:XXIII.1301) ... 1571
Louisiana Physician Order for Scope of Treatment (LAC 48:I.Chapter 2) ... 1603
Governor
Crime Victims Reparations Board—Compensation to Victims (LAC 22:XIII. 103, 301, and 503) ... 1605
Commission on Law Enforcement and Administration of Criminal Justice—Peace Officer Training (LAC 22:III.4703 and 4750) ... 1606
Department of Veterans Affairs—Military Family Assistance Program (LAC 4:VII.961-987) ... 1606
Office of Financial Institutions—Broker-Dealer and Investment Adviser Recordkeeping Requirements (LAC 10:XIII.Chapter 17) ... 1611
Used Motor Vehicle Commission—Licensure and Established Place of Business (LAC 46:V.2905 and 2907) ... 1612
Public Safety and Corrections
Office of State Police, Transportation and Environmental Safety Section—Federal Motor Carrier Regulations (LAC 33:V.10303) ... 1613
Revenue
Policy Service Division—Electronic Filing Requirements for Oil or Gas Severance Tax (LAC 61:III.1525) ... 1613
Treasury
Board of Trustees of the Louisiana State Employees' Retirement System—Election to the Board of Trustees (LAC 58:I.Chapters 3, 4, and 5) ... 1614
Deferred Compensation Commission—Public Employees Deferred Compensation Plan (LAC 32:VII.101, 301, 305, 317, 323, 709,721, 723, and 1107) ... 1617
Wildlife and Fisheries
Wildlife and Fisheries Commission—Methods of Payment for Commercial Licenses and Oyster Tags (LAC 76:VII.413) ... 1622
Oyster Leases (LAC 76:VII.501) ... 1622
Public Seed Grounds East of the Mississippi River and Oyster Lease Relocation (LAC 76:VII.511 and 531) ... 1624
Workforce Commission
Office of Workers' Compensation—Hearing Rules (LAC 40:I.5501-6627) ... 1625
Medical Guidelines (LAC 40:I.Chapters 20-23) ... 1631

IV. NOTICES OF INTENT
Education
Board of Elementary and Secondary Education—Bulletin 111—The Louisiana School, District, and State Accountability System (LAC 28:LXXXIII.2401 and 2403) ... 1764
Bulletin 741—Louisiana Handbook for School Administrators—Red Tape Reduction Waiver and Local Empowerment Program (LAC 28:CXV.344) ... 1866
Bulletin 741 (Nonpublic)—Louisiana Handbook for Nonpublic School Administrators (LAC 28:LXXIX.2109, 2331, and 2335) ... 1869
Student Financial Assistance Commission—LASFAC Committees (LAC 28:V.107 and 109) ... 1871
TOPS Equivalent Courses (LAC 28:IV.703) ... 1872
Tuition Trust Authority—LATTA Committees (LAC 28:VII.107 and 109) ... 1873
Health and Hospitals
Board of Chiropractic Examiners—Specialty Advertising, Unethical Conduct, Code of Ethics (LAC 46:XXVII.320, 501, and 502) ... 1875

Board of Nursing—Alternative to Disciplinary Proceedings (LAC 46:XLVII.3419) 1877
Paperless Licensing Revisions (LAC 46:XLVII.3323, 3329, 3333, 3339, and 4507) 1878
Bureau Health Services Financing—Federally Qualified Health Centers—Diabetes Self-Management Training (LAC 50:XI.Chapters 103-105 and 10701) 1880
Home and Community-Based Services Waivers—Adult Day Health Care (LAC 50:XXI.2103, 2107, 2301, 2501, 2503, 2701, 2901-2905, and 2915) 1883
Home and Community-Based Service Providers—Minimum Licensing Standards (LAC 48:I.Chapter 50) 1888
Nursing Facilities—Minimum Licensing Standards—Approval of Facility Plans (LAC 48:I.9707) 1921
Nursing Facilities—Reimbursement Methodology—Direct Care Multiplier and Fair Rental Value Component (LAC 50:II.20005) 1922
Rural Health Clinics—Diabetes Self-Management Training (LAC 50:XI.Chapters 163-165 and 16701) 1924
Office of the Secretary—Community and Family Support System—Flexible Family Fund (LAC 48:I.Chapter 161) 1926
Office of Public Health—Milk Code (LAC 51:VII; VIII; XXI.105; XXII.1115, 4525, and 4527) 1930
Natural Resources
Office of Conservation—Surface Mining—Statewide Order 29-O-1 (LAC 43:XV.Chapters 1, 23, 29, 31, 35, 54, 65, and 85) 2025

V. POTPOURRI
Health and Hospitals
Bureau of Health Services Financing—Professional Services Program—Optometry Services 2033
Office of Public Health, Maternal and Child Health Section—Public Notice of MCH Block Grant 2033
Natural Resources
Office of Conservation—Orphaned Oilfield Sites 2033
Public Hearing—Docket No. ENV 2011-08 2033
Office of the Secretary, Fishermen's Gear Compensation—Loran Coordinates 2034
Public Safety and Corrections
Board of Private Security Examiners—Little Lake Crude Oil Discharge Draft Settlement Agreement 2034
Revenue
Policy Services Division—Natural Gas Severance Tax Rate 2035
Senate
Senate Committee on Health and Welfare—Legislative Oversight Review—Physical Therapy (LAC 46:LIV.Chapters 1-5) 2035
Transportation and Development
Professional Engineering and Land Surveying Board—Public Hearing—Substantive Changes to Proposed Rules—General Provisions (LAC 46:LXI.Chapters 7, 9, 13, 15, 17, 23, 29 and 31) 2035

VI. INDEX 2038

Executive Orders

EXECUTIVE ORDER BJ 11-08

Executive Branch—DOTD Guidelines for Vehicles, Trucks and Loads Which Haul Hay from Louisiana to Texas

WHEREAS, R.S. 32:387 sets forth the terms and conditions whereby vehicles hauling certain loads may be issued special permits by the Department of Transportation and Development if they are in excess of legal statutory size and weight limits;

WHEREAS, as a result of the effects of a severe and extended drought condition in areas of Texas, a dire necessity has arisen for oversize loads of hay to be expeditiously moved from Louisiana to Texas;

WHEREAS, the economic vitality of the farming industry is extremely dependent on the availability of hay for feed for the livestock; and

WHEREAS, in order to provide emergency assistance to Texas farmers, the State of Louisiana is willing to waive certain permits, fees, and other obligations normally incurred by transporters;

NOW THEREFORE, I, BOBBY JINDAL, Governor of the State of Louisiana, by virtue of the authority vested by the Constitution and the laws of the State of Louisiana, do hereby order and direct as follows:

SECTION 1: The Department of Transportation and Development, the Department of Public Safety, and the Department of Revenue shall waive the following statutory requirements for the shipment of hay:

A. The following sizes and weights for vehicles transporting hay on highways maintained by the State of Louisiana shall not exceed the following limitations without permits:

1. All such vehicles transporting round hay bales to be loaded side by side across trailers creating an dimensions that shall not to exceed twelve (12) feet in width and shall not exceed fourteen (14) feet in height.

B. Permit fees are waived for all carriers while engaged in the transportation of hay to the victims of the drought in Texas.

C. The following requirements shall remain in effect:

1. All such vehicles must travel during daylight hours only, beginning at sunrise and ending at sunset.

2. All such vehicles must travel with the required signs and flags properly placed and indicating that they bear oversized loads.

3. Vehicles must be equipped with mirrors so that drivers are able to have a clear view of the highway at least 200 feet to the rear of the vehicle.

4. Loads must be securely bound to the transporting vehicles.

E. Carriers, owners and/or drivers of any vehicle being operated under this Order are responsible for verifying in advance that the actual dimensions and weights of the vehicles and loads are acceptable for all routes being traveled.

SECTION 2. Nothing in this Order shall be construed to allow any vehicle to exceed weight limits posted for bridges and similar structures, or relieve any vehicle or carrier, owner or driver of any vehicle from compliance with any restrictions other than those specified, or from any statute, rule, order or other legal requirement not specifically waived herein.

SECTION 3. This Order is effective upon signature and shall terminate on September 30, 2011 unless amended, modified, terminated or rescinded by the Governor, or terminated by operation of law.

IN WITNESS WHEREOF, I have set my hand officially and caused to be affixed the Great Seal of

Louisiana, at the Capitol, in the city of Baton Rouge, on this 12th day of May, 2011.

Bobby Jindal
Governor

ATTEST BY
THE GOVERNOR
Tom Schedler
Secretary of State
1106#034

EXECUTIVE ORDER BJ 11-09

Merit Increase Freeze

WHEREAS, extraordinary budgetary shortfalls may require continuing cost reduction measures for the 2010-2011 fiscal year and additional shortfalls are expected during the 2011-2012 fiscal year; and

WHEREAS, it is critical to prioritize critical services to our citizens over pay increases for unclassified employees; and

WHEREAS, difficult and challenging times call for fiscal prudence and shared sacrifice among all of us who serve our fellow citizens; and

WHEREAS, the Governor pursuant to the Constitution and Laws of Louisiana, specifically, La. R.S. 39:75(B)(3), may issue executive orders prohibiting the expenditure of monies for specific items.

NOW THEREFORE, I, BOBBY JINDAL, Governor of the State of Louisiana, by virtue of the authority vested in me by the Constitution and laws of Louisiana do hereby order and direct as follows:

SECTION 1: The authority to award merit increases for all unclassified employees is frozen beginning immediately and continuing through June 30, 2012. During this period of suspension, no appointing authority may grant a merit increase to any unclassified employee nor may any unclassified employee gain eligibility for a merit increase.

SECTION 2: All other elected state officials or entities with constitutional authority are urged to join in this effort to preserve state services to our citizens by exercising their authority to suspend the awarding of salary increases to unclassified state employees starting immediately and continuing through the duration of the 2011/12 fiscal year.

SECTION 3: This freeze shall not affect promotions and performance Planning and Review requirements. Appointing authorities must continue to comply with all Civil Service Rules regarding performance planning and review of employees.

SECTION 4: This Order is effective upon signature and shall continue in effect until amended, modified, terminated, or rescinded by the Governor, or terminated by operation of law.

IN WITNESS WHEREOF, I have set my hand officially and caused to be affixed the Great Seal of Louisiana, at the Capitol, in the city of Baton Rouge, on this 1st day of June, 2011.

Bobby Jindal
Governor

ATTEST BY
THE GOVERNOR
Tom Schedler
Secretary of State
1106#09

EXECUTIVE ORDER BJ 11-10

Flags at Half Staff

WHEREAS, Louisiana Department of Insurance Fraud Section Investigators Kim Sledge and Rhett Jeansonne, both residents of Denham Springs, Louisiana, tragically lost their lives in the line of duty on June 7, 2011; and

WHEREAS, Investigator Kim Sledge began her LDI career in October of 2000, first with the Health Division and subsequently with the Fraud Section. She is survived by her husband JC, daughter Brittany, and her young step children Avery and Jacob. In addition, Kim will be missed by her mother and sisters, and her many friends. She is remembered by her friends and colleagues as a "true country girl" with a love of being outdoors, working in her yard, and caring for her animals; and

WHEREAS, Investigator Rhett Jeansonne began his LDI career in November 2006 as an Investigator. He is survived by his wife Bernadette and their seven year old daughter Sharon, along with his three sons, Kristopher, Kale, and Konner and a grandson, born on May 18th. His many achievements include: National EMS certification, Firefighter and Emergency Responder certification and EMT certification. He served as a volunteer firefighter in Denham Springs. He worked for the State Fire Marshall's office prior to joining the LDI staff. He was also a CPR instructor who trained some of the LDI staff, safety warden, and POD volunteer for the Department; and

WHEREAS, Investigators Kim Sledge and Rhett Jeansonne's dedicated service and ultimate sacrifice make it appropriate and fitting for the State of Louisiana to remember them and their families, to mark their passing, and to honor their memory;

NOW THEREFORE, I, BOBBY JINDAL, Governor of the State of Louisiana, by virtue of the authority vested by the Constitution and laws of the State of Louisiana, do hereby order and direct as follows:

SECTION 1: As an expression of respect for Investigators Kim Sledge and Rhett Jeansonne, effective immediately, the flags of the United States and the State of Louisiana shall be flown at half staff over the State Capitol and all public building and institutions of the State of Louisiana until sunset on Friday, June 10, 2011.

SECTION 2: This Order is effective upon signature and shall remain in effect until sunset, Friday, June 10, 2011, unless amended, modified, terminated, or rescinded prior to that date.

IN WITNESS WHEREOF, I have set my hand officially and caused to be affixed the Great Seal of Louisiana, at the Capitol, in the city of Baton Rouge, on this 9th day of June, 2011.

Bobby Jindal
Governor

ATTEST BY
THE GOVERNOR
Tom Schedler
Secretary of State
1106#036

Emergency Rules

DECLARATION OF EMERGENCY

Office of the Governor
Coastal Protection and Restoration Authority

Prohibition of Activities on Levees and
Flood Control Structures (LAC 4:VII.2795)

The Coastal Protection and Restoration Authority has exercised the Emergency Rule provision provided in R.S. 49:953(B), of the Administrative Procedure Act and has adopted the following Emergency Rule to adopt LAC 4:VII.2795.A.1, Emergency Prohibition of Activities on Levees and Flood Control Structures, which restricts activities on and in the vicinity of flood control levees and other flood control structures of the Mississippi River and its tributaries ("MR and T") or any federal, state or local flood control structure that is or is designed to prevent or reduce flooding, including but not limited to all levees and flood control structures south of the Old River Control Structure, the Atchafalaya Basin and River, and any levee or flood control structure in the coastal area as defined in R.S. 49:214.2(3), and provides for waivers of these prohibitions where appropriate to prevent an undue hardship on existing commerce and floodway residents in the affected areas.

Activities on and in the vicinity of riverine levees, flood control levees, and other flood control structures can impact the soundness and effectiveness of levees and flood control structures, and these threats are enhanced as river stages rise. Any levee or other flood control structure breach or failure during high river stages can be catastrophic, resulting in the loss of property and lives. The Mississippi River and its tributaries have risen to dangerously high levels in recent days prompting a Declaration of Emergency by the governor of Louisiana (Proclamation No. 41 BJ 2011), and currently pose real and present danger to life and property in the affected areas, thus necessitating the adoption of this Emergency Rule regulating activities on and in the vicinity of flood control levees and other flood control structures.

The Coastal Protection and Restoration Authority has determined that failure to restrict activity on and in the vicinity of riverine levees, flood control levees, and other flood control structures may lead to the danger of imminent peril to the public health, safety and welfare of the people and property of the state of Louisiana. The emergency rule (LAC 4:VII:2795, Emergency Prohibition of Activities on Levees and Flood Control Structures) has been adopted by the Coastal Protection and Restoration Authority effective as of 5 p.m. on May 17, 2011, and it will remain in effect until the earlier of its expiration date as provided by statute (R.S. 49:954), or upon the lifting by the governor of the Declaration of Emergency set forth in Proclamation No. 41 BJ 2011.

The authority for adoption of emergency action in this instance rests on the authority of the Coastal Protection and Restoration Authority, in La. Revised Statutes Title 49, Section 214.1 et seq., to establish procedures in accordance with the Administrative Procedure Act to enforce compliance with the comprehensive master and annual coastal protection plan as defined in La. R.S. 49:214 et seq. La. Revised Statutes Title 49, section 214.5.6 (D) provides that the "full police power of the state shall be exercised" by the CPRA "to address the loss and devastation to the state and individuals arising from hurricanes, storm surges and flooding." The Coastal Protection and Restoration Authority is further authorized in Revised Statutes Title 49, section 214.5.2.A(5), to delegate any of its powers, duties and functions to the executive director of the Office of Coastal Protection and Restoration, and to state agencies and political subdivisions, including flood protection authorities or levee districts. Enforcement of the restrictions is delegated to levee districts and all other state and local law enforcement officials; however, the Coastal Protection and Restoration Authority retains primacy for the enforcement of these regulations. This emergency regulation is enacted in furtherance of that authority. R.S. 29:724 authorizes the issuance of executive orders, proclamations and regulations in times of emergency. This regulation is promulgated in conjunction with the governor's Declaration of Emergency (Proclamation No. 41 BJ 2011) pertaining to the imminent threat of flooding of the Mississippi River and its tributaries.

Title 4
ADMINISTRATION
Part VII. Governor's Office
Chapter 27. Coastal Protection and Restoration Authority
§2795. Emergency Regulations

A. Emergency Prohibition of Activities on Levees and Flood Control Structures

1. Restricted Use During Emergency

a. Purpose. Activities on and in the vicinity of riverine levees, flood control levees, and other flood control structures can impact the soundness and effectiveness of those levees and flood control structures. Threats are enhanced as river stages rise. Levee failure during high river stages can be catastrophic. The Mississippi River and its Tributaries (MR and T) have risen to dangerously high levels in recent days prompting a Declaration of Emergency by the governor of Louisiana (Proclamation No. 41 BJ 2011), and currently pose real and present danger to life and property if levees and/or flood control structures are breached.

b. Effective Jurisdiction. These Emergency Prohibitions of Activities on Levees and Flood Control Structures will be effective and enforced for all Mississippi River and tributaries (MR and T) projects, or a federal, state or local flood control structure that is or is designed to prevent or reduce flooding, including but not limited to all levees and flood control structures south of the Old River Control Structure, the Atchafalaya Basin and River, and any levee or flood control structure in the Coastal Area as defined in R.S. 49:214.2(3).

c. All pedestrian and vehicular traffic, including but not limited to, the driving and/or parking of vehicles, all-terrain vehicles, and mowing equipment, is prohibited within

300 feet of the levee centerline of the MR and T projects, or a federal, state or local flood control structure that is or is designed to prevent or reduce flooding except as provided in Subparagraph f of this Paragraph. In addition, work of any nature within 300 feet of the levee centerline of the Mississippi River and tributaries (MR and T) projects, or a federal, state or local flood control structure that is or designed to prevent or reduce flooding (including but not limited to placement of dumpsters, heavy equipment, heavy machinery, heavy trucks and/or stockpiles of supplies of any significant weight (fuel tanks, piping, etc.), transport of heavy loads over the levee or disturbing the grass cover or seepage areas, all subsurface work within 1,500 feet of a MR and T levee, or a federal, state or local flood control structure that is or is designed to prevent or reduce flooding including but not limited to pile driving, digging, excavation, and trenching, and seismic surveys/demolition using explosives within 5,000 feet of any MR and T project, or a federal, state or local flood control project that is or is designed to prevent or reduce flooding is hereby prohibited during the Declaration of Emergency or until this emergency rule is rescinded. Temporary measures such as sandbags, gabion baskets, water-filled tubes or other temporary flood-fighting measures shall be subject to prohibitions on vehicular and pedestrian traffic and any activity that disturbs the performance of such measures, however, subsurface and permitting restrictions established herein shall not apply to such temporary structures.

d. No person shall tie or moor logs, rafts, boats, water craft, or floating objects of any description within 100 feet of the original toe of any levee (the original toe being that established when there is no water against the levee) or 180 feet from the centerline of the levee, whichever distance is further from the centerline of the levee, or, when the water is against the levees, tie or moor floating objects insecurely to mooring posts, revetments, trees or other stationary or supposedly stationary objects on the foreshore where they can be driven against the levees during windstorms or high water events.

e. Waivers to recognized, permitted and current businesses may be granted on a case by case basis, and are dependent on the surrounding surface and subsurface ground conditions in the vicinity of the proposed project or activity, the distance the project is away from the levee and the forecasted river stages. All applications for a waiver must provide a statement that the applicant agrees to hold harmless and indemnify the authority, the state, or any employee or agent thereof for any and all liability arising out of the issuance or use of a waiver, including damage to any levee or flood protection structure. All waiver applications must include a copy of the applicant's existing permit and a detailed description of the activities for which a waiver is being requested. No waiver will be granted for subsurface work within 1,500 feet of a MR and T levee, hurricane protection project or a federal, state or local flood control project, and seismic surveys/demolition using explosives within 5,000 feet of any MR and T project, or a federal, state or local flood control project that is or is designed to prevent or reduce flooding. Requests for waivers shall be submitted to, the levee district of jurisdiction or:

Office of Coastal Protection and Restoration
Flood Protection Division
ATTN: John Monzon
450 Laurel Street, Suite 1200
Baton Rouge, LA 70804

f. The CPRA recognizes the historic nature of this high water event. In this regard, levee districts are permitted to coordinate with the U.S. Army Corps of Engineers, CPRA, and other state and local law enforcement officials to establish limited viewing areas that have a full-time law enforcement presence when open to the public.

g. Authorization and Delegation. The Coastal Protection and Restoration Authority is authorized, in Revised Statutes Title 49, section 214.5.2.A(6), to establish procedures in accordance with the Administrative Procedure Act to enforce compliance with the comprehensive master and annual coastal protection plan as defined in R.S. 49:214 et seq. Revised Statutes Title 49, section 214.5.6(D) provides that the "full police power of the state shall be exercised" by the CPRA "to address the loss and devastation to the state and individuals arising from hurricanes, storm surges and flooding". It is further authorized in Revised Statutes Title 49, section 214.5.2.A(5), to delegate any of its powers, duties and functions to the Executive Director of the Office of Coastal Protection and Restoration, and to state agencies and political subdivisions, including flood protection authorities or levee districts. This emergency regulation is enacted in furtherance of that authority. R.S. 29:724 authorizes the issuance of executive orders, proclamations and regulations in times of emergency. This regulation is promulgated in conjunction with the governor's Declaration of Emergency (Proclamation No. 41 BJ 2011) pertaining to the imminent threat of flooding of the Mississippi River and its tributaries.

h. Construction with Other Statutes, Ordinances and Regulations. To the extent any local ordinance, rule, regulation, and/or permitting requirement of a local governing body conflicts with the provisions of this regulation, this regulation shall control. However, nothing in this regulation shall be construed to supplant or override any local ordinance, rule, regulation, and/or permitting requirement that provides for a more stringent or restrictive limitation on use of a levee, hurricane protection project or a federal, state or local flood control project, and nothing shall be construed to prevent the simultaneous enforcement of this regulation and a consistent local prohibition or limitation. This regulation will not be construed to override existing limitations on use of levees, hurricane protection projects or federal, state or local flood control projects, including, but not limited to, the provisions of R.S. 38:213 (restricting riding or hauling on levees), or to interfere in any way with other statutory prohibitions of a more general nature, such as the trespass prohibitions found in Title 14 of the Louisiana Revised Statutes, all of which may be enforced simultaneously with this regulation.

i. Effectiveness. Except as noted in the following sentence, this emergency regulation is effective as of 5:00 P.M., May 17, 2011, and shall expire on the earlier of its expiration date as provided by statute (R.S. 49:954), or upon

the lifting by the governor of the Declaration of Emergency set forth in Proclamation No. 41 BJ 2011. This regulation shall become effective as to established and permitted commercial businesses operating within an area affected by this regulation 72 hours after the effective date and time of this regulation (as noted in the prior sentence), provided that if such permitted business has, prior to expiration of such 72 hour period, applied for a waiver as set forth above in Subparagraph D of this Paragraph, such waiver application shall act as a temporary waiver permit until OCPR has taken action on that business's waiver request.

j. Enforcement. The CPRA, Office of Coastal Protection and Restoration, levee districts as well as all other state and local law enforcement officials are hereby authorized to enforce the provisions of this regulation.

k. Fees, Fines and Penalties. Violators of this regulation shall be subject to a civil fine imposed by the Office of Coastal Preservation and Restoration of up to $10,000 for each violation. Second and any subsequent violations shall be subject to a civil fine of up to $20,000 for each violation. Violators shall also be subject to the provisions of R.S. 29:724(E) which provides for up to $500 and six months in jail for violations of rules or regulations promulgated in conjunction with a Declaration of emergency by the governor. Further, nothing in this regulation is intended to interfere with or prohibit the imposition of other applicable fines and penalties provided by other statutes and regulations in addition to those imposed by this regulation.

l. Non-interference with Official Duties. This regulation shall not be construed to restrict the proper officers of the state or of any levee district or parish or the federal government and the employees and agents of such governmental entities while in the performance of their duty in inspecting, guarding, or repairing the levees or flood control projects.

AUTHORITY NOTE: Promulgated in accordance with R.S. 49:214.1 et seq.

HISTORICAL NOTE: Promulgated by the Office of the Governor, Coastal Protection and Restoration Authority, LR 37:

Garret Graves
Chairman

1106#003

DECLARATION OF EMERGENCY

Department of Health and Hospitals
Bureau of Health Services Financing

Disproportionate Share Hospital Payments
(LAC 50.V.2501, 2701, 2705, and 2707)

The Department of Health and Hospitals, Bureau of Health Services Financing amends LAC 50:V.2501, §§2705, 2701, 2705, and 2707 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This Emergency Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:953(B)(1) et seq., and shall be in effect for the maximum period allowed under the Act or until adoption of the final Rule, whichever occurs first.

The Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing amended the provisions governing disproportionate share hospital (DSH) payments to revise the provisions governing non-rural community hospitals and federally mandated statutory hospitals to clarify that hospitals qualifying as a non-rural community hospital in state fiscal year 2007-08 may also qualify in the federally mandated statutory hospital category, and to revise the definition of a non-rural community hospital (*Louisiana Register,* Volume 34, Number 11). In compliance with Act 228 of the 2009 Regular Session of the Louisiana Legislature, the department promulgated an Emergency Rule to amend the provisions governing disproportionate share hospital payments to reallocate any remaining funds from the fiscal year 2009 DSH appropriation to non-rural community hospitals and issue a supplemental payment to these hospitals for their uncompensated care costs (*Louisiana Register,* Volume 35, Number 7).

Act 10 of the 2009 Regular Session of the Louisiana Legislature directed the department to amend the DSH qualifying criteria and payment methodologies for non-rural community hospitals. In compliance with Act 10, the Department of Health and Hospitals, Bureau of Health Services Financing promulgated an Emergency Rule which amended the provisions of the June 26, 2009 Emergency Rule governing supplemental DSH payments to non-rural community hospitals (*Louisiana Register*, Volume 36, Number 1). The department promulgated an Emergency Rule which amended the January 20, 2010 Emergency Rule to amend the provisions governing supplemental DSH payments to non-rural community hospitals in order to redistribute the funds allocated for the state fiscal year 2010 DSH appropriation (*Louisiana Register*, Volume 36, Number 7).

The department now proposes to amend the June 29, 2010 Emergency Rule to revise the provisions governing DSH payments to allow for additional payments after completion of the Centers for Medicare and Medicaid Services' mandated independent audit for the state fiscal year. This action is being taken to promote the public health and welfare of uninsured individuals and to ensure their continued access to health care by assuring that hospitals are adequately reimbursed for furnishing uncompensated care.

Effective June 20, 2011, the Department of Health and Hospitals, Bureau of Health Services Financing amends the provisions of the June 29, 2010 Emergency Rule governing DSH payments.

Title 50
PUBLIC HEALTH—MEDICAL ASSISTANCE
Part V. Medical Assistance Program—Hospital Services
Subpart 3. Disproportionate Share Hospital Payments
Chapter 25. Disproportionate Share Hospital Payment Methodologies

§2501. General Provisions

A. - B.3. ...

4. Qualification is based on the hospital's latest filed cost report and related uncompensated cost data as required by the Department. Qualification for small rural hospitals is based on the latest filed cost report. Hospitals must file cost reports in accordance with Medicare deadlines, including extensions. Hospitals that fail to timely file Medicare cost reports and related uncompensated cost data will be assumed to be ineligible for disproportionate share payments. Only

hospitals that return timely disproportionate share qualification documentation will be considered for disproportionate share payments. After the final payment during the state fiscal year has been issued, no adjustment will be given on DSH payments with the exception of public state-operated hospitals, even if subsequently submitted documentation demonstrates an increase in uncompensated care costs for the qualifying hospital. After completion of a Center for Medicare and Medicaid Services' (CMS) mandated independent audit for the state fiscal year, additional payments may occur subject to the conditions specified in §2701 B.1, §2705.D.2, and §2707.B. For hospitals with distinct part psychiatric units, qualification is based on the entire hospital's utilization.

B.5. - E. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 34:654 (April 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:65 (January 2010), amended LR 36:512 (March 2010), LR 37:

Chapter 27. Qualifying Hospitals

§2701. Non-Rural Community Hospitals

A. …

B. DSH payments to a public, non-rural community hospital shall be calculated as follows.

1. Each qualifying public, non-rural community hospital shall certify to the Department of Health and Hospitals its uncompensated care costs. The basis of the certification shall be 100 percent of the hospital's allowable costs for these services, as determined by the most recently filed Medicare/Medicaid cost report. The certification shall be submitted in a form satisfactory to the department no later than October 1 of each fiscal year. The department will claim the federal share for these certified public expenditures. The department's subsequent reimbursement to the hospital shall be in accordance with the qualifying criteria and payment methodology for non-rural community hospitals included in Act 11 of the 2010 Regular Session of the Louisiana Legislature, and may be more or less than the federal share so claimed. Qualifying public, non-rural community hospitals that fail to make such certifications by October 1 may not receive Title XIX claim payments or any disproportionate share payments until the department receives the required certifications. Adjustments to the certification amounts shall be made in accordance with the final uncompensated care costs as calculated per the CMS mandated audit for the state fiscal year.

C. Private, non-rural community hospitals (other than freestanding psychiatric hospitals) shall be reimbursed as follows:

1. If the hospital's qualifying uninsured cost is less than 4 percent of total hospital cost, no payment shall be made.

2. If the hospital's qualifying uninsured cost is equal to or greater than 4 percent of total hospital cost, but less than 7 percent, the payment shall be 50 percent of an amount equal to the difference between the total qualifying uninsured cost as a percent of total hospital cost and 4 percent of total hospital cost.

3. If the hospital's qualifying uninsured cost is equal to or greater than 7 percent of total hospital cost, but less than or equal to 10 percent, the payment shall be 80 percent of an amount equal to the difference between the total qualifying uninsured cost as a percent of total hospital cost and 4 percent of total hospital cost.

4. If the hospital's qualifying uninsured cost is greater than 10 percent of total hospital cost, the payment shall be 90 percent of qualifying uninsured cost for the portion in excess of 10 percent of total hospital cost and 80 percent of an amount equal to 5 percent of total hospital cost.

5. Qualifying uninsured cost as used for this distribution shall mean the hospital's total charges for care provided to uninsured patients multiplied by the hospital's cost-to-charge ratio as required by the CMS DHS audit rule for the applicable cost report period.

D. The department shall determine each qualifying hospital's uninsured percentage on a hospital-wide basis utilizing charges for dates of service from July 1, 2009 through June 30, 2010.

D.1. - D.5. Repealed.

E. Hospitals shall submit supporting patient specific data in a format specified by the department, reports on their efforts to collect reimbursement for medical services from patients to reduce gross uninsured costs and their most current year-end financial statements. Those hospitals that fail to provide such statements shall receive no payments and any payment previously made shall be refunded to the department. Submitted hospital charge data must agree with the hospital's monthly revenue and usage reports which reconcile to the monthly and annual financial statements. The submitted data shall be subject to verification by the department before DSH payments are made.

F. In the event that the total payments calculated for all recipient hospitals are anticipated to exceed the total amount appropriated, the department shall reduce payments on a pro rata basis in order to achieve a total cost that is not in excess of the amounts appropriated for this purpose. Any funding not distributed per the methodology outlined in Paragraph C.1-C.5 of this Section shall be reallocated to these qualifying hospitals based on their reported uninsured costs. The $10,000,000 appropriation for the non-rural community hospital pool shall be effective only for state fiscal year 2011 and distributions from the pool shall be considered nonrecurring.

G. Of the total appropriation for the non-rural community hospital pool, $1,000,000 shall be allocated to public and private non-rural community hospitals with a distinct part psychiatric unit and $1,000,000 shall be allocated to freestanding psychiatric hospitals.

1. To qualify for this payment hospitals must have uninsured cost as defined in §2701.C.5 equal to or greater than 4 percent of total hospital cost and:

a. be a public or private non-rural community hospital, as defined in §2701.A that has a Medicaid enrolled distinct part psychiatric unit; or

b. enrolled in Medicaid as a freestanding psychiatric hospital that pursuant to 42 CFR 441.151 is accredited by the Joint Commission on the Accreditation of Healthcare Organizations.

2. Payment shall be calculated by:

a. dividing each qualifying hospital's distinct part psychiatric unit's uninsured days by the sum of all qualifying psychiatric unit's uninsured days and multiplying by $1,000,000;

b. dividing each qualifying freestanding psychiatric hospital's uninsured days by the sum of all qualifying freestanding psychiatric hospital's uninsured days and multiplying by $1,000,000.

H. The DSH payment shall be made as an annual lump sum payment.

I. Hospitals qualifying as non-rural community hospitals in state fiscal year 2007-2008 and subsequent years may also qualify in the federally mandated statutory hospital category.

J. Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 34:655 (April 2008), amended LR 34:2402 (November 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§2705. Small Rural Hospitals

A. - D.1.b. ...

2. Additional payments shall only be made after finalization of the CMS mandated DSH audit for the state fiscal year. Payments shall be limited to the aggregate amount recouped from small rural hospitals based on these reported audit results. If the small rural hospitals' aggregate amount of underpayments reported per the audit results exceeds the aggregate amount overpaid, the payment redistribution to underpaid shall be paid on a pro rata basis calculated using each hospital's amount underpaid divided by the sum of underpayments for all small rural hospitals.

E. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 34:657 (April 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§2707. Public State-Operated Hospitals

A. ...

B. DSH payments to individual public state-owned or operated hospitals shall be up to 100 percent of the hospital's net uncompensated costs. Final payment shall be made in accordance with final uncompensated care costs as calculated per the CMS mandated audit for the state fiscal year.

C. - D.2.d. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 34:658 (April 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Implementation of the provisions of this Rule may be contingent upon the approval of the U.S. Department of Health and Human Services, Center for Medicaid Services (CMS) if it is determined that submission to CMS for review and approval is required.

Interested persons may submit written comments to Don Gregory, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. He is responsible for responding to all inquiries regarding this Emergency Rule. A copy of this Emergency Rule is available for review by interested parties at parish Medicaid offices.

Bruce D. Greenstein
Secretary

1106#050

DECLARATION OF EMERGENCY

Department of Health and Hospitals
Bureau of Health Services Financing

Federally Qualified Health Centers
Diabetes Self-Management Training
(LAC 50:XI.Chapters 103-105 and 10701)

The Department of Health and Hospitals, Bureau of Health Services Financing amends LAC 50:XI.Chapters 103-105 and §10701 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This Emergency Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:953(B)(1) et seq., and shall be in effect for the maximum period allowed under the Act or until adoption of the final Rule, whichever occurs first.

Act 11 of the 2010 Regular Session of the Louisiana Legislature authorized the Department of Health and Hospitals, through its primary and preventive care activity, to provide reimbursement to providers for rendering services that will educate and encourage Medicaid enrollees to obtain appropriate preventive and primary care in order to improve their overall health and quality of life. In keeping with the intent of Act 11, the Department of Health and Hospitals, Bureau of Health Services Financing promulgated an Emergency Rule which amended the provisions governing federally qualified health centers (FQHCs) to provide Medicaid reimbursement for diabetes self-management training (DSMT) services (*Louisiana Register*, Volume 37, Number 2). It is anticipated that this new service will promote improved patient self-management skills which will reduce diabetes-related complications that adversely affect quality of life, and subsequently reduce Medicaid costs associated with the care of recipients diagnosed with diabetes-related illnesses. The February 20, 2011 Emergency Rule also reorganized the existing provisions governing provider participation and services in a more clear and concise manner in the *Louisiana Administrative Code.* The department now proposes to amend the February 20, 2011 Emergency Rule to clarify the provisions governing service limits.

This action is being taken to promote the health and welfare of Medicaid recipients diagnosed with diabetes and to reduce the Medicaid costs associated with their care.

Effective June 20, 2011, the Department of Health and Hospitals, Bureau of Health Services Financing amends the provisions of the February 20, 2011 Emergency Rule governing federally qualified health centers.

Title 50
PUBLIC HEALTH—MEDICAL ASSISTANCE
Part XI. Clinic Services
Subpart 13. Federally-Qualified Health Centers
Chapter 103. Services
§10301. Scope of Services

A. Medicaid reimbursement is limited to medically necessary services that are covered by the Medicaid State Plan and would be covered if furnished by a physician. The following services shall be covered:

1. services furnished by a physician within the scope of practice of his profession under Louisiana law;
2. services furnished by a:
   a. physician assistant;
   b. nurse practitioner;
   c. nurse midwife;
   d. clinical social worker;
   e. clinical psychologist; or
   f. dentist;
3. services and supplies that are furnished as an incident to professional services furnished by all eligible professionals;
4. other ambulatory services; and
5. diabetes self-management training (DSMT) services.

B. Effective February 20, 2011, the department shall provide coverage of diabetes self-management training services rendered to Medicaid recipients diagnosed with diabetes.

1. The services shall be comprised of one hour of individual instruction and nine hours of group instruction on diabetes self-management.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 30:2328 (October 2004), repromulgated LR 30:2487 (November 2004), amended LR 32:1901 (October 2006), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§10303. Service Limits

A. Federally qualified health center visits (encounters) are limited to 12 visits per year for medically necessary services rendered to Medicaid recipients who are 21 years of age or older. Visits for Medicaid recipients who are under 21 years of age and for prenatal postpartum care are excluded from the service limitation.

1. - 3. Repealed.

B. Recipients of DSMT services shall receive up to 10 hours of services during the first 12-month period beginning with the initial training date.

1. After the first 12-month period has ended, recipients shall only be eligible for two hours of individual instruction on diabetes self-management per calendar year.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 30:2328 (October 2004), repromulgated LR 30:2488 (November 2004), amended LR 32:1901 (October 2006), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Chapter 105. Provider Participation
§10501. Provider Enrollment

A. In order to enroll and participate in the Medicaid Program, an FQHC must submit a completed provider enrollment packet that includes a copy of the HRSA grant approving its FQHC status.

1. - 4. Repealed.

B. The effective date of a FQHC's enrollment to participate in the Medicaid Program shall not be prior to the date of receipt of the completed enrollment packet.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 30:2328 (October 2004), repromulgated LR 30:2488 (November 2004), amended LR 32:1902 (October 2006), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§10503. Standards for Participation

A. Federally qualified health centers must comply with the applicable licensure, accreditation and program participation standards for all services rendered. If a FQHC wishes to initiate participation, it shall be responsible for meeting all of the enrollment criteria of the program. The FQHC provider shall:

1. maintain an acceptable fiscal record keeping system that readily distinguishes one type of service from another type of service that may be provided;
2. retain all records necessary to fully disclose the extent of services provided to recipients for five years from the date of service and furnish such records, and any payments claimed for providing such services, to the Medicaid Program upon request; and
3. abide by and adhere to all federal and state regulations and policy manuals.

B. If a FQHC receives approval for a satellite site, the satellite site must enter into a separate provider agreement and obtain its own Medicaid provider number.

C. In order to receive Medicaid reimbursement for DSMT services, a FQHC must have a DSMT program that meets the quality standards of one of the following accreditation organizations:

1. the American Diabetes Association;
2. the American Association of Diabetes Educators; or
3. the Indian Health Service.

D. All DSMT programs must adhere to the national standards for diabetes self-management education.

1. Each member of the instructional team must:
   a. be a certified diabetes educator (CDE) certified by the National Certification Board for Diabetes Educators; or
   b. have recent didactic and experiential preparation in education and diabetes management.
2. At a minimum, the instructional team must consist of one the following professionals who is a CDE:
   a. a registered dietician;
   b. a registered nurse; or
   c. a pharmacist.
3. All members of the instructional team must obtain the nationally recommended annual continuing education hours for diabetes management.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1902 (October 2006), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:2280 (October 2010), amended LR 37:

Chapter 107. Reimbursement Methodology

§10701. Prospective Payment System

A. - B.2.NOTE …

3. Effective for dates of service on or after February 20, 2011, the Medicaid Program shall include coverage for diabetes self-management training services rendered by qualified health care professionals in the FQHC encounter rate.

a. Separate encounters for DSMT services are not permitted and the delivery of DSMT services alone does not constitute an encounter visit.

C. - F. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1902 (October 2006), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Implementation of the provisions of this Rule may be contingent upon the approval of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), if it is determined that submission to CMS for review and approval is required.

Interested persons may submit written comments to Don Gregory, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. He is responsible for responding to inquiries regarding this Emergency Rule. A copy of this Emergency Rule is available for review by interested parties at parish Medicaid offices.

Bruce D. Greenstein
Secretary

1106#051

DECLARATION OF EMERGENCY

Department of Health and Hospitals
Bureau of Health Services Financing

Home and Community-Based Services Waivers
Adult Day Health Care
(LAC 50:XXI.2103, 2107, 2301, 2501, 2503, 2701, 2901-2905 and 2915)

The Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services amend LAC 50:XXI.2103, §2107, §2301, §2501, §2503, §2701, §2901-2905, and §2915 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This Emergency Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:953(B)(1) et seq., and shall be in effect for the maximum period allowed under the Act or until adoption of the final Rule, whichever occurs first.

The Department of Health and Hospitals, Office of Aging and Adult Services amended the provisions governing the Adult Day Health Care (ADHC) Waiver to redefine and clarify the provisions of the waiver relative to the target population, the request for services registry, the comprehensive plan of care, and support coordination services (*Louisiana Register,* Volume 34, Number 10). The October 20, 2008 Rule also amended the provisions governing the reimbursement methodology to reduce the comprehensive ADHC rate paid to providers as a result of adding support coordination as a separate service since these services were traditionally reimbursed as part of the comprehensive ADHC rate. These provisions were repromulgated by the department in December 2008 to correct an error of omission in the publication (*Louisiana Register,* Volume 34, Number 12). The department promulgated an Emergency Rule which amended the Rule governing the ADHC Waiver to revise the provisions governing: 1) the program description; 2) the allocation of waiver opportunities; and 3) the provision of services and discharge criteria (*Louisiana Register*, Volume 37, Number 1).

The Department now proposes to amend the provisions of the January 1, 2011 Emergency Rule to revise the reimbursement methodology governing the ADHC Waiver to implement a quarter hour pay rate and a provider specific transportation component, and to reduce the direct care floor. This action is being taken to avoid federal sanctions for noncompliance with federal requirements for the provision of waiver services.

Effective June 20, 2011, the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services amend the provisions of the January 1, 2011 Emergency Rule governing the Adult Day Health Care Waiver.

Title 50
PUBLIC HEALTH—MEDICAL ASSISTANCE
Part XXI. Home and Community-Based Services Waivers
Subpart 3. Adult Day Health Care

Chapter 21. General Provisions

§2103. Program Description

A. An Adult Day Health Care Waiver program expands the array of services available to individuals with functional impairments, and helps to bridge the gap between independence and institutional care by allowing them to remain in their own homes and communities. This program provides direct care for individuals who have physical, mental or functional impairments. ADHC waiver participants must attend a minimum of 36 days per calendar quarter, absent extenuating circumstances. Exceptions for extenuating circumstances must be approved by the assigned support coordinator based upon guidance provided by OAAS.

B. - C.6. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 30:2034 (September 2004), amended by the Department of Health and Hospitals, Office of Aging and Adult Services, LR 34:2161 (October 2008), repromulgated LR 34:2566

(December 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 37:

§2107. Programmatic Allocation of Waiver Opportunities

A. …

B. Adult Day Health Care Waiver opportunities shall be offered to individuals on the registry according to priority groups. The following groups shall have priority for ADHC Waiver opportunities in the order listed:

1. individuals with substantiated cases of abuse or neglect with Adult Protective Services (APS) or Elderly Protective Services (EPS) and who, absent ADHC Waiver services, would require institutional placement to prevent further abuse and neglect;

a. - c. repealed.

2. individuals who have been discharged after a hospitalization within the past 30 days that involved a stay of at least one night;

3. individuals presently residing in nursing facilities for 90 or more continuous days; and

4. all other eligible individuals on the Request for Services Registry (RFSR), by date of first request for services.

C. If an applicant is determined to be ineligible for any reason, the next individual on the registry is notified and the process continues until an individual is determined eligible. An ADHC Waiver opportunity is assigned to an individual when eligibility is established and the individual is certified.

D. Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and pursuant to Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Aging and Adult Services, LR 34:2162 (October 2008), repromulgated LR 34:2566 (December 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 37:

Chapter 23. Services

§2301. Covered Services

A. …

1. Adult Day Health Care. ADHC services are a planned, diverse daily program of individual services and group activities structured to enhance the recipient's physical functioning and to provide mental stimulation. Services are furnished on a regularly scheduled basis, not to exceed 10 hours a day, 50 hours a week. An adult day health care center shall, at a minimum, furnish the following services:

a. - j. …

NOTE: Repealed.

2. Support Coordination. These services assist participants in gaining access to necessary waiver and other State Plan services, as well as medical, social, educational and other services, regardless of the funding source for these services. Support coordinators shall be responsible for ongoing monitoring of the provision of services included in the recipient's approved Plan of Care (POC). This is a mandatory service.

A.3. - B. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 30:2036 (September 2004), amended by the Department of Health and Hospitals, Office of Aging and Adult Services, LR 34:2162 (October 2008), repromulgated LR 34:2566 (December 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 37:

Chapter 25. Admission and Discharge Criteria

§2501. Admission Criteria

A. Admission to the ADHC Waiver Program shall be determined in accordance with the following criteria:

1. - 3. …

4. reasonable assurance that the health and welfare of the individual can be maintained in the community with the provision of ADHC Waiver services.

B. Failure of the individual to cooperate in the eligibility determination process or to meet any of the criteria in this Section will result in denial of admission to the ADHC Waiver.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 30:2040 (September 2004), amended by the Department Of Hospitals, Office of Aging and Adult Services, LR 34:2163 (October 2008), repromulgated LR 34:2568 (December 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 37:

§2503. Denial or Discharge Criteria

A. Admission shall be denied or the recipient shall be discharged from the ADHC Waiver Program if any of the following conditions are determined.

1. - 7. …

8. The participant fails to attend the ADHC Center for a minimum of 36 days per calendar quarter.

9. The individual fails to maintain a safe home environment.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and pursuant to Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Aging and Adult Services, LR 34:2163 (October 2008), repromulgated LR 34:2568 (December 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 37:

Chapter 27. Provider Participation

§2701. General Provisions

A. - B. …

C. ADHC providers shall ensure that all non-licensed direct care staff meet the minimum mandatory qualifications and requirements for direct service workers as required by R.S. 40:2179 - 2179.1.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 30:2041 (September 2004), amended by the Department of Health and Hospitals, Office for Aging and Adult Services, LR 34:2164 (October 2008), repromulgated LR 34:2568 (December 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 37:

Chapter 29. Reimbursement

§2901. General Provisions

A. Development. Adult Day Health Care providers shall be reimbursed a per quarter hour rate for services provided

under a prospective payment system (PPS). The system shall be designed in a manner that recognizes and reflects the cost of direct care services provided. The reimbursement methodology is designed to improve the quality of care for all adult day health care waiver recipients by ensuring that direct care services are provided at an acceptable level while fairly reimbursing the providers.

B. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 30:2041 (September 2004), amended by the Department of Health and Hospitals, Office of the Secretary, Office of Aging and Adult Services, LR 32:2257 (December 2006), LR 34:2164 (October 2008), repromulgated LR 34:2569 (December 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 37:

§2903. Cost Reporting

A. Cost Centers Components

1. - 3.e. …

4. Property. This component reimburses for depreciation, interest on capital assets, lease expenses, property taxes and other expenses related to capital assets, excluding property cost related to patient transportation.

5. Transportation. This component reimburses for in-house and contractual driver salaries and related benefits, non-emergency medical transportation, vehicle maintenance and supply expense, and automotive expenses related to ADHC patient transportation.

B. - L. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Aging and Adult Services, LR 34:2164 (October 2008), repromulgated LR 34:2569 (December 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 37:

§2905. Cost Categories Included in the Cost Report

A. - B.19. …

C. Administrative and Operating Costs (AOC)

1. - 5. …

6. Salaries, Other Administrative—gross salaries of other administrative personnel including bookkeepers, receptionists, administrative assistants and other office and clerical personnel.

7. Salaries, Owner or Owner/Administrator—gross salaries of all owners of the center that are paid through the center.

8. Payroll Taxes—cost of employer's portion of Federal Insurance Contribution Act (FICA), Federal Unemployment Tax Act (FUTA), State Unemployment Tax Act (SUTA), and Medicare tax for administrative and operating employees.

9. Group Insurance, AOC—cost of employer's contribution to employee health, life, accident and disability insurance for administrative and operating employees.

10. Pensions, AOC—cost of employer's contribution to employee pensions for administration and operating employees.

11. Uniform Allowance, AOC—employer's cost of uniform allowance and/or uniforms for administration and operating employees.

12. Worker's Compensation, AOC—cost of worker's compensation insurance for administration and operating employees.

13. Contract, Housekeeping—cost of housekeeping services and personnel hired through contract that are not employees of the center.

14. Contract, Laundry—cost of laundry services and personnel hired through contract that are not employees of the center.

15. Contract, Maintenance—cost of maintenance services and persons hired through contract that are not employees of the center.

16. Consultant Fees, Dietician—fees paid to consulting registered dieticians.

17. Accounting Fees—fees incurred for the preparation of the cost report, audits of financial records, bookkeeping, tax return preparation of the adult day health care center and other related services excluding personal tax planning and personal tax return preparation.

18. Amortization Expense, Non-Capital—costs incurred for legal and other expenses when organizing a corporation must be amortized over a period of 60 months. Amortization of costs attributable to the negotiation or settlement of the sale, or purchase of any capital asset on or after July 18, 1984, whether by acquisition or merger, for which any payment has previously been made are nonallowable costs. If allowable cost is reported on this line, an amortization schedule must be submitted with the cost report.

19. Bank Service Charges—fees paid to banks for service charges, excluding penalties and insufficient funds charges.

20. Dietary Supplies—costs of consumable items such as soap, detergent, napkins, paper cups, straws, etc., used in the dietary department.

21. Dues—dues to one organization are allowable.

22. Educational Seminars and Training—the registration cost for attending educational seminars and training by employees of the center and costs incurred in the provision of in-house training for center staff, excluding owners or administrative personnel.

23. Housekeeping Supplies—cost of consumable housekeeping items including waxes, cleaners, soap, brooms and lavatory supplies.

24. Insurance, Professional Liability and Other—includes the costs of insuring the center against injury and malpractice claims.

25. Interest Expense, Non-Capital and Vehicles—interest paid on short term borrowing for center operations.

26. Laundry Supplies—cost of consumable goods used in the laundry including soap, detergent, starch and bleach.

27. Legal Fees—only actual and reasonable attorney fees incurred for non-litigation legal services related to patient care are allowed.

28. Linen Supplies—cost of sheets, blankets, pillows, gowns, under-pads and diapers (reusable and disposable).

29. Miscellaneous—costs incurred in providing center services that cannot be assigned to any other line item on the cost report. Examples of miscellaneous expense are small equipment purchases, all employees' physicals and shots, nominal gifts to all employees, such as a turkey or ham at Christmas, allowable advertising, and flowers purchased for the enjoyment of the clients. Items reported on this line must be specifically identified.

30. Management Fees and Home Office Costs—the cost of purchased management services or home office costs incurred that are allocable to the provider. Costs included that are for related management/home office costs must also be reported on a separate cost report that includes an allocation schedule.

31. Office Supplies and Subscriptions—cost of consumable goods used in the business office such as:

a. pencils, paper and computer supplies;

b. cost of printing forms and stationery including, but not limited to, nursing and medical forms, accounting and census forms, charge tickets, center letterhead and billing forms;

c. cost of subscribing to newspapers, magazines and periodicals.

32. Postage—cost of postage, including stamps, metered postage, freight charges and courier services.

33. Repairs and Maintenance—supplies and services, including electricians, plumbers, extended service agreements, etc., used to repair and maintain the center building, furniture and equipment except vehicles. This includes computer software maintenance.

34. Taxes and Licenses—the cost of taxes and licenses paid that are not included on any other line on Form 6. This includes tags for vehicles, licenses for center staff (including nurse aide re-certifications) and buildings.

35. Telephone and Communications—cost of telephone services, wats lines and fax services.

36. Travel—cost of travel (airfare, lodging, meals, etc.) by the administrator and other authorized personnel to attend professional and continuing educational seminars and meetings or to conduct center business. Commuting expenses and travel allowances are not allowable.

37. Utilities—cost of water, sewer, gas, electric, cable TV and garbage collection services.

38. Allocated Costs, Hospital Based—costs that have been allocated through the step-down process from a hospital as administrative and operating costs.

39. Total Administrative and Operating Costs.

D. Property and Equipment

1. - 7. …

8. Allocated Costs, Hospital Based—costs that have been allocated through the step-down process from a hospital or state institution as property costs when those costs include allocated overhead.

9. Total Property and Equipment.

E. Transportation Costs

1. Salaries, Drivers-gross salaries of personnel involved in transporting clients to and from the center.

2. Non-Emergency Medical Transportation-the cost of purchased non-emergency medical transportation services including, but not limited to:

a. payments to employees for use of personal vehicle;

b. ambulance companies; and

c. other transportation companies for transporting patients of the center.

3. Vehicle Expenses-vehicle maintenance and supplies, including gas and oil.

4. Lease, Automotive-cost of leases for vehicles used for patient care. A mileage log must be maintained. If a leased vehicle is used for both patient care and personal purposes, cost must be allocated based on the mileage log.

5. Total Transportation Costs.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Aging and Adult Services, LR 34:2166 (October 2008), repromulgated LR 34:2571 (December 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 37:

§2915. Provider Reimbursement

A. Cost Determination Definitions

* * *

Base Rate Components—the base rate is the summation of the following:

a. direct care;

b. care related costs;

c. administrative and operating costs;

d. property costs; and

e. transportation costs.

* * *

B. Rate Determination

1. - 5. …

6. Allowable quarter hours are used to calculate the per quarter hour costs for each of the rate components. Allowable quarter hours are calculated using the following criteria:

a. a maximum daily reimbursement limit of 10 hours per participant day;

b. reimbursement will be for full quarter hour (15 minute) increments only; and

c. the quarter hour data used in rate setting shall be from the database of hours provided by the Department.

7. Formulae. Each median cost component shall be calculated as follows.

a. Direct Care Cost Component. Direct care allowable quarter hour costs from all acceptable full year cost reports, except those for which an audit disclaimer has been issued, shall be arrayed from lowest to highest. The cost at the midpoint of the array shall be the median cost. Should there be an even number of arrayed cost, an average of the two midpoint centers shall be the median cost. The median cost shall be trended forward by dividing the value of the Consumer Price Index-Medical Services (South Region) index for December of the year preceding the base rate year by the value of the index for the December of the year preceding the cost report year. The direct care rate component shall be set at 115 percent of the inflated median.

i. Repealed.

b. Care Related Cost Component. Care related allowable quarter hour costs from all acceptable full year cost reports, except those for which an audit disclaimer has been issued, shall be arrayed from lowest to highest. The cost of the center at the midpoint of the array shall be the

median cost. Should there be an even number of arrayed cost, an average of the two midpoint centers shall be the median cost. The median cost shall be trended forward by dividing the value of the Consumer Price Index-All Items (South Region) index for December of the year preceding the base rate year by the value of the index for the December of the year preceding the cost report year. The care related rate component shall be set at 105 percent of the inflated median.

c. Administrative and Operating Cost Component. Administrative and operating allowable quarter hour cost from all acceptable full year cost reports, except those for which an audit disclaimer has been issued, shall be arrayed from lowest to highest. The cost of the midpoint of the array shall be the median cost. Should there be an even number of arrayed cost, an average of the two midpoint centers shall be the median cost. The median cost shall be trended forward by dividing the value of the CPI-All Items (South Region) index for December of the year preceding the base rate year by the value of the index for the December of the year preceding the cost report year. The administrative and operating rate component shall be set at 105 percent of the inflated median.

d. Property Cost Component. The property allowable quarter hour costs from all acceptable full year cost reports, except those for which an audit disclaimer has been issued, shall be arrayed from lowest to highest. The cost at the midpoint of the array shall be the median cost. Should there be an even number of arrayed cost, an average of the two midpoint centers shall be the median cost. This will be the rate component. Inflation will not be added to property costs.

e. Transportation Cost Component. The transportation allowable quarter hour costs from all acceptable full year cost reports, except those for which an audit disclaimer has been issued, will be calculated on a provider by provider basis. Should a provider not have filed an acceptable full year cost report, the provider's transportation cost will be reimbursed as follows:

i. New providers, as described in §2915.E.1, will be reimbursed in an amount equal to the statewide allowable quarter hour median transportation costs.

(a). In order to calculate the statewide allowable quarter hour median transportation costs, all acceptable full year cost reports, except those for which an audit disclaimer has been issued, shall be arrayed from lowest to highest. The cost at the midpoint of the array shall be the median cost. Should there be an even number of arrayed cost, an average of the two midpoint centers shall be the median cost. This will be the rate component. Inflation will not be added to transportation costs.

ii. Providers that have gone through a change of ownership (CHOW), as described in §2915.E.2, will be reimbursed for transportation costs based upon the previous owner's specific allowable quarter hour transportation costs for the period of time between the effective date of the CHOW and the first succeeding base year in which the new owner could possibly file an allowable 12-month cost report. Thereafter, the new owner's data will be used to determine the provider's rate following the procedures specified in this Rule.

iii. Providers that have been issued an audit disclaimer, or have a non-filer status, as described in §2915.E.3, will be reimbursed for transportation costs at a rate equal to the lowest allowable quarter hour transportation cost in the state as of the most recent audited and/or desk reviewed rate database.

8. Budgetary Constraint Rate Adjustment. Effective July 1, 2011, the allowable quarter hour rate components for direct care, care related, administrative and operating, property, and transportation shall be reduced by 10.8563 percent.

9. Interim Adjustments to Rates. If an unanticipated change in conditions occurs that affects the cost of at least 50 percent of the enrolled ADHC providers by an average of five percent or more, the rate may be changed. The Department will determine whether or not the rates should be changed when requested to do so by 25 percent or more of the enrolled providers, or an organization representing at least 25 percent of the enrolled providers. The burden of proof as to the extent and cost effect of the unanticipated change will rest with the entities requesting the change. The Department may initiate a rate change without a request to do so. Changes to the rates may be temporary adjustments or base rate adjustments as described below.

a. Temporary Adjustments. Temporary adjustments do not affect the base rate used to calculate new rates.

i. Changes Reflected in the Economic Indices. Temporary adjustments may be made when changes which will eventually be reflected in the economic indices, such as a change in the minimum wage, a change in FICA or a utility rate change, occur after the end of the period covered by the indices, i.e., after the December preceding the rate calculation. Temporary adjustments are effective only until the next annual base rate calculation.

ii. Lump Sum Adjustments. Lump sum adjustments may be made when the event causing the adjustment requires a substantial financial outlay, such as a change in certification standards mandating additional equipment or furnishings. Such adjustments shall be subject to the Bureau's review and approval of costs prior to reimbursement.

b. Base Rate Adjustment. A base rate adjustment will result in a new base rate component value that will be used to calculate the new rate for the next fiscal year. A base rate adjustment may be made when the event causing the adjustment is not one that would be reflected in the indices.

10. Provider Specific Adjustment. When services required by these provisions are not made available to the recipient by the provider, the Department may adjust the prospective payment rate of that specific provider by an amount that is proportional to the cost of providing the service. This adjustment to the rate will be retroactive to the date that is determined by the Department that the provider last provided the service and shall remain in effect until the Department validates, and accepts in writing, an affidavit that the provider is then providing the service and will continue to provide that service.

C. Cost Settlement. The direct care cost component shall be subject to cost settlement. The direct care floor shall be equal to 70 percent of the median direct care rate component

trended forward for direct care services (plus 70 percent of any direct care incentive added to the rate). The Medicaid Program will recover the difference between the direct care floor and the actual direct care amount expended. If a provider receives an audit disclaimer, the cost settlement for that year will be based on the difference between the direct care floor and the lowest direct care per diem of all facilities in the most recent audited and/or desk reviewed database trended forward to the rate period related to the disclaimer.

D. Support Coordination Services Reimbursement. Support coordination services previously provided by ADHC providers and included in the rate, including the Minimum Data Set Home Care (MDS/HC), the CPOC and home visits will no longer be the responsibility of the ADHC provider. Support coordination services shall be provided as a separate service covered in the ADHC Waiver. As a result of the change in responsibilities, the rate paid to ADHC providers shall be adjusted accordingly.

1. - 2. Repealed.

E. New Facilities, Changes of Ownership of Existing Facilities, and Existing Facilities with Disclaimer or Non-Filer Status

1. New Facilities are those entities whose beds have not previously been certified to participate, or otherwise have participated, in the Medicaid program. New facilities will be reimbursed in accordance with this Rule and receiving the direct care, care related, administrative and operating, property rate components as determined in §2915.B.1 - §2915.B.7. These new facilities will also receive the state-wide average transportation rate component, as calculated in §2915.B.7.e.i.(a), effective the preceding July 1.

2. A change of ownership exists if the beds of the new owner have previously been certified to participate, or otherwise have participated, in the Medicaid program under the previous owner's provider agreement. Rates paid to facilities that have undergone a change in ownership will be based upon the rate paid to the previous owner for all rate components. Thereafter, the new owner's data will be used to determine the facility's rate following the procedures in this rule.

3. Existing providers that have been issued an audit disclaimer, or are a provider who has failed to file a complete cost report in accordance with §2903, will be reimbursed based upon the statewide allowable quarter hour median costs for the direct care, care related, administrative and operating, and property rate components as determined in §2915.B.1 - §2915.B.7. The transportation component will be reimbursed as described in §2915.B.7.e.iii.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Aging and Adult Services, LR 34:2170 (October 2008), repromulgated LR 34:2575 (December 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 37:

Implementation of the provisions of this Rule may be contingent upon the approval of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), if it is determined that submission to CMS for review and approval is required.

Interested persons may submit written comments to Don Gregory, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. He is responsible for responding to inquiries regarding this Emergency Rule. A copy of this Emergency Rule is available for review by interested parties at parish Medicaid offices.

Bruce D. Greenstein
Secretary

1106#053

DECLARATION OF EMERGENCY

Department of Health and Hospitals
Bureau of Health Services Financing

Home and Community-Based Services Waivers
Elderly and Disabled Adult Waiver
Emergency Opportunities and Reimbursement Methodology
(LAC 50:XXI.8105, 9101, 9107-9121)

The Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services amend LAC 50:XX1.8105, 9101 and adopts §§9107-9121 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act and as directed by Act 11 of the 2010 Regular Session of the Louisiana Legislature which states: "The secretary is directed to utilize various cost containment measures to ensure expenditures in the Medicaid Program do not exceed the level appropriated in this Schedule, including but not limited to precertification, preadmission screening, diversion, fraud control, utilization review and management, prior authorization, service limitations, drug therapy management, disease management, cost sharing, and other measures as permitted under federal law." This Emergency Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:953(B)(1) et seq., and shall be in effect for the maximum period allowed under the Act or until adoption of the final Rule, whichever occurs first.

As a result of a budgetary shortfall in state fiscal year 2009, the department amended the provisions governing the reimbursement methodology for the Elderly and Disabled Adult (EDA) Waiver to reduce the reimbursement rates paid for designated services (*Louisiana Register,* Volume 35, Number 9).

As a result of a budgetary shortfall in state fiscal year 2011, the department promulgated an Emergency Rule which amended the provisions governing the reimbursement methodology for EDA Waiver services to further reduce the reimbursement rates for personal assistance and adult day health care services and adopted provisions governing the reimbursement for adult day health care services (*Louisiana Register*, Volume 36, Number 8).

The Department now proposes to amend the August 1, 2010 Emergency Rule to adopt provisions to allow for emergency waiver opportunities for individuals who require emergency waiver services, and to revise the reimbursement methodology for adult day health care services to implement a quarter hour reimbursement rate. This action is being taken to avoid a budget deficit in the medical assistance

programs and to promote the health and welfare of EDA Waiver recipients.

Effective July 1, 2011, the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services amend the provisions of the August 1, 2011 Emergency Rule governing the Elderly and Disabled Adult Waiver.

Title 50
PUBLIC HEALTH—MEDICAL ASSISTANCE
Part XXI. Home and Community Based Services Waivers
Subpart 7. Elderly and Disabled Adults
Chapter 81. General Provisions
§8105. Programmatic Allocation of Waiver Opportunities

A. - B.1. …

2. individuals diagnosed with Amyotrophic Lateral Sclerosis (ALS), also known as Lou Gehrig's disease;

3. individuals admitted to a nursing facility who are approved for a stay of more than 90 days;

4. - 5. …

C. If an applicant is determined to be ineligible for any reason, the next individual on the registry is notified as stated above and the process continues until an individual is determined eligible. An EDA Waiver opportunity is assigned to an individual when eligibility is established and the individual is certified.

D. Notwithstanding the priority group provisions, 75 EDA Waiver opportunities are reserved for qualifying individuals who have been diagnosed with Amyotrophic Lateral Sclerosis (ALS). Qualifying individuals who have been diagnosed with ALS shall be offered an opportunity on a first-come, first-serve basis.

E. Notwithstanding the priority group provisions, up to 100 EDA Waiver opportunities may be granted to qualified individuals who require emergency waiver services. These individuals shall be offered an opportunity on a first-come, first-serve basis.

1. To be considered for an emergency waiver opportunity, the individual must currently receive the maximum amount of services allowable under the Long Term Personal Care Services Program and require institutional placement, unless offered an emergency waiver opportunity.

2. The following criteria shall be considered in determining whether or not to grant an emergency waiver opportunity:

a. support through other programs is either unavailable or inadequate;

b. the death or incapacitation of an informal caregiver leaves the person without other supports;

c. the support from an informal caregiver is not available due to a family crisis; or

d. the person lives alone and has no access to informal support.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 30:1699 (August 2004), amended by the Department of Health and Hospitals, Office of the Secretary, Division of Long Term Supports and Services, LR 32:1245 (July 2006), amended by the Department of Health and Hospitals, Office of Aging and Adult Services, LR 34:1030 (June 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 35:2447 (November 2009), amended LR 37:900 (March 2011), LR 37:

Chapter 91. Reimbursement
Subchapter A. General Provisions
§9101. Reimbursement Methodology

A. Reimbursement for EDA Waiver services, with the exception of ADHC services, shall be a prospective flat rate for each approved unit of service provided to the recipient. Adult day health care services shall be reimbursed according to the provisions of Subchapter B of this Chapter 91.

B. – C. …

D. Effective for dates of service on or after August 1, 2010, the reimbursement rates for personal assistance services in the EDA Waiver shall be reduced by 2 percent of the rates on file as of July 31, 2010.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Aging and Adult Services, LR 34:251 (February 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 35:1893 (September 2009), amended LR 37:

Subchapter B. Adult Day Health Care Services Reimbursement
§9107. General Provisions

A. Adult day health care services shall be reimbursed a per quarter hour rate for services provided under a prospective payment system (PPS). The system shall be designed in a manner that recognizes and reflects the cost of direct care services provided. The reimbursement methodology is designed to improve the quality of care for all EDA waiver recipients by ensuring that direct care services are provided at an acceptable level while fairly reimbursing the providers.

B. Reimbursement shall not be made for EDA Waiver services provided prior to the Department's approval of the CPOC.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 37:

§9109. Cost Reporting

A. Cost Centers Components

1. Direct Care Costs. This component reimburses for in-house and contractual direct care staffing and fringe benefits and direct care supplies.

2. Care Related Costs. This component reimburses for in-house and contractual salaries and fringe benefits for activity and social services staff, raw food costs and care related supplies for activities and social services.

3. Administrative and Operating Costs. This component reimburses for in-house or contractual salaries and related benefits for administrative, dietary, housekeeping and maintenance staff. Also included are:

a. utilities;

b. accounting;

c. dietary;

d. housekeeping and maintenance supplies; and

e. all other administrative and operating type expenditures.

4. Property. This component reimburses for depreciation, interest on capital assets, lease expenses, property taxes and other expenses related to capital assets.

B. Providers of ADHC services are required to file acceptable annual cost reports of all reasonable and allowable costs. An acceptable cost report is one that is prepared in accordance with the requirements of this Section and for which the provider has supporting documentation necessary for completion of a desk review or audit. The annual cost reports are the basis for determining reimbursement rates. A copy of all reports and statistical data must be retained by the center for no less than five years following the date reports are submitted to the bureau. A chart of accounts and an accounting system on the accrual basis or converted to the accrual basis at year end are required in the cost report preparation process. The bureau or its designee will perform desk reviews of the cost reports. In addition to the desk review, a representative number of the facilities shall be subject to a full-scope, annual on-site audit. All ADHC cost reports shall be filed with a fiscal year from July 1 through June 30.

C. The cost reporting forms and instructions developed by the bureau must be used by all facilities participating in the Louisiana Medicaid Program who render ADHC services. Hospital based and other provider based facilities which use Medicare forms for step down in completing their ADHC Medicaid cost reports must submit copies of the applicable Medicare cost report forms also. All amounts must be rounded to the nearest dollar and must foot and cross foot. Only per diem cost amounts will not be rounded. Cost reports submitted that have not been rounded in accordance with this policy will be returned and will not be considered as received until they are resubmitted.

D. Annual Reporting. Cost reports are to be filed on or before the last day of September following the close of the reporting period. Should the due date fall on a Saturday, Sunday, or an official state or federal holiday, the due date shall be the following business day. The cost report forms and schedules must be filed in duplicate together with two copies of the following documents:

1. a working trial balance that includes the appropriate cost report line numbers to which each account can be traced. This may be done by writing the cost report category and line numbers by each ending balance or by running a trial balance in cost report category and line number order that totals the account;

2. a depreciation schedule. The depreciation schedule which reconciles to the depreciation expense reported on the cost report must be submitted. If the center files a home office cost report, copies of the home office depreciation schedules must also be submitted with the home office cost report. All hospital based facilities must submit two copies of a depreciation schedule that clearly shows and totals assets that are hospital only, ADHC only and shared assets;

3. an amortization schedule(s), if applicable;

4. a schedule of adjustment and reclassification entries;

5. a narrative description of purchased management services and a copy of contracts for managed services, if applicable;

6. For management services provided by a related party or home office, a description of the basis used to allocate the costs to providers in the group and to non-provider activities and copies of the cost allocation worksheet, if applicable. Costs included that are for related management/home office costs must also be reported on a separate cost report that includes an allocation schedule; and

7. all allocation worksheets must be submitted by hospital-based facilities. The Medicare worksheets that must be attached by facilities using the Medicare forms for allocation are:

a. A;
b. A-6;
c. A-7 parts I, II and III;
d. A-8;
e. A-8-1;
f. B part 1; and
g. B-1.

E. Each copy of the cost report must have the original signatures of an officer or center administrator on the certification. The cost report and related documents must be submitted to the address indicated on the cost report instruction form. In order to avoid a penalty for delinquency, cost reports must be postmarked on or before the due date.

F. When it is determined, upon initial review for completeness, that an incomplete or improperly completed cost report has been submitted, the provider will be notified. The provider will be allowed a specified amount of time to submit the requested information without incurring the penalty for a delinquent cost report. For cost reports that are submitted by the due date, 10 working days from the date of the provider's receipt of the request for additional information will be allowed for the submission of the additional information. For cost reports that are submitted after the due date, five working days from the date of the provider's receipt of the request for additional information will be allowed for the submission of the additional information. An exception exists in the event that the due date comes after the specified number of days for submission of the requested information. In these cases, the provider will be allowed to submit the additional requested information on or before the due date of the cost report. If requested additional information has not been submitted by the specified date, a second request for the information will be made. Requested information not received after the second request may not be subsequently submitted and shall not be considered for reimbursement purposes. An appeal of the disallowance of the costs associated with the requested information may not be made. Allowable costs will be adjusted to disallow any expenses for which requested information is not submitted.

G. Accounting Basis. The cost report must be prepared on the accrual basis of accounting. If a center is on a cash basis, it will be necessary to convert from a cash basis to an accrual basis for cost reporting purposes. Particular attention must be given to an accurate accrual of all costs at the year-end for the equitable distribution of costs to the applicable period. Care must be given to the proper allocation of costs for contracts to the period covered by such contracts. Amounts earned although not actually received and amounts

owed to creditors but not paid must be included in the reporting period.

H. Supporting Information. Providers are required to maintain adequate financial records and statistical data for proper determination of reimbursable costs. Financial and statistical records must be maintained by the center for five years from the date the cost report is submitted to the Bureau. Cost information must be current, accurate and in sufficient detail to support amounts reported in the cost report. This includes all ledgers, journals, records, and original evidences of cost (canceled checks, purchase orders, invoices, vouchers, inventories, time cards, payrolls, bases for apportioning costs, etc.) that pertain to the reported costs. Census data reported on the cost report must be supportable by daily census records. Such information must be adequate and available for auditing.

I. Employee Record

1. The provider shall retain written verification of hours worked by individual employees.

a. Records may be sign-in sheets or time cards, but shall indicate the date and hours worked.

b. Records shall include all employees even on a contractual or consultant basis.

2. Verification of criminal background check.

3. Verification of employee orientation and in-service training.

4. Verification of the employee's communicable disease screening.

J. Billing Records

1. The provider shall maintain billing records in accordance with recognized fiscal and accounting procedures. Individual records shall be maintained for each client. These records shall meet the following criteria.

a. Records shall clearly detail each charge and each payment made on behalf of the client.

b. Records shall be current and shall clearly reveal to whom charges were made and for whom payments were received.

c. Records shall itemize each billing entry.

d. Records shall show the amount of each payment received and the date received.

2. The provider shall maintain supporting fiscal documents and other records necessary to ensure that claims are made in accordance with federal and state requirements.

K. Non-acceptable Descriptions. "Miscellaneous", "other" and "various", without further detailed explanation, are not acceptable descriptions for cost reporting purposes. If any of these are used as descriptions in the cost report, a request for information will not be made and the related line item expense will be automatically disallowed. The provider will not be allowed to submit the proper detail of the expense at a later date, and an appeal of the disallowance of the costs may not be made.

L. Exceptions. Limited exceptions to the cost report filing requirements will be considered on an individual provider basis upon written request from the provider to the Bureau of Health Services Financing, Rate and Audit Review Section. If an exception is allowed, the provider must attach a statement describing fully the nature of the exception for which prior written permission was requested and granted. Exceptions which may be allowed with written approval are as follows.

1. If the center has been purchased or established during the reporting period, a partial year cost report may be filed in lieu of the required 12-month report.

2. If the center experiences unavoidable difficulties in preparing the cost report by the prescribed due date, an extension may be requested prior to the due date. Requests for exception must contain a full statement of the cause of the difficulties that rendered timely preparation of the cost report impossible.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 37:

§9111. Cost Categories Included in the Cost Report

A. Direct Care (DC) Costs

1. Salaries, Aides-gross salaries of certified nurse aides and nurse aides in training.

2. Salaries, LPNs-gross salaries of nonsupervisory licensed practical nurses and graduate practical nurses.

3. Salaries, RNs-gross salaries of nonsupervisory registered nurses and graduate nurses (excluding director of nursing and resident assessment instrument coordinator).

4. Salaries, Social Services-gross salaries of nonsupervisory licensed social services personnel providing medically needed social services to attain or maintain the highest practicable physical, mental, or psychosocial well being of the residents.

5. Salaries, Activities—gross salaries of nonsupervisory activities/recreational personnel providing an ongoing program of activities designed to meet, in accordance with the comprehensive assessment, the interest and the physical, mental, and psychosocial well being of the residents.

6. Payroll Taxes—cost of employer's portion of Federal Insurance Contribution Act (FICA), Federal Unemployment Tax Act (FUTA), State Unemployment Tax Act (SUTA), and Medicare tax for direct care employees.

7. Group Insurance, DC—cost of employer's contribution to employee health, life, accident and disability insurance for direct care employees.

8. Pensions, DC—cost of employer's contribution to employee pensions for direct care employees.

9. Uniform Allowance, DC—employer's cost of uniform allowance and/or uniforms for direct care employees.

10. Worker's Comp, DC—cost of worker's compensation insurance for direct care employees.

11. Contract, Aides—cost of aides through contract that are not center employees.

12. Contract, LPNs—cost of LPNs and graduate practical nurses hired through contract that are not center employees.

13. Contract, RNs—cost of RNs and graduate nurses hired through contract that are not center employees.

14. Drugs, Over-the-Counter and Legend—cost of over-the-counter and legend drugs provided by the center to its residents. This is for drugs not covered by Medicaid.

15. Medical Supplies—cost of patient-specific items of medical supplies such as catheters, syringes and sterile dressings.

16. Medical Waste Disposal—cost of medical waste disposal including storage containers and disposal costs.

17. Other Supplies, DC—cost of items used in the direct care of residents which are not patient-specific such as recreational/activity supplies, prep supplies, alcohol pads, betadine solution in bulk, tongue depressors, cotton balls, thermometers, and blood pressure cuffs.

18. Allocated Costs, Hospital Based—the amount of costs that have been allocated through the step-down process from a hospital or state institution as direct care costs when those costs include allocated overhead.

19. Total Direct Care Costs—sum of the above line items.

B. Care Related (CR) Costs

1. Salaries—gross salaries for care related supervisory staff including supervisors or directors over nursing, social service and activities/recreation.

2. Salaries, Dietary—gross salaries of kitchen personnel including dietary supervisors, cooks, helpers and dishwashers.

3. Payroll Taxes—cost of employer's portion of Federal Insurance Contribution Act (FICA), Federal Unemployment Tax Act (FUTA), State Unemployment Tax Act (SUTA), and Medicare tax for care related employees.

4. Group Insurance, CR—cost of employer's contribution to employee health, life, accident and disability insurance for care related employees.

5. Pensions, CR—cost of employer's contribution to employee pensions for care related employees.

6. Uniform Allowance, CR—employer's cost of uniform allowance and/or uniforms for care related employees.

7. Worker's Comp, CR—cost of worker's compensation insurance for care related employees.

8. Barber and Beauty Expense—the cost of barber and beauty services provided to patients for which no charges are made.

9. Consultant Fees, Activities—fees paid to activities personnel, not on the center's payroll, for providing advisory and educational services to the center.

10. Consultant Fees, Nursing—fees paid to nursing personnel, not on the center's payroll, for providing advisory and educational services to the center.

11. Consultant Fees, Pharmacy—fees paid to a registered pharmacist, not on the center's payroll, for providing advisory and educational services to the center.

12. Consultant Fees, Social Worker—fees paid to a social worker, not on the center's payroll, for providing advisory and educational services to the center.

13. Consultant Fees, Therapists—fees paid to a licensed therapist, not on the center's payroll, for providing advisory and educational services to the center.

14. Food, Raw—cost of food products used to provide meals and snacks to residents. Hospital based facilities must allocate food based on the number of meals served.

15. Food, Supplements—cost of food products given in addition to normal meals and snacks under a doctor's orders. Hospital based facilities must allocate food-supplements based on the number of meals served.

16. Supplies, CR—the costs of supplies used for rendering care related services to the patients of the center. All personal care related items such as shampoo and soap administered by all staff must be included on this line.

17. Allocated Costs, Hospital Based—the amount of costs that have been allocated through the step-down process from a hospital or state institution as care related costs when those costs include allocated overhead.

18. Total Care Related Costs—the sum of the care related cost line items.

19. Contract, Dietary—cost of dietary services and personnel hired through contract that are not employees of the center.

C. Administrative and Operating Costs (AOC)

1. Salaries, Administrator-gross salary of administrators excluding owners. Hospital based facilities must attach a schedule of the administrator's salary before allocation, the allocation method, and the amount allocated to the nursing center.

2. Salaries, Assistant Administrator—gross salary of assistant administrators excluding owners.

3. Salaries, Housekeeping—gross salaries of housekeeping personnel including housekeeping supervisors, maids and janitors.

4. Salaries, Laundry—gross salaries of laundry personnel.

5. Salaries, Maintenance—gross salaries of personnel involved in operating and maintaining the physical plant, including maintenance personnel or plant engineers.

6. Salaries, Drivers—gross salaries of personnel involved in transporting clients to and from the center.

7. Salaries, Other Administrative—gross salaries of other administrative personnel including bookkeepers, receptionists, administrative assistants and other office and clerical personnel.

8. Salaries, Owner or Owner/Administrator—gross salaries of all owners of the center that are paid through the center.

9. Payroll Taxes—cost of employer's portion of Federal Insurance Contribution Act (FICA), Federal Unemployment Tax Act (FUTA), State Unemployment Tax Act (SUTA), and Medicare tax for administrative and operating employees.

10. Group Insurance, AOC—cost of employer's contribution to employee health, life, accident and disability insurance for administrative and operating employees.

11. Pensions, AOC—cost of employer's contribution to employee pensions for administration and operating employees.

12. Uniform Allowance, AOC—employer's cost of uniform allowance and/or uniforms for administration and operating employees.

13. Worker's Compensation, AOC—cost of worker's compensation insurance for administration and operating employees.

14. Contract, Housekeeping—cost of housekeeping services and personnel hired through contract that are not employees of the center.

15. Contract, Laundry—cost of laundry services and personnel hired through contract that are not employees of the center.

16. Contract, Maintenance—cost of maintenance services and persons hired through contract that are not employees of the center.

17. Consultant Fees, Dietician—fees paid to consulting registered dieticians.

18. Accounting Fees—fees incurred for the preparation of the cost report, audits of financial records, bookkeeping, tax return preparation of the adult day health care center and other related services excluding personal tax planning and personal tax return preparation.

19. Amortization Expense, Non-Capital—costs incurred for legal and other expenses when organizing a corporation must be amortized over a period of 60 months. Amortization of costs attributable to the negotiation or settlement of the sale or purchase of any capital asset on or after July 18, 1984, whether by acquisition or merger, for which any payment has previously been made are nonallowable costs. If allowable cost is reported on this line, an amortization schedule must be submitted with the cost report.

20. Bank Service Charges—fees paid to banks for service charges, excluding penalties and insufficient funds charges.

21. Dietary Supplies—costs of consumable items such as soap, detergent, napkins, paper cups, straws, etc., used in the dietary department.

22. Dues—dues to one organization are allowable.

23. Educational Seminars and Training—the registration cost for attending educational seminars and training by employees of the center and costs incurred in the provision of in-house training for center staff, excluding owners or administrative personnel.

24. Housekeeping Supplies—cost of consumable housekeeping items including waxes, cleaners, soap, brooms and lavatory supplies.

25. Insurance, Professional Liability and Other—includes the costs of insuring the center against injury and malpractice claims.

26. Interest Expense, Non-Capital and Vehicles—interest paid on short term borrowing for center operations.

27. Laundry Supplies—cost of consumable goods used in the laundry including soap, detergent, starch and bleach.

28. Legal Fees—only actual and reasonable attorney fees incurred for non-litigation legal services related to patient care are allowed.

29. Linen Supplies—cost of sheets, blankets, pillows, gowns, under-pads and diapers (reusable and disposable).

30. Miscellaneous—costs incurred in providing center services that cannot be assigned to any other line item on the cost report. Examples of miscellaneous expense are small equipment purchases, all employees' physicals and shots, nominal gifts to all employees, such as a turkey or ham at Christmas, allowable advertising, and flowers purchased for the enjoyment of the clients. Items reported on this line must be specifically identified.

31. Management Fees and Home Office Costs—the cost of purchased management services or home office costs incurred that are allocable to the provider. Costs included that are for related management/home office costs must also be reported on a separate cost report that includes an allocation schedule.

32. Nonemergency Medical Transportation—the cost of purchased nonemergency medical transportation services including, but not limited to, payments to employees for use of personal vehicle, ambulance companies and other transportation companies for transporting patients of the center.

33. Office Supplies and Subscriptions—cost of consumable goods used in the business office such as:

a. pencils, paper and computer supplies;

b. cost of printing forms and stationery including, but not limited to, nursing and medical forms, accounting and census forms, charge tickets, center letterhead and billing forms;

c. cost of subscribing to newspapers, magazines and periodicals.

34. Postage—cost of postage, including stamps, metered postage, freight charges and courier services.

35. Repairs and Maintenance—supplies and services, including electricians, plumbers, extended service agreements, etc., used to repair and maintain the center building, furniture and equipment except vehicles. This includes computer software maintenance.

36. Taxes and Licenses—the cost of taxes and licenses paid that are not included on any other line on Form 6. This includes tags for vehicles, licenses for center staff (including nurse aide re-certifications) and buildings.

37. Telephone and Communications—cost of telephone services, wats lines and fax services.

38. Travel—cost of travel (airfare, lodging, meals, etc.) by the administrator and other authorized personnel to attend professional and continuing educational seminars and meetings or to conduct center business. Commuting expenses and travel allowances are not allowable.

39. Vehicle Expenses—vehicle maintenance and supplies, including gas and oil.

40. Utilities—cost of water, sewer, gas, electric, cable TV and garbage collection services.

41. Allocated Costs, Hospital Based—costs that have been allocated through the step-down process from a hospital as administrative and operating costs.

42. Total Administrative and Operating Costs.

D. Property and Equipment

1. Amortization Expense, Capital—legal and other costs incurred when financing the center must be amortized over the life of the mortgage. Amortization of goodwill is not an allowable cost. Amortization of costs attributable to the negotiation or settlement of the sale or purchase of any capital asset on or after July 18, 1984, whether by acquisition or merger, for which any payment has previously been made are nonallowable costs. If allowable cost is reported on this line, an amortization schedule must be submitted with the cost report.

2. Depreciation—depreciation on the center's buildings, furniture, equipment, leasehold improvements and land improvements.

3. Interest Expense, Capital—interest paid or accrued on notes, mortgages, and other loans, the proceeds of which were used to purchase the center's land, buildings and/or furniture, equipment and vehicles.

4. Property Insurance—cost of fire and casualty insurance on center buildings, equipment and vehicles. Hospital-based facilities and state-owned facilities must allocate property insurance based on the number of square feet.

5. Property Taxes—taxes levied on the center's buildings, equipment and vehicles. Hospital-based facilities

and state-owned facilities must allocate property insurance based on the number of square feet.

6. Rent, Building—cost of leasing the center's real property.

7. Rent, Furniture and Equipment—cost of leasing the center's furniture and equipment, excluding vehicles.

8. Lease, Automotive—cost of leases for vehicles used for patient care. A mileage log must be maintained. If a leased vehicle is used for both patient care and personal purposes, cost must be allocated based on the mileage log.

9. Allocated Costs, Hospital Based—costs that have been allocated through the step-down process from a hospital or state institution as property costs when those costs include allocated overhead.

10. Total Property and Equipment.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 37:

§9113. Allowable Costs

A. Allowable costs include those costs incurred by providers to conform to state licensure and federal certification standards. General cost principles are applied during the desk review and audit process to determine allowable costs.

1. These general cost principles include determining whether the cost is:

a. ordinary, necessary, and related to the delivery of care;

b. what a prudent and cost conscious business person would pay for the specific goods or services in the open market or in an arm's length transaction; and

c. for goods or services actually provided to the center.

B. Through the desk review and/or audit process, adjustments and/or disallowances may be made to a provider's reported costs. The Medicare Provider Reimbursement Manual is the final authority for allowable costs unless the department has set a more restrictive policy.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 37:

§9115. Nonallowable Costs

A. Costs that are not based on the reasonable cost of services covered under Medicare and are not related to the care of recipients are considered nonallowable costs.

B. Reasonable cost does not include the following:

1. costs not related to client care;

2. costs specifically not reimbursed under the program;

3. costs that flow from the provision of luxury items or services (items or services substantially in excess or more expensive than those generally considered necessary for the provision of the care);

4. costs that are found to be substantially out of line with other centers that are similar in size, scope of services and other relevant factors;

5. costs exceeding what a prudent and cost-conscious buyer would incur to purchase the goods or services.

C. General nonallowable costs:

1. services for which Medicaid recipients are charged a fee;

2. depreciation of non-client care assets;

3. services that are reimbursable by other state or federally funded programs;

4. goods or services unrelated to client care;

5. unreasonable costs.

D. Specific nonallowable costs (this is not an all inclusive listing):

1. advertising—costs of advertising to the general public that seeks to increase patient utilization of the ADHC center;

2. bad debts—accounts receivable that are written off as not collectible;

3. contributions—amounts donated to charitable or other organizations;

4. courtesy allowances;

5. director's fees;

6. educational costs for clients;

7. gifts;

8. goodwill or interest (debt service) on goodwill;

9. costs of income producing items such as fund raising costs, promotional advertising, or public relations costs and other income producing items;

10. income taxes, state and federal taxes on net income levied or expected to be levied by the federal or state government;

11. insurance, officers—cost of insurance on officers and key employees of the center when the insurance is not provided to all employees;

12. judgments or settlements of any kind;

13. lobbying costs or political contributions, either directly or through a trade organization;

14. non-client entertainment;

15. non-Medicaid related care costs—costs allocated to portions of a center that are not licensed as the reporting ADHC or are not certified to participate in Title XIX;

16. officers' life insurance with the center or owner as beneficiary;

17. payments to the parent organization or other related party;

18. penalties and sanctions—penalties and sanctions assessed by the Centers for Medicare and Medicaid Services, the Internal Revenue Service or the State Tax Commission; insufficient funds charges;

19. personal comfort items; and

20. personal use of vehicles.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 37:

§9117. Audits

A. Each provider shall file an annual center cost report and, if applicable, a central office cost report.

B. The provider shall be subject to financial and compliance audits.

C. All providers who elect to participate in the Medicaid Program shall be subject to audit by state or federal regulators or their designees. Audit selection shall be at the discretion of the department.

1. The department conducts desk reviews of all of the cost reports received and also conducts on-site audits of provider cost reports.

2. The records necessary to verify information submitted to the department on Medicaid cost reports, including related-party transactions and other business activities engaged in by the provider, must be accessible to the department's audit staff.

D. In addition to the adjustments made during desk reviews and on-site audits, the department may exclude or adjust certain expenses in the cost report data base in order to base rates on the reasonable and necessary costs that an economical and efficient provider must incur.

E. The center shall retain such records or files as required by the department and shall have them available for inspection for five years from the date of service or until all audit exceptions are resolved, whichever period is longer.

F. If a center's audit results in repeat findings and adjustments, the department may:

1. withhold vendor payments until the center submits documentation that the non-compliance has been resolved;

2. exclude the provider's cost from the database used for rate setting purposes; and

3. impose civil monetary penalties until the center submits documentation that the non-compliance has been resolved.

G. If the department's auditors determine that a center's financial and/or census records are unauditable, the vendor payments may be withheld until the center submits auditable records. The provider shall be responsible for costs incurred by the department's auditors when additional services or procedures are performed to complete the audit.

H. Vendor payments may also be withheld under the following conditions:

1. a center fails to submit corrective action plans in response to financial and compliance audit findings within 15 days after receiving the notification letter from the department; or

2. a center fails to respond satisfactorily to the department's request for information within 15 days after receiving the department's notification letter.

I. The provider shall cooperate with the audit process by:

1. promptly providing all documents needed for review;

2. providing adequate space for uninterrupted review of records;

3. making persons responsible for center records and cost report preparation available during the audit;

4. arranging for all pertinent personnel to attend the closing conference;

5. insuring that complete information is maintained in client's records;

6. developing a plan of correction for areas of noncompliance with state and federal regulations immediately after the exit conference time limit of 30 days.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 37:

§9119. Exclusions from the Database

A. The following providers shall be excluded from the database used to calculate the rates:

1. providers with disclaimed audits; and

2. providers with cost reports for periods other than a 12-month period.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 37:

§9121. Provider Reimbursement

A. Cost Determination Definitions

Adjustment Factor—computed by dividing the value of the index for December of the year preceding the rate year by the value of the index one year earlier (December of the second preceding year).

Base Rate—calculated in accordance with §9121.B.5, plus any base rate adjustments granted in accordance with §9121.B.7 which are in effect at the time of calculation of new rates or adjustments.

Base Rate Components—the base rate is the summation of the following:

a. direct care;

b. care related costs;

c. administrative and operating costs;

d. property costs; and

e. transportation costs.

Indices—

a. CPI, All Items—the Consumer Price Index for All Urban Consumers-South Region (All Items line) as published by the United States Department of Labor.

b. CPI, Medical Services—the Consumer Price Index for All Urban Consumers-South Region (Medical Services line) as published by the United States Department of Labor.

B. Rate Determination

1. The base rate is calculated based on the most recent audited or desk reviewed cost for all ADHC providers filing acceptable full year cost reports.

2. Audited and desk reviewed costs for each component are ranked by center to determine the value of each component at the median.

3. The median costs for each component are multiplied in accordance with §9121.B.4 then by the appropriate economic adjustment factors for each successive year to determine base rate components. For subsequent years, the components thus computed become the base rate components to be multiplied by the appropriate economic adjustment factors, unless they are adjusted as provided in §9121.B.7 below. Application of an inflationary adjustment to reimbursement rates in non-rebasing years shall apply only when the state legislature allocates funds for this purpose. The inflationary adjustment shall be made prorating allocated funds based on the weight of the rate components.

4. The inflated median shall be increased to establish the base rate median component as follows.

a. The inflated direct care median shall be multiplied times 115 percent to establish the direct care base rate component.

b. The inflated care related median shall be multiplied times 105 percent to establish the care related base rate component.

c. The administrative and operating median shall be multiplied times 105 percent to establish the administrative and operating base rate component.

5. At least every three years, audited and desk reviewed cost report items will be compared to the rate components calculated for the cost report year to insure that the rates remain reasonably related to costs.

6. Allowable quarter hours are used to calculate the per quarter hour costs for each of the rate components. Allowable quarter hours are calculated using the following criteria:

a. A maximum daily reimbursement limit of 10 hours per participant day.

i. Repeal.

b. Reimbursement will be for full quarter hour (15 minutes) increments only.

c. The quarter hour data used in rate setting shall be from the waiver contractor's database. These hours shall be provided to the waiver contractor by the Department.

d. Repealed.

7. Formulae. Each median cost component shall be calculated as follows.

a. Direct Care Component. Direct care allowable quarter hour costs from all acceptable full year cost reports, except those for which an audit disclaimer has been issued, shall be arrayed from lowest to highest. The cost at the midpoint of the array shall be the median cost. Should there be an even number of arrayed cost, an average of the two midpoint centers shall be the median cost. The median cost shall be trended forward by dividing the value of the CPI-Medical Services (South Region) index for December of the year preceding the base rate year by the value of the index for the December of the year preceding the cost report year. The direct care rate component shall be set at 115 percent of the inflated median.

i.-ii. Repealed.

b. Care Related Cost Component. Care related allowable quarter hour costs from all acceptable full year cost reports, except those for which an audit disclaimer has been issued, shall be arrayed from lowest to highest. The cost of the center at the midpoint of the array shall be the median cost. Should there be an even number of arrayed cost, an average of the two midpoint centers shall be the median cost. The median cost shall be trended forward by dividing the value of the CPI-All Items (South Region) index for December of the year preceding the base rate year by the value of the index for the December of the year preceding the cost report year. The care related rate component shall be set at 105 percent of the inflated median.

c. Administrative and Operating Cost Component. Administrative and operating allowable quarter hour cost from all acceptable full year cost reports, except those for which an audit disclaimer has been issued, shall be arrayed from lowest to highest. The cost of the midpoint of the array shall be the median cost. Should there be an even number of arrayed cost, an average of the two midpoint centers shall be the median cost. The median cost shall be trended forward by dividing the value of the CPI-All Items (South Region) index for December of the year preceding the base rate year by the value of the index for the December of the year preceding the cost report year. The administrative and operating rate component shall be set at 105 percent of the inflated median.

d. Property Cost Component. The property allowable quarter hour costs from all acceptable full year cost reports, except those for which an audit disclaimer has been issued, shall be arrayed from lowest to highest. The cost at the midpoint of the array shall be the median cost. Should there be an even number of arrayed cost, an average of the two midpoint centers shall be the median cost. This will be the rate component. Inflation will not be added to property costs.

e. Transportation Cost Component. The transportation allowable quarter hour costs from all acceptable full year cost reports, except those for which an audit disclaimer or has been issued, will be calculated on a provider by provider basis. Should a provider not have filed an acceptable full year cost report the providers transportation cost will be reimbursed as follows:

i. New providers, as described in §9121.F.1, will be reimbursed in an amount equal to the statewide allowable quarter hour median transportation costs.

(a). In order to calculate the statewide allowable quarter hour median transportation costs, all acceptable full year cost reports, except those for which an audit disclaimer or has been issued, shall be arrayed from lowest to highest. The cost at the midpoint of the array shall be the median cost. Should there be an even number of arrayed cost, an average of the two midpoint centers shall be the median cost. This will be the rate component. Inflation will not be added to transportation costs.

ii. Providers that have gone through a change of ownership (CHOW), as described in §9121.F.2, will be reimbursed for transportation costs based upon the previous owner's specific allowable quarter hour transportation costs for the period of time between the effective date of the CHOW and the first succeeding base year in which the new owner could possibly file an allowable 12 month cost report. Thereafter, the new owner's data will be used to determine the provider's rate following the procedures specified in this rule.

iii. Providers that have been issued an audit disclaimer, or have a non-filer status, as described in §9121.F.3, will be reimbursed for transportation costs at a rate equal to the lowest allowable quarter hour transportation cost in the state as of the most recent audited and/or desk reviewed rate database.

8. Budgetary Constraint Rate Adjustment. Effective July 1, 2011 the allowable quarter hour rate components for direct care, care related, administrative and operating, property, and transportation shall be reduced by 10.8563 percent.

9. Interim Adjustments to Rates. If an unanticipated change in conditions occurs that affects the cost of at least 50 percent of the enrolled ADHC providers by an average of five percent or more, the rate may be changed. The Department will determine whether or not the rates should be changed when requested to do so by 25 percent or more of the enrolled providers, or an organization representing at least 25 percent of the enrolled providers. The burden of proof as to the extent and cost effect of the unanticipated

change will rest with the entities requesting the change. The Department may initiate a rate change without a request to do so. Changes to the rates may be temporary adjustments or base rate adjustments as described below.

a. Temporary Adjustments. Temporary adjustments do not affect the base rate used to calculate new rates.

i. Changes Reflected in the Economic Indices. Temporary adjustments may be made when changes which will eventually be reflected in the economic indices, such as a change in the minimum wage, a change in FICA or a utility rate change, occur after the end of the period covered by the indices, i.e., after the December preceding the rate calculation. Temporary adjustments are effective only until the next annual base rate calculation.

ii. Lump Sum Adjustments. Lump sum adjustments may be made when the event causing the adjustment requires a substantial financial outlay, such as a change in certification standards mandating additional equipment or furnishings. Such adjustments shall be subject to the Bureau's review and approval of costs prior to reimbursement.

b. Base Rate Adjustment. A base rate adjustment will result in a new base rate component value that will be used to calculate the new rate for the next fiscal year. A base rate adjustment may be made when the event causing the adjustment is not one that would be reflected in the indices.

10. Provider Specific Adjustment. When services required by these provisions are not made available to the recipient by the provider, the Department may adjust the prospective payment rate of that specific provider by an amount that is proportional to the cost of providing the service. This adjustment to the rate will be retroactive to the date that is determined by the Department that the provider last provided the service and shall remain in effect until the Department validates, and accepts in writing, an affidavit that the provider is then providing the service and will continue to provide that service.

C. Cost Settlement. The direct care cost component shall be subject to cost settlement. The direct care floor shall be equal to 70 percent of the median direct care rate component trended forward for direct care services (plus 70 percent of any direct care incentive added to the rate). The Medicaid Program will recover the difference between the direct care floor and the actual direct care amount expended. If a provider receives an audit disclaimer, the cost settlement for that year will be based on the difference between the direct care floor and the lowest direct care per diem of all facilities in the most recent audited and/or desk reviewed database trended forward to the rate period related to the disclaimer.

D. Support Coordination Services Reimbursement. Support coordination services previously provided by ADHC providers and included in the rate, including the Minimum Data Set Home Care (MDS/HC), the social assessment, the nursing assessment, the CPOC and home visits will no longer be the responsibility of the ADHC provider. Support coordination services shall be provided as a separate service covered in the waiver. As a result of the change in responsibilities, the rate paid to providers shall be adjusted accordingly.

1. Effective January 1, 2009, the rate paid to ADHC providers on December 31, 2008 shall be reduced by $4.67 per day which is the cost of providing support coordination services separately.

2. This rate reduction will extend until such time that the ADHC provider's rate is rebased using cost reports that do not reflect the cost of delivering support coordination services.

E. Effective for dates of service on or after August 1, 2010, the reimbursement rate for ADHC services provided in the EDA Waiver shall be reduced by 2 percent of the rates in effect on July 31, 2010.

F. New Facilities, Changes of Ownership of Existing Facilities, and Existing Facilities with Disclaimer or Non-Filer Status

1. New Facilities are those entities whose beds have not previously been certified to participate, or otherwise participated, in the Medicaid program. New facilities will be reimbursed in accordance with this rule and receiving the direct care, care related, administrative and operating, property rate components as determined in §9121.B.1 - §9121.B.7. These new facilities will also receive the state-wide average transportation rate component, as calculated in §9121.B.7.e.i.a, effective the preceding July 1.

2. A change of ownership exists if the beds of the new owner have previously been certified to participate, or otherwise participated, in the Medicaid program under the previous owner's provider agreement. Rates paid to facilities that have undergone a change in ownership will be based upon the rate paid to the previous owner for all rate components. Thereafter, the new owner's data will be used to determine the facility's rate following the procedures in this rule.

3. Existing providers that have been issued an audit disclaimer, or are a provider who has failed to file a complete cost report in accordance with §9109, will be reimbursed based upon the statewide allowable quarter hour median costs for the direct care, care related, administrative and operating, and property rate components as determined in §9121.B.1 - §9121.B.7. The transportation component will be reimbursed as described in §9121.B.7.e.iii.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 37:

Implementation of the provisions of this Rule may be contingent upon the approval of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), if it is determined that submission to CMS for review and approval is required.

Interested persons may submit written comments to Don Gregory, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. He is responsible for responding to inquiries regarding this Emergency Rule. A copy of this Emergency Rule is available for review by interested parties at parish Medicaid offices.

Bruce D. Greenstein
Secretary

1106#054

DECLARATION OF EMERGENCY

Department of Health and Hospitals
Bureau of Health Services Financing

Home and Community-Based Service Providers
Minimum Licensing Standards
(LAC 48:I.Chapter 50)

The Department of Health and Hospitals, Bureau of Health Services Financing adopts LAC 48:I.Chapter 50 in the Medical Assistance Program as authorized by R.S. 36:254 and R.S. 40:2120.1. This Emergency Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:953(B)(1) et seq., and shall be in effect for the maximum period allowed under the Act or until adoption of the final Rule, whichever occurs first.

Act 839 of the 2008 Regular Session of the Louisiana Legislature directed the Department of Health and Hospitals to adopt provisions governing the minimum licensing standards for home and community-based services (HCBS) providers and gave the department the authority to issue a single license to all providers of home and community-based services rather than a separate license for each provider type. Providers of the following services will be licensed under the comprehensive licensing standards: Adult Day Care, Family Support, Personal Care Attendant (PCA), Respite Care, Substitute Family Care, Supervised Independent Living (SIL) and Supported Employment. In compliance with the directives of Act 839, the department promulgated a Notice of Intent which proposed to revise and combine the existing licensing standards for providers of Adult Day Care services, Family Support services, Personal Care services, Respite Care services, and Supervised Independent Living services, and to adopt minimum licensing standards for providers of Substitute Family Care and Supported Employment services in order to establish comprehensive HCBS provider licensing standards and a single HCBS license (*Louisiana Register,* Volume 36, Number 6). A public hearing was conducted on July 28, 2010. As a result of the comments received, the department has now determined that it is necessary to revise and republish the provisions of the June 20, 2010 Notice of Intent. This action is being taken to promote the health and welfare of Louisiana citizens by assuring continued access to home and community-based services through the development of a more comprehensive and efficient licensing infrastructure. It is estimated that implementation of this Emergency Rule will have no programmatic costs for state fiscal year 2011-12.

Effective July 1, 2011, the Department of Health and Hospitals, Bureau of Health Services Financing adopts provisions to establish comprehensive minimum licensing standards for HCBS providers and a single HCBS license.

Title 48
PUBLIC HEALTH—GENERAL
Part 1. General Administration
Subpart 3. Licensing and Certification
Chapter 50. Home and Community-Based Services Providers Licensing Standards
Subchapter A. General Provisions
§5001. Introduction

A. Pursuant to R.S. 40:2120.2, the Department of Health and Hospitals hereby establishes the minimum licensing standards for home and community-based services (HCBS) providers. These licensing provisions contain the core requirements for HCBS providers as well as the module-specific requirements, depending upon the services rendered by the HCBS provider. These regulations are separate and apart from Medicaid Standards of Participation or any other requirements established by the Medicaid Program for reimbursement purposes.

B. Any person or entity applying for an HCBS provider license or who is operating as a provider of home and community-based services shall meet all of the core licensing requirements contained in this Chapter, as well as the module-specific requirements, unless otherwise specifically noted within these provisions.

C. Providers of the following services shall be licensed under the HCBS license:

1. Adult Day Care (ADC);
2. Family Support;
3. Personal Care Attendant (PCA);
4. Respite;
5. Substitute Family Care (SFC);
6. Supervised Independent Living (SIL), including the Shared Living Conversion services in a waiver home; and
7. Supported Employment.

D. The following entities shall be exempt from the licensure requirements for HCBS providers:

1. any person, agency, institution, society, corporation, or group that solely:
   a. prepares and delivers meals;
   b. provides sitter services; or
   c. provides housekeeping services;
2. any person, agency, institution, society, corporation, or group that provides gratuitous home and community-based services;
3. any individual licensed practical nurse (LPN) or registered nurse (RN) who has a current Louisiana license in good standing;
4. staffing agencies that supply contract workers to a health care provider licensed by the department; and
5. any person who is employed as part of a departmentally authorized self-direction program;
   a. For purposes of these provisions, a self-direction program shall be defined as a service delivery option based upon the principle of self-determination. The program

enables participants and/or their authorized representative(s) to become the employer of the people they choose to hire to provide supports to them.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5003. Definitions

Accredited—the process of review and acceptance by an accreditation body such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the Commission on Accreditation of Rehabilitation Facilities (CARF) or Council on Accreditation (COA).

Activities of Daily Living—the functions or tasks which are performed either independently or with supervision that assist an individual to live in a community setting, or that provide assistance for mobility (i.e., bathing, dressing, eating, grooming, walking, transferring and toileting).

Adult Day Care Services—structured and comprehensive services provided in a group setting that are designed to meet the individual needs of adults with functional impairments. This program provides a variety of health, social and related support services in a protective setting for a portion of a 24-hour day.

Client—an individual who is receiving services from a home and community-based service provider.

Department—the Louisiana Department of Health and Hospitals (DHH) or any of its sections, bureaus, offices or its contracted designee.

DHH Region—the geographical administrative regions designated by the Department of Health and Hospitals.

Developmental Disability—a severe, chronic condition as defined in the Developmental Disabilities Law of 2005, R.S. 28:451.l-455.2.

Family Support Services—advocacy services, family counseling, including genetic counseling, family subsidy programs, parent-to-parent outreach, legal assistance, income maintenance, parent training, homemaker services, minor home renovations, marriage and family education, and other related programs.

Health Standards Section—the licensing and certification section of the Department of Health and Hospitals.

Home and Community-Based Service Provider—an agency, institution, society, corporation, person(s) or any other group licensed by the department to provide one or more home and community-based services as defined in R.S. 40:2120.1 or these licensing provisions.

Incident—a death, serious illness, allegation of abuse, neglect or exploitation or an event involving law enforcement or behavioral event which causes serious injury to the client or others.

Individual Service Plan—a service plan developed for each client that is based on a comprehensive assessment which identifies the individual's strengths and needs in order to establish goals and objectives so that outcomes to service delivery can be measured.

Instrumental Activities of Daily Living—the functions or tasks that are not necessary for fundamental functioning but assist an individual to be able to live in a community setting. These are activities such as light house-keeping, food preparation and storage, grocery shopping, laundry, reminders to take medication, scheduling medical appointments, arranging transportation to medical appointments and accompanying the client to medical appointments.

Personal Care Attendant Services—services required for a person with a disability to become physically independent to maintain physical function or to remain in, or return to, the community.

Respite Care—an intermittent service designed to provide temporary relief to unpaid, informal caregivers of the elderly and/or people with disabilities.

Service Area—the DHH administrative region in which the provider's geographic business location is located and for which the license is issued.

Substitute Family Care Caregiver—a single or dual parent family living in a home setting which has been certified through a home study assessment as adequate and appropriate to provide care to the client by the SFC provider. At least one family member will be designated as a principal SFC caregiver.

Substitute Family Care Services—provide 24-hour personal care, supportive services and supervision to adults who meet the criteria for having a developmental disability.

Supervised Independent Living via a Shared Living Conversion model—a home and community-based shared living model for up to six persons, chosen by clients of the Residential Options Waiver (ROW), or any successor waiver, as their living option.

Supervised Independent Living Services—necessary training, social skills and medical services to enable a person who has mental illness or a developmental disability, and who is living in congregate, individual homes or individual apartments, to live as independently as possible in the community.

Supported Employment—a system of supports for people with disabilities in regards to ongoing employment in integrated settings. Supported employment can provide assistance in a variety of areas including:

1. job development;
2. job coaches;
3. job retention;
4. transportation;
5. assistive technology;
6. specialized job training; and
7. individually tailored supervision.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5005. Licensure Requirements

A. All HCBS providers shall be licensed by the Department of Health and Hospitals. It shall be unlawful to operate as a home and community-based service provider without a license issued by the department. DHH is the only licensing authority for HCBS providers in Louisiana.

B. An HCBS license shall:

1. be issued only to the person or entity named in the license application;

2. be valid only for the HCBS provider to which it is issued and only for the specific geographic address of that provider;

3. designate which home and community-based services the provider can provide;

4. enable the provider to render delineated home and community-based services within a DHH region;

5. be valid for one year from the date of issuance, unless revoked, suspended, modified or terminated prior to that date, or unless a provisional license is issued;

6. expire on the last day of the twelfth month after the date of issuance, unless timely renewed by the HCBS provider;

7. not be subject to sale, assignment, donation or other transfer, whether voluntary or involuntary; and

8. be posted in a conspicuous place on the licensed premises at all times.

C. An HCBS provider shall provide only those home and community-based services or modules specified on its license and only to clients residing in the provider's designated service area, DHH Region or at the provider's licensed location.

D. An HCBS provider may apply for a waiver from the Health Standards Section (HSS) to provide services to a client residing outside of the provider's designated service area or DHH Region only under the following condition:

1. A waiver may be granted by the department if there is no other HCBS provider in the client's service area or DHH Region that is licensed and that has the capacity to provide the required services to the client, or for other good cause shown by the HCBS provider and client.

2. The provider must submit a written waiver request to HSS prior to providing services to the client residing outside of the designated service area or DHH Region.

3. The written waiver request shall be specific to one client and shall include the reasons for which the waiver is requested.

E. In order for the HCBS provider to be considered operational and retain licensed status, the provider shall meet the following conditions.

1. Each HCBS provider shall have a business location which shall not be located in an occupied personal residence and shall conform to the provisions of §5027 of this Chapter.

a. The business location shall be part of the licensed location of the HCBS provider and shall be in the DHH Region for which the license is issued.

b. The business location shall have at least one employee on duty at the business location during stated hours of operation.

c. An HCBS provider which provides ADC services or out of home (center-based) respite care services may have the business location at the ADC building or center-based respite building.

2. Adult day care facilities shall have clearly defined days and hours of operation posted. The ADC must be open at least five hours on days of operation. Center-based respite facilities shall have the capacity to provide 24 hour services. All other HCBS providers shall render services at all times to clients receiving services in the home, according to the individual service plan (ISP).

3. There shall be adequate direct care staff and professional services staff employed and available to be assigned to provide services to persons in their homes as per the plan of care and for persons receiving ADC services and center-based respite services, during the provider's or facility's hours of operation.

4. Each HCBS provider shall have a published telephone number which is available and accessible 24 hours a day, seven days a week, including holidays.

F. The licensed HCBS provider shall abide by and adhere to any state law, rule, policy, procedure, manual or memorandum pertaining to HCBS providers.

G. A separately licensed HCBS provider shall not use a name which is substantially the same as the name of another HCBS provider licensed by the department. An HCBS provider shall not use a name which is likely to mislead the client or family into believing it is owned, endorsed or operated by the State of Louisiana.

H. Upon promulgation of the final Rule governing these provisions, existing providers of the following home and community-based services shall be required to apply for an HCBS provider license at the time of renewal of their current license(s):

1. Adult Day Care;
2. Family Support;
3. Personal Care Attendant;
4. Respite;
5. Supervised Independent Living; and
6. Supported Employment.

I. If an existing provider currently has multiple licenses, such as PCA, Respite and SIL, the provider shall be required to apply for an HCBS provider license at the time the first such license is due for renewal. The HCBS provider license shall include all modules for which the provider is currently licensed, and will replace all of the separate licenses.

J. If applicable, each HCBS provider shall obtain facility need review approval prior to licensing.

1. An existing licensed PCA, Respite or SIL provider who is applying for an HCBS provider license at the time of license renewal shall not be required to apply for facility need review approval. However, if an existing licensed provider, who is not currently providing PCA, Respite or SIL services wants to begin providing these services, the provider shall be required to apply for facility need review approval for each of the requested services.

EXAMPLE: A currently licensed PCA provider with no Respite license is now applying for his HCBS provider license and wants to add the respite module. The PCA provider shall be required to apply for facility need review approval for the respite module.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5007. Initial Licensure Application Process

A. An initial application for licensing as an HCBS provider shall be obtained from the department. A completed initial license application packet for an HCBS provider shall be submitted to and approved by the department prior to an applicant providing HCBS services.

B. The initial licensing application packet shall include:

1. a completed HCBS licensure application and the non-refundable licensing fee as established by statute;

2. a copy of the approval letter of the architectural facility plans for the adult day care module and the center-based respite module from the Office of the State Fire Marshal and any other office/entity designated by the department to review and approve the facility's architectural plans;

3. a copy of the on-site inspection report with approval for occupancy by the Office of the State Fire Marshal, if applicable;

4. a copy of the health inspection report with approval of occupancy from the Office of Public Health for the adult day care module and the center-based respite module;

5. a copy of a statewide criminal background check, including sex offender registry status, on all owners and administrators;

6. proof of financial viability, comprised of the following:

a. a line of credit issued from a federally insured, licensed lending institution in the amount of at least $50,000;

b. general and professional liability insurance of at least $300,000; and

c. worker's compensation insurance;

7. a completed disclosure of ownership and control information form;

8. the days and hours of operation;

9. an organizational chart and names, including position titles, of key administrative personnel and governing body; and

10. any other documentation or information required by the department for licensure.

C. Any person convicted of one of the following felonies is prohibited from being the owner or the administrator of an HCBS provider agency. For purposes of these provisions, the licensing application shall be rejected by the department for any felony conviction relating to:

1. the violence, abuse, or negligence of a person;

2. the misappropriation of property belonging to another person;

3. cruelty, exploitation or the sexual battery of the infirmed;

4. a drug offense;

5. crimes of a sexual nature;

6. a firearm or deadly weapon;

7. Medicare or Medicaid fraud; or

8. fraud or misappropriation of federal or state funds.

D. If the initial licensing packet is incomplete, the applicant shall be notified of the missing information and shall have 90 days from receipt of the notification to submit the additional requested information.

1. If the additional requested information is not submitted to the department within 90 days, the application shall be closed.

2. If an initial licensing application is closed, an applicant who is still interested in becoming an HCBS provider must submit a new initial licensing packet with a new initial licensing fee to start the initial licensing process, subject to any facility need review approval.

E. Applicants for HCBS licensure shall be required to attend a mandatory training class when a completed initial licensing application packet has been received by the department.

F. Upon completion of the mandatory training class and written notification of satisfactory class completion from the department, an HCBS applicant shall be required to admit one client and contact the HSS field office to schedule an initial licensing survey.

1. Prior to scheduling the initial survey, applicants must be:

a. fully operational;

b. in compliance with all licensing standards; and

c. providing care to only one client at the time of the initial survey.

2. If the applicant has not admitted one client or called the field office to schedule a survey within 30 days of receipt of the written notification from the department, the application will be closed. If an applicant is still interested in becoming an HCBS provider, a new initial licensing packet with a new initial licensing fee must be submitted to the department to start the initial licensing process, subject to any facility need review approval.

G. Applicants must be in compliance with all appropriate federal, state, departmental or local statutes, laws, ordinances, rules, regulations and fees before the HCBS provider will be issued an initial license to operate.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5009. Initial Licensing Surveys

A. Prior to the initial license being issued, an initial on-site licensing survey shall be conducted to ensure compliance with the licensing laws and standards.

B. In the event that the initial licensing survey finds that the HCBS provider is compliant with all licensing laws, regulations and other required statutes, laws, ordinances, rules, regulations, and fees, the department shall issue a full license to the provider. The license shall be valid until the expiration date shown on the license, unless the license is modified, revoked, suspended or terminated.

C. In the event that the initial licensing survey finds that the HCBS provider is noncompliant with any licensing laws or regulations, or any other required rules or regulations that present a potential threat to the health, safety, or welfare of the clients, the department shall deny the initial license.

D. In the event that the initial licensing survey finds that the HCBS provider is noncompliant with any licensing laws or regulations, or any other required rules or regulations, but the department in its sole discretion determines that the noncompliance does not present a threat to the health, safety or welfare of the clients, the department may issue a provisional initial license for a period not to exceed six months. The provider shall submit a plan of correction to the department for approval, and the provider shall be required to correct all such noncompliance or deficiencies prior to the expiration of the provisional license.

1. If all such noncompliance or deficiencies are corrected on the follow-up survey, a full license will be issued.

2. If all such noncompliance or deficiencies are not corrected on the follow-up survey, or new deficiencies affecting the health, safety or welfare of a client are cited, the provisional license will expire and the provider shall be required to begin the initial licensing process again by submitting a new initial license application packet and the appropriate licensing fee.

E. The initial licensing survey of an HCBS provider shall be an announced survey. Follow-up surveys to the initial licensing surveys are unannounced surveys.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5011. Types of Licenses and Expiration Dates

A. The department shall have the authority to issue the following types of licenses:

1. Full Initial License. The department shall issue a full license to the HCBS provider when the initial licensing survey finds that the provider is compliant with all licensing laws and regulations, and is compliant with all other required statutes, laws, ordinances, rules, regulations, and fees. The license shall be valid until the expiration date shown on the license, unless the license is modified, revoked, suspended, or terminated.

2. Provisional Initial License. The department may issue a provisional initial license to the HCBS provider when the initial licensing survey finds that the HCBS provider is noncompliant with any licensing laws or regulations or any other required statutes, laws, ordinances, rules, regulations or fees, but the department determines that the noncompliance does not present a threat to the health, safety or welfare of the clients.

3. Full Renewal License. The department may issue a full renewal license to an existing licensed HCBS provider who is in substantial compliance with all applicable federal, state, departmental, and local statutes, laws, ordinances, rules, regulations and fees. The license shall be valid until the expiration date shown on the license, unless the license is modified, revoked, suspended, or terminated.

B. The department, in its sole discretion, may issue a provisional license to an existing licensed HCBS provider for a period not to exceed six months, for any of the following reasons:

1. the existing HCBS provider has more than five deficient practices or deficiencies cited during any one survey;

2. the existing HCBS provider has more than three validated complaints in a 12 month period:

a. A validated complaint is a complaint received by the Health Standards Section and found to be substantiated;

3. the existing HCBS provider has been issued a deficiency that involved placing a client at risk for serious harm or death;

4. the existing HCBS provider has failed to correct deficient practices within 60 days of being cited for such deficient practices or at the time of a follow-up survey; or

5. the existing HCBS provider is not in substantial compliance with all applicable federal, state, departmental and local statutes, laws, ordinances, rules regulations and fees at the time of renewal of the license.

C. When the department issues a provisional license to an existing licensed HCBS provider, the provider shall submit a plan of correction to DHH for approval, and the provider shall be required to correct all such noncompliance or deficiencies prior to the expiration of the provisional license. The department shall conduct a follow-up survey, either on-site or by desk review, of the HCBS provider prior to the expiration of the provisional license.

1. If the follow-up survey determines that the HCBS provider has corrected the deficient practices and has maintained compliance during the period of the provisional license, the department may issue a full license for the remainder of the year until the anniversary date of the HCBS license.

2. If the follow-up survey determines that all non-compliance or deficiencies have not been corrected, or if new deficiencies that are a threat to the health, safety or welfare of a client are cited on the follow-up survey, the provisional license shall expire and the provider shall be required to begin the initial licensing process again by submitting a new initial license application packet and fee, subject to any facility need review approval.

3. The department shall issue written notice to the provider of the results of the follow-up survey.

D. If an existing licensed HCBS provider has been issued a notice of license revocation, suspension or termination, and the provider's license is due for annual renewal, the department shall deny the license renewal application and shall not issue a renewal license.

1. If a timely administrative appeal has been filed by the provider regarding the license revocation, suspension, or termination, the administrative appeal shall be suspensive, and the provider shall be allowed to continue to operate and provide services until such time as the administrative tribunal or department issues a decision on the license revocation, suspension, or termination.

2. If the secretary of the department determines that the violations of the HCBS provider pose an imminent or immediate threat to the health, welfare, or safety of a client, the imposition of such action may be immediate and may be enforced during the pendency of the administrative appeal. If the secretary of the department makes such a determination, the HCBS provider will be notified in writing.

3. The denial of the license renewal application does not affect in any manner the license revocation, suspension, or termination.

E. The renewal of a license does not in any manner affect any sanction, civil monetary penalty or other action imposed by the department against the provider.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5013. Changes in Licensee Information or Personnel

A. An HCBS license shall be valid only for the person or entity named in the license application and only for the specific geographic address listed on the license application.

B. Any change regarding the HCBS provider's entity name, "doing business as" name, mailing address, telephone number or any combination thereof, shall be reported in writing to the department within two days of the change.

C. Any change regarding the HCBS provider's key administrative personnel shall be reported in writing to the department within 10 days of the change.

1. Key administrative personnel include the:

a. administrator;

b. director of nursing, if applicable; and

c. medical director, if applicable.

2. The HCBS provider's notice to the department shall include the individual's:

a. name;

b. address;

c. hire date; and

d. qualifications.

D. A change of ownership (CHOW) of the HCBS provider shall be reported in writing to the department within five days of the change. The license of an HCBS provider is not transferable or assignable and cannot be sold. The new owner shall submit the legal CHOW document, all documents required for a new license and the applicable licensing fee. Once all application requirements are completed and approved by the department, a new license shall be issued to the new owner.

1. An HCBS provider that is under license revocation may not undergo a CHOW.

2. If the CHOW results in a change of geographic address, an on-site survey may be required prior to issuance of the new license.

E. If the HCBS provider changes its name without a change in ownership, the HCBS provider shall report such change to the department in writing five days prior to the change. The change in the HCBS provider name requires a change in the HCBS provider license. Payment of the applicable fee is required to re-issue the license.

F. Any request for a duplicate license shall be accompanied by the applicable fee.

G. If the HCBS provider changes the physical address of its geographic location without a change in ownership, the HCBS provider shall report such change to DHH in writing at least five days prior to the change. Because the license of an HCBS provider is valid only for the geographic location of that provider, and is not transferrable or assignable, the provider shall submit a new licensing application.

1. An on-site survey may be required prior to the issuance of the new license.

2. The change in the HCBS provider's physical address results in a new anniversary date and the full licensing fee must be paid.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5015. Renewal of License

A. The HCBS provider shall submit a completed license renewal application packet to the department at least 30 days prior to the expiration of the current license. The license renewal application packet shall include:

1. the license renewal application;

2. the days and hours of operation;

3. a current State Fire Marshal report, if applicable;

4. a current Office of Public Health inspection report for the adult day care module and the center-based respite module;

5. the non-refundable license renewal fee;

6. any other documentation required by the department; and

7. proof of financial viability, comprised of the following:

a. a line of credit issued from a federally insured, licensed lending institution in the amount of at least $50,000;

b. general and professional liability insurance of at least $300,000; and

c. worker's compensation insurance.

B. The department may perform an on-site survey and inspection upon annual renewal of a license.

C. Failure to submit a completed license renewal application packet prior to the expiration of the current license will result in the voluntary non-renewal of the HCBS license.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5016. Deemed Status through Accreditation

A. An HCBS provider may request deemed status from the department. The department may accept accreditation in lieu of a routine on-site resurvey provided that:

1. the accreditation is obtained through an organization approved by the Department;

2. all services provided under the HCBS license must be accredited; and

3. the provider forwards the accrediting body's findings to the Health Standards Section within 30 days of its accreditation.

B. The accreditation will be accepted as evidence of satisfactory compliance with all provisions of these requirements.

C. The following set of circumstances can cause the state agency to perform a full licensing survey on an accredited HCBS provider:

1. any valid complaints in the preceding 12-month period;

2. addition of services;

3. a change of ownership in the preceding 12-month period;

4. issuance of a provisions license in the preceding 12-month period;

5. serious violations of licensing standards or professional standards of practice that were identified in the preceding 12-month period; or

6. reports of inappropriate treatment or service resulting in death or serious injury.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5017. Survey Activities

A. The department, or its designee, may conduct periodic licensing surveys and other surveys as deemed necessary to ensure compliance with all laws, rules and regulations governing HCBS providers and to ensure client health, safety and welfare. These surveys may be conducted on-site or by administrative review and shall be unannounced.

B. The department shall also conduct complaint surveys. The complaint surveys shall be conducted in accordance with R.S. 40:2009.13 et seq.

C. The department may require an acceptable plan of correction from a provider for any survey where deficiencies have been cited, regardless of whether the department takes other action against the facility for the deficiencies cited in the survey. The acceptable plan of correction shall be approved by the department.

D. A follow-up survey may be conducted for any survey where deficiencies have been cited to ensure correction of the deficient practices.

E. The department may issue appropriate sanctions for noncompliance, deficiencies and violations of law, rules and regulations. Sanctions include, but are not limited to:

1. civil monetary penalties;
2. directed plans of correction; and
3. license revocation.

F. DHH surveyors and staff shall be:

1. given access to all areas of the provider agency, as necessary, and all relevant files during any survey; and
2. allowed to interview any provider staff, client or other persons as necessary or required to conduct the survey.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5019. Statement of Deficiencies

A. The following statements of deficiencies issued by the department to the HCBS provider shall be posted in a conspicuous place on the licensed premises:

1. the most recent annual survey statement of deficiencies; and
2. any subsequent complaint survey statement of deficiencies.

B. Any statement of deficiencies issued by the department to an HCBS provider shall be available for disclosure to the public 30 days after the provider submits an acceptable plan of correction to the deficiencies or 90 days after the statement of deficiencies is issued to the provider, whichever occurs first.

C. Unless otherwise provided in statute or in these licensing provisions, a provider shall have the right to an informal reconsideration of any deficiencies cited as a result of a survey or investigation.

1. Correction of the violation, noncompliance or deficiency shall not be the basis for the reconsideration.
2. The informal reconsideration of the deficiencies shall be requested in writing within 10 days of receipt of the statement of deficiencies, unless otherwise provided in these standards.
3. The request for informal reconsideration of the deficiencies shall be made to the department's Health Standards Section and will be considered timely if received by HSS within 10 days of the provider's receipt of the statement deficiencies.
4. If a timely request for an informal reconsideration is received, the department shall schedule and conduct the informal reconsideration.
5. The provider shall be notified in writing of the results of the informal reconsideration.
6. Except as provided for complaint surveys pursuant to R.S. 40:2009.13 et seq., and as provided in these licensing provisions for license denials, revocations and non-renewals, the decision of the informal reconsideration team shall be the final administrative decision regarding the deficiencies.
   a. There is no administrative appeal right of such deficiencies.
7. Pursuant to R.S. 40:2009.13 et seq., for complaint surveys in which the Health Standards Section determines that the complaint involves issues that have resulted in or are likely to result in serious harm or death, as defined in the statute, the determination of the informal reconsideration may be appealed administratively to the Division of Administrative Law or its successor. The hearing before the Division of Administrative Law, or its successor, is limited only to whether the investigation or complaint survey was conducted properly or improperly. The Division of Administrative Law shall not delete or remove deficiencies as a result of such hearing.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5021. Denial of License, Revocation of License, Denial of License Renewal

A. The department may deny an application for an initial license or a license renewal, or may revoke a license in accordance with the provisions of the Administrative Procedure Act. These actions may be taken against the entire license or certain modules of the license.

B. Denial of an Initial License

1. The department shall deny an initial license in the event that the initial licensing survey finds that the HCBS provider is noncompliant with any licensing laws or regulations, or any other required statutes or regulations that present a potential threat to the health, safety or welfare of the clients.
2. The department shall deny an initial license for any of the reasons a license may be revoked or non-renewed pursuant to these licensing provisions.
3. If the department denies an initial license, the applicant for an HCBS provider license shall discharge the client receiving services.

C. Voluntary Non-Renewal of a License. If a provider fails to timely renew its license, the license expires on its face and is considered voluntarily surrendered. There are no appeal rights for such surrender or non-renewal of the license, as this is a voluntary action on the part of the provider.

D. Revocation of License or Denial of License Renewal. An HCBS provider license may be revoked or denied renewal for any of the following reasons, including but not limited to:

1. failure to be in substantial compliance with the HCBS licensing laws, rules and regulations;
2. failure to be in substantial compliance with other required statutes, laws, ordinances, rules or regulations;
3. failure to comply with the terms and provisions of a settlement agreement or education letter;
4. failure to uphold client rights whereby deficient practices result in harm, injury or death of a client;
5. failure to protect a client from a harmful act of an employee or other client including, but not limited to:
   a. mental or physical abuse, neglect, exploitation or extortion;
   b. any action posing a threat to a client's health and safety;
   c. coercion;
   d. threat or intimidation;
   e. harassment; or
   f. criminal activity;
6. failure to notify the proper authorities, as required by federal or state law or regulations, of all suspected cases of the acts outlined in §5021.D.5;
7. knowingly making a false statement in any of the following areas, including but not limited to:

a. application for initial license or renewal of license;

b. data forms;

c. clinical records, client records or provider records;

d. matters under investigation by the department or the Office of the Attorney General; or

e. information submitted for reimbursement from any payment source;

8. knowingly making a false statement or providing false, forged or altered information or documentation to DHH employees or to law enforcement agencies;

9. the use of false, fraudulent or misleading advertising; or

10. an owner, officer, member, manager, administrator, director or person designated to manage or supervise client care has pled guilty or nolo contendere to a felony, or has been convicted of a felony, as documented by a certified copy of the record of the court;

a. For purposes of these provisions, conviction of a felony involves any felony conviction relating to:

i. the violence, abuse, or negligence of a person;

ii. the misappropriation of property belonging to another person;

iii. cruelty, exploitation or the sexual battery of the infirmed;

iv. a drug offense;

v. crimes of a sexual nature;

vi. a firearm or deadly weapon;

vii. Medicare or Medicaid fraud; or

viii. fraud or misappropriation of federal or state funds;

11. failure to comply with all reporting requirements in a timely manner, as required by the department;

12. failure to allow or refusal to allow the department to conduct an investigation or survey or to interview provider staff or clients;

13. interference with the survey process, including but not limited to, harassment, intimidation, or threats against the survey staff;

14. failure to allow or refusal to allow access to provider, facility or client records by authorized departmental personnel;

15. bribery, harassment, intimidation or solicitation of any client designed to cause that client to use or retain the services of any particular HCBS provider;

16. cessation of business or non-operational status;

17. failure to repay an identified overpayment to the department or failure to enter into a payment agreement to repay such overpayment; or

18. failure to timely pay outstanding fees, fines, sanctions or other debts owed to the department.

E. In the event an HCBS provider license is revoked, renewal is denied (other than for cessation of business or non-operational status) or the license is surrendered in lieu of an adverse action, any owner, board member, director or administrator, and any other person named on the license application of such HCBS provider is prohibited from owning, managing, directing or operating another HCBS agency for a period of two years from the date of the final disposition of the revocation, denial action or surrender.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5023. Notice and Appeal of License Denial, License Revocation and License Non-Renewal

A. Notice of a license denial, license revocation or license non-renewal (i.e. denial of license renewal) shall be given to the provider in writing.

B. The HCBS provider has a right to an informal reconsideration of the license denial, license revocation or license non-renewal. There is no right to an informal reconsideration of a voluntary non-renewal or surrender of a license by the provider.

1. The HCBS provider shall request the informal reconsideration within 15 days of the receipt of the notice of the license denial, license revocation or license non-renewal. The request for informal reconsideration shall be in writing and shall be forwarded to the department's Health Standards Section. The request for informal reconsideration shall be considered timely if received by the Health Standards Section within 15 days from the provider's receipt of the notice.

2. The request for informal reconsideration shall include any documentation that demonstrates that the determination was made in error.

3. If a timely request for an informal reconsideration is received by HSS, an informal reconsideration shall be scheduled and the provider will receive written notification of the date of the informal reconsideration.

4. The provider shall have the right to appear in person at the informal reconsideration and may be represented by counsel.

5. Correction of a violation or deficiency which is the basis for the license denial, revocation or non-renewal shall not be a basis for reconsideration.

6. The informal reconsideration process is not in lieu of the administrative appeals process.

7. The provider will be notified in writing of the results of the informal reconsideration.

C. The HCBS provider has a right to an administrative appeal of the license denial, license revocation or license non-renewal. There is no right to an administrative appeal of a voluntary non-renewal or surrender of a license by the provider.

1. The HCBS provider shall request the administrative appeal within 30 days of the receipt of the results of the informal reconsideration.

a. The HCBS provider may forego its rights to an informal reconsideration, and if so, shall request the administrative appeal within 30 days of the receipt of the notice of the license denial, revocation or non-renewal.

2. The request for administrative appeal shall be in writing and shall be submitted to the Division of Administrative Law or its successor. The request shall include any documentation that demonstrates that the determination was made in error and shall include the basis and specific reasons for the appeal.

3. If a timely request for an administrative appeal is received by the Division of Administrative Law, or its successor, the administrative appeal of the license revocation or license non-renewal shall be suspensive, and the provider shall be allowed to continue to operate and provide services

until such time as the department issues a final administrative decision.

a. If the secretary of the department determines that the violations of the provider pose an imminent or immediate threat to the health, welfare or safety of a client, the imposition of the license revocation or license non-renewal may be immediate and may be enforced during the pendency of the administrative appeal. If the secretary of the department makes such a determination, the provider will be notified in writing.

4. Correction of a violation or a deficiency which is the basis for the denial, revocation or non-renewal shall not be a basis for an administrative appeal.

D. If an existing licensed HCBS provider has been issued a notice of license revocation, and the provider's license is due for annual renewal, the department shall deny the license renewal application. The denial of the license renewal application does not affect, in any manner, the license revocation.

E. If a timely administrative appeal has been filed by the provider on a license denial, license non-renewal or license revocation, the Division of Administrative Law, or its successor, shall conduct the hearing within 90 days of the docketing of the administrative appeal. One extension, not to exceed 90 days, may be granted by the Division of Administrative Law, or its successor, if good cause is shown.

1. If the final agency decision is to reverse the license denial, license non-renewal or license revocation, the provider's license will be re-instated or granted upon the payment of any licensing fees, outstanding sanctions or other fees due to the department.

2. If the final agency decision is to affirm the license non-renewal or license revocation, the provider shall discharge any and all clients receiving services according to the provisions of this Chapter.

a. Within 10 days of the final agency decision, the provider must notify HSS, in writing, of the secure and confidential location where the client records will be stored.

F. There is no right to an informal reconsideration or an administrative appeal of the issuance of a provisional initial license to a new HCBS provider, or the issuance of a provisional license to an existing HCBS provider. A provider who has been issued a provisional license is licensed and operational for the term of the provisional license. The issuance of a provisional license is not considered to be a denial of license, renewal or revocation.

G. A provider with a provisional initial license or an existing provider with a provisional license that expires due to noncompliance or deficiencies cited at the follow-up survey, shall have the right to an informal reconsideration and the right to an administrative appeal, as to the deficiencies.

1. The correction of a violation, noncompliance or deficiency after the follow-up survey shall not be the basis for the informal reconsideration or for the administrative appeal.

2. The informal reconsideration and the administrative appeal are limited to whether the deficiencies were properly cited at the follow-up survey.

3. The provider shall request the informal reconsideration in writing, which shall be received by the Health Standards Section within five days of receipt of the notice of the results of the follow-up survey from the department.

4. The provider shall request the administrative appeal within 15 days of receipt of the notice of the results of the follow-up survey from the department. The request for administrative appeal shall be in writing and shall be submitted to the Division of Administrative Law or its successor.

5. A provider with a provisional initial license or an existing provider with a provisional license that expires under the provisions of this Chapter shall cease providing services and discharge clients unless the Division of Administrative Law, or its successor, issues a stay of the expiration.

a. The stay may be granted by the Division of Administrative Law, or its successor, upon application by the provider at the time the administrative appeal is filed and only after a contradictory hearing and only upon a showing that there is no potential harm to the clients being served by the provider.

6. If a timely administrative appeal has been filed by a provider with a provisional initial license that has expired, or by an existing provider whose provisional license has expired under the provisions of this Chapter, the Division of Administrative Law, or its successor, shall conduct the hearing within 90 days of the docketing of the administrative appeal. One extension, not to exceed 90 days, may be granted by the Division of Administrative Law, or its successor, if good cause is shown.

a. If the final agency decision is to remove all deficiencies, the provider's license will be re-instated upon the payment of any outstanding sanctions and licensing or other fees due to the department.

b. If the final agency decision is to uphold the deficiencies and affirm the expiration of the provisional license, the provider shall discharge any and all clients receiving services.

i. Within 10 days of the final agency decision, the provider must notify HSS in writing of the secure and confidential location where the client records will be stored.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5025. Inactivation of License due to a Declared Disaster or Emergency

A. An HCBS provider licensed in a parish which is the subject of an executive order or proclamation of emergency or disaster issued in accordance with R.S. 29:724 or R.S. 29:766, may seek to inactivate its license for a period not to exceed one year, provided that the following conditions are met:

1. the licensed provider shall submit written notification to the Health Standards Section within 60 days of the date of the executive order or proclamation of emergency or disaster that:

a. the HCBS provider has experienced an interruption in the provisions of services as a result of events that are the subject of such executive order or proclamation of emergency or disaster issued in accordance with R.S. 29:724 or R.S. 29:766;

b. the licensed HCBS provider intends to resume operation as an HCBS provider in the same service area;

c. includes an attestation that the emergency or disaster is the sole casual factor in the interruption of the provision of services;

d. includes an attestation that all clients have been properly discharged or transferred to another provider; and

e. provides a list of each client and where that client is discharged or transferred to;

2. the licensed HCBS provider resumes operating as a HCBS provider in the same service area within one year of the issuance of an executive order or proclamation of emergency or disaster in accordance with R.S. 29:724 or R.S. 29:766;

3. the licensed HCBS provider continues to pay all fees and cost due and owed to the department including, but not limited to, annual licensing fees and outstanding civil monetary penalties; and

4. the licensed HCBS provider continues to submit required documentation and information to the department.

B. Upon receiving a completed written request to inactivate a HCBS provider license, the department shall issue a notice of inactivation of license to the HCBS provider.

C. Upon completion of repairs, renovations, rebuilding or replacement, an HCBS provider which has received a notice of inactivation of its license from the department shall be allowed to reinstate its license upon the following conditions being met.

1. The HCBS provider shall submit a written license reinstatement request to the licensing agency of the department 60 days prior to the anticipated date of reopening.

a. The license reinstatement request shall inform the department of the anticipated date of opening, and shall request scheduling of a licensing survey.

b. The license reinstatement request shall include a completed licensing application with appropriate licensing fees.

2. The provider resumes operating as an HCBS provider in the same service area within one year.

D. Upon receiving a completed written request to reinstate an HCBS provider license, the department shall conduct a licensing survey. If the HCBS provider meets the requirements for licensure and the requirements under this Section, the department shall issue a notice of reinstatement of the HCBS provider license.

1. The licensed capacity of the reinstated license shall not exceed the licensed capacity of the HCBS provider at the time of the request to inactivate the license.

E. No change of ownership in the HCBS provider shall occur until such HCBS provider has completed repairs, renovations, rebuilding or replacement construction, and has resumed operations as an HCBS provider.

F. The provisions of this Section shall not apply to an HCBS provider which has voluntarily surrendered its license and ceased operation.

G. Failure to comply with any of the provisions of this Section shall be deemed a voluntary surrender of the HCBS provider license and any applicable facility need review approval for licensure.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Subchapter B. Administration and Organization

§5027. Governing Body

A. An HCBS provider shall have an identifiable governing body with responsibility for and authority over the policies and activities of the program/agency.

1. A provider shall have documents identifying all members of the governing body, their addresses, their terms of membership, officers of the governing body and terms of office of any officers.

2. The governing body shall be comprised of three or more persons and shall hold formal meetings at least twice a year.

3. There shall be written minutes of all formal meetings of the governing body and by-laws specifying frequency of meetings and quorum requirements.

B. The governing body of an HCBS provider shall:

1. ensure the provider's continual compliance and conformity with all relevant federal, state, local and municipal laws and regulations;

2. ensure that the provider is adequately funded and fiscally sound;

3. review and approve the provider's annual budget;

4. designate a person to act as administrator and delegate sufficient authority to this person to manage the provider agency;

5. formulate and annually review, in consultation with the administrator, written policies concerning the provider's philosophy, goals, current services, personnel practices, job descriptions and fiscal management;

6. annually evaluate the administrator's performance;

7. have the authority to dismiss the administrator;

8. meet with designated representatives of the department whenever required to do so;

9. inform the department, or its designee, prior to initiating any substantial changes in the services provided by the provider; and

10. ensure statewide criminal background checks on all unlicensed persons.

C. An HCBS provider shall maintain an administrative file that includes:

1. documents identifying the governing body;

2. a list of members and officers of the governing body, along with their addresses and terms of membership;

3. minutes of formal meetings and by-laws of the governing body, if applicable;

4. documentation of the provider's authority to operate under state law;

5. an organizational chart of the provider which clearly delineates the line of authority;

6. all leases, contracts and purchases-of-service agreements to which the provider is a party;

7. insurance policies;

8. annual budgets and audit reports; and

9. a master list of all the community resources used by the provider.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORY NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5029. Policy and Procedures

A. An HCBS provider shall provide supervision and services that:

1. conform to the department's rules and regulations;

2. meet the needs of the clients as identified and addressed in the ISP;

3. provide for the full protection of clients' rights; and

4. promote the social, physical and mental well-being of clients;

B. An HCBS provider shall make any required information or records, and any information reasonably related to assessment of compliance with these requirements, available to the department.

C. An HCBS provider shall allow designated representatives of the department, in performance of their mandated duties, to:

1. inspect all aspects of an HCBS provider's operations which directly or indirectly impact clients; and

2. conduct interviews with any staff member or client of the provider.

D. An HCBS provider shall, upon request by the department, make available the legal ownership documents.

E. The HCBS provider shall have written policies and procedures approved by the owner or governing body, which must be implemented and followed, that address at a minimum the following:

1. confidentiality and confidentiality agreements;

2. security of files;

3. publicity and marketing, including the prohibition of illegal or coercive inducement, solicitation and kickbacks;

4. personnel;

5. client rights;

6. grievance procedures;

7. client funds;

8. emergency preparedness;

9. abuse and neglect;

10. incidents and accidents, including medical emergencies;

11. universal precautions;

12. documentation; and

13. admission and discharge procedures.

F. An HCBS provider shall have written personnel policies, which must be implemented and followed, that include:

1. a plan for recruitment, screening, orientation, ongoing training, development, supervision and performance evaluation of staff members;

2. written job descriptions for each staff position, including volunteers;

3. policies that shall, at a minimum, be consistent with Office of Public Health guidelines to indicate whether, when, and how staff have a health assessment;

4. an employee grievance procedure;

5. abuse reporting procedures that require all employees to report any incidents of abuse or mistreatment, whether that abuse or mistreatment is done by another staff member, a family member, a client or any other person; and

6. a written policy to prevent discrimination.

G. An HCBS provider shall maintain, in force at all times, the requirements for financial viability under this rule.

H. The provider shall have written policies and procedures for behavior management which:

1. prohibits:

a. corporeal punishment;

b. chemical restraints;

c. psychological and verbal abuse;

d. seclusion;

e. forced exercise;

f. physical and mechanical restraints;

f. any cruel, severe, unusual, degrading or unnecessary punishment; and

g. any procedure which denies:

i. food;

ii. drink;

iii. visits with family; or

iv. use of restroom facilities;

2. ensure that non-intrusive positive approaches to address the meaning/origins of behaviors are used prior to the development of a restrictive plan; and

3. cover any behavioral emergency and provide documentation of the event in an incident report format.

I. An HCBS provider shall comply with all federal and state laws, rules and regulations in the development and implementation of its policies and procedures.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORY NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5031. Business Location

A. All HCBS providers shall have a business location in the DHH Region for which the license is issued. The business location shall be a part of the physical geographic licensed location and shall be where the provider:

1. maintains staff to perform administrative functions;

2. maintains the provider's personnel records;

3. maintains the provider's client service records; and

4. holds itself out to the public as being a location for receipt of client referrals.

B. The business location shall have a separate entrance and exit from any other entity, business or trade, and shall have appropriate signage indicating the legal or trade name and address of the health care provider. The HCBS provider shall operate independently from any other business or entity, and shall not operate office space with any other business or entity.

1. The HCBS provider may share common areas with another business or entity. Common areas include foyers, kitchens, conference rooms, hallways, stairs, elevators or escalators when used to provide access to the provider's separate entrance.

2. Records or other confidential information shall not be stored in areas deemed to be common areas.

C. The business location shall:

1. be commercial office space or, if located in a residential area, be zoned for appropriate commercial use and shall be used solely for the operation of the business;

a. the business location may not be located in an occupied personal residence;

2. have approval from the Louisiana Office of the State Fire Marshal;

3. have a published telephone number which is available and accessible 24 hours a day, seven days a week, including holidays;

4. have a business fax number that is operational 24 hours a day, seven days a week;

5. have internet access and a working e-mail address;

a. the e-mail address shall be provided to the department;

6. have hours of operation posted in a location outside of the business that is easily visible to persons receiving services and the general public; and

7. have space for storage of client records in an area that is secure and does not breach confidentiality of personal health information.

D. Branch Offices and Satellites of HCBS Providers

1. An HCBS provider who currently provides in-home services such as PCA, respite or SIL services may apply to the department for approval to operate a branch office to provide those same services. The branch office falls under the license of the parent agency and shall be located in the same DHH Region as the parent agency.

2. An HCBS provider who currently provides ADC services or provides center-based respite services may apply to the department for approval to operate a satellite location to provide additional ADC services or center-based respite services at that satellite location. The satellite location falls under the license of the parent agency and shall be located in the same DHH Region as the parent agency.

3. No branch office or satellite location may be opened without written approval from the department. In order for a branch office or satellite location to be approved, the parent agency must have full licensure for at least one year. Branch office approvals and satellite location approvals will be renewed at the time of renewal of the parent agency's license, if the parent agency meets the requirements for licensure.

4. A branch office or a satellite location shall not be approved if any of the following conditions exist:

a. the parent agency was cited with more than five deficiencies on its last annual survey or on a complaint survey within the last 12 months;

b. the parent agency was cited with a deficiency resulting in immediate jeopardy or actual harm to a client on its last annual survey or on a complaint survey within the last 12 months;

c. the parent agency has a provisional license;

d. the parent agency is under license revocation;

e. the parent agency is undergoing a change of ownership; or

f. adverse action, including license revocation, denial or suspension, has been taken against the license of other agencies operated by the owner of the parent agency.

5. The branch office or satellite location shall be held out to the public as a branch, division, or satellite of the parent agency so that the public will be aware of the identity of the agency operating the branch or satellite.

a. Reference to the name of the parent agency shall be contained in any written documents, signs or other promotional materials relating to the branch or satellite.

6. Original personnel files shall not be maintained at the branch office or satellite location.

7. A branch office or a satellite location is subject to survey, including complaint surveys, by the department at any time to determine compliance with minimum licensing standards.

8. A branch office or a satellite location shall:

a. serve as part of the geographic service area approved for the parent agency;

b. retain all original clinical records for its clients. Duplicate records need not be maintained at the parent agency, but shall be made available to state surveyors during any survey upon request within a reasonable amount of time;

c. maintain a statement of personnel policies on-site for staff usage;

d. post and maintain regular office hours; and

e. staff the branch office or satellite location during regular office hours.

9. Each branch office shall be assessed a fee of $200, assessed at the time the license application is made for the branch and once a year thereafter for renewal of the branch license. This fee is non-refundable and is in addition to any other fees that may be assessed according to the laws, rules, regulations and standards.

10. Each satellite location shall be assessed a fee of $250, assessed at the time the license application is made for the satellite location and once a year thereafter for renewal of the satellite location license. This fee is non-refundable and is in addition to any other fees that may be assessed according to the laws, rules, regulations and standards.

11. The department at its sole discretion, and taking into consideration resources of the department, may approve branch offices for HCBS providers rending in-home services.

12. The department at its sole discretion, and taking into consideration resources of the department, may approve satellite locations for HCBS providers rendering center-based respite or adult day care services.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Subchapter C. Admission, Transfer and Discharge Criteria

§5033. Admissions

A. An HCBS provider shall have written admissions policies and criteria which shall include the following:

1. intake policy and procedures;

2. admission criteria and procedures;

3. admission criteria and procedures for minors;

4. policy regarding the determination of legal status, according to appropriate state laws, before admission;

5. the age of the populations served;

6. the services provided by the provider's program(s); and

7. criteria for discharge.

B. The written description of admissions policies and criteria shall be provided to the department upon request, and made available to the client and his/her legal representative.

C. An HCBS provider shall ensure that the client, the legal representative, where appropriate, or other persons are provided an opportunity to participate in the admission process and decisions.

1. Proper consents shall be obtained before admission.

2. Where such involvement of the client is not possible or not desirable, the reasons for their exclusion shall be recorded.

D. An HCBS provider shall not refuse admission to any client on the grounds of race, national origin, ethnicity or disability.

E. An HCBS provider shall meet the needs of each client admitted to his/her program as identified and addressed in the client's ISP.

F. When refusing admission to a client, a provider shall provide a written statement as to the reason for the refusal. This shall be provided to designated representatives of the department upon request.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5035. Voluntary Transfers and Discharges

A. A client has the right to choose a provider. This right includes the right to be discharged from his current provider, be transferred to another provider and to discontinue services altogether.

B. Upon notice by the client or authorized representative that the client has selected another provider or has decided to discontinue services, the HCBS provider shall have the responsibility of planning for a client's voluntary transfer or discharge.

C. The transfer or discharge responsibilities of the HCBS provider shall include:

1. holding a transfer or discharge planning conference with the client, family, support coordinator, legal representative and advocate, if such are known, in order to facilitate a smooth transfer or discharge, unless the client declines such a meeting;

2. providing a current individual service plan (ISP). Upon written request and authorization by the client or authorized representative, a copy of the current ISP shall be provided to the client or receiving provider; and

3. preparing a written discharge summary. The discharge summary shall include, at a minimum, a summary on the health, developmental issues, behavioral issues, social issues, and nutritional status of the client. Upon written request and authorization by the client or authorized representative, a copy of the discharge summary shall be disclosed to the client or receiving provider.

D. The written discharge summary shall be completed within five working days of the notice by the client or authorized representative that the client has selected another provider or has decided to discontinue services.

1. The provider's preparation of the discharge summary shall not impede or impair the client's right to be transferred or discharged immediately if the client so chooses.

E. The provider shall not coerce the client to stay with the provider agency or interfere in any way with the client's decision to transfer. Failure to cooperate with the client's decision to transfer to another provider will result in adverse action by the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5037. Involuntary Transfers and Discharges

A. An HCBS provider shall not transfer or discharge the client from the provider except under the following circumstances. These situations will be considered involuntary transfers or discharges.

1. The client's health has improved sufficiently so that the client no longer needs the services rendered by the provider.

2. The safety or health of a client(s) or provider staff is endangered.

3. The client has failed to pay any outstanding amounts for services for which he is liable within 15 days after receipt of written notice from the provider.

4. The provider ceases to operate.

5. The client moves from the geographical region serviced by the HCBS provider.

6. The client or family refuses to cooperate or interferes with attaining the objectives of the HCBS provider.

7. The HCBS provider closes a particular module so that certain services are no longer provided.

B. When the provider proposes to involuntarily transfer or discharge a client, compliance with the provisions of this Section shall be fully documented in the client's records.

C. An HCBS provider shall provide a written notice of the involuntary transfer or discharge to the client, a family member of the client, if known, and to the authorized representative, if known, at least 30 days prior to the transfer or discharge.

1. The written notice shall be sent via certified mail, return receipt requested.

2. When the safety or health of clients or provider staff is endangered, written notice shall be given as soon as practicable before the transfer or discharge.

3. When the client has failed to pay any outstanding amounts for services for which he is liable, written notice may be given immediately. Payment is due within 15 days of receipt of written notice from the provider that an amount is due and owing.

4. The notice of involuntary discharge or transfer shall be in writing and in a language and manner that the client understands.

5. A copy of the notice of involuntary discharge or transfer shall be placed in the client's clinical record.

D. The written notice of involuntary transfer or discharge shall include:

1. a reason for the transfer or discharge;

2. the effective date of the transfer or discharge;

3. an explanation of a client's right to personal and/or third party representation at all stages of the transfer or discharge process;

4. contact information for the Advocacy Center;

a. the contact information shall include the addresses and telephone numbers for the Advocacy Center locations in Shreveport, Lafayette, and New Orleans;

5. names of provider personnel available to assist the client and family in decision making and transfer arrangements;

6. the date, time and place for the discharge planning conference;

7. a statement regarding the client's appeal rights;

8. the name of the director, current address and telephone number of the Division of Administrative Law or its successor; and

9. a statement regarding the client's right to remain with the provider and not be transferred or discharged if an appeal is timely filed.

E. Appeal Rights for Involuntary Transfers or Discharges

1. If a timely appeal is filed by the client or authorized representative disputing the involuntary discharge, the provider shall not transfer or discharge the client pursuant to the provisions of this Section.

NOTE: The provider's failure to comply with these requirements may result in revocation of a provider's license.

2. If nonpayment is the basis of the involuntary transfer or discharge, the client shall have the right to pay the balance owed to the provider up to the date of the transfer or discharge and is then entitled to remain with the agency if outstanding balances are paid.

3. If a client files a timely appeal request, the Division of Administrative Law, or its successor, shall hold an appeal hearing at the agency or by telephone, if agreed upon by the appellant, within 30 days from the date the appeal is filed with the Division of Administrative Law or its successor.

a. If the basis of the involuntary discharge is due to endangerment of the health or safety of the staff or individuals, the provider may make a written request to the Division of Administrative Law, or its successor, to hold a pre-hearing conference.

i. If a pre-hearing conference request is received by the Division of Administrative Law, or its successor, the pre-hearing conference shall be held within 10 days of receipt of the written request from the provider.

4. The Division of Administrative Law, or its successor, shall issue a decision within 30 days from the date of the appeal hearing.

5. The burden of proof is on the provider to show, by a preponderance of the evidence, that the transfer or discharge of the client is justified pursuant to the provisions of the minimum licensing standards.

F. Client's Right to Remain with the Provider Pending the Appeal Process

1. If a client is given 30 days written notice of the involuntary transfer or discharge and the client or authorized representative files a timely appeal, the client may remain with the provider and not be transferred or discharged until the Division of Administrative Law, or its successor, renders a decision on the appeal.

2. If a client is given less than 30 days written notice and files a timely appeal of an involuntary transfer/discharge based on the health and safety of individuals or provider staff being endangered, the client may remain with the provider and not be transferred or discharged until one of the following occurs:

a. the Division of Administrative Law, or its successor, holds a pre-hearing conference regarding the safety or health of the staff or individuals; or

b. the Division of Administrative Law, or its successor, renders a decision on the appeal.

3. If a client is given less than 30 days written notice and files a timely appeal of an involuntary transfer/discharge based on the client's failure to pay any outstanding amounts for services within the allotted time, the provider may discharge or transfer the client.

4. If a client is given less than 30 days written notice and files a timely appeal of an involuntary transfer/discharge based on the client moving outside of the provider's geographic service area, the client may remain with the provider and not be transferred or discharged until the Division of Administrative Law, or its successor, renders a decision on the appeal.

G. The transfer or discharge responsibilities of the HCBS provider shall include:

1. holding a transfer or discharge planning conference with the client, family, support coordinator, legal representative and advocate, if such are known, in order to facilitate a smooth transfer or discharge;

2. development of discharge options that will provide reasonable assurance that the client will be transferred or discharged to a setting that can be expected to meet his/her needs;

3. preparing an updated ISP; and

4. preparing a written discharge summary. The discharge summary shall include, at a minimum, a summary of the health, developmental issues, behavioral issues, social issues and nutritional status of the client. Upon written request and authorization by the client or authorized representative, a copy of the discharge summary and/or updated ISP shall be disclosed to the client or receiving provider.

H. The agency shall provide all services required prior to discharge that are contained in the final update of the individual service plan and in the transfer or discharge plan.

1. The provider shall not be required to provide services if the discharge is due to the client moving out of the provider's geographical region. An HCBS provider is prohibited from providing services outside of its geographical region without the Department's approval.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Subchapter D. Service Delivery

§5039. General Provisions

A. The HCBS provider shall ensure that the client receives the necessary care and services to attain or maintain the highest practicable physical, mental and psychosocial well-being of the client, in accordance with the comprehensive assessment and individual service plan.

B. All services provided to the client shall be provided in accordance with an individual service plan.

C. Assessment of Needs

1. Prior to any service being rendered, an HCBS provider shall conduct an assessment of the client's needs. The assessment shall include, at a minimum:

a. risk assessment, including:

i. life safety (i.e. the ability to access emergency services, basic safety practices and evaluation of the living unit);

ii. home environment;

iii. environmental risk; and

iv. medical risk;

b. medical assessments, including:

i. diagnosis;

ii. medications, including methods of administration; and

iii. current services and treatment regimen;

c. activities of daily living;

d. instrumental activities of daily living including money management, if applicable;

e. communication skills;

f. social skills; and

g. psychosocial skills including behavioral needs.

2. Each assessment shall be conducted by a licensed professional or a team of licensed professionals who are qualified and appropriate to conduct the assessment, and shall determine the necessary supports and services which shall be addressed in the ISP. If medical issues are identified in the assessment, a licensed physician or licensed registered nurse (RN) shall perform a medical assessment to determine necessary supports and services which shall be addressed in the ISP.

3. The assessment shall be conducted prior to admission and at least annually thereafter. The assessment may be conducted more often as the client's needs change.

4. An HCBS comprehensive assessment performed for a client in accordance with policies and procedures established by Medicaid or by a DHH program office for reimbursement purposes can substitute for the assessment required under these provisions.

D. Service Agreement

1. An HCBS provider shall ensure that a written service agreement is completed prior to admission of a client. A copy of the agreement, signed by all parties involved, shall be maintained in the client's record and shall be made available upon request by the department, the client and the legal representative, where appropriate.

2. The service agreement shall include:

a. a delineation of the respective roles and responsibilities of the provider;

b. specification of all of the services to be rendered by the provider;

c. the provider's expectations concerning the client; and

d. specification of the financial arrangements, including any fees to be paid by the client.

3. An HCBS plan of care or agreement to provide services signed by the provider or client in accordance with policies and procedures established by Medicaid or by a DHH program office for reimbursement purposes can substitute for the agreement required under these provisions.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5041. Individual Service Plan

A. Upon admission, an individual service plan shall be developed for each client based upon a comprehensive assessment.

B. The client shall participate in the planning process. If the client is unable to participate in all or part of the planning, the provider shall document the parts or times and reasons why the client did not participate.

C. The agency shall document that they consulted with the client or legal representative regarding who should be involved in the planning process.

D. The agency shall document who attends the planning meeting.

E. The provider shall ensure that the ISP and any subsequent revisions are explained to the client receiving services and, where appropriate, the legal representative, in language that is understandable to them.

F. The ISP shall include the following components:

1. the findings of the comprehensive assessment;

2. a statement of goals to be achieved or worked towards for the person receiving services and their family or legal representative;

3. daily activities and specialized services that will be provided directly or arranged for;

4. target dates for completion or re-evaluation of the stated goals; and

5. identification of all persons responsible for implementing or coordinating implementation of the plan.

G. The provider shall ensure that all agency staff working directly with the person receiving services are appropriately informed of and trained on the ISP.

H. A comprehensive plan of care or ISP prepared in accordance with policies and procedures established by Medicaid or by a DHH program office for reimbursement purposes may be substituted for the individual service plan.

I. Each client's ISP shall be reviewed, revised, updated and amended annually, and more often as necessary, to reflect changes in the client's needs, services and personal outcomes.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5043. Contract Services

A. A provider may enter into contracts or other agreements with other companies or individuals to provide services to a client. The provider is still responsible for the management of the client's care and for all services provided to the client by the contractor or its personnel.

B. When services are provided through contract, a written contract must be established. The contract shall include all of the following items:

1. designation of the services that are being arranged for by contract;

2. specification of the period of time that the contract is to be in effect;

3. a statement that the services provided to the client are in accordance with the individual service plan;

4. a statement that the services are being provided within the scope and limitations set forth in the individual service plan and may not be altered in type, scope or duration by the contractor;

5. assurance that the contractor meets the same requirements as those for the provider's staff, such as staff qualifications, functions, evaluations, orientation and in-service training;

a. the provider shall be responsible for assuring the contractor's compliance with all personnel and agency policies required for HCBS providers during the contractual period;

6. assurance that the contractor completes the clinical record in the same timely manner as required by the staff of the provider;

7. payment of fees and terms; and

8. assurance that reporting requirements are met.

C. The provider and contractor shall document review of their contract on an annual basis.

D. The provider shall coordinate services with contract personnel to assure continuity of client care.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5045. Transportation

A. An HCBS provider shall arrange for or provide transportation necessary for implementing the client's service plan.

B. Any vehicle owned by the agency or its employees used to transport clients shall be:

1. properly licensed and inspected in accordance with state law;
2. maintained in a safe condition;
3. operated at a temperature that does not compromise the health, safety or needs of the client; and
4. operated in conformity with all of the applicable motor vehicle laws.

C. The provider shall have documentation of liability insurance coverage for any vehicle owned by the agency or its employees and used to transport clients. The personal liability insurance of a provider's employee shall not be substituted for the required coverage.

D. Any staff member of the provider, or other person acting on behalf of the provider, who is operating a vehicle owned by the agency or its employees for the purpose of transporting clients shall be properly licensed to operate that class of vehicle in accordance with state law.

E. The provider shall have documentation of successful completion of a safe driving course for each employee who transports clients.

1. Employees shall successfully complete a safe driving course within 90 days of hiring, every three years thereafter, and within 90 days of the provider's discovery of any moving violation.

F. Upon hire, the provider shall conduct a driving history record of each employee, and annually thereafter.

G. The provider shall not allow the number of persons in any vehicle used to transport clients to exceed the number of available seats with seatbelts in the vehicle.

H. The provider shall ascertain the nature of any need or problem of a client which might cause difficulties during transportation. This information shall be communicated to agency staff who will transport clients.

I. The following additional arrangements are required for transporting non-ambulatory clients and those who cannot otherwise be transferred to and from the vehicle.

1. A ramp device to permit entry and exit of a client from the vehicle shall be provided for vehicles.
   a. A mechanical lift may be utilized, provided that a ramp is also available in case of emergency, unless the mechanical lift has a manual override.
2. Wheelchairs used in transit shall be securely fastened inside the vehicle utilizing approved wheelchair fasteners.
3. The arrangement of the wheelchairs shall not impede access to the exit door of the vehicle.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Subchapter E. Client Protections

§5049. Client Rights

A. Unless adjudicated by a court of competent jurisdiction, clients served by HCBS providers shall have the same rights, benefits and privileges guaranteed by the constitution and the laws of the United States and Louisiana.

B. There shall be written policies and procedures that protect the client's welfare, including the means by which the protections will be implemented and enforced.

C. Each HCBS provider's written policies and procedures, at a minimum, shall ensure the client's right to:

1. human dignity;
2. impartial access to treatment regardless of race, religion, sex, ethnicity, age or disability;
3. cultural access as evidenced by:
   a. interpretive services;
   b. translated materials;
   c. the use of native language when possible; and
   d. staff trained in cultural awareness;
4. have sign language interpretation, allow for the use of service animals and/or mechanical aids and devices that assist those persons in achieving maximum service benefits when the person has special needs;
5. privacy;
6. confidentiality;
7. access his/her records upon the client's written consent for release of information;
8. a complete explanation of the nature of services and procedures to be received, including:
   a. risks;
   b. benefits; and
   c. available alternative services;
9. actively participate in services, including:
   a. assessment/reassessment;
   b. service plan development; and
   c. discharge;
10. refuse specific services or participate in any activity that is against their will and for which they have not given consent;
11. obtain copies of the provider's complaint or grievance procedures;
12. file a complaint or grievance without retribution, retaliation or discharge;
13. be informed of the financial aspect of services;
14. be informed of the need for parental or guardian consent for treatment of services, if appropriate;
15. personally manage financial affairs, unless legally determined otherwise;
16. give informed written consent prior to being involved in research projects;
17. refuse to participate in any research project without compromising access to services;
18. be free from mental, emotional and physical abuse and neglect;
19. be free from chemical or physical restraints;
20. receive services that are delivered in a professional manner and are respectful of the client's wishes concerning their home environment;
21. receive services in the least intrusive manner appropriate to their needs;

22. contact any advocacy resources as needed, especially during grievance procedures; and

23. discontinue services with one provider and freely choose the services of another provider.

D. An HCBS provider shall assist in obtaining an independent advocate:

1. if the client's rights or desires may be in jeopardy;
2. if the client is in conflict with the provider; or
3. upon any request of the client.

E. The client has the right to select an independent advocate, which may be:

1. a legal assistance corporation;
2. a state advocacy and protection agency;
3. a trusted church or family member; or
4. any other competent key person not affiliated in any way with the licensed provider.

F. The client, client's family and legal guardian, if one is known, shall be informed of their rights, both verbally and in writing in a language they are able to understand.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5051. Grievances

A. The agency shall establish and follow a written grievance procedure to be used to formally resolve complaints by clients, their family member(s) or a legal representative regarding provision of services. The written grievance procedure shall be provided to the client.

1. The notice of grievance procedure shall include the names of organizations that provide free legal assistance.

B. The client, family member or legal representative shall be entitled to initiate a grievance at any time.

C. The agency shall annually explain the grievance procedure to the client, family member(s) or a legal representative, utilizing the most appropriate strategy for ensuring an understanding of what the grievance process entails.

1. The agency shall provide the grievance procedure in writing and grievance forms shall be made available.

D. The administrator of the agency, or his/her designee, shall investigate all grievances and shall make all reasonable attempts to address the grievance.

E. The administrator of the agency, or his/her designee, shall issue a written report and/or decision within five business days of receipt of the grievance to the:

1. client;
2. client's advocate;
3. authorized representative; and
4. the person making the grievance.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Subchapter F. Provider Responsibilities

§5053. General Provisions

A. HCBS providers shall have qualified staff sufficient in number to meet the needs of each client as specified in the ISP and to respond in emergency situations.

B. Additional staff shall be employed as necessary to ensure proper care of clients and adequate provision of services.

C. Staff shall have sufficient communication and language skills to enable them to perform their duties and interact effectively with clients and other staff persons.

D. All client calls to the provider's published telephone number shall be returned within an appropriate amount of time not to exceed 24 hours. Each client shall be informed of the provider's published telephone number, in writing, as well as through any other method of communication most readily understood by the client according to the following schedule:

1. upon admission to the HCBS provider agency;
2. at least once per year after admission; and
3. when the provider's published telephone number changes.

E. HCBS providers shall establish policies and procedures relative to the reporting of abuse and neglect of clients, pursuant to the provisions of R.S. 15:1504-1505, R.S. 40:2009.20 and any subsequently enacted laws. Providers shall ensure that staff complies with these regulations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORY NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5055. Core Staffing Requirements

A. Administrative Staff. The following administrative staff is required for all HCBS providers:

1. a qualified administrator at each licensed geographic location who shall meet the qualifications as established in these provisions; and

2. other administrative staff as necessary to properly safeguard the health, safety and welfare of the clients receiving services.

B. Administrator Qualifications

1. The administrator shall be a resident of the state of Louisiana and shall have the following educational qualifications and experience:

a. a master's degree in a human services field including, but not limited to:

i. nursing, hospital or nursing facility administration;
ii. physical therapy;
iii. social work;
iv. psychology;
v. gerontology;
vi. rehabilitation counseling; or
vii. health care administration; plus
viii. a minimum of three years of verifiable work experience with persons with disabilities or the elderly, with one year of the three years being at the administrative level; or

b. a bachelor's degree in a human services field including, but not limited to:

i. nursing, hospital or nursing facility administration;
ii. physical therapy;
iii. social work;
iv. psychology
v. gerontology;

vi. rehabilitation counseling; or

vii. health care administration; plus

viii. a minimum of four years verifiable work experience with persons with disabilities or the elderly, with two years of the four years being at the administrative level;

c. be a registered nurse with a minimum of seven years of verifiable work experience with persons with disabilities or the elderly, with three years of the seven years being at the administrative level; or

d. have a Juris Doctorate or a Master's or PhD in business management, provided there is a full-time individual on staff in a managerial position who has a human service degree.

2. Any person convicted of a felony as defined in these provisions is prohibited from serving as the administrator of an HCBS provider agency.

C. Administrator Responsibilities. The administrator shall:

1. be a full time employee of the HCBS provider and shall not be a contract employee;

2. be available in person or by telecommunication at all times for all aspects of agency operation;

3. designate in writing an individual who meets the qualifications for an administrator to assume the authority and control of the agency if the administrator is unavailable;

4. direct the operations of the agency;

5. be responsible for compliance with all regulations, laws, policies and procedures applicable to home and community-based service providers;

6. employ qualified individuals and ensure adequate staff education and evaluations;

7. ensure the accuracy of public information and materials;

8. act as liaison between staff, contract personnel and the governing body;

9. implement an ongoing, accurate and effective budgeting and accounting system;

10. ensure that all staff receive proper orientation and training on policies and procedures, client care and services and documentation, as required by law or as necessary to fulfill each staff person's responsibilities;

11. assure that services are delivered according to the client's individual service plan; and

12. not serve as administrator for more than one licensed HCBS provider.

D. Professional Services Staff

1. The provider shall employ, contract with or assure access to all necessary professional staff to meet the needs of each client as identified and addressed in the client's ISP. The professional staff shall include, but not be limited to:

a. licensed practical nurses;

b. registered nurses;

c. speech therapists;

d. physical therapists;

e. occupational therapists;

f. social workers; and

g. psychologists.

2. Professional staff employed or contracted by the provider shall hold a current, valid license issued by the appropriate licensing board and shall comply with continuing education requirements of the appropriate board.

3. The provider shall maintain proof of annual verification of current license of all professional staff.

4. All professional services furnished or provided shall be provided in accordance with acceptable professional practice standards, according to the scope of practice requirements for each licensed discipline.

E. Direct Care Staff

1. The provider shall be staffed with direct care staff to properly safeguard the health, safety and welfare of clients.

2. The provider shall employ direct care staff to ensure the provision of home and community-based services as required by the ISP.

3. The HCBS provider shall have back-up staff available on a 24-hour basis to ensure that services to the client are uninterrupted in the event that the primary direct care staff for the client is unable to report to work.

F. Direct Care Staff Qualifications

1. All providers who receive state or federal funds, and compensate their direct service workers with such funds, shall ensure that all non-licensed direct care staff meet the minimum mandatory qualifications and requirements for direct service workers as required by R.S. 40:2179-40:2179.1 or a subsequently amended statute and any rules published pursuant to those statutes.

2. All direct care staff shall have the ability to read, write and carry out directions competently as assigned.

a. The training must address areas of weakness, as determined by the worker's performance reviews, and may address the special needs of clients.

3. All direct care staff shall be trained in recognizing and responding to the medical emergencies of clients.

G. Direct Care Staff Responsibilities. The direct care staff shall:

1. provide personal care services to the client, per the ISP;

2. provide the direct care services to the client at the time and place assigned;

3. report and communicate changes in a client's condition to a supervisor immediately upon discovery of the change;

4. report and communicate a client's request for services or change in services to a supervisor on the date of such request;

5. follow emergency medical training while attending the client;

6. subsequently report any medical emergencies to the supervisor, the provider or others, pursuant to the provider policies and procedures;

7. report any suspected abuse, neglect or exploitation of clients to a supervisor on the date of discovery, and as required by law;

8. be trained on daily documentation such as progress notes and progress reports; and

9. be responsible for daily documentation of services provided and status of clients to be reported on progress notes and/or progress reports.

H. Volunteers/Student Interns

1. A provider utilizing volunteers or student interns on a regular basis shall have a written plan for using such resources. This plan shall be given to all volunteers and

interns. The plan shall indicate that all volunteers and interns shall:

a. be directly supervised by a paid staff member;

b. be oriented and trained in the philosophy, policy and procedures of the provider, confidentiality requirements and the needs of clients; and

c. have documentation of three reference checks.

2. Volunteer/student interns shall be a supplement to staff employed by the provider but shall not provide direct care services to clients.

I. Direct Care Staff Supervisor. The HCBS provider shall designate and assign a direct care staff supervisor to monitor and supervise the direct care staff.

1. The supervisor shall be selected based upon the needs of the client outlined in the ISP.

2. A provider may have more than one direct care staff supervisor.

3. Staff in supervisor positions shall have annual training in supervisory and management techniques.

J. Direct Care Supervision

1. A direct care staff supervisor shall make an onsite supervisor visit of each direct care staff not to exceed 90 days between visits. Supervisory visits should occur more frequently:

a. if dictated by the ISP;

b. as needed to address worker performance;

c. to address a client's change in status; or

d. to assure services are provided in accordance with the ISP.

2. The supervisory visit shall be unannounced and utilized to evaluate the direct care staff's ability to perform assigned duties, determine whether services are being provided in accordance with the ISP and whether goals are being met.

3. Documentation of supervision shall include:

a. the worker/client relationship;

b. services provided;

c. observations of the worker performing assigned duties;

d. instructions and comments given to the worker during the onsite visit;

e. verification that the worker is actually reporting to the work site according to the frequency specified in the ISP; and

f. client satisfaction with service delivery.

4. An annual performance evaluation for each direct care staff person shall be documented in his/her personnel record.

K. Direct Care Staff Training

1. The provider shall ensure that each direct care staff satisfactorily completes a minimum of 16 hours of training upon hire and before providing direct care and services to clients. Such training shall include the following topics and shall be documented in each employee's personnel record:

a. the provider's policies and procedures;

b. emergency and safety procedures;

c. recognizing and responding to medical emergencies that require an immediate call to 911;

d. client's rights;

e. detecting and reporting suspected abuse and neglect, utilizing the department's approved training curriculum;

f. reporting critical incidents;

g. universal precautions;

h. documentation;

i. implementing service plans;

j. confidentiality;

k. detecting signs of illness or dysfunction that warrant medical or nursing intervention;

l. basic skills required to meet the health needs and problems of the client; and

m. the management of aggressive behavior, including acceptable and prohibited responses.

2. The provider shall ensure that each direct care staff satisfactorily completes a basic first aid course within 45 days of hire.

3.

L. Competency Evaluation

1. A competency evaluation must be developed and conducted to ensure that each direct care staff, at a minimum, is able to demonstrate competencies in the training areas in §5055.K.

2. Written or oral examinations shall be provided.

3. The examination shall reflect the content and emphasis of the training curriculum components in §5055.K and shall be developed in accordance with accepted educational principles.

4. A substitute examination, including an oral component, will be developed for those direct care staff with limited literacy skills. This examination shall contain all of the content that is included in the written examination and shall also include a written reading comprehension component that will determine competency to read job-related information.

M. Continuing Education

1. Annually thereafter, the provider shall ensure that each direct care staff person satisfactorily completes a minimum of 16 hours of continuing training in order to ensure continuing competence. Orientation and normal supervision shall not be considered for meeting this requirement. This training shall address the special needs of clients and may address areas of employee weakness as determined by the direct care staff's performance reviews.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5057. Client Records

A. Client records shall be maintained in the HCBS provider's office. Current progress notes shall be maintained at the home. The provider shall have a written record for each client which shall include:

1. other identifying data including:

a. name;

b. date of birth;

c. address;

d. telephone number;

e. social security number; and

f. legal status;

2. a copy of the client's ISP or Medicaid comprehensive plan of care, as well as any modifications or updates to the service plan;

3. the client's history including, where applicable:

a. family data;

b. next of kin;
c. educational background;
d. employment record;
e. prior medical history; and
f. prior service history;

4. the service agreement or comprehensive plan of care;

5. written authorization signed by the client or, where appropriate, the legally responsible person for emergency care;

6. written authorization signed by the client or, where appropriate, the legally responsible person for managing the client's money, if applicable;

7. a full and complete separate accounting of each client's personal funds which includes a written record of all of the financial transactions involving the personal funds of the client deposited with the provider;

a. the client (or his legal representative) shall be afforded reasonable access to such record;

b. the financial records shall be available through quarterly statements;

c. the provider shall safeguard and account for any such funds;

8. required assessment(s) and additional assessments that the provider may have received or is privy to;

9. the names, addresses and telephone numbers of the client's physician(s) and dentist;

10. written progress notes or equivalent documentation and reports of the services delivered for each client for each visit. The written progress notes shall include, at a minimum:

a. the date and time of the visit and services;
b. the services delivered;
c. who delivered or performed the services;
d. observed changes in the physical and mental condition(s) of the client, if applicable; and
e. doctor appointments scheduled or attended that day;

11. health and medical records of the client, including:

a. a medical history, including allergies;

b. a description of any serious or life threatening medical condition(s);

c. a description of any medical treatment or medication necessary for the treatment of any medical condition; and

d. physician delegation form for the administration of medication or treatment, if applicable; and

12. a copy of any advance directive that has been provided to the HCBS provider, or any physician orders relating to end of life care and services.

B. HCBS providers shall maintain client records for a period of five years.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5059. Client Funds and Assets

A. The HCBS provider shall develop and implement written policies and procedures to protect client funds.

B. If the provider manages a client's personal funds, the provider must furnish a written statement which includes the client's rights regarding personal funds, a list of the services offered and charges, if any, to the client and/or his/her legal or responsible representative.

C. If a client chooses to entrust funds with the provider, the provider shall obtain written authorization from the client and/or his/her legal or responsible representative for the safekeeping and management of the funds.

D. The provider shall:

1. provide each client with an account statement on a quarterly basis with a receipt listing the amount of money the provider is holding in trust for the client;

2. maintain a current balance sheet containing all financial transactions to include the signatures of staff and the client for each transaction;

3. provide a list or account statement regarding personal funds upon request of the client;

4. maintain a copy of each quarterly account statement in the client's record;

5. keep funds received from the client for management in a separate account and maintain receipts from all purchases with each receipt being signed by the client and the staff assisting the client with the purchase, or by the staff assisting the client with the purchase and an independent staff when the client is not capable of verifying the purchase; and

6. not commingle the clients' funds with the provider's operating account.

E. A client with a personal fund account managed by the HCBS provider may sign an account agreement acknowledging that any funds deposited into the personal account, by the client or on his/her behalf, are jointly owned by the client and his legal representative or next of kin. The account agreement shall state that:

1. the funds in the account shall be jointly owned with the right of survivorship;

2. the funds in the account shall be used by the client or on behalf of the client;

3. the client or the joint owner may deposit funds into the account; and

4. the client or joint owner may endorse any check, draft or other instrument to the order of any joint owner, for deposit into the account.

F. If the provider is managing funds for a client and he/she is discharged, any remaining funds shall be refunded to the client or his/her legal or responsible representative within five business days of notification of discharge.

G. Distribution of Funds upon the Death of a Client

1. Unless otherwise provided by state law, upon the death of a client, the provider shall provide the executor or administrator of the client's estate or the client's responsible representative with a complete account statement of the client's funds and personal property being held by the provider.

2. If a valid account agreement has been executed by the client, the provider shall transfer the funds in the client's personal fund account to the joint owner within 30 days of the client's death. This provision only applies to personal fund accounts not in excess of $2,000.

3. If a valid account agreement has not been executed, the provider shall comply with the federal and state laws and regulations regarding the disbursement of funds in the account and the properties of the deceased. The provider shall comply with R.S. 9:151–181, the Louisiana Uniform

Unclaimed Property Act, and the procedures of the Louisiana Department of the Treasury regarding the handling of a deceased client's funds that remain unclaimed.

H. A termination date of the account and the reason for termination shall be recorded on the client's participation file. A notation shall read, "to close account." The endorsed cancelled check with check number noted on the ledger sheet shall serve as sufficient receipt and documentation.

I. Burial or Insurance Policies

1. Upon discharge of a client, the provider shall immediately remit any burial policies or insurance policies to the client or his/her legal or responsible representative.

2. Upon the death of a client, the provider shall act upon any burial or insurance policies of the client accordingly.

J. The provisions of this section shall have no effect on federal or state tax obligations or liabilities of the deceased client's estate. If there are other laws or regulations which conflict with these provisions, those laws or regulations will govern over and supersede the conflicting provisions.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5061. Quality Enhancement Plan

A. An HCBS provider shall have a quality enhancement (QE) plan which puts systems in place to effectively identify issues for which quality monitoring, remediation and improvement activities are necessary. The QE plan includes plans of action to correct identified issues including monitoring the effect of implemented changes and making needed revisions to the action plan.

B. The QE plan shall include:

1. a process for obtaining input annually from the client/guardian/authorized representatives and family members ,as applicable. This process shall include, but not be limited to:

a. satisfaction surveys done by mail or telephone;

b. focus groups; and

c. other processes for receiving input regarding the quality of services received;

2. a 10 percent sample review of client case records and/or site visits on a quarterly bases to assure that:

a. individual service plans are up to date;

b. records are complete and current; and

c. supervisory visits are current and documented;

3. a process for identifying on a quarterly basis the risk factors that affect or may affect the health, safety and/or welfare of individuals being supported which includes, but is not limited to:

a. review and resolution of complaints;

b. review and resolution of incidents; and

c. Office of Protective Services' investigations of abuse, neglect and exploitation;

4. a process to review and resolve individual client issues that are identified; and

5. a process to review and develop action plans to resolve all system wide issues identified as a result of the processes above.

C. The QE program outcomes shall be reported to the administrator for action, as necessary, for any identified systemic problems.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5063. Emergency Preparedness

A. A disaster or emergency may be a local, community-wide, regional or statewide event. Disasters or emergencies may include, but are not limited to:

1. tornados;
2. fires;
3. floods;
4. hurricanes;
5. power outages;
6. chemical spills;
7. biohazards;
8. train wrecks; or
9. declared health crisis.

B. Providers shall ensure that each client has an individual plan for dealing with emergencies and disasters and shall assist clients in identifying the specific resources available through family, friends, the neighborhood and the community.

C. Continuity of Operations. The provider shall have an emergency preparedness plan to maintain continuity of the agency's operations in preparation for, during and after an emergency or disaster. The plan shall be designed to manage the consequences of all hazards, declared disasters or other emergencies that disrupt the provider's ability to render care and treatment, or threatens the lives or safety of the clients.

D. The provider shall follow and execute its emergency preparedness plan in the event of the occurrence of a declared disaster or other emergency. The plan shall include, at a minimum:

1. provisions for the delivery of essential services to each client as identified in the individualized emergency plan for each client, whether the client is in a shelter or other location;

2. provisions for the management of staff, including provisions for adequate, qualified staff as well as for distribution and assignment of responsibilities and functions;

3. provisions for back-up staff;

4. the method that the provider will utilize in notifying the client's family or caregiver if the client is evacuated to another location either by the provider or with the assistance or knowledge of the provider. This notification shall include:

a. the date and approximate time that the facility or client is evacuating;

b. the place or location to which the client(s) is evacuating which includes the name, address and telephone number; and

c. a telephone number that the family or responsible representative may call for information regarding the provider's evacuation;

5. provisions for ensuring that supplies, medications, clothing and a copy of the service plan are sent with the client, if the client is evacuated; and

6. the procedure or methods that will be used to ensure that identification accompanies the individual. The identification shall include the following information:

a. current and active diagnosis;

b. medication, including dosage and times administered;

c. allergies;

d. special dietary needs or restrictions; and

e. next of kin, including contact information.

E. If the state, parish or local Office of Homeland Security and Emergency Preparedness (OHSEP) orders a mandatory evacuation of the parish or the area in which the agency is serving, the agency shall ensure that all clients are evacuated according to the client's individual plan and the agency's emergency preparedness plan.

1. The provider shall not abandon a client during a disaster or emergency. The provider shall not evacuate a client to a shelter without ensuring staff and supplies remain with the client at the shelter, in accordance with the client's service plan.

F. Emergency Plan Review and Summary. The provider shall review and update its emergency preparedness plan, as well as each client's emergency plan at least annually.

G. The provider shall cooperate with the department and with the local or parish OHSEP in the event of an emergency or disaster and shall provide information as requested.

H. The provider shall monitor weather warnings and watches as well as evacuation order from local and state emergency preparedness officials.

I. All agency employees shall be trained in emergency or disaster preparedness. Training shall include orientation, ongoing training and participation in planned drills for all personnel.

J. Upon request by the department, the HCBSP shall submit a copy of its emergency preparedness plan and a written summary attesting how the plan was followed and executed. The summary shall contain, at a minimum:

1. pertinent plan provisions and how the plan was followed and executed;

2. plan provisions that were not followed;

3. reasons and mitigating circumstances for failure to follow and execute certain plan provisions;

4. contingency arrangements made for those plan provisions not followed; and

5. a list of all injuries and deaths of clients that occurred during execution of the plan, evacuation or temporary relocation including the date, time, causes and circumstances of the injuries and deaths.

K. Inactivation of License due to a Declared Disaster or Emergency.

1. An HCBS provider licensed in a parish which is the subject of an executive order or proclamation of emergency or disaster, as issued in accordance with R.S. 29:724 or R.S. 29:766 may seek to inactivate its license for a period not to exceed one year, provided that the following conditions are met:

a. the licensed provider shall submit written notification to the Health Standards Section within 60 days of the date of the executive order or proclamation of emergency or disaster that:

i. the HCBS provider has experienced an interruption in the provisions of services as a result of events that are the subject of such executive order or proclamation of emergency or disaster issued in accordance with R.S. 29:724 or R.S. 29:766;

ii. the licensed HCBS provider intends to resume operation as an HCBS provider in the same service area;

iii. includes an attestation that the emergency or disaster is the sole casual factor in the interruption of the provision of services;

iv. includes an attestation that all clients have been properly discharged or transferred to another provider; and

v. provides a list of each client and where that client is discharged or transferred to;

b. the licensed HCBS provider resumes operating as a HCBS provider in the same service area within one year of the issuance of an executive order or proclamation of emergency or disaster in accordance with R.S. 29:724 or R.S. 29:766;

c. the licensed HCBS provider continues to pay all fees and cost due and owed to the department including, but not limited to, annual licensing fees and outstanding civil monetary penalties; and

d. the licensed HCBS provider continues to submit required documentation and information to the department.

2. Upon receiving a completed written request to inactivate a HCBS provider license, the department shall issue a notice of inactivation of license to the HCBS provider.

3. Upon completion of repairs, renovations, rebuilding or replacement, an HCBS provider which has received a notice of inactivation of its license from the department shall be allowed to reinstate its license upon the following conditions being met.

a. The HCBS provider shall submit a written license reinstatement request to the licensing agency of the department 60 days prior to the anticipated date of reopening.

b. The license reinstatement request shall inform the department of the anticipated date of opening, and shall request scheduling of a licensing survey.

c. The license reinstatement request shall include a completed licensing application with appropriate licensing fees.

d. The provider resumes operating as an HCBS provider in the same service area within one year.

4. Upon receiving a completed written request to reinstate an HCBS provider license, the department shall conduct a licensing survey. If the HCBS provider meets the requirements for licensure and the requirements under this Section, the department shall issue a notice of reinstatement of the HCBS provider license.

a. The licensed capacity of the reinstated license shall not exceed the licensed capacity of the HCBS provider at the time of the request to inactivate the license.

5. No change of ownership in the HCBS provider shall occur until such HCBS provider has completed repairs, renovations, rebuilding or replacement construction, and has resumed operations as an HCBS provider.

6. The provisions of this Section shall not apply to an HCBS provider which has voluntarily surrendered its license and ceased operation.

7. Failure to comply with any of the provisions of this Section shall be deemed a voluntary surrender of the HCBS provider license and any applicable facility need review approval for licensure.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Subchapter G. Adult Day Care Module

§5071. General Provisions

A. Providers applying for the Adult Day Care module under the HCBS license shall meet the core licensing requirements as well as the module specific requirements of this Section.

B. Adult Day Care is designed to meet the individual needs of functionally impaired adults. This is a structured and comprehensive group program which provides a variety of health, social, and related support services in a protective setting for a portion of the 24-hour day.

C. An ADC program shall provide services for 10 or more functionally impaired adults who are not related to the owner or operator of the HCBS provider.

1. For the purposes of this Section, "*functionally impaired adult*" shall be defined as individuals 17 years of age or older who are physically, mentally or socially impaired to a degree that requires supervision.

D. The following two programs shall be provided under the ADC Module:

1. Day Habilitation Services

a. Day habilitation services include assistance with acquisition, retention or improvement in self-help, socialization, and adaptive skills that take place in a non-residential setting separate from the recipient's private residence or other residential living arrangement. Day habilitation services provide activities and environments designed to foster the acquisition of skills, appropriate behavior, greater independence and personal choice.

b. Services are furnished to a client who is 17 years of age or older and has a developmental disability, or who is a functionally impaired adult, on a regularly scheduled basis during normal daytime working hours for one or more days per week, or as specified in the recipient's service plan.

c. Day habilitation services focus on enabling the recipient to attain or maintain his or her maximum functional level, and shall be coordinated with any physical, occupational, or speech therapies in the service plan. These services may also serve to reinforce skills or lessons taught in other settings.

2. Prevocational/Employment-Related Services

a. Prevocational/employment-related services prepare a recipient for paid or unpaid employment. Services include teaching such concepts as compliance, attendance, task completion, problem solving and safety. Services are not job-task oriented, but are aimed at a generalized result. These services are reflected in the recipient's service plan and are directed to habilitative (e.g. attention span, motor skills) rather than explicit employment objectives.

b. Prevocational services are provided to clients who are not expected to join the general work force or participate in a transitional sheltered workshop within one year of service initiation.

c. This service is not available to clients eligible to receive services under a program funded under the Rehabilitation Act of 1973 or the IDEA.

E. When applying for the ADC module under the HCBS provider license, the provider shall indicate whether it is providing day habilitation, prevocational/employment-related services or both.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5073. Operational Requirements

A. The client/staff ratio in an ADC facility shall be one staff person per eight clients, unless additional staff coverage is needed to meet the needs of the client, as specified in the service plan.

B. Staff Training

1. ADC Staff in supervisory positions shall have annual training in supervisory and management techniques.

2. Each ADC facility shall have a training supervisor who shall receive at least 15 hours of annual vocational and/or community-based employment training.

3. Once the training supervisor receives all of the required training, he/she shall be responsible for ensuring that direct care staff receives training on vocational and/or community-based employment training.

C. Food and Nutrition

1. If meals are prepared by the facility or contracted from an outside source, the following conditions shall be met:

a. menus shall be written in advance and shall provide for a variety of nutritional foods;

b. records of menus, as served, shall be filed and maintained for at least 30 days;

c. modified diets shall be prescribed by a physician;

d. only food and drink of safe quality shall be purchased;

e. storage, preparation, and serving techniques shall be provided to ensure nutrients are retained and spoilage is prevented;

f. food preparation areas and utensils shall be kept clean and sanitary;

g. there shall be an adequate area for eating; and

h. the facility shall designate one staff member who shall be responsible for meal preparation/serving if meals are prepared in the facility.

2. When meals are not prepared by the facility, the following conditions shall be met:

a. provisions shall be made for obtaining food for clients who do not bring their lunch; and

b. there shall be an adequate area for eating.

3. Drinking water shall be readily available. If a water fountain is not available, single-use disposable cups shall be used.

4. Dining areas shall be adequately equipped with tables, chairs, eating utensils and dishes designed to meet the functional needs of clients.

5. Adequate refrigeration of food shall be maintained.

D. General Safety Practices

1. A facility shall not maintain any firearms or chemical weapons at any time.

2. A facility shall ensure that all poisonous, toxic and flammable materials are safely stored in appropriate containers and labeled as to the contents. Such materials shall be maintained only as necessary and shall be used in such a manner as to ensure the safety of clients, staff and visitors.

3. Adequate supervision/training shall be provided where potentially harmful materials such as cleaning solvents and/or detergents are used.

4. A facility shall ensure that a first aid kit is available in the facility and in all vehicles used to transport clients.

5. Medication shall be locked in a secure storage area or cabinet.

6. Fire drills shall be performed at least once a month.

E. Physical Environment

1. The ADC building shall be constructed, equipped and maintained to ensure the safety of all individuals. The building shall be maintained in good repair and kept free from hazards such as those created by any damage or defective parts of the building.

2. The provider shall maintain all areas of the facility that are accessible to individuals, and ensure that all structures on the ground of the facility are in good repair and kept free from any reasonable foreseeable hazards to health or safety.

3. The facility shall be accessible to and functional for those cared for, the staff and the public. All necessary accommodations shall be made to meet the needs of clients. Training or supports shall be provided to help clients effectively negotiate their environments.

4. There shall be a minimum of 35 square feet of space per client. Kitchens, bathrooms and halls used as passageways, and other spaces not directly associated with program activities, shall not be considered as floor space available to clients.

5. There shall be storage space, as needed by the program, for training and vocational materials, office supplies, etc.

6. Rooms used for recipient activities shall be well ventilated and lighted.

7. There shall be separate space for storage of a client's personal belongings.

8. Chairs and tables shall be adequate in number to serve the clients.

9. Bathrooms and lavatories shall be accessible, operable and equipped with toilet paper, soap and paper towels or hand drying machines. Every bathroom shall be wheelchair accessible.

a. For existing, licensed ADCs, there shall be one bathroom per every 12 persons at the ADC facility.

b. For newly licensed, newly constructed, renovated or relocated ADCs, there shall be two bathrooms, one for male and one for female, each having a commode/toilet and lavatory for every 15 persons at the ADC facility. c. Individuals shall be provided privacy when using bathroom facilities.

d. Every bathroom door shall be designed to permit opening of the locked door from the outside, in an emergency, and the opening device shall be readily accessible to the staff.

10. Stairways shall be kept free of obstruction and fire exit doors shall be maintained in working order. All stairways shall be equipped with handrails.

11. There shall be a telephone available and accessible to all clients.

12. The ADC shall be equipped with a functional air conditioning and heating unit(s) which maintains an ambient temperature between 65 and 80 degrees Fahrenheit throughout the ADC.

13. The building in which the ADC is located shall meet the standards of the Americans with Disabilities Act.

F. Employment of Clients

1. The provider shall meet all of the state and federal wage and hour regulations regarding employment of clients who are admitted to the agency.

a. The provider must maintain full financial records of clients' earnings if the facility pays the client.

b. The provider shall have written assurance that the conditions and compensation of work are in compliance with applicable state and federal employment regulations.

c. The provider must have a U.S. Department of Labor Sub-Minimum Wage Certificate if the provider pays sub-minimum wage.

2. Clients shall not be required to perform any kind of work involving the operation or maintenance of the facility without compensation in accordance with the U.S. Department of Labor sub-minimum standard.

3. Clients shall be directly supervised when operating any type of power driven equipment such as lawn mowers or electrical saws, unless:

a. the ID team has determined that direct supervision is not necessary;

b. equipment has safety guards or devices; and

c. adequate training is given to the recipient and the training is documented.

4. Clients shall be provided with the necessary safety apparel and safety devices to perform the job.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Subchapter H. Family Support Module

§5075. General Provisions

A. Providers applying for the Family Support module under the HCBS license shall meet the core licensing requirements as well as the module specific requirements of this Section.

B. The purpose of family support services is to:

1. keep the family of a person with a disability together by promoting unity, independence of the family in problem solving and maintenance of the family as the primary responsible caretaker;

2. determine if barriers to home placement for persons with a disability can be eliminated or relocated through financial assistance for purchases, special equipment and supplies;

3. allow a person with a disability to remain in or return to a family setting as an alternative to placement in a more restrictive setting; and

4. link families of a person with a disability to existing support services and to supplement those services where necessary (i.e. transportation to reach services when not otherwise provided).

C. Services covered by the family support module may include:

1. special equipment;
2. limited adaptive housing;
3. medical expenses and medications;
4. nutritional consultation and regime;
5. related transportation;
6. special clothing;
7. special therapies;
8. respite care;

9. dental care; and
10. family training and therapy.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5077. Operational Requirements

A. Providers shall ensure that each family receiving services is assigned a service coordinator.

B. The service coordinator shall perform the following tasks:

1. prepare a family study, based on a home visit interview with the client, in order to ascertain what appropriate family support services may be provided;
2. visit each client at least quarterly;
3. maintain documentation of all significant contacts; and
4. review and evaluate, at least every six months, the care, support and treatment each client is receiving.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Subchapter I. Personal Care Attendant Module

§5079. General Provisions

A. Providers applying for the Personal Care Attendant module under the HCBS license shall meet the core licensing requirement as well as the module specific requirements of this Section.

B. Personal care attendant services may include:

1. assistance and prompting with:
   a. personal hygiene;
   b. dressing;
   c. bathing;
   d. grooming;
   e. eating;
   f. toileting;
   g. ambulation or transfers;
   h. behavioral support;
   i. other personal care needs; and
   j. any medical task which can be delegated;
2. assistance and/or training in the performance of tasks related to:
   a. maintaining a safe and clean home environment such as housekeeping, bed making, dusting, vacuuming and laundry;
   b. cooking;
   c. shopping;
   d. budget management;
   e. bill paying; and
   f. evacuating the home in emergency situations;
3. personal support and assistance in participating in community, health and leisure activities which may include transporting and/or accompanying the participant to these activities;
4. support and assistance in developing relationships with neighbors and others in the community and in strengthening existing informal, social networks and natural supports; and
5. enabling and promoting individualized community supports targeted toward inclusion into meaningful, integrated experiences (e.g. volunteer work and community awareness) activities.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5081. Operational Requirements

A. PCA providers shall schedule personal care attendant staff in the manner and location as required by each client's ISP.

B. PCA providers shall have a plan that identifies at least one trained and qualified back-up worker for each client served.

1. It is the responsibility of the provider to ensure that a trained and qualified back-up worker is available as needed to meet the requirements of the ISP.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORY NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Subchapter J. Respite Care

§5083. General Provisions

A. Providers applying for the Respite Care module under the HCBS license shall meet the core licensing requirement as well as the applicable module specific requirements of this Section.

B. The goal of respite care is to provide temporary, intermittent relief to informal caregivers in order to help prevent unnecessary or premature institutionalization while improving the overall quality of life for both the informal caregiver and the client.

C. Respite care may be provided as an in-home or center-based service. The services may be provided in the client's home or in a licensed respite center.

D. Providers of in-home respite care services must comply with:

1. all HCBS providers core licensing requirements;
2. PCA module specific requirements; and
3. the respite care services module in-home requirements.

E. Providers of center-based respite care services must comply with:

1. all HCBS providers core licensing requirements;
2. respite care services module in-home requirements; and
3. respite care services module center-based requirements.

F. When applying for the respite care service module under the HCBS provider license, the provider shall indicate whether it is providing in-home respite care, center-based respite care or both.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5085. Operational Requirements for In-Home Respite Care

A. All in-home respite care service providers shall:

1. make available to clients, the public and HSS the day and hours that respite is to be provided;
2. make available to clients, the public and HSS a detailed description of populations served as well as services and programming; and

B. In-home respite care service providers shall have adequate administrative, support, professional and direct care staff to meet the needs of clients at all times.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5087. Operational Requirements for Center-Based Respite Care

A. All center-based respite care service providers shall meet the following daily aspects of care.

1. The daily schedule shall be developed in relation to the needs of the clients.

2. Clients shall be assisted in ADL's as needed.

a. The provider shall ensure that the family supplies the client with his/her own clothing.

3. The provider shall make available to each client an adequate number of supervised recreational activities.

B. All center-based respite care service providers shall meet the following health aspects of care.

1. Responsibility for the health supervision of the client shall be placed with the client's personal physician.

a. The provider shall have written agreements for obtaining diagnosis and treatment of medical and dental problems for clients who do not have a personal physician. This agreement can be with a local hospital, clinic or physician.

2. Arrangements for medical isolation shall be available. The provider shall inform the family to remove the client when necessary.

3. Medication shall be prescribed only by a licensed physician.

C. Food and Nutrition

1. Planning, preparation and serving of foods shall be in accordance with the nutritional, social, emotional and medical needs of the clients. The diet shall include a variety of food, and be attractively served. Clients shall be encouraged, but not forced, to eat all of the food served.

2. Food provided shall be of adequate quality and in sufficient quantity to provide the nutrients for proper growth and development.

3. Clients shall be provided a minimum of three meals daily, plus snacks.

4. All milk and milk products used for drinking shall be Grade A and pasteurized.

5. There shall be no more than 14 hours between the last meal or snack on one day and the first meal of the following day.

D. The provider shall request from the family that all clients over five years of age have money for personal use. Money received by a client shall be his own personal property and shall be accounted for separately from the provider's funds.

E. Privacy

1. The HCBS provider staff shall function in a manner that allows appropriate privacy for each client.

2. The space and furnishings shall be designed and planned to enable the staff to respect the clients' right to privacy and at the same time provide adequate supervision according to the ages and developmental needs of the client.

3. The provider shall not use reports or pictures, nor release (or cause to be released) research data, from which clients can be identified without written consent from the client, parents or legal guardians.

F. Contact with Family, Friends and Representatives

1. Clients in care shall be allowed to send and receive uncensored mail and conduct private telephone conversations with family members.

2. If it has been determined that the best interests of the client necessitate restrictions on communications or visits, these restrictions shall be documented in the service plan.

3. If limits on communication or visits are indicated for practical reasons, such as expense of travel or telephone calls, such limitations shall be determined with the participation of the client and family.

G. Furnishings and Equipment

1. Furnishings and equipment shall be adequate, sufficient and substantial for the needs of the age groups in care.

2. All bedrooms shall be on or above street grade level and be outside rooms. Bedrooms shall accommodate no more than four residents. Bedrooms must provide at least 60 square feet per person in multiple sleeping rooms and not less than 80 square feet in single rooms.

3. Each resident shall be provided a separate bed of proper size and height, a clean, comfortable mattress and bedding appropriate for weather and climate.

4. There shall be separate sleeping rooms for adults and for adolescents. When possible, there should be individual sleeping rooms for clients whose behavior would be upsetting to others.

5. Appropriate furniture shall be provided, such as a chest of drawers, a table or desk, an individual closet with clothes racks and shelves accessible to the residents.

6. Individual storage space reserved for the client's exclusive use shall be provided for personal possessions such as clothing and other items so that they are easily accessible to the resident during his/her stay.

H. Bath and Toilet Facilities

1. There shall be a separate toilet/bathing area for males and females beyond pre-school age. The provider shall have one toilet/bathing area for each eight clients admitted, but in no case shall have less than two toilet/bathing areas.

2. Toilets should be convenient to sleeping rooms and play rooms.

3. Toilets, bathtubs and showers shall provide for individual privacy unless specifically contraindicated for the individual, as stated in the service plan.

4. Bath/toilet area shall be accessible, operable and equipped with toilet paper, soap and paper towels or hand drying machines.

5. Every bath/toilet shall be wheelchair accessible.

6. Individuals shall be provided privacy when using a bath/toilet area.

7. Every bath/toilet area door shall be designed to permit opening of the locked door from the outside, in an emergency. The opening device shall be readily accessible to the staff.

I. There shall be a designated space for dining. Dining room tables and chairs shall be adjusted in height to suit the ages of the clients.

J. Heat and Ventilation

1. The temperature shall be maintained within a reasonable comfort range (65 to 80 degrees Fahrenheit).

2. Each habitable room shall have access to direct outside ventilation by means of windows, louvers, air conditioner, or mechanical ventilation horizontally and vertically.

K. Health and Safety

1. The facility shall comply with all applicable building codes, fire and safety laws, ordinances and regulations.

2. Secure railings shall be provided for flights of more than four steps and for all galleries more than four feet from the ground.

3. Where clients under age two are in care, gates shall be provided at the head and foot of each flight of stairs accessible to these clients.

4. Before swimming pools are made available for client use, written documentation must be received by DHH confirming that the pool meets the requirements of the Virginia Graeme Baker Pool and Spa Safety Act of 2007 or, in lieu of, written documentation confirming that the pool meets the requirements of ANSI/APSP-7 (2006 Edition) which is entitled the "American National Standard for Suction Entrapment Avoidance in Swimming Pools, Wading pools, Spas, Hot Tubs and Catch Basins."

a. An outdoor swimming pool shall be enclosed by a six foot high fence. All entrances and exits to pools shall be closed and locked when not in use. Machinery rooms shall be locked to prevent clients from entering.

b. An individual, 18 years of age or older, shall be on duty when clients are swimming in ponds, lakes or pools where a lifeguard is not on duty. The individual is to be certified in water safety by the American Red Cross.

c. There shall be written plans and procedures for water safety.

5. Storage closets or chests containing medicine or poisons shall be securely locked.

6. Garden tools, knives and other dangerous instruments shall be inaccessible to clients without supervision.

7. Electrical devices shall have appropriate safety controls.

L. Maintenance

1. Buildings and grounds shall be kept clean and in good repair.

2. Outdoor areas shall be well drained.

3. Equipment and furniture shall be safely and sturdily constructed and free of hazards to clients and staff.

4. The arrangement of furniture in living areas shall not block exit ways.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Subchapter K. Substitute Family Care Module

§5089. General Provisions

A. Providers applying for the Substitute Family Care module under the HCBS license shall meet the core licensing requirements as well as the module specific requirements of this Section. In addition to complying with the appropriate licensing regulations, SFC providers shall also establish:

1. an advisory committee comprised of persons with developmental disabilities and their families to provide guidance on the aspirations of persons with developmental disabilities who live in home and community settings.

2. a medical decision-making committee for each SFC client who is unable to give informed consent for surgical or medical treatment which shall fulfill the requirements for executing medical decision-making for those clients as required by R.S. 40.1299.53 or its successor statute.

B. Substitute family care services provide 24-hour personal care, supportive services, and supervision to adults who meet the criteria for having a developmental disability.

C. The SFC Program is designed to:

1. support individuals with developmental disabilities in a home environment in the community through an array of naturally occurring and arranged community resources similar to those enjoyed by most individuals living in the community in all stages of life;

2. expand residential options for persons with developmental disabilities;

a. This residential option also takes into account compatibility of the substitute family and the participant, including individual interests, age, health, needs for privacy, supervision and support needs;

3. provide meaningful opportunities for people to participate in activities of their choosing whereby creating a quality of life not available in other settings.

4. serve persons who require intensive services for medical, developmental or psychological challenges;

a. The SFC provider is required to provide the technical assistance, professional resources and more intensive follow-up to assure the health, safety and welfare of the client(s).

D. Substitute family care services are delivered by a principal caregiver, in the caregiver's home, under the oversight and management of a licensed SFC provider.

1. The SFC caregiver is responsible for providing the client with a supportive family atmosphere in which the availability, quality and continuity of services are appropriate to the age, capabilities, health conditions and special needs of the individual.

2. The licensed SFC provider shall not be allowed to serve as the SFC caregiver.

E. Potential clients of the SFC program shall meet the following criteria:

1. have a developmental disability as defined in R.S. 28:451.1-455.2 of the Louisiana Developmental Disability Law or its successor statute;

2. be at least 18 years of age; and

3. have an assessment and service plan pursuant to the requirements of the HCBS provider licensing rule;

a. The assessment and service plan shall assure that the individual's health, safety and welfare needs can be met in the SFC setting.

F. SFC Caregiver Qualifications

1. An SFC caregiver shall be certified by the SFC provider before any clients are served. In order to be certified, the SFC caregiver applicant shall:

a. undergo a professional home study;

b. participate in all required orientations, trainings, monitoring and corrective actions required by the SFC provider; and

c. meet all of the caregiver specific requirements of this Section.

2. The personal qualifications required for certification include:

a. Residency. The caregiver shall reside in the state of Louisiana and shall provide SFC services in the caregiver's home. The caregiver's home shall be located in the state of Louisiana and in the region in which the SFC provider is licensed.

b. Criminal Record and Background Clearance. Members of the SFC caregiver's household shall not have any felony convictions. Other persons approved to provide care or supervision of the SFC client for the SFC caregiver shall not have any felony convictions.

i. Prior to certification, the SFC caregiver, all members of the SFC caregiver applicant's household and persons approved to provide care or supervision of the SFC client on a regular or intermittent basis, shall undergo a criminal record and background check.

ii. Annually thereafter, the SFC caregiver, all members of the SFC caregiver applicant's household and persons approved to provide care or supervision of the SFC client on a regular or intermittent basis, shall have background checks.

c. Age. The SFC principal caregiver shall be at least 21 years of age. Maximum age of the SFC principal caregiver shall be relevant only as it affects his/her ability to provide for the SFC client as determined by the SFC provider through the home assessment. The record must contain proof of age.

3. The SFC caregiver may be either single or married. Evidence of marital status must be filed in the SFC provider's records and may include a copy of legal documents adequate to verify marital status.

4. The SFC caregiver is not prohibited from employment outside the home or from conducting a business in the home provided that:

a. the SFC home shall not be licensed as another healthcare provider;

b. such employment or business activities do not interfere with the care of the client;

c. such employment or business activities do not interfere with the responsibilities of the SFC caregiver to the client;

d. a pre-approved, written plan for supervision of the participant which identifies adequate supervision for the participant is in place; and

e. the plan for supervision is signed by both the SFC caregiver and the administrator or designee of the SFC provider.

G. The SFC caregiver shall not be certified as a foster care parent(s) for the Department of Social Services (DSS) while serving as a caregiver for a licensed SFC provider.

1. The SFC provider, administrator or designee shall request confirmation from DSS that the SFC caregiver applicant is not presently participating as a foster care parent and document this communication in the SFC provider's case record.

H. In addition to the discharge criteria in the core requirements, the client shall be discharged from the SFC program upon the client meeting any of the following criteria:

1. incarceration or placement under the jurisdiction of penal authorities or courts for more than 30 days;

2. lives in or changes his/her residence to another region in Louisiana or another state;

3. admission to an acute care hospital, rehabilitation hospital, intermediate care facility for persons with developmental disabilities (ICF/DD) or nursing facility with the intent to stay longer than 90 consecutive days;

4. the client and/or his legally responsible party(s) fails to cooperate in the development or continuation of the service planning process or service delivery;

5. a determination is made that the client's health and safety cannot be assured in the SFC setting; or

6. failure to participate in SFC services for 30 consecutive days for any reason other than admission to an acute care hospital, rehabilitation hospital, ICF/DD facility or nursing facility.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5090. Operational Requirements for Substitute Family Care Providers

A. Training

1. Prior to the introduction of an SFC client into a SFC home, the SFC provider shall ensure that the caregiver receives a minimum of six hours of training designed to assure the health and safety of the client, including any areas relevant to the SFC client's support needs.

a. The provider shall also conduct a formal review of the SFC client's support needs, particularly regarding medical and behavioral concerns as well as any other pertinent areas.

2. Within the first 90 days following the client's move into the home, the SFC provider shall provide and document training to the SFC caregiver(s) on:

a. the client's support plan and the provider's responsibilities to assure successful implementation of the plan;

b. emergency plans and evacuation procedures;

c. client rights and responsibilities; and

d. any other training deemed necessary to support the person's individual needs.

3. Annually, the SFC provider shall provide the following training to the SFC caregiver:

a. six hours of approved training related to the client's needs and interests including the client's specific priorities and preferences; and

b. six hours of approved training on issues of health and safety such as the identification and reporting of allegations of abuse, neglect or exploitation.

4. On an as needed basis the SFC provider shall provide the SFC caregiver with additional training as may be deemed necessary by the provider.

B. Supervision and Monitoring. The SFC provider shall provide ongoing supervision of the SFC caregiver to ensure quality of services and compliance with licensing standards.

Ongoing supervision and monitoring shall consist of the following.

1. The SFC provider shall conduct in-person monthly reviews of each SFC caregiver and/or household in order to:

a. monitor the health and safety status of the client through visits;

i. more frequent visits shall be made when concerns are identified;

b. monitor the implementation of the client's service plan to ensure that it is effective in promoting accomplishment of the client's goals;

c. assure that all services included in the service plan are readily available and utilized as planned;

d. assure that the objectives of the medical, behavioral or other plans are being accomplished as demonstrated by the client's progress; and

e. resolve discrepancies or deficiencies in service provision.

2. The SFC provider shall conduct annual reviews of each SFC caregiver and/or household in order to assure the annual certification relating to health, safety and welfare issues and the client's adjustment to the SFC setting. The annual review shall include:

a. written summaries of the SFC caregiver's performance of responsibilities and care for the client(s) placed in the home;

b. written evaluation of the strengths and needs of the SFC home and the client's relationship with the SFC caregiver, including the goals and future performance;

c. review of all of the licensing standards to ensure compliance with established standards;

d. review of any concerns or the need for corrective action, if indicated; and

e. complete annual inventory of the client's possessions.

C. The SFC provider shall assure the following minimum services are provided by the SFC caregiver:

1. 24-hour care and supervision, including provisions for:

a. a flexible, meaningful daily routine;

b. household tasks;

c. food and nutrition;

d. clothing;

e. care of personal belongings;

f. hygiene; and

g. routine medical and dental care;

2. room and board;

3. routine and reasonable transportation;

4. assurance of minimum health, safety and welfare needs;

5. participation in school, work or recreational/leisure activities, as appropriate;

6. access to a 24-hour emergency response through written emergency response procedures for handling emergencies and contact numbers for appropriate staff for after hours; and

a. For purposes of these provisions, after hours shall include holidays, weekends, and hours between 4:31 p.m. and 7:59 a.m. on Monday through Friday;

7. general supervision of personal needs funds retained for the client's use if specified in the service plan.

D. Client Records

1. SFC Providers shall ensure that the SFC caregiver complies with the following standards for client records.

a. Information about clients and services of the contract agency shall be kept confidential and shared with third parties only upon the written authorization of the client or his/her authorized representative, except as otherwise specified in law.

b. The SFC caregiver shall make all client records available to the department or its designee and any other state or federal agency having authority to review such records.

c. The SFC caregiver shall ensure the privacy of the client's protected health information.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5091. Operational Requirements for Substitute Family Care Caregivers

A. The SFC caregiver(s) shall provide adequate environments that meet the needs of the clients.

B. The SFC caregiver's home shall be located within a 25 mile radius of community facilities, resources and services such as medical care, schools, recreation facilities, churches and other community facilities, unless a waiver is granted by the department.

C. The home of the SFC family shall not be used as lodging for any person(s) who is not subject to the prior approval certification process of the SFC family. The SFC family shall notify the administrator, or designee of the SFC provider, of any person(s) allowed to live in the home following the initial certification.

1. In a non-emergent situation, prior notification is required. In an emergent situation, notification shall be made within 48 hours of the additional person's move into the substitute's family home.

2. All persons residing with the SFC family, even on a non-permanent basis, shall undergo criminal record and background checks.

3. The SFC family shall accept persons requiring care or supervision only through the SFC provider with whom they have a current contract.

D. The SFC caregiver shall care for no more than two SFC clients in the caregiver's home. The SFC caregiver shall allow no more than three persons unrelated to the principal caregiver to live in the home. These three persons include the SFC clients.

E. The SFC caregiver shall have a stable income sufficient to meet routine expenses, independent of the payments for their substitute family care services, as demonstrated by a reasonable comparison between income and expenses conducted by the administrator or designee of the SFC provider.

F. The SFC caregiver must have a plan that outlines in detail the supports to be provided. This plan shall be approved and updated as required by the SFC provider. The SFC caregiver shall allow only approved persons to provide care or supervision to the SFC client.

1. An adequate support system for the supervision and care of the participant in both on-going and emergent situations shall include:

a. identification of any person(s) who will supervise the participant on a regular basis which must be prior approved by the administrator or designee of the SFC agency provider;

b. identification of any person(s) who will supervise for non-planned (emergency) assumption of supervisory duties who has not been previously identified and who shall be reported to the agency provider administrator or designee within 12 hours; and

c. established eligibility for available and appropriate community resources.

G. The SFC caregiver and/or household shall receive referrals only from the licensed SFC provider with whom it has a contract.

H. SFC Caregiver's Home Environment

1. The home of the SFC caregiver shall be safe and in good repair, comparable to other family homes in the neighborhood. The home and its exterior shall be free from materials and objects which constitute a danger to the individual(s) who reside in the home.

2. SFC homes featuring either a swimming or wading pool must ensure that safety precautions prevent unsupervised accessibility to clients.

3. The home of the SFC caregiver shall have:

a. functional air conditioning and heating units which maintain an ambient temperature between 65 and 80 degrees Fahrenheit;

b. a working telephone;

c. secure storage of drugs and poisons;

d. secure storage of alcoholic beverages;

e. pest control;

f. secure storage of fire arms and ammunition;

g. household first aid supplies to treat minor cuts or burns;

h. plumbing in proper working order and availability of a method to maintain safe water temperatures for bathing; and

i. a clean and sanitary home, free from any health and/or safety hazards.

4. The SFC home shall be free from fire hazards such as faulty electrical cords, faulty appliances and non-maintained fireplaces and chimneys, and shall have the following:

a. operating smoke alarms within 10 feet of each bedroom;

b. portable chemical fire extinguishers located in the kitchen area of the home;

c. posted emergency evacuation plans which shall be practiced at least quarterly; and

d. two unrestricted doors which can be used as exits.

5. The SFC home shall maintain environments that meet the following standards.

a. There shall be a bedroom for each client with at least 80 square feet exclusive of closets, vestibules and bathrooms and equipped with a locking door, unless contraindicated by any condition of the client.

i. The department may grant a waiver from individual bedroom and square feet requirements upon good cause shown, as long as the health, safety and welfare of the client are not at risk.

b. Each client shall have his own bed unit, including frame, which is appropriate to his/her size and is fitted with a non-toxic mattress with a water proof cover.

c. Each client shall have a private dresser or similar storage area for personal belongings that is readily accessible to the client.

d. There shall be a closet, permanent or portable, to store clothing or aids to physical functioning, if any, which is readily accessible to the client.

e. The client shall have access to a working telephone.

f. The home shall have one bathroom for every two members of the SFC household, unless waived by the department.

g. The home shall have cooking and refrigeration equipment and kitchen and or dining areas with appropriate furniture that allows the client to participate in food preparation and family meals.

h. The home shall have sufficient living or family room space, furnished comfortably and accessible to all members of the household.

i. The home shall have adequate light in each room, hallway and entry to meet the requirements of the activities that occur in those areas.

j. The home shall have window coverings to ensure privacy.

I. Automobile Insurance and Safety Requirements

1. Each SFC caregiver shall have a safe and dependable means of transportation available as needed for the client.

2. The SFC caregiver shall provide the following information to the SFC provider who is responsible for maintaining copies in its records:

a. current and valid driver's licenses of persons routinely transporting the client;

b. current auto insurance verifications demonstrating at least minimal liability insurance coverage;

c. documentation of visual reviews of current inspection stickers; and

d. documentation of a driving history report on each family member who will be transporting the client.

3. If the client(s) are authorized to operate the family vehicle, sufficient liability insurance specific to the client(s) use shall be maintained at all times.

J. Client Records

1. The SFC caregiver shall forward all client records, including progress notes and client service notes to the SFC provider on a monthly basis. The following information shall be maintained in the client records in the SFC caregiver's home:

a. client's name, sex, race and date of birth;

b. client's address and the telephone number of the client's current place of employment, school or day provider;

c. clients' Medicaid/Medicare and other insurance cards and numbers;

d. client's social security number and legal status;

e. name and telephone number of the client's preferred hospital, physician and dentist ;

f. name and telephone number of the closest living relative or emergency contact person for the client;

g. preferred religion (optional) of the client;

h. Medicaid eligibility information;

i. medical information, including, but not limited to:

i. current medications, including dosages, frequency and means of delivery;

ii. the condition for which each medication is prescribed; and

iii. allergies;

j. identification and emergency contact information on persons identified as having authority to make emergency medical decisions in the case of the individual's inability to do so independently;

k. progress notes written on at least a monthly basis summarizing services and interventions provided and progress toward service objectives; and

i. Checklists alone are not adequate documentation for progress notes;

l. a copy of the client's ISP and any vocational and behavioral plans.

2. Each SFC family shall have documentation attesting to the receipt of an adequate explanation of:

a. the client's rights and responsibilities;

b. grievance procedures;

c. critical incident reports; and

d. formal grievances filed by the client.

3. All records maintained by the SFC caregiver shall clearly identify the:

a. date the information was entered or updated in the record;

b. signature or initials of the person entering the information; and

c. documentation of the need for ongoing services.

K. The SFC caregiver shall be required to take immediate actions to protect the health, safety and welfare of clients at all times.

1. When a client has been involved in a critical incident or is in immediate jeopardy, the SFC caregiver shall seek immediate assistance from emergency medical services and local law enforcement agencies, as needed.

2. If abuse, neglect or exploitation is suspected or alleged, the SFC caregiver is required to report such abuse, neglect or exploitation in accordance with R.S.40:2009.20 or any successor statute.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Subchapter L. Supervised Independent Living Module

§5093. General Provisions

A. Providers applying for the Supervised Independent Living Module under the HCBS license shall meet the core licensing requirements as well as the module specific requirements of this Section.

B. When applying for the SIL module under the HCBS provider license, the provider shall indicate whether the provider is initially applying as an SIL or as an SIL via shared living conversion process, or both.

C. Clients receiving SIL services must be at least 18 years of age. An SIL living situation is created when an SIL client utilizes an apartment, house or other single living unit as his place of residence.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5094. Operational Requirements for the Supervised Independent Living Module

A. A provider shall ensure that the living situation is freely selected by the client and that the living situation shall be:

1. accessible and functional, considering any physical limitations or other disability of the client;

2. free from any hazard to the health or safety of the client;

3. properly equipped with accommodations for activities of daily living;

4. in compliance with applicable health, safety, sanitation and zoning codes;

5. a living situation that affords the client individual privacy;

6. arranged such that if there is more than one client in the living situation, the living environment does not conflict with the individual clients ISP;

7. equipped with a separate functional kitchen area including space for food storage and a preparation area.

8. equipped with a separate functional private bathroom. There shall be at least one bathroom for every two clients residing at the SIL. Entrance to a bathroom from one bedroom shall not be through another bedroom. Entrance to the client's bathroom shall be accessible without the client having to traverse through another client's bedroom;

9. equipped with a separate living area;

10. equipped with a separate private bedroom with a locking door, if not contraindicated by a condition of the client residing in the room.

a. There shall be at least one bedroom for each two clients living in the SIL. There shall be a window in each bedroom. Each bedroom shall contain a minimum of 80 square feet for single resident bedrooms or 120 square feet for two resident bedrooms. This square footage shall be exclusive of closets, vestibules and bathrooms.

b. There shall be no more than two clients per bedroom. Each client shall be provided his own bed. However, a married couple may share a bed;

11. equipped with hot and cold water faucets that are easily identifiable and are equipped with a method for scald control;

12. equipped with functional utilities, including:

a. water;

b. sewer; and

c. electricity;

13. equipped with functional air conditioning and heating units which maintain an ambient temperature between 65 and 80 degrees Fahrenheit throughout the SIL;

14. kept in a clean, comfortable home-like environment;

15. equipped with the following furnishings:

a. a bed unit per client which includes a frame, clean mattress and clean pillow;

b. a private dresser or similar storage area for personal belongings that is readily accessible to the resident. There shall be one dresser per client;

c. one closet, permanent or portable, to store clothing or aids to physical functioning, if any, which is

readily accessible to the resident. There shall be one closet per client;

d. a minimum of two chairs per client;

e. a table for dining;

f. window treatments to ensure privacy; and

g. adequate light in each room, hallway and entry to meet the requirements of the activities that occur in those areas; and

16. equipped with a functional smoke detector and fire extinguisher.

B. An SIL shall provide any client placed in the living situation:

1. 24-hour access to a working telephone in the SIL;

2. access to transportation; and

3. access to any services in the client's approved ISP.

C. The department shall have the right to inspect the SIL and client's living situation.

D. An SIL provider shall ensure that no more than four clients are placed in an apartment, house or other single living unit utilized as a supervised independent living situation.

1. A SIL living situation shall make allowances for the needs of each client to ensure reasonable privacy which shall not conflict with the program plan of any resident of the living situation.

2. No clients shall be placed together in a living situation against their choice. The consent of each client shall be documented in the clients' record.

E. Supervision

1. For purposes of this Section, a supervisor is defined as a person, so designated by the provider agency, due to experience and expertise relating to client needs.

2. The licensed/certified professional shall meet the following requirements:

a. have one year of experience working directly with persons with mental retardation or other developmental disabilities and is one of the following:

i. a doctor of medicine or osteopathy;

ii. a registered nurse;

iii. an individual who holds at least a bachelor's degree in a health care service field such as occupational therapy, physical therapy, psychology, or social work.

3. A supervisor or a licensed/certified professional qualified in the state of Louisiana must have a minimum of three documented contacts per week with the client, with at least one contact being face-to-face in the home with the client. The other two contacts may be made by telephone.

a. No combination of SIL telephone contacts and the face-to-face contact will be accepted as having met more than one of the required contacts on the same date. Providers may make as many contacts in a day as are necessary to meet the needs of the client. However, only one of those contacts will be accepted as having met one of the three required contacts.

4. Attempted face-to-face contacts or telephone contacts are unacceptable and will not count towards meeting the requirements.

F. In addition to the core licensing requirements, the SIL provider shall:

1. provide assistance to the client in obtaining and maintaining housing;

2. allow participation in the development, administration and oversight of the client's service plan to assure its effectiveness in meeting the client's needs; and

3. assure that bill payment is completed monthly in the plan of care, if applicable.

G. An SIL provider shall assess the following in conjunction with the client or client's legal representative when selecting the location of the SIL situation for the client:

a. risks associated with the location;

b. client cost;

c. proximity to the client's family and friends;

d. access to transportation;

e. proximity to health care and related services;

f. client choice;

g. proximity to the client's place of employment; and

h. access to community services.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5095. Supervised Independent Living Shared Living Conversion Process

A. The SIL Shared Living Conversion process is a situation in which a home and community-based shared living model, for up to six persons, may be chosen as a living option for participants in the Residential Options Waiver or any successor waiver.

B. Only an existing ICF/DD group or community home with up to 8 beds as of promulgation of the final Rule governing these provisions, may voluntarily and permanently close its home and its related licensed, Medicaid certified and enrolled ICF/DD beds to convert to new community-based waiver opportunities (slots) for up to six persons in shared living model or in combination with other ROW residential options. These shared living models will be located in the community.

1. Notwithstanding any other provision to the contrary, an SIL Shared Living Conversion model shall ensure that no more than six ROW waiver clients live in an apartment, house or other single living situation upon conversion.

C. The DHH Office for Citizens with Developmental Disabilities (OCDD) shall approve all individuals who may be admitted to live in and to receive services in an SIL Shared Living Conversion model.

D. The ICF/DD provider who wishes to convert an ICF/DD to an SIL via the Shared Living Conversion model shall be approved by OCDD and shall be licensed by HSS prior to providing services in this setting, and prior to accepting any ROW participant or applicant for residential or any other developmental disability service(s).

E. An ICF/DD provider who elects to convert to an SIL via the Shared Living Conversion model may convert to one or more conversion models, provided that the total number of SIL Shared Living Conversion slots; beds shall not exceed the number of Medicaid facility need review bed approvals of the ICF(s)/DD so converted.

1. The conversion of an ICF(s)/DD to an SIL via the Shared Living Conversion process may be granted only for

the number of beds specified in the applicant's SIL Shared Living Conversion model application to OCDD.

2. At no point in the future may the provider of a converted SIL, which converted via the Shared Living Conversion process, be allowed to increase the number of SIL slots approved at the time of conversion.

3. Any remaining Medicaid facility need review bed approvals associated with an ICF/DD that is being converted cannot be sold or transferred and are automatically considered terminated.

F. An ICF/DD provider who elects to convert to an SIL via the Shared Living Conversion process shall obtain the approval of all of the residents of the home(s) (or the responsible parties for these residents) regarding the conversion of the ICF/DD prior to beginning the process of conversion.

G. Application Process

1. The ICF/DD owner or governing board must sign a conversion agreement with OCDD regarding the specific beds to be converted and submit a plan for the conversion of these beds into ROW shared living or other ROW residential waiver opportunities, along with a copy of the corresponding and current ICF/DD license(s) issued by HSS.

a. This conversion plan must be approved and signed by OCDD and the owner or signatory of the governing board prior to the submittal of a HCBS provider, SIL module licensing application to DHH-HSS.

2. A licensed and certified ICF/DD provider who elects to convert an ICF/DD to an SIL via the Shared Living Conversion process shall submit a licensing application for a HCBS provider license, SIL Module. The ICF/DD applicant seeking to convert shall submit the following information with his licensing application:

a. a letter from OCDD stating that the owner or governing board has completed the assessment and planning requirements for conversion and that the owner or governing board may begin the licensing process for an HCBS provider, SIL Module;

b. a letter of intent from the owner or authorized representative of the governing board stating:

i. that the license to operate an ICF/DD will be voluntarily surrendered upon successfully completing an initial licensing survey and becoming licensed as an SIL via the Shared Living Conversion process; and

ii. that the ICF/DD Medicaid facility need review bed approvals will be terminated upon the satisfactory review of the conversion as determined by OCDD, pursuant to its 90 day post conversion site visit; and

3. an executed copy of the conversion agreement.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Subchapter M. Supported Employment Module

§5099. General Provisions

A. The provider applying to be licensed as a supported employment provider agency shall meet all of the HCBS provider core licensing requirements with the exception of the following requirements. The supported employment provider agency is not required to:

1. return all telephone calls from clients within one hour, other than during working hours;

2. have written policies and procedures approved by the owner or governing body that addresses client funds and emergency preparedness;

3. have written policies and procedures for behavior management, provided that the provider has no client with behavior management issues;

4. ensure that the administrator shall be available to be onsite at the supported employment provider location within one hour;

5. have nursing services staff and direct care staff;

6. have a client's assessment of needs conducted by a registered nurse; and

7. maintain two weeks of progress notes at the client's home.

B. The administrator of the supported employment provider agency shall be exempt from the education qualifications listing in the core licensing requirements of this Chapter.

C. The assessment of needs shall be done prior to placement of the client on a job site. A Medicaid HCBS comprehensive assessment approved by a DHH program office for a Medicaid recipient shall not substitute for the assessment of needs. A comprehensive plan of care approved by the department for Medicaid or waiver reimbursement shall not substitute for the ISP.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORY NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Interested persons may submit written comments to Don Gregory, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. He is responsible for responding to inquiries regarding this Emergency Rule. A copy of this Emergency Rule is available for review by interested parties at parish Medicaid offices.

Bruce D. Greenstein
Secretary

1106#052

DECLARATION OF EMERGENCY

Department of Health and Hospitals
Bureau of Health Services Financing

Inpatient Hospital Services—Major Teaching Hospitals—Supplemental Payments
(LAC 50:V.1333)

The Department of Health and Hospitals, Bureau of Health Services Financing adopts LAC 50:V.1333 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This Emergency Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:953(B)(1) et seq., and shall be in effect for the maximum period allowed under the Act or until adoption of the final Rule, whichever occurs first.

The Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing amended the provisions governing the reimbursement methodology for inpatient hospital services to provide for a supplemental

Medicaid payment to non-rural, non-state acute care hospitals for having a Medicaid inpatient utilization greater than 30 percent and teaching hospitals for furnishing additional graduate medical education services as a result of the suspension of training programs at the Medical Center of Louisiana at New Orleans due to the impact of Hurricane Katrina (*Louisiana Register,* Volume 34, Number 5).

The Department of Health and Hospitals, Bureau of Health Services Financing now proposes to amend the provisions governing the reimbursement methodology for inpatient hospital services to provide a supplemental Medicaid payment to acute care hospitals designated as major teaching hospitals to facilitate the development of public-private collaborations in order to preserve access to medically necessary services for Medicaid recipients.

This action is being taken to promote the health and welfare of Medicaid recipients by encouraging provider participation in the Medicaid Program so as to assure sufficient access to hospital services. It is estimated that the implementation of this Emergency Rule will increase expenditures in the Medicaid Program by approximately $5,000,000 for state fiscal year 2011-12.

Effective July 1, 2011, the Department of Health and Hospitals, Bureau of Health Services Financing amends the provisions governing the reimbursement methodology for inpatient hospital services rendered by non-rural, non-state hospitals designated as major teaching hospitals.

Title 50
PUBLIC HEALTH—MEDICAL ASSISTANCE
Part V. Hospital Services
Subpart 1. Inpatient Hospitals
Chapter 13. Teaching Hospitals
Subchapter B. Reimbursement Methodology
§1333. Major Teaching Hospitals

A. …

B. Effective for dates of service on or after July 1, 2011, a quarterly supplemental payment shall be issued to non-rural, non-state acute care hospitals for inpatient services rendered during the quarter. These payments shall be used to facilitate the development of public-private collaborations to preserve access to medically necessary services for Medicaid recipients. Aggregate payments to qualifying hospitals shall not exceed the maximum allowable cap for the quarter.

1. Qualifying Criteria. In order to qualify for the supplemental payments the non-rural, non-state acute care hospital must:

a. be designated as a major teaching hospital by the Department of Health and Hospitals in state fiscal year 2011;

b. have provided at least 25,000 Medicaid acute care paid days for state fiscal year 2010 dates of service; and

c. have provided at least 5,000 Medicaid distinct part psychiatric unit paid days for state fiscal year 2010 dates of service.

2. Payments shall be distributed quarterly and shall be calculated using the Medicaid paid days for service dates in state fiscal year 2010 as a proxy for SFY 2012 service dates.

3. Payments are applicable to Medicaid service dates provided during the first quarter of state fiscal year 2012 only and shall not exceed $14,000,000.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Implementation of the provisions of this Rule may be contingent upon the approval of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) if it is determined that submission to CMS for review and approval is required.

Interested persons may submit written comments to Don Gregory, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. He is responsible for responding to all inquiries regarding this Emergency Rule. A copy of this Emergency Rule is available for review by interested parties at parish Medicaid offices.

Bruce D. Greenstein
Secretary

1106#055

DECLARATION OF EMERGENCY

Department of Health and Hospitals
Bureau of Health Services Financing

Inpatient Hospital Services—Major Teaching Hospitals—Qualifying Criteria
(LAC 50:V.1301-1309)

The Department of Health and Hospitals, Bureau of Health Services Financing proposes to adopt LAC 50:V.1301-1309 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This Emergency Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:953(B)(1) et seq., and shall be in effect for the maximum period allowed under the Act or until adoption of the final Rule, whichever occurs first.

The Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing adopted a rule that established the reimbursement of major and minor teaching hospitals as peer groups under the prospective reimbursement methodology for hospitals (*Louisiana Register*, Volume 20, Number 6). The department amended the June 20, 1994 Rule to adopt new criteria for the reimbursement of graduate medical education (GME) pursuant to Section 15 Schedule 09 of Act 19 of the 1998 Regular Session of the Louisiana Legislature and R.S. 39:71 et seq (*Louisiana Register*, Volume 26, Number 3).

Act 347 of the 2009 Regular Session of the Louisiana Legislature revised the qualifying criteria for major teaching hospitals. In compliance with Act 347, the department promulgated an Emergency Rule which amended the provisions governing the qualifying criteria for major teaching hospitals. This Emergency Rule also repromulgated the March 20, 2000 Rule governing teaching hospitals in a codified format for inclusion in the *Louisiana Administrative Code* (*Louisiana Register,* Volume 36, Number 6). This Emergency Rule is being promulgated to continue the provisions of the July 1, 2010 Emergency Rule. This action is being taken to promote the health and welfare of Medicaid recipients by encouraging provider participation in the Medicaid Program so as to assure sufficient access to hospital services.

Effective June 29, 2011, the Department of Health and Hospitals, Bureau of Health Services Financing amends the provisions governing inpatient hospital services rendered by

non-rural, non-state hospitals designated as teaching hospitals.

Title 50
PUBLIC HEALTH—MEDICAL ASSISTANCE
Part V. Hospital Services
Subpart 1. Inpatient Hospital Services
Chapter 13. Teaching Hospitals
Subchapter A. General Provisions
§1301. Major Teaching Hospitals

A. The Louisiana Medical Assistance Program's recognition of a major teaching hospital is limited to facilities having a documented affiliation agreement with a Louisiana medical school accredited by the Liaison Committee on Medical Education (LCME). A major teaching hospital shall meet one of the following criteria:

1. be a major participant in at least four approved medical residency programs. At least two of the programs must be in medicine, surgery, obstetrics/gynecology, pediatrics, family practice, emergency medicine or psychiatry; or

2. maintain an intern and resident full-time equivalency of at least 20 filled positions with an approved medical residency program in family practice located more than 150 miles from the medical school accredited by the LCME.

B. For the purposes of recognition as a major teaching hospital, a facility shall be considered a "major participant" in a graduate medical education program if it meets the following criteria. The facility must:

1. pay for all of the costs of the training program in the non-hospital or hospital setting, including:

a. the residents' salaries and fringe benefits;

b. the portion of the cost of teaching physicians' salaries and fringe benefits attributable to direct graduate medical education; and

c. other direct administrative costs of the program; and

2. participate in residency programs that:

a. require residents to rotate for a required experience;

b. require explicit approval by the appropriate Residency Review Committee (RRC) of the medical school with which the facility is affiliated prior to utilization of the facility; or

c. provide residency rotations of more than one sixth of the program length or more than a total of six months at the facility and are listed as part of an accredited program in the *Graduate Medical Education Directory* of the Accreditation Council for Graduate Medical Education (ACGME).

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§1303. Minor Teaching Hospitals

A. The Louisiana Medical Assistance Program's recognition of a minor teaching hospital is limited to facilities having a documented affiliation agreement with a Louisiana medical school accredited by the LCME. A minor teaching hospital shall meet the following criteria:

1. must participate significantly in at least one approved medical residency program in either medicine, surgery, obstetrics/gynecology, pediatrics, family practice, emergency medicine or psychiatry; and

2. maintain an intern and resident full time equivalency of at least six filled positions.

B. For the purposes of recognition as a minor teaching hospital, a facility is considered to "participate significantly" in a graduate medical education program if it meets the following criteria. The facility must:

1. pay for all of the costs of the training program in the non-hospital or hospital setting, including:

a. the residents' salaries and fringe benefits;

b. the portion of the cost of teaching physicians' salaries and fringe benefits attributable to direct graduate medical education; and

c. other direct administrative costs of the program; and

2. participate in residency programs that:

a. require residents to rotate for a required experience;

b. require explicit approval by the appropriate Residency Review Committee of the medical school with which the facility is affiliated prior to utilization of the facility; or

c. provide residency rotations of more than one sixth of the program length or more than a total of six months at the facility and are listed as part of an accredited program in the *Graduate Medical Education Directory* of the Accreditation Council for Graduate Medical Education.

i. If not listed, the sponsoring institution must have notified the ACGME, in writing, that the residents rotate through the facility and spend more than 1/6th of the program length or more than a total of six months at the facility.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§1305. Approved Medical Residency Program

A. An approved medical residency program is one that meets one of the following criteria:

1. counts toward certification of the participant in a specialty or sub-specialty listed in the current edition of either *The Directory of Graduate Medical Education Programs* published by the American Medical Association, Department of Directories and Publications, or *The Annual Report and Reference Handbook* published by the American Board of Medical Specialties;

2. is approved by the ACGME as a fellowship program in geriatric medicine; or

3. is a program that would be accredited except for the accrediting agency's reliance upon an accreditation standard that requires an entity to perform an induced abortion or require, provide, or refer for training in the performance of induced abortions, or make arrangements for such training regardless of whether the standard provides exceptions or exemptions.

B. A residency program at a non-hospital facility may be counted by a hospital if:

1. there is a written agreement with the non-hospital facility that requires the hospital facility to pay for the cost of the training program; and

2. the agreement requires that the time that residents spend in the non-hospital setting is for patient care.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§1307. Graduate Medical Education

A. The bureau adopts criteria for the reimbursement of graduate medical education (GME) in facilities that do not qualify as major or minor teaching facilities. GME recognized by the Medical Assistance Program for reimbursement shall be limited to facilities having a documented affiliation agreement with a Louisiana medical school accredited by the LCME.

B. Payment for GME costs shall be limited to the direct cost of interns and residents in addition to the teaching physician supervisory costs. Teaching physician supervisory costs shall be limited in accordance with the provisions of the Medicare Provider Reimbursement Manual. The GME component of the rate shall be based on hospital specific graduate medical education Medicaid cost for the latest year on which hospital prospective reimbursements are rebased trended forward in accordance with the prospective reimbursement methodology for hospitals.

C. Hospitals implementing GME programs approved after the latest year on which hospital prospective reimbursements have been rebased shall have a GME component based on the first full cost reporting period that the approved GME program is in existence trended forward in accordance with the prospective reimbursement methodology for hospitals.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§1309. Requirements for Reimbursement

A. Qualification for teaching hospital status or to receive reimbursement for GME costs shall be re-established at the beginning of each fiscal year.

B. To be reimbursed as a teaching hospital or to receive reimbursement for GME costs, a facility shall submit the following documentation to the Bureau of Health Services Financing, Program Operations Section within 30 days of the beginning of each state fiscal year:

1. a copy of the executed affiliation agreement for the time period for which the teaching hospital status or GME reimbursement applies;

2. a copy of any agreements with non-hospital facilities; and

3. a signed Certification For Teaching Hospital Recognition.

C. Each hospital which is reimbursed as a teaching hospital or receives reimbursement for GME costs shall submit the following documentation to the Bureau of Health Services Financing, Program Operations Section, within 90 days of the end of each state fiscal year:

1. a copy of the Intern and Resident Information

System report that is submitted annually to the Medicare intermediary; and

2. a copy of any notice given to the ACGME that residents rotate through a facility for more than one sixth of the program length or more than a total of six months.

D. Copies of all contracts, payroll records and time allocations related to graduate medical education must be maintained by the hospital and available for review by the state and federal agencies or their agents upon request.

E. No teaching hospital shall receive a per diem rate greater than 115 percent of its facility specific cost based on the latest rebasing year trended forward to the rate year in accordance with the prospective reimbursement methodology for hospitals.

F. The peer group maximum for minor teaching hospitals shall be the peer group maximum for minor teaching hospitals or the peer group maximum for peer group five, whichever is greater.

G. If it is subsequently discovered that a hospital has been reimbursed as a major or minor teaching hospital and did not qualify for that peer group for any reimbursement period, retroactive adjustment shall be made to reflect the correct peer group to which the facility should have been assigned. The resulting overpayment will be recovered through either immediate repayment by the hospital or recoupment from any funds due to the hospital from the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Implementation of the provisions of this Rule may be contingent upon the approval of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), if it is determined that submission to CMS for review and approval is required.

Interested persons may submit written comments to Don Gregory, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. He is responsible for responding to all inquiries regarding this Emergency Rule. A copy of this Emergency Rule is available for review by interested parties at parish Medicaid offices.

Bruce D. Greenstein
Secretary

1106#063

DECLARATION OF EMERGENCY

Department of Health and Hospitals
Bureau of Health Services Financing

Inpatient Hospital Services—Neonatal and Pediatric Intensive Care Units and Outlier Payment Methodologies
(LAC 50:V.953-954 and 967)

The Department of Health and Hospitals, Bureau of Health Services Financing amends LAC 50:V.953-954 and §967 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This Emergency Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:953(B)(1) et seq., and shall be in effect for the maximum period allowed under the Act or until adoption of the final Rule, whichever occurs first.

The Department of Health and Hospitals, Bureau of Health Services Financing amended the provisions

governing the reimbursement methodology for inpatient hospital services rendered by non-rural, non-state hospitals to align the prospective per diem rates more closely with reported costs, including the neonatal intensive care unit (NICU) and pediatric intensive care unit (PICU) rates (*Louisiana Register*, Volume 35, Number 9).

The Department of Health and Hospitals, Bureau of Health Services Financing repromulgated all of the provisions governing outlier payments for inpatient hospital services in a codified format for inclusion in the *Louisiana Administrative Code* (*Louisiana Register,* Volume 36, Number 3).

The department promulgated an Emergency Rule which amended the provisions governing the reimbursement methodology for inpatient hospital services to adjust the reimbursement rates paid for NICU and PICU services rendered by non-rural, non-state hospitals and to revise the outlier payment methodology (*Louisiana Register,* Volume 37, Number 3). This Emergency Rule is being promulgated to continue the provisions of the March 1, 2011 Emergency Rule. This action is being taken to promote the health and welfare of Medicaid recipients by maintaining access to neonatal and pediatric intensive care unit services and encouraging the continued participation of hospitals in the Medicaid Program.

Effective June 30, 2011 the Department of Health and Hospitals, Bureau of Health Services Financing amends the provisions governing the reimbursement methodology for inpatient hospital services to adjust the reimbursement rates paid to non-rural, non-state hospitals for neonatal and pediatric intensive care unit services and to revise the provisions governing outlier payments.

Title 50

PUBLIC HEALTH—MEDICAL ASSISTANCE

Part V. Hospital Services

Chapter 9. Non-Rural, Non-State Hospitals

Subchapter B. Reimbursement Methodology

§953. Acute Care Hospitals

A. - G. …

H. Neonatal Intensive Care Units (NICU)

1. - 2. …

3. Effective for dates of service on or after March 1, 2011, the per diem rates for Medicaid inpatient services rendered by NICU Level III and NICU Level III regional units, recognized by the department as such on December 31, 2010, shall be adjusted to include an increase that varies based on the following five tiers:

a. Tier 1. If the qualifying hospital's average percentage exceeds 10 percent, the additional per diem increase shall be $601.98;

b. Tier 2. If the qualifying hospital's average percentage is less than or equal to 10 percent, but exceeds 5 percent, the additional per diem increase shall be $624.66;

c. Tier 3. If the qualifying hospital's average percentage is less than or equal to 5 percent, but exceeds 1.5 percent, the additional per diem increase shall be $419.83;

d. Tier 4. If the qualifying hospital's average percentage is less than or equal to 1.5 percent, but greater than 0 percent, and the hospital received greater than .25 percent of the outlier payments for dates of service in state fiscal year (SFY) 2008 and SFY 2009 and calendar year 2010, the additional per diem increase shall be $263.33; or

e. Tier 5. If the qualifying hospital received less than .25 percent, but greater than 0 percent of the outlier payments for dates of service in SFY 2008 and SFY 2009 and calendar year 2010, the additional per diem increase shall be $35.

4. A qualifying hospital's placement into a tier will be determined by the average of its percentage of paid NICU Medicaid days for SFY 2010 dates of service to the total of all qualifying hospitals' paid NICU days for the same time period, and its percentage of NICU patient outlier payments made as of December 31, 2010 for dates of service in SFY 2008 and SFY 2009 and calendar year 2010 to the total NICU outlier payments made to all qualifying hospitals for these same time periods.

a. This average shall be weighted to provide that each hospital's percentage of paid NICU days will comprise 25 percent of this average, while the percentage of outlier payments will comprise 75 percent. In order to qualify for Tiers 1 through 4, a hospital must have received at least .25 percent of outlier payments in SFY 2008, SFY 2009, and calendar year 2010.

b. SFY 2010 is used as the base period to determine the allocation of NICU and PICU outlier payments for hospitals having both NICU and PICU units.

c. If the daily paid outlier amount per paid NICU day for any hospital is greater than the mean plus one standard deviation of the same calculation for all NICU Level III and NICU Level III regional hospitals, then the basis for calculating the hospital's percentage of NICU patient outlier payments shall be to substitute a payment amount equal to the highest daily paid outlier amount of any hospital not exceeding this limit, multiplied by the exceeding hospital's paid NICU days for SFY 2010, to take the place of the hospital's actual paid outlier amount.

NOTE: Children's specialty hospitals are not eligible for the per diem adjustments established in §953.H.3.

5. The department shall evaluate all rates and tiers two years after implementation.

I. Pediatric Intensive Care Unit (PICU)

1. - 2. …

3. Effective for dates of service on or after March 1, 2011, the per diem rates for Medicaid inpatient services rendered by PICU Level I and PICU Level II units, recognized by the department as such on December 31, 2010, shall be adjusted to include an increase that varies based on the following four tiers:

a. Tier 1. If the qualifying hospital's average percentage exceeds 20 percent, the additional per diem increase shall be $418.34;

b. Tier 2. If the qualifying hospital's average percentage is less than or equal to 20 percent, but exceeds 10 percent, the additional per diem increase shall be $278.63;

c. Tier 3. If the qualifying hospital's average percentage is less than or equal to 10 percent, but exceeds 0 percent and the hospital received greater than .25 percent of the outlier payments for dates of service in SFY 2008 and SFY 2009 and calendar year 2010, the additional per diem increase shall be $178.27; or

d. Tier 4. If the qualifying hospital received less than .25 percent, but greater than 0 percent of the outlier payments for dates of service in SFY 2008, SFY 2009 and calendar year 2010, the additional per diem increase shall be $35.

4. A qualifying hospital's placement into a tier will be determined by the average of its percentage of paid PICU Medicaid days for SFY 2010 dates of service to the total of all qualifying hospitals' paid PICU days for the same time period, and its percentage of PICU patient outlier payments made as of December 31, 2010 for dates of service in SFY 2008 and SFY 2009 and calendar year 2010 to the total PICU outlier payments made to all qualifying hospitals for these same time periods.

a. This average shall be weighted to provide that each hospital's percentage of paid PICU days will comprise 25 percent of this average, while the percentage of outlier payments will comprise 75 percent. In order to qualify for Tiers 1 through 3, a hospital must have received at least .25 percent of outlier payments in SFY 2008, SFY 2009, and calendar year 2010.

b. SFY 2010 is used as the base period to determine the allocation of NICU and PICU outlier payments for hospitals having both NICU and PICU units.

c. If the daily paid outlier amount per paid PICU day for any hospital is greater than the mean plus one standard deviation of the same calculation for all PICU Level I and PICU Level II hospitals, then the basis for calculating the hospital's percentage of PICU patient outlier payments shall be to substitute a payment amount equal to the highest daily paid outlier amount of any hospital not exceeding this limit, multiplied by the exceeding hospital's paid PICU days for SFY 2010, to take the place of the hospital's actual paid outlier amount.

NOTE: Children's specialty hospitals are not eligible for the per diem adjustments established in §953.I.3.

5. The department shall evaluate all rates and tiers two years after implementation.

J. - O.1. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 34:876 (May 2008), amended LR 34:877 (May 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 35:1895 (September 2009), amended LR 36:1552 (July 2010), LR 36:2561 (November 2010), LR 37:

§954. Outlier Payments

A. - B. …

C. To qualify as a payable outlier claim, a deadline of not later than six months subsequent to the date that the final claim is paid shall be established for receipt of the written request for outlier payments.

1. Effective March 1, 2011, in addition to the 6 month timely filing deadline, outlier claims for dates of service on or before February 28, 2011 must be received by the department on or before May 31, 2011 in order to qualify for payment. Claims for this time period received by the department after May 31, 2011 shall not qualify for payment.

D. Effective for dates of service on or after March 1, 2011, a catastrophic outlier pool shall be established with annual payments limited to $10,000,000. In order to qualify for payments from this pool, the following conditions must be met:

1. the claims must be for cases for:

a. children less than six years of age who received inpatient services in a disproportionate share hospital setting; or

b. infants less than one year of age who receive inpatient services in any acute care hospital setting; and

2. the costs of the case must exceed $150,000.

a. The hospital specific cost to charge ratio utilized to calculate the claim costs shall be calculated using the Medicaid NICU or PICU costs and charge data from the most current cost report.

E. The initial outlier pool will cover eligible claims with admission dates from the period beginning March 1, 2011 through June 30, 2011.

1. Payment for the initial partial year pool will be $3,333,333 and shall be the costs of each hospital's qualifying claims net of claim payments divided by the sum of all qualifying claims costs in excess of payments, multiplied by $3,333,333.

2. Cases with admission dates on or before February 28, 2011 that continue beyond the March 1, 2011 effective date, and that exceed the $150,000 cost threshold, shall be eligible for payment in the initial catastrophic outlier pool.

3. Only the costs of the cases applicable to dates of service on or after March 1, 2011 shall be allowable for determination of payment from the pool.

F. Beginning with SFY 2012, the outlier pool will cover eligible claims with admission dates during the state fiscal year (July 1 through June 30) and shall not exceed $10,000,000 annually. Payment shall be the costs of each hospital's eligible claims less the prospective payment, divided by the sum of all eligible claims costs in excess of payments, multiplied by $10,000,000.

G. The claim must be submitted no later than six months subsequent to the date that the final claim is paid and no later than September 15 of each year.

H. Qualifying cases for which payments are not finalized by September 1 shall be eligible for inclusion for payment in the subsequent state fiscal year outlier pool.

I. Outliers are not payable for:

1. transplant procedures; or

2. services provided to patients with Medicaid coverage that is secondary to other payer sources.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:519 (March 2010), amended LR 37:

§967. Children's Specialty Hospitals

A. - F. …

G. Children's specialty hospitals are not eligible for the per diem adjustments established in §953.H.3 and §953.I.3.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:2562 (November 2010), amended LR 37:

Implementation of the provisions of this Rule may be contingent upon the approval of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), if it is determined that submission to CMS for review and approval is required.

Interested persons may submit written comments to Don Gregory, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. He is responsible for responding to inquiries regarding this Emergency Rule. A copy of this Emergency Rule is available for review by interested parties at parish Medicaid offices.

Bruce D. Greenstein
Secretary

1106#065

DECLARATION OF EMERGENCY

Department of Health and Hospitals
Bureau of Health Services Financing

Intermediate Care Facilities for Persons with Developmental Disabilities—Public Facilities Reimbursement Methodology
(LAC 50:VII.32965-32969)

The Department of Health and Hospitals, Bureau of Health Services Financing adopts LAC 50:VII.32965-32969 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This Emergency Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:953(B)(1) et seq., and shall be in effect for the maximum period allowed under the Act or until adoption of the final Rule, whichever occurs first.

The Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing amended the provisions governing the reimbursement methodology for state-operated intermediate care facilities for persons with developmental disabilities (ICFs/DD) and established payments using a formula that established per diem rates at the Medicare upper payment limit for these services (*Louisiana Register*, Volume 29, Number 11). Upon submission of the corresponding State Plan amendment to the Centers for Medicare and Medicaid Services for review and approval, the department determined that it was also necessary to establish provisions in the Medicaid State Plan governing the reimbursement methodology for quasi-public ICFs/DD. The department promulgated an Emergency Rule which amended the provisions governing the reimbursement methodology for public ICFs/DD to establish a transitional Medicaid reimbursement rate for community homes that are being privatized (*Louisiana Register,* Volume 36, Number 8). This Emergency Rule also adopted all of the provisions governing reimbursements to state-owned and operated facilities and quasi-public facilities in a codified format for inclusion in the *Louisiana Administrative Code.* The department now proposes to amend the August 1, 2010 Emergency Rule to revise the provisions governing transitional rates for public facilities. This action is being taken to avoid a budget deficit in the medical assistance programs.

Effective July 1, 2011, the Department of Health and Hospitals, Bureau of Health Services Financing amends the provisions of the August 1, 2010 Emergency Rule governing the reimbursement methodology for public intermediate care facilities for persons with developmental disabilities.

Title 50
PUBLIC HEALTH—MEDICAL ASSISTANCE
Part VII. Long Term Care
Subpart 3. Intermediate Care Facilities for Persons with Developmental Disabilities
Chapter 329. Reimbursement Methodology
Subchapter C. Public Facilities

§32965. State-Owned and Operated Facilities

A. Medicaid payments to state-owned and operated intermediate care facilities for persons with developmental disabilities are based on the Medicare formula for determining the routine service cost limits as follows:

1. calculate each state-owned and operated ICF/DD's per diem routine costs in a base year;
2. calculate 112 percent of the average per diem routine costs; and
3. inflate 112 percent of the per diem routine costs using the skilled nursing facility (SNF) market basket index of inflation.

B. Each state-owned and operated facility's capital and ancillary costs will be paid by Medicaid on a "pass-through" basis.

C. The sum of the calculations for routine service costs and the capital and ancillary costs "pass-through" shall be the per diem rate for each state-owned and operated ICF/DD. The base year cost reports to be used for the initial calculations shall be the cost reports for the fiscal year ended June 30, 2002.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§32967. Quasi-Public Facilities

A. Medicaid payment to quasi-public facilities is a facility-specific prospective rate based on budgeted costs. Providers shall be required to submit a projected budget for the state fiscal year beginning July 1.

B. The payment rates for quasi-public facilities shall be determined as follows:

1. determine each ICF/DD's per diem for the base year beginning July 1;
2. calculate the inflation factor using an average CPI index applied to each facility's per diem for the base year to determine the inflated per diem;
3. calculate the median per diem for the facilities' base year;
4. calculate the facility's routine cost per diem for the SFY beginning July 1 by using the lowest of the budgeted, inflated or median per diem rates plus any additional allowances; and
5. calculate the final approved per diem rate for each facility by adding routine costs plus any "pass through" amounts for ancillary services, provider fees, and grant expenses.

C. Providers may request a final rate adjustment subject to submission of supportive documentation and approval by the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§32969. Transitional Rates for Public Facilities

A. Effective August 1, 2010, the department shall establish a transitional Medicaid reimbursement rate of $302.08 per day per individual for a public ICF/DD community home that is transitioning to a private facility, provided that the community home meets the following criteria. The community home:

1. shall have a fully executed Cooperative Endeavor Agreement (CEA) with the Office for Citizens with Developmental Disabilities for the private operation of the facility;

2. shall have a high concentration of medically fragile individuals being served, as determined by the department;

a. for purposes of these provisions, a medically fragile individual shall refer to an individual who has a medically complex condition characterized by multiple, significant medical problems that require extended care;

3. incurs or will incur higher existing costs not currently captured in the private ICF/DD rate methodology; and

4. shall have six to eight beds.

B. The transitional Medicaid reimbursement rate shall only be for the period of transition, which is defined as the term of the CEA or a period of three years, whichever is shorter.

C. The transitional Medicaid reimbursement rate is all-inclusive and incorporates the following cost components:

1. direct care staffing;
2. medical/nursing staff, up to 23 hours per day;
3. medical supplies;
4. transportation;
5. administrative; and
6. the provider fee.

D. If the community home meets the criteria in §32969.C and the individuals served require that the community home has a licensed nurse at the facility 24 hours per day, seven days per week, the community home may apply for a supplement to the transitional rate. The supplement to the rate shall not exceed $25.33 per day per individual.

E. The total transitional Medicaid reimbursement rate, including the supplement, shall not exceed $327.41 per day per individual.

F. The transitional rate and supplement shall not be subject to the following:

1. inflationary factors or adjustments;
2. rebasing;
3. budgetary reductions; or
4. other rate adjustments.

G. Effective July 1, 2011, the transitional rate for public facilities over 50 beds that are privatizing shall be restored to the rates in effect on January 1, 2009 for a six to eight bed facility.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Implementation of the provisions of this Rule may be contingent upon the approval of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), if it is determined that submission to CMS for review and approval is required.

Interested persons may submit written comments to Don Gregory, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. He is responsible for responding to inquiries regarding this Emergency Rule. A copy of this Emergency Rule is available for review by interested parties at parish Medicaid offices.

Bruce D. Greenstein
Secretary

1106#056

DECLARATION OF EMERGENCY

Department of Health and Hospitals
Bureau of Health Services Financing

Medical Transportation Program—Emergency Ambulance Services—Supplemental Payments
(LAC 50:XXVII.327)

The Department of Health and Hospitals, Bureau of Health Services Financing adopts LAC 50:XXVII.327 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This Emergency Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:953(B)(1) et seq., and shall be in effect for the maximum period allowed under the Act or until adoption of the final Rule, whichever occurs first.

The Department of Health and Hospitals, Bureau of Health Services Financing provides reimbursement for emergency ambulance transportation services. The department now proposes to establish supplemental payments for governmental ambulance providers who render emergency medical transportation services to low income and needy patients in the state of Louisiana.

This action is being taken to promote the health and welfare of Medicaid recipients by ensuring continued access to emergency ambulance services. It is estimated that implementation of this Emergency Rule will increase expenditures in the Medicaid Program by approximately $14,441,539, of which approximately $10,013,763 will be paid from federal funds. The required state match of approximately $4,427,776 will be paid through an intergovernmental transfer from a qualifying statewide ambulance service district.

Effective July 1, 2011, the Department of Health and Hospitals, Bureau of Health Services Financing adopts the provisions to establish supplemental payments for emergency medical transportation services rendered by governmental ambulance providers.

Title 50
PUBLIC HEALTH—MEDICAL ASSISTANCE
Part XXVII. Medical Transportation Program
Chapter 3. Emergency Medical Transportation
Subchapter B. Ground Transportation
§327. Supplemental Payments for Governmental Ambulance Providers

A. Effective for dates of service on or after July 1, 2011, quarterly supplemental payments shall be issued to qualifying governmental ambulance providers for

emergency medical transportation services rendered during the quarter.

B. Qualifying Criteria. In order to qualify for this supplemental payment, the governmental ambulance provider must be affiliated with a statewide ambulance service district through a Low Income and Needy Care Transportation Agreement.

1. For purposes of these provisions, a governmental ambulance provider is defined as a provider of emergency medical transportation which is owned or operated by a local governmental entity.

2. For purposes of these provisions, a Low Income and Needy Care Transportation Agreement is a written agreement between an ambulance provider and a statewide ambulance service district to facilitate enhanced emergency transportation services to low income and needy patients.

C. Payment Methodology. Each qualifying ambulance provider may receive quarterly supplemental payments for emergency transportation services rendered during the quarter. Quarterly payment distribution to a qualifying ambulance provider shall be based on a formula which may recognize and adjust payment amounts for differences such as governmental or non-governmental ownership, rural or urban primary service area, payer mix of patients served, amount of uninsured patients served, and other factors. Payments shall be limited to the difference between Medicaid payments for emergency transportation services provided by the provider and the amount of the provider's usual charges. Medicaid billed charges and payments shall be based on a 12 consecutive month period for claims data selected by the department.

D. Calculation of Provider's Usual Charges. For purposes of this payment, usual charges, for the state fiscal year (SFY) beginning July 1, 2011 shall be calculated as follows:

1. An average of the following amounts shall be made:

a. the amounts billed to cash paying patients;

b. the amounts billed to patients covered by indemnity insurers with which the provider has no contractual arrangement; and

c. fee-for-service rates it contractually agrees to accept from any payor, including any discounted fee-for-service rates negotiated with managed care plans.

2. Amounts not included in the average are:

a. free of charge services provided to uninsured patients;

b. charges to uninsured patients at a substantially reduced rate;

c. capitated payments;

d. rates offered under hybrid fee-for-service arrangements whereby more than 10 percent of the individual's or entity's maximum potential compensation could be paid in the form of a bonus or withheld payment; and

e. fees set by Medicare, state health care programs, and other federal health care programs.

3. In the SFY beginning July 1, 2011, usual charges shall be determined by a study conducted by the department of ambulance providers' charges. For each SFY thereafter, each provider's usual charges shall be based, at the option of the department, on a recalculation of the provider's usual charges or on the previous year's usual charges increased by the Medicare Ambulance Inflation Factor.

4. The payment shall not exceed the amount under Subparagraph D.4.f of this Section, which is calculated as follows.

a. The department shall identify qualifying ambulance providers that received reimbursement from Medicaid for emergency transportation services during the quarter.

b. For each qualifying ambulance provider described in Subparagraph D.4.a of this Section, the department shall identify the emergency medical transportation services for which the qualifying ambulance provider was reimbursed.

c. For each qualifying ambulance provider described in Subparagraph D.4.a of this Section, the department shall calculate the reimbursement paid to the qualifying ambulance provider for the emergency medical transportation services identified under Subparagraph D.4.b of this Section.

d. For each qualifying ambulance provider described in Subparagraph D.4.a of this Section, the department shall calculate the qualifying ambulance provider's usual charges for each of the Medicaid provider's services identified under Subparagraph D.4.b of this Section.

e. For each qualifying ambulance provider described in Subparagraph D.4.a of this Section, the department shall subtract an amount equal to the reimbursement calculated for each of the emergency medical transportation services under Subparagraph D.4.c of this Section from an amount equal to the amount calculated for each of the qualifying ambulance transportation services under Subparagraph D.4.d of this Section.

f. For each Medicaid provider described in Subparagraph D.4.a of this Section, the department shall calculate the sum of each of the amounts calculated for each emergency medical transportation service under Subparagraph D.4.e of this Section.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Implementation of the provisions of this Rule may be contingent upon the approval of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), if it is determined that submission to CMS for review and approval is required.

Interested persons may submit written comments to Don Gregory, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. He is responsible for responding to inquiries regarding this Emergency Rule. A copy of this Emergency Rule is available for review by interested parties at parish Medicaid offices.

Bruce D. Greenstein
Secretary

1106#057

DECLARATION OF EMERGENCY

Department of Health and Hospitals
Bureau of Health Services Financing

Nursing Facilities—Minimum Licensing Standards—Approval of Facility Plans (LAC 48:I.9707)

The Department of Health and Hospitals, Bureau of Health Services Financing amends LAC 48:I.9707 in the Medical Assistance Program as authorized by R.S. 36:254 and R.S. 40:2009.1-2116.4. This Emergency Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:953(B)(1), et seq., and shall be in effect for the maximum period allowed under the Act or until adoption of the final Rule, whichever occurs first.

The Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing repealed the existing nursing facility licensing regulations and established new licensing regulations in order to assure that a high quality of care was provided to persons residing in nursing facilities (*Louisiana Register,* Volume 24, Number 1).

The department now proposes to amend the January 20, 1998 Rule to revise the provisions governing the approval of facility plans in order to require nursing facilities to comply with the Facility Guidelines Institute's requirements for the design and construction of healthcare facilities, and to allow certain facilities to opt out of compliance under certain conditions. This action is being taken to avoid imminent peril to the public health and welfare by ensuring that planned nursing facilities do not incur delays and prohibitive expenses by being required to meet new regulatory standards for those projects already under construction or in late planning stages. It is estimated that implementation of this Emergency Rule will have no programmatic costs for state fiscal year 2011-12.

Effective July 1, 2011, the Department of Health and Hospitals, Bureau of Health Services Financing amends the provisions governing the approval of plans included in the minimum licensing standards for nursing facilities.

Title 48
PUBLIC HEALTH - GENERAL
Part I. General Administration
Subpart 3. Licensing and Certification
Chapter 97. Nursing Facilities
Subchapter A. General Provisions
§9707. Approval of Plans

A. Plans and specifications for new construction of, or to a nursing facility, and any major alterations to a nursing facility shall be submitted for approval to the Department of Health and Hospitals, or the specific entity designated by the department, to conduct reviews of plans and specifications of such new construction or major alterations.

B. The plans and specifications shall comply with all of the following:

1. these nursing facility licensing requirements;

2. the Facility Guidelines Institute (FGI) *Guidelines for Design and Construction of Healthcare Facilities*, specifically the Section(s) regarding nursing facilities;

a. nursing facilities that submit plans prior to January 1, 2014 may opt out of complying with the specific reference in the FGI *Guidelines for Design and Construction of Healthcare Facilities* regarding the use of central air handling systems for outside air requirements for resident bedrooms; and

3. the Office of the State Fire Marshal's requirements for plan submittals and compliance with all codes required by that office.

C. The applicant must furnish one complete set of plans and specifications to the Department of Health and Hospitals or the specific entity designated by the department to conduct plan reviews, together with fees and other information as may be required.

1. …

2. No residential conversions shall be considered for a nursing facility license.

D. - E. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2009.1-2116.4.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 24:46 (January 1998), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Interested persons may submit written comments to Don Gregory, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. He is responsible for responding to inquiries regarding this Emergency Rule. A copy of this Emergency Rule is available for review by interested parties at parish Medicaid offices.

Bruce D. Greenstein
Secretary

1106#058

DECLARATION OF EMERGENCY

Department of Health and Hospitals
Bureau of Health Services Financing

Nursing Facilities—Reimbursement Methodology—Direct Care Multiplier and Fair Rental Value Component (LAC 50:II.20005)

The Department of Health and Hospitals, Bureau of Health Services Financing amends LAC 50:II.20005 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This Emergency Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:953(B)(1) et seq., and shall be in effect for the maximum period allowed under the Act or until adoption if the final Rule, whichever occurs first.

In anticipation of projected expenditures in the Medical Vendor Program exceeding the funding allocated in the General Appropriations Act for state fiscal year 2011, the Department of Health and Hospitals, Bureau of Health Services Financing amended the provisions governing the reimbursement methodology for nursing facilities to reduce the per diem rates paid to non-state nursing facilities (*Louisiana Register*, Volume 37, Number 4).

Act 150 of the 2010 Regular Session of the Louisiana Legislature directed the department to amend the case mix reimbursement methodology for nursing facilities to revise the provisions governing the direct care and care related

costs, to change the minimum occupancy penalty, and to provide for changes in the frequency of rate rebasing and related matters. In compliance with the directives of Act 150, the department promulgated a Notice of Intent which proposed to amend the provisions governing the reimbursement methodology for nursing facilities to increase the direct care and care related price multiplier, provide for the exclusion of certain costs from the direct care and care related median cost, and to increase the fair rental value minimum occupancy percentage (*Louisiana Register,* Volume 37, Number 3). A public hearing was held April 28, 2011.

As a result of the comments received, the department has now determined that it is necessary to revise and republish the provisions of the March 20, 2011 Notice of Intent (*Louisiana Register,* Volume 37, Number 6). This action is being taken in order to avoid a budget deficit in the medical assistance programs. It is estimated that implementation of this Emergency Rule will reduce expenditures in the Medicaid Program by approximately $195,000 for FY 2011-12.

Effective July 1, 2011, the Department of Health and Hospitals, Bureau of Health Services Financing amends the provisions governing the reimbursement methodology for nursing facilities.

Title 50
PUBLIC HEALTH—MEDICAL ASSISTANCE
Part II. Nursing Facilities
Subpart 5. Reimbursement
Chapter 200. Reimbursement Methodology
§20005. Rate Determination
[Formerly LAC 50:VII.1305]

A. - D.1.c. ...

d. Effective July 1, 2011, the statewide direct care and care related price is established at 112.40 percent of the direct care and care related resident-day-weighted median cost.

D.1.e. - D.3.b.ii. ...

iii. Effective July 1, 2011, the nursing facility's annual fair rental value shall be divided by the greater of the facility's annualized actual resident days during the cost reporting period or 85 percent of the annualized licensed capacity of the facility to determine the FRV per diem or capital component of the rate. Annualized total patient days will be adjusted to reflect any increase or decrease in the number of licensed beds as of the date of rebase by applying to the increase or decrease the greater of the facility's actual occupancy rate during the base year cost report period or 85 percent of the annualized licensed capacity of the facility.

D.3.b.iv. - G. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254, R.S. 46:2742, and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of Family Security, LR 10:467 (June 1984), repealed and promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 28:1791 (August 2002), amended LR 31:1596 (July 2005), LR 32:2263 (December 2006), LR 33:2203 (October 2007), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:325 (February 2010), repromulgated LR 36:520 (March 2010), amended LR 36:1556 (July 2010), amended LR 36:1782 (August 2010), amended LR 36:2566 (November 2010), amended LR 37:1174 (April 2011), amended LR 37:

Implementation of the provisions of this Rule may be contingent upon the approval of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), if it is determined that submission to CMS for review and approval is required.

Interested persons may submit written comments to Don Gregory, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. He is responsible for responding to inquiries regarding this Emergency Rule. A copy of this Emergency Rule is available for review by interested parties at parish Medicaid offices.

Bruce D. Greenstein
Secretary

1106#059

DECLARATION OF EMERGENCY

Department of Health and Hospitals
Bureau of Health Services Financing

Outpatient Hospital Services—Diabetes Self-Management Training
(LAC 50:V.Chapter 63)

The Department of Health and Hospitals, Bureau of Health Services Financing adopts LAC 50:V.Chapter 63 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This Emergency Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:953(B)(1) et seq., and shall be in effect for the maximum period allowed under the Act or until adoption of the final Rule, whichever occurs first.

Act 11 of the 2010 Regular Session of the Louisiana Legislature authorized the Department of Health and Hospitals, through its primary and preventive care activity, to provide reimbursement to providers for rendering services that will educate and encourage Medicaid enrollees to obtain appropriate preventive and primary care in order to improve their overall health and quality of life. In keeping with the intent of Act 11, the Department of Health and Hospitals, Bureau of Health Services Financing promulgated an Emergency Rule which amended the provisions governing the Hospital Program to provide Medicaid reimbursement for diabetes self-management training (DSMT) services rendered in an outpatient hospital setting (*Louisiana Register*, Volume 37, Number 2). It is anticipated that this new service will promote improved patient self-management skills which will reduce diabetes-related complications that adversely affect quality of life, and subsequently reduce Medicaid costs associated with the care of recipients diagnosed with diabetes-related illnesses. The department now proposes to amend the February 20, 2011 Emergency Rule to clarify the provisions governing service limits. This action is being taken to promote the health and welfare of Medicaid recipients diagnosed with diabetes and to ultimately reduce the Medicaid costs associated with their care. Effective June 20, 2011, the Department of Health and Hospitals, Bureau of Health Services Financing amends

the provisions of the February 20, 2011 Emergency Rule governing the Hospital Program to provide coverage for diabetes self-management training services rendered in an outpatient hospital setting.

Title 50

PUBLIC HEALTH—MEDICAL ASSISTANCE

Part V. Hospital Services

Subpart 5. Outpatient Hospital Services

Chapter 63. Diabetes Education Services

Subchapter A. General Provisions

§6301. Introduction

A. Effective for dates of service on or after February 20, 2011, the department shall provide coverage of diabetes self-management training (DSMT) services rendered to Medicaid recipients diagnosed with diabetes.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§6303. Scope of Services

A. DSMT services shall be comprised of one hour of individual instruction and nine hours of group instruction on diabetes self-management.

B. Service Limits. Recipients shall receive up to 10 hours of services during the first 12-month period beginning with the initial training date. After the first 12-month period has ended, recipients shall only be eligible for two hours of individual instruction on diabetes self-management per calendar year.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§6305. Provider Participation

A. In order to receive Medicaid reimbursement, outpatient hospitals must have a DSMT program that meets the quality standards of one of the following accreditation organizations:

1. the American Diabetes Association;
2. the American Association of Diabetes Educators; or
3. the Indian Health Service.

B. All DSMT programs must adhere to the national standards for diabetes self-management education.

1. Each member of the instructional team must:

a. be a certified diabetes educator (CDE) certified by the National Certification Board for Diabetes Educators; or

b. have recent didactic and experiential preparation in education and diabetes management.

2. At a minimum, the instructional team must consist of one the following professionals who is a CDE:

a. a registered dietician;

b. a registered nurse; or

c. a pharmacist.

3. All members of the instructional team must obtain the nationally recommended annual continuing education hours for diabetes management.

C. Members of the instructional team must be either employed by or have a contract with a Medicaid enrolled outpatient hospital that will submit the claims for reimbursement of outpatient DSMT services rendered by the team. AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Subchapter B. Reimbursement

§6311. Reimbursement Methodology

A. Effective for dates of service on or after February 20, 2011, the Medicaid Program shall provide reimbursement for diabetes self-management training services rendered by qualified health care professionals in an outpatient hospital setting.

B. Reimbursement for DSMT services shall be a flat fee based on the appropriate Healthcare Common Procedure Coding (HCPC) code.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Implementation of the provisions of this Rule may be contingent upon the approval of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), if it is determined that submission to CMS for review and approval is required.

Interested persons may submit written comments to Don Gregory, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. He is responsible for responding to inquiries regarding this Emergency Rule. A copy of this Emergency Rule is available for review by interested parties at parish Medicaid offices.

Bruce D. Greenstein
Secretary

1106#060

DECLARATION OF EMERGENCY

Department of Health and Hospitals
Bureau of Health Services Financing

Professional Services Program—Diabetes Self-Management Training
(LAC 50:IX.Chapter 7 and 15103)

The Department of Health and Hospitals, Bureau of Health Services Financing adopts LAC 50:IX.Chapter 7 and §15103 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This Emergency Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:953(B)(1) et seq., and shall be in effect for the maximum period allowed under the Act or until adoption of the final Rule, whichever occurs first.

Act 11 of the 2010 Regular Session of the Louisiana Legislature authorized the Department of Health and Hospitals, through its primary and preventive care activity, to provide reimbursement to providers for rendering services that will educate and encourage Medicaid enrollees to obtain appropriate preventive and primary care in order to improve their overall health and quality of life. In keeping with the intent of Act 11, the Department of Health and Hospitals, Bureau of Health Services Financing promulgated an Emergency Rule which amended the provisions governing the Professional Services Program to provide Medicaid

reimbursement for diabetes self-management training (DSMT) services (*Louisiana Register*, Volume 37, Number 2). It is anticipated that this new service will promote improved patient self-management skills which will reduce diabetes-related complications that adversely affect quality of life, and subsequently reduce Medicaid costs associated with the care of recipients diagnosed with diabetes-related illnesses.

The department now proposes to amend the provisions of the February 20, 2011 Emergency Rule governing the Professional Services Program in order to clarify the provider participation requirements for the provision of DSMT services. This action is being taken to promote the health and welfare of Medicaid recipients diagnosed with diabetes and to reduce the Medicaid costs associated with their care.

Effective June 20, 2011, the Department of Health and Hospitals, Bureau of Health Services Financing amends the provisions of the February 20, 2011 Emergency Rule governing diabetes self-management training services rendered in the Professional Services Program.

Title 50
PUBLIC HEALTH-MEDICAL ASSISTANCE
Part IX. Professional Services Program
Subpart 1. General Provisions
Chapter 7. Diabetes Education Services
§701. General Provisions

A. Effective for dates of service on or after February 20, 2011, the department shall provide coverage of diabetes self-management training (DSMT) services rendered to Medicaid recipients diagnosed with diabetes.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§703. Scope of Services

A. DSMT shall be comprised of one hour of individual instruction and nine hours of group instruction on diabetes self-management.

B. Service Limits. Recipients shall receive up to 10 hours of services during the first 12-month period beginning with the initial training. After the first 12-month period has ended, recipients shall only be eligible for two hours of individual instruction on diabetes self-management per calendar year.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§705. Provider Participation

A. In order to receive Medicaid reimbursement, professional services providers must have a DSMT program that meets the quality standards of one of the following accreditation organizations:

1. the American Diabetes Association;
2. the American Association of Diabetes Educators; or
3. the Indian Health Service.

B. All DSMT programs must adhere to the national standards for diabetes self-management education.

1. Each member of the instructional team must:

a. be a certified diabetes educator (CDE) certified by the National Certification Board for Diabetes Educators; or

b. have recent didactic and experiential preparation in education and diabetes management.

2. At a minimum, the instructional team must consist of one the following professionals who are also a CDE:

a. a registered dietician;
b. a registered nurse; or
c. a pharmacist.

3. All members of the instructional team must obtain the nationally recommended annual continuing education hours for diabetes management.

C. Members of the instructional team must be either employed by or have a contract with a Medicaid enrolled professional services provider that will submit the claims for reimbursement of DSMT services rendered by the team.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Subpart 15. Reimbursement
Chapter 151. Reimbursement Methodology
Subchapter A. General Provisions
§15103. Diabetes Education Services

A. Effective for dates of service on or after February 20, 2011, the Medicaid Program shall provide reimbursement for diabetes self-management training services rendered by qualified health care professionals.

B. Reimbursement for DSMT services shall be a flat fee based on the appropriate Healthcare Common Procedure Coding (HCPC) code.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Implementation of the provisions of this Rule may be contingent upon the approval of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), if it is determined that submission to CMS for review and approval is required.

Interested persons may submit written comments to Don Gregory, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. He is responsible for responding to inquiries regarding this Emergency Rule. A copy of this Emergency Rule is available for review by interested parties at parish Medicaid offices.

Bruce D. Greenstein
Secretary

1106#061

DECLARATION OF EMERGENCY

Department of Health and Hospitals
Bureau of Health Services Financing

Professional Services Program—Reimbursement Methodology—Supplemental Payments
(LAC 50:IX.15151 and 15153)

The Department of Health and Hospitals, Bureau of Health Services Financing adopts §15151 and §15153 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the social Security Act. This Emergency Rule is promulgated in accordance with the

provisions of the Administrative Procedure Act, R.S. 49:953(B)(1) et seq., and shall be in effect for the maximum period allowed under the Act or until adoption of the final Rule, whichever occurs first.

The Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing adopted provisions in the Professional Services Program to provide supplemental payments to physicians and other eligible professional service practitioners employed by state-owned or operated entities (*Louisiana Register,* Volume 32, Number 6). The department promulgated an Emergency Rule which amended the provisions governing the reimbursement methodology for professional services to provide a supplemental payment to physicians and other professional practitioners employed by, or under contract with, non-state owned or operated governmental entities (*Louisiana Register,* Volume 36, Number 6). In addition, this Emergency Rule also repromulgated the provisions of the June 20, 2006 Rule in a codified format for inclusion in the *Louisiana Administrative Code*. This Emergency Rule is being promulgated to continue the provisions of the July 1, 2010 Emergency Rule. This action is being taken to promote the health and welfare of Medicaid recipients by encouraging continued provider participation in the Medicaid Program and ensuring recipient access to services.

Effective June 29, 2011, the Department of Health and Hospitals, Bureau of Health Services Financing amends the provisions governing the reimbursement methodology for services rendered by physicians and other professional service practitioners.

Title 50
PUBLIC HEALTH—MEDICAL ASSISTANCE
Part IX. Professional Services Program
Subpart 15. Reimbursement
Chapter 151. Reimbursement Methodology
Subchapter F. Supplemental Payments

§15151. Qualifying Criteria – State Owned or Operated Professional Services Practices

A. In order to qualify to receive supplemental payments, physicians and other eligible professional service practitioners must be:

1. licensed by the state of Louisiana;
2. enrolled as a Louisiana Medicaid provider; and
3. employed by a state-owned or operated entity, such as a state-operated hospital or other state entity, including a state academic health system, which:
   a. has been designated by the bureau as an essential provider; and
   b. has furnished satisfactory data to DHH regarding the commercial insurance payments made to its employed physicians and other professional service practitioners.

B. The supplemental payment to each qualifying physician or other eligible professional services practitioner in the practice plan will equal the difference between the Medicaid payments otherwise made to these qualifying providers for professional services and the average amount that would have been paid at the equivalent community rate. The community rate is defined as the average amount that would have been paid by commercial insurers for the same services.

C. The supplemental payments shall be calculated by applying a conversion factor to actual charges for claims paid during a quarter for Medicaid services provided by the state-owned or operated practice plan providers. The commercial payments and respective charges shall be obtained for the state fiscal year preceding the reimbursement year. If this data is not provided satisfactorily to DHH, the default conversion factor shall equal "1." This conversion factor shall be established annually for qualifying physicians/practitioners by:

1. determining the amount that private commercial insurance companies paid for commercial claims submitted by the state-owned or operated practice plan or entity; and
2. dividing that amount by the respective charges for these payers.

D. The actual charges for paid Medicaid services shall be multiplied by the conversion factor to determine the maximum allowable Medicaid reimbursement. For eligible non-physician practitioners, the maximum allowable Medicaid reimbursement shall be limited to 80 percent of this amount.

E. The actual base Medicaid payments to the qualifying physicians/practitioners employed by a state-owned or operated entity shall then be subtracted from the maximum Medicaid reimbursable amount to determine the supplemental payment amount.

F. The supplemental payment for services provided by the qualifying state-owned or operated physician practice plan will be implemented through a quarterly supplemental payment to providers, based on specific Medicaid paid claim data.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§15153. Qualifying Criteria—Non-State Owned or Operated Professional Services Practices

A. Effective for dates of service on or after July 1, 2010, physicians and other professional service practitioners who are employed by, or under contract with, a non-state owned or operated governmental entity, such as a non-state owned or operated public hospital, may qualify for supplemental payments for services rendered to Medicaid recipients. To qualify for the supplemental payment, the physician or professional service practitioner must be:

1. licensed by the state of Louisiana; and
2. enrolled as a Louisiana Medicaid provider.

B. The supplemental payment will be determined in a manner to bring payments for these services up to the community rate level.

1. For purposes of these provisions, the community rate shall be defined as the rates paid by commercial payers for the same service.

C. The non-state governmental entity shall periodically furnish satisfactory data for calculating the community rate as requested by DHH.

D. The supplemental payment amount shall be determined by establishing a Medicare to community rate conversion factor for the physician or physician practice plan. At the end of each quarter, for each Medicaid claim paid during the quarter, a Medicare payment amount will be calculated and the Medicare to community rate conversion factor will be applied to the result. Medicaid payments made for the claims paid during the quarter will then be subtracted

from this amount to establish the supplemental payment amount for that quarter.

E. The supplemental payments shall be made on a quarterly basis and the Medicare to community rate conversion factor shall be recalculated periodically as determined by the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Interested persons may submit written comments to Don Gregory, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. He is responsible for responding to inquiries regarding this Emergency Rule. A copy of this Emergency Rule is available for review by interested parties at parish Medicaid offices.

Bruce D. Greenstein
Secretary

1106#065

DECLARATION OF EMERGENCY

Department of Health and Hospitals
Bureau of Health Services Financing

Rural Health Clinics—Diabetes Self-Management Training
(LAC 50:XI.Chapters 163-165 and 16701)

The Department of Health and Hospitals, Bureau of Health Services Financing amends LAC 50:XI.Chapters 163-165 and §16701 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This Emergency Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:953(B)(1) et seq., and shall be in effect for the maximum period allowed under the Act or until adoption of the final Rule, whichever occurs first.

Act 11 of the 2010 Regular Session of the Louisiana Legislature authorized the Department of Health and Hospitals, through its primary and preventive care activity, to provide reimbursement to providers for rendering services that will educate and encourage Medicaid enrollees to obtain appropriate preventive and primary care in order to improve their overall health and quality of life. In keeping with the intent of Act 11, the Department of Health and Hospitals, Bureau of Health Services Financing promulgated an Emergency Rule which amended the provisions governing rural health clinics to provide Medicaid reimbursement for diabetes self-management training (DSMT) services (*Louisiana Register*, Volume 37, Number 2). It is anticipated that this new service will promote improved patient self-management skills which will reduce diabetes-related complications that adversely affect quality of life, and subsequently reduce Medicaid costs associated with the care of recipients diagnosed with diabetes-related illnesses. The February 20, 2011 Emergency Rule also reorganized the existing provisions governing provider participation and services in a more clear and concise manner in the *Louisiana Administrative Code*. The department now proposes to amend the February 20, 2011 Emergency Rule to clarify the provisions governing service limits.

This action is being taken to promote the health and welfare of Medicaid recipients diagnosed with diabetes and to reduce the Medicaid costs associated with their care.

Effective June 20, 2011, the Department of Health and Hospitals, Bureau of Health Services Financing amends the provisions of the February 20, 2011 Emergency Rule governing rural health clinics.

Title 50
PUBLIC HEALTH-MEDICAL ASSISTANCE
Part XI. Clinic Services
Subpart 15. Rural Health Clinics

Chapter 163. Services

§16301. Scope of Services

A. Medicaid reimbursement is limited to medically necessary services that are covered by the Medicaid State Plan and would be covered if furnished by a physician. The following services shall be covered:

1. services furnished by a physician, within the scope of practice of his profession under Louisiana law;
2. services furnished by a:
   a. physician assistant;
   b. nurse practitioner;
   c. nurse midwife;
   d. clinical social worker;
   e. clinical psychologist; or
   f. dentist;
3. services and supplies that are furnished as an incident to professional services furnished by all eligible professionals;
4. other ambulatory services; and
5. diabetes self-management training (DSMT) services.

B. Effective February 20, 2011, the department shall provide coverage of diabetes self-management training services rendered to Medicaid recipients diagnosed with diabetes.

1. The services shall be comprised of one hour of individual instruction and nine hours of group instruction on diabetes self-management.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1904 (October 2006), repromulgated LR 32:2267 (December 2006), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§16303. Service Limits

A. Rural health clinic visits (encounters) are limited to 12 visits per year for medically necessary services rendered to Medicaid recipients who are 21 years of age or older. Visits for Medicaid recipients who are under 21 years of age and for prenatal and postpartum care are excluded from the service limitation.

1. - 3. Repealed.

B. Recipients of DSMT services shall receive up to 10 hours of services during the first 12-month period beginning with the initial training date.

1. After the first 12-month period ends, recipients shall only be eligible for two hours of individual instruction on diabetes self-management per calendar year.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1905 (October 2006), repromulgated LR 32:2267 (December 2006), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Chapter 165. Provider Participation

§16501. Provider Enrollment

A. In order to enroll and participate in the Medicaid Program, a RHC must submit a completed provider enrollment packet.

1. - 4. Repealed.

B. The effective date of enrollment to participate in the Medicaid Program shall not be prior to the date of receipt of the completed enrollment packet.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1905 (October 2006), repromulgated LR 32:2267 (December 2006), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§16503. Standards for Participation

A. Rural health clinics must comply with the applicable licensure, accreditation and program participation standards for all services rendered. If a RHC wishes to initiate participation, it shall be responsible for meeting all of the enrollment criteria of the program. The RHC provider shall:

1. maintain an acceptable fiscal record keeping system that readily distinguishes one type of service from another type of service that may be provided;

2. retain all records necessary to fully disclose the extent of services provided to recipients for five years from the date of service and furnish such records, and any payments claimed for providing such services, to the Medicaid Program upon request; and

3. abide by and adhere to all federal and state regulations and policy manuals.

B. Medicaid enrollment can be no sooner than Medicaid's receipt of the complete enrollment packet. A complete enrollment packet for RHCs must include a copy of the CMS provider certification letter approving rural health clinic status.

C. In order to receive Medicaid reimbursement for DSMT services, a RHC must have a DSMT program that meets the quality standards of one of the following accreditation organizations:

1. the American Diabetes Association;
2. the American Association of Diabetes Educators; or
3. the Indian Health Service.

D. All DSMT programs must adhere to the national standards for diabetes self-management education.

1. Each member of the instructional team must:

a. be a certified diabetes educator (CDE) certified by the National Certification Board for Diabetes Educators; or

b. have recent didactic and experiential preparation in education and diabetes management.

2. At a minimum, the instructional team must consist of one the following professionals who is a CDE:

a. a registered dietician;
b. a registered nurse; or
c. a pharmacist.

3. All members of the instructional team must obtain the nationally recommended annual continuing education hours for diabetes management.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1905 (October 2006), repromulgated LR 32:2267 (December 2006), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Chapter 167. Reimbursement Methodology

§16701. Prospective Payment System

A. - B.2.NOTE. …

3. Effective for dates of service on or after February 20, 2011, the Medicaid Program shall include coverage for diabetes self-management training services rendered by qualified health care professionals in the RHC encounter rate.

a. Separate encounters for DSMT services are not permitted and the delivery of DSMT services alone does not constitute an encounter visit.

C. - D. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1905 (October 2006), repromulgated LR 32:2267 (December 2006), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Implementation of the provisions of this Rule may be contingent upon the approval of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), if it is determined that submission to CMS for review and approval is required.

Interested persons may submit written comments to Don Gregory, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. He is responsible for responding to inquiries regarding this Emergency Rule. A copy of this Emergency Rule is available for review by interested parties at parish Medicaid offices.

Bruce D. Greenstein
Secretary

1106#062

DECLARATION OF EMERGENCY

Department of Natural Resources
Office of Conservation

Statewide Orders No. 29-B and 29-B-a
(LAC 43:XIX.Chapters 2 and 11)

This Order extends the deadline of drilling and completion operational and safety requirements for wells drilled in search or for the production of oil or natural gas at water locations

Pursuant to the power delegated under the laws of the state of Louisiana, and particularly Title 30 of the Revised Statutes of 1950, as amended, and in conformity with the provisions of the Louisiana Administrative Procedure Act, Title 49, sections 953(B)(1) and (2), 954(B)(2), as amended,

the following Emergency Rule and reasons therefore are now adopted and promulgated by the Commissioner of Conservation as being necessary to protect the public health, safety and welfare of the people of the state of Louisiana, as well as the environment generally, by extending the effectiveness of the Emergency Rule it supersedes for drilling and completion operational and safety requirements for wells drilled in search of oil and natural gas at water locations. The following Emergency Rule provides for Commissioner of Conservation approved exceptions to equipment requirements on workover operations. Furthermore, the extension of the Rule allows more time to complete comprehensive rule amendments.

Need And Purpose For Emergency Rule. In light of the Gulf of Mexico Deepwater Horizon oil spill incident in federal waters approximately fifty miles off Louisiana's coast and the threat posed to the natural resources of the state, and the economic livelihood and property of the citizens of the state caused thereby, the Office of Conservation began a new review of its current drilling and completion operational and safety requirements for wells drilled in search of oil and natural gas at water locations. While the incidents of blowout of Louisiana wells is minimal, occurring at less than three-tenths of one percent of the wells drilled in Louisiana since 1987, the great risk posed by blowouts at water locations to the public health, safety and welfare of the people of the state, as well as the environment generally, necessitated the rule amendments contained herein.

After implementation of the Emergency Rule, Conservation formed an ad hoc committee to further study comprehensive rulemaking in order to promulgate new permanent regulations which ensure increased operational and safety requirements for the drilling or completion of oil and gas wells at water locations within the state.

Synopsis of Emergency Rule. The Emergency Rule set forth hereinafter is intended to provide greater protection to the public health, safety and welfare of the people of the state, as well as the environment generally by extending the effectiveness of new operational and safety requirements for the drilling and completion of oil and gas wells at water locations. Following the Gulf of Mexico Deepwater Horizon oil spill, the Office of Conservation ("Conservation") investigated the possible expansion of Statewide Orders No. 29-B and 29-B-a requirements relating to well control at water locations. As part of the rule expansion project, Conservation reviewed the well control regulations of the U.S. Department of the Interior's Mineral Management Service or MMS (now named the Bureau of Ocean Energy Management, Regulation and Enforcement). Except in the instances where it was determined that the MMS provisions were repetitive of other provisions already being incorporated, were duplicative of existing Conservation regulations or were not applicable to the situations encountered in Louisiana's waters, all provisions of the MMS regulations concerning well control issues at water locations were by the preceding Emergency Rules, which this rule supersedes, integrated into Conservation's Statewide Orders No. 29-B and 29-B-a. Conservation is currently performing a comprehensive review of its regulations as it considers future amendments to its operational rules and regulations found in Statewide Order No. 29-B and elsewhere. Specifically, the Emergency Rule extends the effectiveness of a new Chapter within Statewide Order No. 29-B (LAC 43:XIX.Chapter 2) to provide additional rules concerning the drilling and completion of oil and gas wells at water locations, specifically providing for the following: rig movement and reporting requirements, additional requirements for applications to drill, casing program requirements, mandatory diverter systems and blowout preventer requirements, oil and gas well-workover operations, diesel engine safety requirements, and drilling fluid regulations. Further, the Emergency Rule amends Statewide Order No. 29-B-a (LAC 43:XIX.Chapter 11) to provide for and expand upon rules concerning the required use of storm chokes in oil and gas wells at water locations. Reasons. Recognizing the potential advantages of expanding the operational and safety requirements for the drilling and completion of oil and gas wells at water locations within the state, it has been determined that failure to establish such requirements in the form of an administrative rule may lead to the existence of an imminent peril to the public health, safety and welfare of the people of the state of Louisiana, as well as the environment generally. By this Emergency Rule Conservation extends the effectiveness of the following requirements until such time as final comprehensive rules may be promulgated.

Protection of the public and our environment therefore requires the Commissioner of Conservation to extend the following rules in order to assure that drilling and completion of oil and gas wells at water locations within the state are undertaken in accordance with all reasonable care and protection to the health, safety of the public, oil and gas personnel and the environment generally. The Emergency Rule, Amendment to Statewide Order No. 29-B (LAC 43:XIX.Chapter 2) and Statewide Order No. 29-B-a (LAC 43:XIXChapter 11) (Emergency Rule) set forth hereinafter are adopted and extended by the Office of Conservation.

The Emergency Rule signed by the commissioner and effective January 12, 2011 is hereby rescinded and replaced by the following Emergency Rule.

The effective date of this Emergency Rule will be May 12, 2011.

Title 43
NATURAL RESOURCES
Part XIX. Office of Conservation—General Operations
Subpart 1. Statewide Order No. 29-B
Chapter 2. Additional Requirements for Water Locations

§201. Applicability

A. In addition to the requirements set forth in Chapter 1 of this Subpart, all oil and gas wells being drilled or completed at a water location within the State shall comply with this Chapter.

B. Unless otherwise stated herein, nothing within this Chapter shall alter the obligation of oil and gas operators to meet the requirements of Chapter 1 of this Subpart.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:4 et seq.

HISTORICAL NOTE: Promulgated by the Department of Natural Resources, Office of Conservation, LR 37:

§203. Application to Drill

A. In addition to the requirements set forth in Section 103 of this Subpart, at the time of submittal of an application for permit to drill, the applicant will provide an electronic

copy on a disk of the Spill Prevention Control (SPC) plan that was submitted to DEQ pursuant to the provisions of Part IX of Title 33 of the Louisiana Administrative Code or any successor rule. Such plan shall become a part of the official well file.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:4 et seq.

HISTORICAL NOTE: Promulgated by the Department of Natural Resources, Office of Conservation, LR 37:

§204. Rig Movement and Reporting

A. The Operator must report the movement of all drilling and workover rig units on and off locations to the appropriate district manager with the rig name, well serial number and expected time of arrival and departure.

B. Drilling operations on a platform with producing wells or other hydrocarbon flow must comply with the following.

1. An emergency shutdown station must be installed near the driller's console.

2. All producible wells located in the affected wellbay must be shut in below the surface and at the wellhead when:

a. a rig or related equipment is moved on and off a platform. This includes rigging up and rigging down activities within 500 feet of the affected platform;

b. a drilling unit is moved or skid between wells on a platform;

c. a mobile offshore drilling unit (MODU) moves within 500 feet of a platform.

3. Production may be resumed once the MODU is in place, secured, and ready to begin drilling operations.

C. The movement of rigs and related equipment on and off a platform or from well to well on the same platform, including rigging up and rigging down, shall be conducted in a safe manner. All wells in the same well-bay which are capable of producing hydrocarbons shall be shut in below the surface with a pump-through-type tubing plug and at the surface with a closed master valve prior to moving well-completion rigs and related equipment, unless otherwise approved by the district manager. A closed surface-controlled subsurface safety valve of the pump-through type may be used in lieu of the pump-through-type tubing plug, provided that the surface control has been locked out of operation. The well from which the rig or related equipment is to be moved shall also be equipped with a back-pressure valve prior to removing the blowout preventer (BOP) system and installing the tree.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:4 et seq.

HISTORICAL NOTE: Promulgated by the Department of Natural Resources, Office of Conservation, LR 37:

§205. Casing Program

A. General Requirements

1. The operator shall case and cement all wells with a sufficient number of strings of casing and quantity and quality of cement in a manner necessary to prevent fluid migration in the wellbore, protect the underground source of drinking water (USDW) from contamination, support unconsolidated sediments, and otherwise provide a means of control of the formation pressures and fluids.

2. The operator shall install casing necessary to withstand collapse, bursting, tensile, and other stresses that may be encountered and the well shall be cemented in a manner which will anchor and support the casing. Safety factors in casing program design shall be of sufficient magnitude to provide optimum well control while drilling and to assure safe operations for the life of the well.

3. All tubulars and cement shall meet or exceed API standards. Cementing jobs shall be designed so that cement composition, placement techniques, and waiting times ensure that the cement placed behind the bottom 500 feet of casing attains a minimum compressive strength of 500 psi before drilling out of the casing or before commencing completion operations.

4. Centralizers

a. Surface casing shall be centralized by means of placing centralizers in the following manner.

i. A centralizer shall be placed on every third joint from the shoe to surface, with two centralizers being placed on each of the lowermost three joints of casing.

ii. If conductor pipe is set, three centralizers shall be equally spaced on surface casing to fall within the conductor pipe.

b. Intermediate and production casing, and drilling and production liners shall be centralized by means of a centralizer placed every third joint from the shoe to top of cement. Additionally, two centralizers shall be placed on each of the lowermost three joints of casing.

c. All centralizers shall meet API standards.

5. A copy of the documentation furnished by the manufacturer, if new, or supplier, if reconditioned, which certifies tubular condition, shall be provided with the Well History and Work Resume Report (Form WH-1).

B. Conductor Pipe. A conductor pipe is that pipe ordinarily used for the purpose of supporting unconsolidated surface deposits. A conductor pipe shall be used during the drilling of any oil and gas well and shall be set at depth that allows use of a diverter system.

C. Surface Casing

1. Where no danger of pollution of the USDW exists, the minimum amount of surface ~~of~~ or first-intermediate casing to be set shall be determined from Table 1 hereof, except that in no case shall less surface casing be set than an amount needed to protect the USDW unless an alternative method of USDW protection is approved by the district manager.

Table 1

Total Depth of Contact	Casing Required	Surface Casing Test Pressure (lbs. per sq. in.)
0-2500	100	300
2500-3000	150	600
3000-4000	300	600
4000-5000	400	600
5000-6000	500	750
6000-7000	800	1000
7000-8000	1000	1000
8000-9000	1400	1000
9000-Deeper	1800	1000

a. In known low-pressure areas, exceptions to the above may be granted by the commissioner or his agent. If, however, in the opinion of the commissioner, or his agent, the above regulations shall be found inadequate, and additional or lesser amount of surface casing and/or test

pressure shall be required for the purpose of safety and the protection of the USDW.

2. Surface casing shall be cemented with a sufficient volume of cement to insure cement returns to the surface.

3. Surface casing shall be tested before drilling the plug by applying a minimum pump pressure as set forth in Table 1 after at least 200 feet of the mud-laden fluid has been displaced with water at the top of the column. If at the end of 30 minutes the pressure gauge shows a drop of 10 percent of test pressure as outlined in Table 1, the operator shall be required to take such corrective measures as will insure that such surface casing will hold said pressure for 30 minutes without a drop of more than 10 percent of the test pressure. The provisions of Paragraph E.7 below, for the producing casing, shall also apply to the surface casing.

4. Cement shall be allowed to stand a minimum of 12 hours under pressure before initiating test or drilling plug. Under pressure is complied with if one float valve is used or if pressure is held otherwise.

D. Intermediate Casing/Drilling Liner

1. Intermediate casing is that casing used as protection against caving of heaving formations or when other means are not adequate for the purpose of segregating upper oil, gas or water-bearing strata. Intermediate casing/drilling liner shall be set when required by abnormal pressure or other well conditions.

2. If an intermediate casing string is deemed necessary by the district manager for the prevention of underground waste, such regulations pertaining to a minimum setting depth, quality of casing, and cementing and testing of sand, shall be determined by the Office of Conservation after due hearing. The provisions of Paragraph E.7 below, for the producing casing, shall also apply to the intermediate casing.

3. Intermediate casing/drilling liner shall be at minimum, cemented in such a manner, at least 500 feet above all known hydrocarbon bearing formations to insure isolation and, if applicable, all abnormal pressure formations are isolated from normal pressure formations, but in no case shall less cement be used than the amount necessary to fill the casing/liner annulus to a point 500 feet above the shoe or the top of the liner whichever is less. If a liner is used as an intermediate string, the cement shall be tested by a fluid entry test (-0.5 ppg EMW) to determine whether a seal between the liner top and next larger casing string has been achieved, and the liner-lap point must be at least 300 feet above the previous casing shoe. The drilling liner (and liner-lap) shall be tested to a pressure at least equal to the anticipated pressure to which the liner will be subjected to during the formation-integrity test below that liner shoe, or subsequent liner shoes if set. Testing shall be in accordance with Subsection G below.

4. Before drilling the plug in the intermediate string of casing, the casing shall be tested by pump pressure, as determined from Table 2 hereof, after 200 feet of mud-laden fluid in the casing has been displaced by water at the top of the column.

Table 2. Intermediate Casing and Liner	
Depth Set	**Test Pressure (lbs. per sq. in.)**
2000-3000'	800
3000-6000'	1000
6000-9000'	1200

Table 2. Intermediate Casing and Liner	
Depth Set	**Test Pressure (lbs. per sq. in.)**
9000-and deeper	1500

a. If at the end of 30 minutes the pressure gauge shows a drop of 10 percent of the test pressure or more, the operator shall be required to take such corrective measures as will insure that casing is so set and cemented that it will hold said pressure for 30 minutes without a drop of more than 10 percent of the test pressure on the gauge.

5. Cement shall be allowed to stand a minimum of 12 hours under pressure and a minimum total of 24 hours before initiating pressure test. Under pressure is complied with if one or more float valves are employed and are shown to be holding the cement in place, or when other means of holding pressure is used. When an operator elects to perforate and squeeze or to cement around the shoe, he may proceed with such work after 12 hours have elapsed after placing the first cement.

6. If the test is unsatisfactory, the operator shall not proceed with the drilling of the well until a satisfactory test has been obtained.

E. Producing String

1. Producing string, production casing or production liner is that casing used for the purpose of segregating the horizon from which production is obtained and affording a means of communication between such horizons and the surface.

2. The producing string of casing shall consist of new or reconditioned casing, tested at mill test pressure or as otherwise designated by the Office of Conservation.

3. Cement shall be by the pump-and-plug method, or another method approved by the Office of Conservation. Production casing/production liner shall be at minimum, cemented in such a manner, at least 500 feet above all known hydrocarbon bearing formations to insure isolation and, if applicable, all abnormal pressure formations are isolated from normal pressure formations, but in no case shall less cement be used than the amount necessary to fill the casing/liner annulus to a point 500 feet above the shoe or the top of the liner whichever is less. If a liner is used as a producing string, the cement shall be tested by a fluid entry test (-0.5 ppg EMW) to determine whether a seal between the liner top and next larger casing string has been achieved, and the liner-lap point must be at least 300 feet above the previous casing shoe. The production liner (and liner-lap) shall be tested to a pressure at least equal to the anticipated pressure to which the liner will be subjected to during the formation-integrity test below that liner shoe, or subsequent liner shoes if set. Testing shall be in accordance with Subsection G below.

4. The amount of cement to be left remaining in the casing, until the requirements of Paragraph 5 below have been met, shall be not less than 20 feet. This shall be accomplished through the use of a float-collar, or other approved or practicable means, unless a full-hole cementer, or its equivalent, is used.

5. Cement shall be allowed to stand a minimum of 12 hours under pressure and a minimum total of 24 hours before initiating pressure test in the producing or oil string. Under pressure is complied with if one or more float valves are employed and are shown to be holding the cement in

place, or when other means of holding pressure is used. When an operator elects to perforate and squeeze or to cement around the shoe, he may proceed with such work after 12 hours have elapsed after placing the first cement.

6. Before drilling the plug in the producing string of casing, the casing shall be tested by pump pressure, as determined from Table 3 hereof, after 200 feet of mud-laden fluid in the casing has been displaced by water at the top of the column.

Table 3. Producing String	
Depth Set	Test Pressure (lbs. per sq. in.)
2000-3000'	800
3000-6000'	1000
6000-9000'	1200
9000-and deeper	1500

a. If at the end of 30 minutes the pressure gauge shows a drop of 10 percent of the test pressure or more, the operator shall be required to take such corrective measures as will insure that the producing string of casing is so set and cemented that it will hold said pressure for 30 minutes without a drop of more than 10 percent of the test pressure on the gauge.

7. If the commissioner's agent is not present at the time designated by the operator for inspection of the casing tests of the producing string, the operator shall have such tests witnessed, preferably by an offset operator. An affidavit of test, on the form prescribed by the district office, signed by the operator and witness, shall be furnished to the district office showing that the test conformed satisfactorily to the above mentioned regulations before proceeding with the completion. If test is satisfactory, normal operations may be resumed immediately.

8. If the test is unsatisfactory, the operator shall not proceed with the completion of the well until a satisfactory test has been obtained.

F. Cement Evaluation

1. Cement evaluation tests (cement bond or temperature survey) shall be conducted for all casing and liners installed below surface casing to assure compliance with LAC 43:XIX.205.D.3 and E.3.

2. Remedial cementing operations that are required to achieve compliance with LAC 43:XIX.205.D.3 and E.3 shall be conducted following receipt of an approved work permit from the district manager for the proposed operations.

3. Cementing and wireline records demonstrating the presence of the required cement tops shall be retained by the operator for a period of two years.

G. Leak-off Tests

1. A pressure integrity test must be conducted below the surface casing or liner and all intermediate casings or liners. The district manager may require a pressure-integrity test at the conductor casing shoe if warranted by local geologic conditions or the planned casing setting depth. Each pressure integrity test must be conducted after drilling at least 10 feet but no more than 50 feet of new hole below the casing shoe and must be tested to either the formation leak-off pressure or to the anticipated equivalent drilling fluid weight at the setting depth of the next casing string.

a. The pressure integrity test and related hole-behavior observations, such as pore-pressure test results, gas-cut drilling fluid, and well kicks must be used to adjust the drilling fluid program and the setting depth of the next casing string. All test results must be recorded and hole-behavior observations made during the course of drilling related to formation integrity and pore pressure in the driller's report.

b. While drilling, a safe drilling margin must be maintained. When this safe margin cannot be maintained, drilling operations must be suspended until the situation is remedied.

H. Prolonged Drilling Operations

1. If wellbore operations continue for more than 30 days within a casing string run to the surface:

a. drilling operations must be stopped as soon as practicable, and the effects of the prolonged operations on continued drilling operations and the life of the well evaluated. At a minimum, the operator shall:

i. caliper or pressure test the casing; and

ii. report evaluation results to the district manager and obtain approval of those results before resuming operations;

b. if casing integrity as determined by the evaluation has deteriorated to a level below minimum safety factors, the casing must be repaired or another casing string run. Approval from the district manager shall be obtained prior to any casing repair activity.

I. Tubing and Completion

1. Well-completion operations means the work conducted to establish the production of a well after the production-casing string has been set, cemented, and pressure-tested.

2. Prior to engaging in well-completion operations, crew members shall be instructed in the safety requirements of the operations to be performed, possible hazards to be encountered, and general safety considerations to protect personnel, equipment, and the environment. Date and time of safety meetings shall be recorded and available for review by the Office of Conservation.

3. When well-completion operations are conducted on a platform where there are other hydrocarbon-producing wells or other hydrocarbon flow, an emergency shutdown system (ESD) manually controlled station shall be installed near the driller's console or well-servicing unit operator's work station.

4. No tubing string shall be placed in service or continue to be used unless such tubing string has the necessary strength and pressure integrity and is otherwise suitable for its intended use.

5. A valve, or its equivalent, tested to a pressure of not less than the calculated bottomhole pressure of the well, shall be installed below any and all tubing outlet connections.

6. When a well develops a casing pressure, upon completion, equivalent to more than three-quarters of the internal pressure that will develop the minimum yield point of the casing, such well shall be required by the district manager to be killed, and a tubing packer to be set so as to keep such excessive pressure off of the casing.

7. Wellhead Connections. Wellhead connections shall be tested prior to installation at a pressure indicated by the district manager in conformance with conditions existing in areas in which they are used. Whenever such tests are made

in the field, they shall be witnessed by an agent of the Office of Conservation. Tubing and tubingheads shall be free from obstructions in wells used for bottomhole pressure test purposes.

8. When the tree is installed, the wellhead shall be equipped so that all annuli can be monitored for sustained pressure. If sustained casing pressure is observed on a well, the operator shall immediately notify the district manager.

9. Wellhead, tree, and related equipment shall have a pressure rating greater than the shut-in tubing pressure and shall be designed, installed, used, maintained, and tested so as to achieve and maintain pressure control. New wells completed as flowing or gas-lift wells shall be equipped with a minimum of one master valve and one surface safety valve, installed above the master valve, in the vertical run of the tree.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:4 et seq.

HISTORICAL NOTE: Promulgated by the Department of Natural Resources, Office of Conservation, LR 37:

§207. Diverter Systems and Blowout Preventers

A. Diverter System. A diverter system shall be required when drilling surface hole in areas where drilling hazards are known or anticipated to exist. The district manager may, at his discretion, require the use of a diverter system on any well. In cases where it is required, a diverter system consisting of a diverter sealing element, diverter lines, and control systems must be designed, installed, used, maintained, and tested to ensure proper diversion of gases, water, drilling fluids, and other materials away from facilities and personnel. The diverter system shall be designed to incorporate the following elements and characteristics:

1. dual diverter lines arranged to provide for maximum diversion capability;

2. at least two diverter control stations. One station shall be on the drilling floor. The other station shall be in a readily accessible location away from the drilling floor;

3. remote-controlled valves in the diverter lines. All valves in the diverter system shall be full-opening. Installation of manual or butterfly valves in any part of the diverter system is prohibited;

4. minimize the number of turns in the diverter lines, maximize the radius of curvature of turns, and minimize or eliminate all right angles and sharp turns;

5. anchor and support systems to prevent whipping and vibration;

6. rigid piping for diverter lines. The use of flexible hoses with integral end couplings in lieu of rigid piping for diverter lines shall be approved by the district manager.

B. Diverter Testing Requirements

1. When the diverter system is installed, the diverter components including the sealing element, diverter valves, control systems, stations and vent lines shall be function and pressure tested.

2. For drilling operations with a surface wellhead configuration, the system shall be function tested at least once every 24-hour period after the initial test.

3. After nippling-up on conductor casing, the diverter sealing element and diverter valves are to be pressure tested to a minimum of 200 psig. Subsequent pressure tests are to be conducted within seven days after the previous test.

4. Function tests and pressure tests shall be alternated between control stations.

5. Recordkeeping Requirements

a. Pressure and function tests are to be recorded in the driller's report and certified (signed and dated) by the operator's representative.

b. The control station used during a function or pressure test is to be recorded in the driller's report.

c. Problems or irregularities during the tests are to be recorded along with actions taken to remedy same in the driller's report.

d. All reports pertaining to diverter function and/or pressure tests are to be retained for inspection at the wellsite for the duration of drilling operations.

C. BOP Systems. The operator shall specify and insure that contractors design, install, use, maintain and test the BOP system to ensure well control during drilling, workover and all other appropriate operations. The surface BOP stack shall be installed before drilling below surface casing.

1. BOP system components for drilling activity located over a body of water shall be designed and utilized, as necessary, to control the well under all potential conditions that might occur during the operations being conducted and at minimum, shall include the following components:

a. annular-type well control component;

b. hydraulically-operated blind rams;

c. hydraulically-operated shear rams;

d. two sets of hydraulically-operated pipe rams.

2. Drilling activity with a tapered drill string shall require the installation of two or more sets of conventional or variable-bore pipe rams in the BOP stack to provide, at minimum, two sets of rams capable of sealing around the larger-size drill string and one set of pipe rams capable of sealing around the smaller-size drill string.

3. A set of hydraulically-operated combination rams may be used for the blind rams and shear rams.

4. All connections used in the surface BOP system must be flanged, including the connections between the well control stack and the first full-opening valve on the choke line and the kill line.

5. The Commissioner of Conservation, following a public hearing, may grant exceptions to the requirements of LAC 43:XIX.207.C-J.

D. BOP Working Pressure. The working pressure rating of any BOP component, excluding annular-type preventers, shall exceed the maximum anticipated surface pressure (MASP) to which it may be subjected.

E. BOP Auxiliary Equipment. All BOP systems shall be equipped and provided with the following:

1. a hydraulically actuated accumulator system which shall provide 1.5 times volume of fluid capacity to close and hold closed all BOP components, with a minimum pressure of 200 psig above the pre-charge pressure without assistance from a charging system;

2. a backup to the primary accumulator-charging system, supplied by a power source independent from the power source to the primary, which shall be sufficient to close all BOP components and hold them closed;

3. accumulator regulators supplied by rig air without a secondary source of pneumatic supply shall be equipped

with manual overrides or other devices to ensure capability of hydraulic operation if the rig air is lost;

4. at least one operable remote BOP control station in addition to the one on the drilling floor. This control station shall be in a readily accessible location away from the drilling floor. If a BOP control station does not perform properly, operations shall be suspended until that station is operable;

5. a drilling spool with side outlets, if side outlets are not provided in the body of the BOP stack, to provide for separate kill and choke lines;

6. a kill line and a separate choke line are required. Each line must be equipped with two full-opening valves and at least one of the valves must be remotely controlled. The choke line shall be installed above the bottom ram. A manual valve must be used instead of the remotely controlled valve on the kill line if a check valve is installed between the two full-opening manual valves and the pump or manifold. The valves must have a working pressure rating equal to or greater than the working pressure rating of the connection to which they are attached, and must be installed between the well control stack and the choke or kill line. For operations with expected surface pressures greater than 3,500 psi, the kill line must be connected to a pump or manifold. The kill line inlet on the BOP stack must not be used for taking fluid returns from the wellbore;

7. a valve installed below the swivel (upper kelly cock), essentially full-opening, and a similar valve installed at the bottom of the kelly (lower kelly cock). An operator must be able to strip the lower kelly cock through the BOP stack. A wrench to fit each valve shall be stored in a location readily accessible to the drilling crew. If drilling with a mud motor and utilizing drill pipe in lieu of a kelly, you must install one kelly valve above, and one strippable kelly valve below the joint of pipe used in place of a kelly. On a top-drive system equipped with a remote-controlled valve, you must install a strippable kelly-type valve below the remote-controlled valve;

8. an essentially full-opening drill-string safety valve in the open position on the rig floor shall be available at all times while drilling operations are being conducted. This valve shall be maintained on the rig floor to fit all connections that are in the drill string. A wrench to fit the drill-string safety valve shall be stored in a location readily accessible to the drilling crew;

9. a safety valve shall be available on the rig floor assembled with the proper connection to fit the casing string being run in the hole;

10. locking devices installed on the ram-type preventers.

F. BOP Maintenance and Testing Requirements

1. The BOP system shall be visually inspected on a daily basis.

2. Pressure tests (low and high pressure) of the BOP system are to be conducted at the following times and intervals:

a. during a shop test prior to transport of the BOPs to the drilling location. Shop tests are not required for equipment that is transported directly from one well location to another;

b. immediately following installation of the BOPs;

c. within 14 days of the previous BOP pressure test, alternating between control stations and at a staggered interval to allow each crew to operate the equipment. If either control system is not functional, further operations shall be suspended until the nonfunctional, system is operable. Exceptions may be granted by the district manager in cases where a trip is scheduled to occur within 2 days after the 14-day testing deadline;

d. before drilling out each string of casing or liner (The district manager may require that a conservation enforcement specialist witness the test prior to drilling out each casing string or liner);

e. not more than 48 hours before a well is drilled to a depth that is within 1000 feet of a hydrogen sulfide zone (The district manager may require that a conservation enforcement specialist witness the test prior to drilling to a depth that is within 1000 feet of a hydrogen sulfide zone.);

f. when the BOP tests are postponed due to well control problem(s), the BOP test is to be performed on the first trip out of the hole, and reasons for postponing the testing are to be recorded in the driller's report.

3. Low pressure tests (200-300 psig) of the BOP system (choke manifold, kelly valves, drill-string safety valves, etc.) are to be performed at the times and intervals specified in LAC 43:XIX.207.F.2 in accordance with the following provisions.

a. Test pressures are to be held for a minimum of five minutes.

b. Variable bore pipe rams are to be tested against the largest and smallest sizes of pipe in use, excluding drill collars and bottom hole assembly.

c. Bonnet seals are to be tested before running the casing when casing rams are installed in the BOP stack.

4. High pressure tests of the BOP system are to be performed at the times and intervals specified in LAC 43:XIX.207.F.2 in accordance with the following provisions.

a. Test pressures are to be held for a minimum of five minutes.

b. Ram-type BOP's, choke manifolds, and associated equipment are to be tested to the rated working pressure of the equipment or 500 psi greater than the calculated MASP for the applicable section of the hole.

c. Annular-type BOPs are to be tested to 70 percent of the rated working pressure of the equipment.

5. The annular and ram-type BOPs with the exception of the blind-shear rams are to be function tested every seven days between pressure tests. All BOP test records should be certified (signed and dated) by the operator's representative.

a. Blind-shear rams are to be tested at all casing points and at an interval not to exceed 30 days.

6. If the BOP equipment does not hold the required pressure during a test, the problem must be remedied and a retest of the affected component(s) performed. Additional BOP testing requirements:

a. use water to test the surface BOP system;

b. if a control station is not functional operations shall be suspended until that station is operable;

c. test affected BOP components following the disconnection or repair of any well-pressure containment seal in the wellhead or BOP stack assembly.

G. BOP Record Keeping. The time, date and results of pressure tests, function tests, and inspections of the BOP system are to be recorded in the driller's report. All pressure tests shall be recorded on an analog chart or digital recorder. All documents are to be retained for inspection at the wellsite for the duration of drilling operations and are to be retained in the operator's files for a period of two years.

H. BOP Well Control Drills. Weekly well control drills with each drilling crew are to be conducted during a period of activity that minimizes the risk to drilling operations. The drills must cover a range of drilling operations, including drilling with a diverter (if applicable), on-bottom drilling, and tripping. Each drill must be recorded in the driller's report and is to include the time required to close the BOP system, as well as, the total time to complete the entire drill.

I. Well Control Safety Training. In order to ensure that all drilling personnel understand and can properly perform their duties prior to drilling wells which are subject to the jurisdiction of the Office of Conservation, the operator shall require that contract drilling companies provide and/or implement the following:

1. periodic training for drilling contractor employees which ensures that employees maintain an understanding of, and competency in, well control practices;

2. procedures to verify adequate retention of the knowledge and skills that the contract drilling employees need to perform their assigned well control duties.

J. Well Control Operations

1. The operator must take necessary precautions to keep wells under control at all times and must:

a. use the best available and safest drilling technology to monitor and evaluate well conditions and to minimize the potential for the well to flow or kick;

b. have a person onsite during drilling operations who represents the operators interests and can fulfill the operators responsibilities;

c. ensure that the tool pusher, operator's representative, or a member of the drilling crew maintains continuous surveillance on the rig floor from the beginning of drilling operations until the well is completed or abandoned, unless you have secured the well with blowout preventers (BOPs), bridge plugs, cement plugs, or packers;

d. use and maintain equipment and materials necessary to ensure the safety and protection of personnel, equipment, natural resources, and the environment.

2. Whenever drilling operations are interrupted, a downhole safety device must be installed, such as a cement plug, bridge plug, or packer. The device must be installed at an appropriate depth within a properly cemented casing string or liner.

a. Among the events that may cause interruption to drilling operations are:

i. evacuation of the drilling crew;

ii. inability to keep the drilling rig on location; or

iii. repair to major drilling or well-control equipment.

3. If the diverter or BOP stack is nippled down while waiting on cement, it must be determined, before nippling down, when it will be safe to do so based on knowledge of formation conditions, cement composition, effects of nippling down, presence of potential drilling hazards, well conditions during drilling, cementing, and post cementing, as well as past experience.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:4 et seq.

HISTORICAL NOTE: Promulgated by the Department of Natural Resources, Office of Conservation, LR 37:

§209. Casing-Heads

A. All wells shall be equipped with casing-heads with a test pressure in conformance with conditions existing in areas in which they are used. Casing-head body, as soon as installed shall be equipped with proper connections and valves accessible to the surface. Reconditioning shall be required on any well showing pressure on the casing-head, or leaking gas or oil between the oil string and next larger size casing string, when, in the opinion of the district managers, such pressure or leakage assume hazardous proportions or indicate the existence of underground waste. Mud-laden fluid may be pumped between any two strings of casing at the top of the hole, but no cement shall be used except by special permission of the commissioner or his agent.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:4 et seq.

HISTORICAL NOTE: Promulgated by the Department of Natural Resources, Office of Conservation, LR 37:

§211. Oil and Gas Well-Workover Operations

A. Definitions. When used in this Section, the following terms shall have the meanings given below.

Expected Surface Pressure—the highest pressure predicted to be exerted upon the surface of a well. In calculating expected surface pressure, reservoir pressure as well as applied surface pressure must be considered.

Routine Operations—any of the following operations conducted on a well with the tree installed including cutting paraffin, removing and setting pump-through-type tubing plugs, gas-lift valves, and subsurface safety valves which can be removed by wireline operations, bailing sand, pressure surveys, swabbing, scale or corrosion treatment, caliper and gauge surveys, corrosion inhibitor treatment, removing or replacing subsurface pumps, through-tubing logging, wireline fishing, and setting and retrieving other subsurface flow-control devices.

Workover Operations—the work conducted on wells after the initial completion for the purpose of maintaining or restoring the productivity of a well.

B. When well-workover operations are conducted on a well with the tree removed, an emergency shutdown system (ESD) manually controlled station shall be installed near the driller's console or well-servicing unit operator's work station, except when there is no other hydrocarbon-producing well or other hydrocarbon flow on the platform.

C. Prior to engaging in well-workover operations, crew members shall be instructed in the safety requirements of the operations to be performed, possible hazards to be encountered, and general safety considerations to protect personnel, equipment, and the environment. Date and time of safety meetings shall be recorded and available for review.

D. Well-control Fluids, Equipment, and Operations. The following requirements apply during all well-workover operations with the tree removed:

1. The minimum BOP-system components when the expected surface pressure is less than or equal to 5,000 psi shall include one annular-type well control component, one set of pipe rams, and one set of blind-shear rams.

2. The minimum BOP-system components when the expected surface pressure is greater than 5,000 psi shall include one annular-type well control component, two sets of pipe rams, and one set of blind-shear rams.

3. BOP auxillary equipment in accordance with the requirements of LAC 43:XIX.207.E.

4. When coming out of the hole with drill pipe or a workover string, the annulus shall be filled with well-control fluid before the change in such fluid level decreases the hydrostatic pressure 75 pounds per square inch (psi) or every five stands of drill pipe or workover string, whichever gives a lower decrease in hydrostatic pressure. The number of stands of drill pipe or workover string and drill collars that may be pulled prior to filling the hole and the equivalent well-control fluid volume shall be calculated and posted near the operator's station. A mechanical, volumetric, or electronic device for measuring the amount of well-control fluid required to fill the hold shall be utilized.

5. The following well-control-fluid equipment shall be installed, maintained, and utilized:

a. a fill-up line above the uppermost BOP;

b. a well-control, fluid-volume measuring device for determining fluid volumes when filling the hole on trips; and

c. a recording mud-pit-level indicator to determine mud-pit-volume gains and losses. This indicator shall include both a visual and an audible warning device.

E. The minimum BOP-system components for well-workover operations with the tree in place and performed through the wellhead inside of conventional tubing using small-diameter jointed pipe (usually 3/4 inch to 1 1/4 inch) as a work string, i.e., small-tubing operations, shall include two sets of pipe rams, and one set of blind rams.

1. An essentially full-opening work-string safety valve in the open position on the rig floor shall be available at all times while well-workover operations are being conducted. This valve shall be maintained on the rig floor to fit all connections that are in the work string. A wrench to fit the work-string safety valve shall be stored in a location readily accessible to the workover crew.

F. For coiled tubing operations with the production tree in place, you must meet the following minimum requirements for the BOP system.

1. BOP system components must be in the following order from the top down when expected surface pressures are less than or equal to 3,500 psi:

a. stripper or annular-type well control component;

b. hydraulically-operated blind rams;

c. hydraulically-operated shear rams;

d. kill line inlet;

e. hydraulically operated two-way slip rams;

f. hydraulically operated pipe rams.

2. BOP system components must be in the following order from the top down when expected surface pressures are greater than 3,500 psi:

a. stripper or annular-type well control component;

b. hydraulically-operated blind rams;

c. hydraulically-operated shear rams;

d. kill line inlet;

e. hydraulically-operated two-way slip rams;

f. hydraulically-operated pipe rams;

g. hydraulically-operated blind-shear rams. These rams should be located as close to the tree as practical.

3. BOP system components must be in the following order from the top down for wells with returns taken through an outlet on the BOP stack:

a. stripper or annular-type well control component;

b. hydraulically-operated blind rams;

c. hydraulically-operated shear rams;

d. kill line inlet;

e. hydraulically-operated two-way slip rams;

f. hydraulically-operated pipe rams;

g. a flow tee or cross;

h. hydraulically-operated pipe rams;

i. hydraulically-operated blind-shear rams on wells with surface pressures less than or equal to 3,500 psi. As an option, the pipe rams can be placed below the blind-shear rams. The blind-shear rams should be placed as close to the tree as practical.

4. A set of hydraulically-operated combination rams may be used for the blind rams and shear rams.

5. A set of hydraulically-operated combination rams may be used for the hydraulic two-way slip rams and the hydraulically-operated pipe rams.

6. A dual check valve assembly must be attached to the coiled tubing connector at the downhole end of the coiled tubing string for all coiled tubing well-workover operations. To conduct operations without a downhole check valve, it must be approved by the district manager.

7. A kill line and a separate choke line are required. Each line must be equipped with two full-opening valves and at least one of the valves must be remotely controlled. A manual valve must be used instead of the remotely controlled valve on the kill line if a check valve is installed between the two full-opening manual valves and the pump or manifold. The valves must have a working pressure rating equal to or greater than the working pressure rating of the connection to which they are attached, and must be installed between the well control stack and the choke or kill line. For operations with expected surface pressures greater than 3,500 psi, the kill line must be connected to a pump or manifold. The kill line inlet on the BOP stack must not be used for taking fluid returns from the wellbore.

8. The hydraulic-actuating system must provide sufficient accumulator capacity to close-open-close each component in the BOP stack. This cycle must be completed with at least 200 psi above the pre-charge pressure without assistance from a charging system.

9. All connections used in the surface BOP system from the tree to the uppermost required ram must be flanged, including the connections between the well control stack and the first full-opening valve on the choke line and the kill line.

10. The coiled tubing connector must be tested to a low pressure of 200 to 300 psi, followed by a high pressure test to the rated working pressure of the connector or the expected surface pressure, whichever is less. The dual check valves must be successfully pressure tested to the rated working pressure of the connector, the rated working pressure of the dual check valve, expected surface pressure,

or the collapse pressure of the coiled tubing, whichever is less.

G. The minimum BOP-system components for well-workover operations with the tree in place and performed by moving tubing or drill pipe in or out of a well under pressure utilizing equipment specifically designed for that purpose, i.e., snubbing operations, shall include the following:

1. one set of pipe rams hydraulically operated; and

2. two sets of stripper-type pipe rams hydraulically operated with spacer spool.

H. Test pressures must be recorded during BOP and coiled tubing tests on a pressure chart, or with a digital recorder, unless otherwise approved by the district manager. The test interval for each BOP system component must be five minutes, except for coiled tubing operations, which must include a 10 minute high-pressure test for the coiled tubing string.

I. Wireline Operations. The operator shall comply with the following requirements during routine, as defined in Subsection A of this Section, and nonroutine wireline workover operations.

1. Wireline operations shall be conducted so as to minimize leakage of well fluids. Any leakage that does occur shall be contained to prevent pollution.

2. All wireline perforating operations and all other wireline operations where communication exists between the completed hydrocarbon-bearing zone(s) and the wellbore shall use a lubricator assembly containing at least one wireline valve.

3. When the lubricator is initially installed on the well, it shall be successfully pressure tested to the expected shut-in surface pressure.

J. Following completion of the well-workover activity, all such records shall be retained by the operator for a period of two years.

K. An essentially full-opening work-string safety valve in the open position on the rig floor shall be available at all times while well-workover operations are being conducted. This valve shall be maintained on the rig floor to fit all connections that are in the work string. A wrench to fit the work-string safety valve shall be stored in a location readily accessible to the workover crew.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:4 et seq.

HISTORICAL NOTE: Promulgated by the Department of Natural Resources, Office of Conservation, LR 37:

§213. Diesel Engine Safety Requirements

A. Each diesel engine with an air take device must be equipped to shut down the diesel engine in the event of a runaway.

1. A diesel engine that is not continuously manned, must be equipped with an automatic shutdown device.

2. A diesel engine that is continuously manned, may be equipped with either an automatic or remote manual air intake shutdown device.

3. A diesel engine does not have to be equipped with an air intake device if it meets one of the following criteria:

a. starts a larger engine;

b. powers a firewater pump;

c. powers an emergency generator;

d. powers a bop accumulator system;

e. provides air supply to divers or confined entry personnel;

f. powers temporary equipment on a nonproducing platform;

g. powers an escape capsule; or

h. powers a portable single-cylinder rig washer.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:4 et seq.

HISTORICAL NOTE: Promulgated by the Department of Natural Resources, Office of Conservation, LR 37:

§215. Drilling Fluids

A. The inspectors and engineers of the Office of Conservation shall have access to the mud records of any drilling well, except those records which pertain to special muds and special work with respect to patentable rights, and shall be allowed to conduct any essential test or tests on the mud used in the drilling of a well. When the conditions and tests indicate a need for a change in the mud or drilling fluid program in order to insure proper control of the well, the district manager shall require the operator or company to use due diligence in correcting any objectionable conditions.

B. Well-control fluids, equipment, and operations shall be designed, utilized, maintained, and/or tested as necessary to control the well in foreseeable conditions and circumstances.

C. The well shall be continuously monitored during all operations and shall not be left unattended at any time unless the well is shut in and secured.

D. The following well-control-fluid equipment shall be installed, maintained, and utilized:

1. a fill-up line above the uppermost BOP;

2. a well-control, fluid-volume measuring device for determining fluid volumes when filling the hole on trips; and

3. a recording mud-pit-level indicator to determine mud-pit-volume gains and losses. This indicator shall include both a visual and an audible warning device.

E. Safe Practices

1. Before starting out of the hole with drill pipe, the drilling fluid must be properly conditioned. A volume of drilling fluid equal to the annular volume must be circulated with the drill pipe just off-bottom. This practice may be omitted if documentation in the driller's report shows:

a. no indication of formation fluid influx before starting to pull the drill pipe from the hole;

b. the weight of returning drilling fluid is within 0.2 pounds per gallon of the drilling fluid entering the hole.

2. Record each time drilling fluid is circulated in the hole in the driller’s report.

3. When coming out of the hole with drill pipe, the annulus must be filled with drilling fluid before the hydrostatic pressure decreases by 75 psi, or every five stands of drill pipe, whichever gives a lower decrease in hydrostatic pressure. The number of stands of drill pipe and drill collars that you may pull must be calculated before you fill the hole. Both sets of numbers must be posted near the driller's station. A mechanical, volumetric, or electronic device must be used to measure the drilling fluid required to fill the hole.

4. Controlled rates must be used to run and pull drill pipe and downhole tools so you do not swab or surge the well.

5. When there is an indication of swabbing or influx of formation fluids, appropriate measures must be taken to control the well. Circulate and condition the well, on or near-bottom, unless well or drilling-fluid conditions prevent running the drill pipe back to the bottom.

6. The maximum pressures must be calculated and posted near the driller's console that you may safely contain under a shut-in BOP for each casing string. The pressures posted must consider the surface pressure at which the formation at the shoe would break down, the rated working pressure of the BOP stack, and 70 percent of casing burst (or casing test as approved by the district manager). As a minimum, you must post the following two pressures:

a. the surface pressure at which the shoe would break down. This calculation must consider the current drilling fluid weight in the hole; and

b. the lesser of the BOP's rated working pressure or 70 percent of casing-burst pressure (or casing test otherwise approved by the district manager).

7. An operable drilling fluid-gas separator and degasser must be installed before you begin drilling operations. This equipment must be maintained throughout the drilling of the well.

8. The test fluids in the hole must be circulated or reverse circulated before pulling drill-stem test tools from the hole. If circulating out test fluids is not feasible, with an appropriate kill weight fluid test fluids may be bullhead out of the drill-stem test string and tools.

9. When circulating, the drilling fluid must be tested at least once each work shift or more frequently if conditions warrant. The tests must conform to industry-accepted practices and include density, viscosity, and gel strength; hydrogen ion concentration; filtration; and any other tests the district manager requires for monitoring and maintaining drilling fluid quality, prevention of downhole equipment problems and for kick detection. The test results must be recorded in the drilling fluid report.

F. Monitoring Drilling Fluids

1. Once drilling fluid returns are established, the following drilling fluid-system monitoring equipment must be installed throughout subsequent drilling operations. This equipment must have the following indicators on the rig floor:

a. pit level indicator to determine drilling fluid-pit volume gains and losses. This indicator must include both a visual and an audible warning device;

b. volume measuring device to accurately determine drilling fluid volumes required to fill the hole on trips;

c. return indicator devices that indicate the relationship between drilling fluid-return flow rate and pump discharge rate. This indicator must include both a visual and an audible warning device; and

d. gas-detecting equipment to monitor the drilling fluid returns. The indicator may be located in the drilling fluid-logging compartment or on the rig floor. If the indicators are only in the logging compartment, you must continually man the equipment and have a means of immediate communication with the rig floor. If the indicators are on the rig floor only, an audible alarm must be installed.

G. Drilling Fluid Quantities

1. Quantities of drilling fluid and drilling fluid materials must be maintained and replenished at the drill site as necessary to ensure well control. These quantities must be determined based on known or anticipated drilling conditions, rig storage capacity, weather conditions, and estimated time for delivery.

2. The daily inventories of drilling fluid and drilling fluid materials must be recorded, including weight materials and additives in the drilling fluid report.

3. If there are not sufficient quantities of drilling fluid and drilling fluid material to maintain well control, the drilling operations must be suspended.

H. Drilling Fluid-Handling Areas

1. Drilling fluid-handling areas must be classified according to API RP 500, Recommended Practice for Classification of Locations for Electrical Installations at Petroleum Facilities, Classified as Class I, Division 1 and Division 2 or API RP 505, Recommended Practice for Classification of Locations for Electrical Installations at Petroleum Facilities, Classified as Class 1, Zone 0, Zone 1, and Zone 2. In areas where dangerous concentrations of combustible gas may accumulate. A ventilation system and gas monitors must be installed and maintained. Drilling fluid-handling areas must have the following safety equipment:

a. a ventilation system capable of replacing the air once every 5 minutes or 1.0 cubic feet of air-volume flow per minute, per square foot of area, whichever is greater. In addition:

i. if natural means provide adequate ventilation, then a mechanical ventilation system is not necessary;

ii. if a mechanical system does not run continuously, then it must activate when gas detectors indicate the presence of 1 percent or more of combustible gas by volume; and

iii. if discharges from a mechanical ventilation system may be hazardous, the drilling fluid-handling area must be maintained at a negative pressure. The negative pressure area must be protected by using at least one of the following: a pressure-sensitive alarm, open-door alarms on each access to the area, automatic door-closing devices, air locks, or other devices approved by the district manager;

b. gas detectors and alarms except in open areas where adequate ventilation is provided by natural means. Gas detectors must be tested and recalibrated quarterly. No more than 90 days may elapse between tests;

c. explosion-proof or pressurized electrical equipment to prevent the ignition of explosive gases. Where air is used for pressuring equipment, the air intake must be located outside of and as far as practicable from hazardous areas; and

d. alarms that activate when the mechanical ventilation system fails.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:4 et seq.

HISTORICAL NOTE: Promulgated by the Department of Natural Resources, Office of Conservation, LR 37:

Subpart 4. Statewide Order No. 29-B-a

Chapter 11. Required Use of Storm Chokes

§1101. Scope

A. Order establishing rules and regulations concerning the required use of storm chokes to prevent blowouts or uncontrolled flow in the case of damage to surface equipment.

AUTHORITY NOTE: Promulgated in accordance with Act 157 of the Legislature of 1940.

HISTORICAL NOTE: Adopted by the Department of Conservation, March 15, 1946, amended March 1, 1961, amended and promulgated by the Department of Natural Resources, Office of Conservation, LR 20:1127 (October 1994), amended LR 37:

§1103. Applicability

A. All wells capable of flow with a surface pressure in excess of 100 pounds, falling within the following categories, shall be equipped with storm chokes:

1. any locations inaccessible during periods of storm and/or floods, including spillways;

2. located in bodies of water being actively navigated;

3. located in wildlife refuges and/or game preserves;

4. located within 660 feet of railroads, ship channels, and other actively navigated bodies of water;

5. located within 660 feet of state and federal highways in southeast Louisiana, in that area east of a north-south line drawn through New Iberia and south of an east-west line through Opelousas;

6. located within 660 feet of state and federal highways in northeast Louisiana, in that area bounded on the west by the Ouachita River, on the north by the Arkansas-Louisiana line, on the east by the Mississippi River, and on the south by the Black and Red Rivers;

7. located within 660 feet of the following highways:

a. U.S. Highway 71 between Alexandria and Krotz Springs;

b. U.S. Highway 190 between Opelousas and Krotz Springs;

c. U.S. Highway 90 between Lake Charles and the Sabine River;

8. located within the corporate limits of any city, town, village, or other municipality.

AUTHORITY NOTE: Promulgated in accordance with Act 157 of the Legislature of 1940.

HISTORICAL NOTE: Adopted by the Department of Conservation, March 15, 1946, amended March 1, 1961, amended and promulgated by Department of Natural Resources, Office of Conservation, LR 20:1128 (October 1994), amended LR 37:

§1104. General Requirements for Storm Choke Use at Water Locations

A. This Section only applies to oil and gas wells at water locations.

B. A subsurface safety valve shall be designed, installed, used, maintained, and tested to ensure reliable operation.

1. The device shall be installed at a depth of 100 feet or more below the seafloor within 2 days after production is established.

2. Until a subsurface safety device is installed, the well shall be attended in the immediate vicinity so that emergency actions may be taken while the well is open to flow. During testing and inspection procedures, the well shall not be left unattended while open to production unless a properly operating subsurface-safety device has been installed in the well.

3. The well shall not be open to flow while the subsurface safety device is removed, except when flowing of the well is necessary for a particular operation such as cutting paraffin, bailing sand, or similar operations.

4. All SSSV's must be inspected, installed, used, maintained, and tested in accordance with American Petroleum Institute Recommended Practice 14B, Recommended Practice for Design, Installation, Repair, and Operation of Subsurface Safety Valve Systems.

C. Temporary Removal for Routine Operations

1. Each wireline or pumpdown-retrievable subsurface safety device may be removed, without further authorization or notice, for a routine operation which does not require the approval of Form DM-4R.

2. The well shall be identified by a sign on the wellhead stating that the subsurface safety device has been removed. If the master valve is open, a trained person shall be in the immediate vicinity of the well to attend the well so that emergency actions may be taken, if necessary.

3. A platform well shall be monitored, but a person need not remain in the well-bay area continuously if the master valve is closed. If the well is on a satellite structure, it must be attended or a pump-through plug installed in the tubing at least 100 feet below the mud line and the master valve closed, unless otherwise approved by the district manager.

4. Each operator shall maintain records indicating the date a subsurface safety valve is removed, the reason for its removal, and the date it is reinstalled

D. Emergency Action. In the event of an emergency, such as an impending storm, any well not equipped with a subsurface safety device and which is capable of natural flow shall have the device properly installed as soon as possible with due consideration being given to personnel safety.

E. Design and Operation

1. All SSSVs must be inspected, installed, maintained, and tested in accordance with API RP 14H, Recommended Practice for Installation, Maintenance, and Repair of Surface Safety Valves and Underwater Safety Valves Offshore.

2. Testing requirements for subsurface safety devices are as follows.

a. All SSSV's shall be tested for operation and for leakage at least once each calendar month, but at no time shall more than six weeks elapse between tests. SSSV's must be tested in accordance with the test procedures specified in API RP 14H. If a SSSV does not operate properly or if any fluid flow is observed during the leakage test, the valve shall be repaired or replaced.

b. Each subsurface-controlled SSSV installed in a well shall be removed, inspected, and repaired or adjusted, as necessary, and reinstalled or replaced at intervals not exceeding 6 months for those valves not installed in a landing nipple and 12 months for those valves installed in a landing nipple.

3. Records must be retained for a period of two years for each safety device installed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:4 et seq.

HISTORICAL NOTE: Promulgated by the Department of Natural Resources, Office of Conservation, LR 37:

§1105. Waivers

A. Onshore Wells. Where the use of storm chokes would unduly interfere with normal operation of a well, the district manager may, upon submission of pertinent data, in writing, waive the requirements of this order.

B. Offshore Wells

1. The district manager, upon submission of pertinent data, in writing explaining the efforts made to overcome the particular difficulties encountered, may waive the use of a subsurface safety valve under the following circumstances,

and may, in his discretion, require in lieu thereof a surface safety valve:

a. where sand is produced to such an extent or in such a manner as to tend to plug the tubing or make inoperative the subsurface safety valve;

b. when the flowing pressure of the well is in excess of 100 psi but is inadequate to activate the subsurface safety valve;

c. where flow rate fluctuations or water production difficulties are so severe that the subsurface safety valve would prevent the well from producing at its allowable rate;

d. where mechanical well conditions do not permit the installation of a subsurface safety valve;

e. in such other cases as the district manager may deem necessary to grant an exception.

AUTHORITY NOTE: Promulgated in accordance with Act 157 of the Legislature of 1940.

HISTORICAL NOTE: Adopted by the Department of Conservation, March 1, 1961, amended March 15, 1961, amended and promulgated by Department of Natural Resources, Office of Conservation, LR 20:1128 (October 1994), amended LR 37:

James H. Welsh
Commissioner

1106#002

DECLARATION OF EMERGENCY

Department of Wildlife and Fisheries
Office of The Secretary

Atchafalaya Basin Closure Continuation

Due to excessive high water throughout the Mississippi Valley, the Atchafalaya Basin and points south are experiencing flooding, which has been greatly exacerbated by the opening of the Morganza Floodway. The governor has issued an Emergency Proclamation, No. 41BJ2011, to address flooding issues throughout the state. Entergy (Entergy Gulf States Inc.) has approximately four miles of high voltage electrical transmission line which spans that area from the Henderson Levee to the Butte LaRose Levee. This line currently has approximately 12 feet of clearance. The water level is expected to rise an additional 5 feet, which would provide only 7 feet of clearance. This would create a deadly hazard for boaters in the vicinity of the line. Without emergency action by this department, Entergy would be required to de-energize the line. Should the line have to be de-energized, a number of customers, as well as the welcome center on I-10 would be without service, a situation which all parties wish to avoid. To avoid de-energizing the line, Entergy has requested the department to restrict boat traffic in the vicinity of this line. Therefore, in an effort to avoid the loss of electricity to citizens for an indefinite period of time, while avoiding the electrocution of boaters, and in accordance with the provisions of R.S. 34:851.14.1, the department has determined that it is necessary to prohibit all boating in the below described area:

That portion of the Atchafalaya Basin Spillway which is contiguous to the Entergy line and which is more particularly described as follows:

The entirety of that portion of the Atchafalaya Basin Spillway between the West Protection (Guide) Levee and the Butte LaRose Levee on the west bank of the Atchafalaya River, which is south of a line running from 30.331556, -91.7881 to 30.349317, -91.723331 and which is north of Interstate 10, which coincides with a line running from 30.323706, -91.788605 to 30.342755, -91.7196.

During this closure all watercraft are prohibited in the closed area. This closure was first put into effect on Thursday, May 26, 2011 at 6 a.m. It was anticipated that it would be possible to lift this closure prior to seven days beyond the June 2011 Wildlife and Fisheries Commission meeting; however, lingering high water levels make it apparent that the closure must be continued in effect past that time. This Declaration of Emergency closure shall become effective for all boaters at 6 a.m. on Thursday, June 9, 2011. This Declaration of Emergency closure shall remain in effect for the maximum period allowed under the Administrative Procedure Act or until rescinded by the secretary.

Robert J. Barham
Secretary

1106#032

DECLARATION OF EMERGENCY

Department of Wildlife and Fisheries
Office of The Secretary

Atchafalaya Basin Flooding Closure

Due to excessive high water throughout the Mississippi Valley, the Atchafalaya Basin and points south are experiencing flooding, which has been greatly exacerbated by the opening of the Morganza Floodway. The governor has issued an Emergency Proclamation, No. 41BJ2011, to address flooding issues throughout the state. Entergy (Entergy Gulf States Inc.) has approximately four miles of high voltage electrical transmission line which spans that area from the Henderson Levee to the Butte LaRose Levee. This line currently has approximately 12 feet of clearance. The water level is expected to rise an additional 5 feet, which would provide only 7 feet of clearance. This would create a deadly hazard for boaters in the vicinity of the line. Without emergency action by this department, Entergy would be required to de-energize the line. Should the line have to be de-energized, a number of customers, as well as the Welcome Center on I-10 would be without service, a situation which all parties wish to avoid. To avoid de-energizing the line, Entergy has requested the department to restrict boat traffic in the vicinity of this line. Therefore, in an effort to avoid the loss of electricity to citizens for an indefinite period of time, while avoiding the electrocution of boaters, and in accordance with the provisions of R.S. 34:851.14.1, the department has determined that it is necessary to prohibit all boating in the below described area:

That portion of the Atchafalaya Basin Spillway which is contiguous to the Entergy line and which is more particularly described as follows:

The entirety of that portion of the Atchafalaya Basin Spillway between the West Protection (Guide) Levee and the Butte LaRose Levee on the west bank of the Atchafalaya River, which is south of a line running from 30.331556, -91.7881 to 30.349317, -91.723331 and which is north of

Interstate 10, which coincides with a line running from 30.323706, -91.788605 to 30.342755, -91.7196.

During this closure all watercraft are prohibited in the closed area. This Declaration of Emergency closure shall become effective for all boaters at 6 a.m. on Thursday, May 26, 2011. This Declaration of Emergency closure shall remain in effect for the maximum period allowed under the Administrative Procedure Act or until rescinded by the secretary.

Robert J. Barham
Secretary

1106#013

DECLARATION OF EMERGENCY

Department of Wildlife and Fisheries
Wildlife and Fisheries Commission

Oyster Bedding Season—CSA 1

In accordance with the emergency provisions of the Administrative Procedure Act, R.S. 49:953, and under the authority of R.S. 56:433(B)1 which provides that the Wildlife and Fisheries Commission may designate what parts or portions of the natural reefs may be fished for oysters, the Wildlife and Fisheries Commission hereby declares that the public oyster seed grounds within the following areas shall open for the harvest of seed oysters for bedding purposes only at one-half hour before sunrise on Saturday, May 14, 2011 and shall close at one-half hour after sunset on Tuesday, May 31, 2011:

1. Department of Health and Hospitals' harvest area 1;
2. Department of Health and Hospitals' harvest area 2;
3. that portion of Department of Health and Hospitals' harvest area 3 located north of a line of latitude 30 degrees 00 minutes 00.0 seconds N and east of a line of longitude 89 degrees 22 minutes 50.0 seconds W.

The special bedding-only season described above shall be opened with the following provisions.

1. All oysters on board a vessel actively harvesting oysters in the public seed grounds described above shall be presumed to have been taken from the public seed grounds described above.
2. No oyster harvester who is actively harvesting oysters in the public seed ground described above shall have on board his vessel any sacks or containers which may be used to hold oysters for transport to market.
3. No harvester shall sell, or transport with his vessel, oysters intended for market sales on the same day that he harvested seed oysters from the public seed grounds described above.

Harvestable quantities of oyster resources exist in these public oyster seed grounds and the opening of the Bonnet Carre' Spillway may place those resources in imminent peril. As significant oyster mortalities could be experienced due to the anticipated depression of salinity, allowing limited harvest of the resource prior to the oyster mortality is in the best interest of the public.

The Secretary of the Department of Wildlife and Fisheries is authorized to take emergency action as necessary to open or close public oyster areas based on the best available biological data upon notification to the Chairman of the Wildlife and Fisheries Commission.

Stephen W. Sagrera
Chairman

1105#001

Rules

RULE

Board of Elementary and Secondary Education

Bulletin 746—Louisiana Standards for State Certification of School Personnel—Requirements to Add Early Childhood (Grades PK-3)(LAC 28:CXXXI.605)

Editor's Note: This Rule is being repromulgated to correct a citation error. The original Rule may be viewed on page 883 of the March 20, 2011 edition of the Louisiana Register.

In accordance with R.S. 49:950 et seq., the Administrative Procedure Act, the Board of Elementary and Secondary Education has amended *Bulletin 746—Louisiana Standards for State Certification of School Personnel:* §605. Requirements to add Early Childhood (Grades PK-3). This revision in policy specifies that to add Early Childhood PK-3 to an existing teaching certificate, PRAXIS examination #0521 must be completed. This revision is a correction of current Bulletin 746 policy.

Title 28
EDUCATION
Part CXXXI. Bulletin 746—Louisiana Standards for State Certification of School Personnel
Chapter 6. Endorsements to Existing Certificates
Subchapter A. Regular Education Level and Area Endorsements
§605. Requirements to add Early Childhood (Grades PK-3)

A. Individuals holding a valid elementary certificate (e.g., 1-4, 1-5, 1-6, or 1-8) must achieve one of the following:

1. passing score for Praxis principles of learning and teaching early childhood (#0521); or
2. 12 semester hours of combined nursery school and kindergarten coursework.

B. Individuals holding a valid upper elementary or middle school certificate (e.g., 4-8, 5-8, 6-8), secondary school certificate (e.g., 6-12, 7-12, 9-12), special education certificate (other than early interventionist), or an all-level K-12 certificate (art, dance, foreign language, health, physical education, health and physical education, music) must achieve the following:

1. passing score for Praxis elementary education: content knowledge exam (#0014);
2. passing score for Praxis principles of learning and teaching early childhood (#0521) OR accumulate 12 credit hours of combined nursery school and kindergarten coursework;
3. nine semester hours of reading coursework.

C. - C.3. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 17:6 (A)(10), (11), (15); R.S. 17:7(6); R.S. 17:10; R.S. 17:22(6); R.S. 17:391.1-391.10; R.S. 17:411.

HISTORICAL NOTE: Promulgated by the Board of Elementary and Secondary Education, LR 32:1815 (October 2006), amended LR 37:1561 (March 2011).

Catherine R. Pozniak
Executive Director

1103#034

RULE

Student Financial Assistance Commission
Office of Student Financial Assistance

Scholarship/Grant Programs—Academic Year (LAC 28:IV.301)

The Louisiana Student Financial Assistance Commission (LASFAC) has amended its Scholarship/Grant rules (R.S. 17:3021-3025, 3041.10-3041.15, 3042.1, 3048.1, 3048.5 and 3048.6). (SG11129R)

Title 28
EDUCATION
Part IV. Student Financial Assistance—Higher Education Scholarship and Grant Programs
Chapter 3. Definitions
§301. Definitions

A. Words and terms not otherwise defined in this Chapter shall have the meanings ascribed to such words and terms in this Section. Where the masculine is used in these rules, it includes the feminine, and vice versa; where the singular is used, it includes the plural, and vice versa.

Academic Year (college)—

a. Through the 2007-2008 academic year, the two- and four-year college and university academic year begins with the fall term of the award year, includes the winter term, if applicable, and concludes with the completion of the spring term of the award year. Intersessions ending during the academic year are included in the academic year. The two- and four-year college and university academic year does not include summer sessions or intersessions that do not end during the academic year.

b. During the 2008-2009 academic year, the academic year begins with the fall term of the award year, includes the winter term, if applicable, and concludes with the completion of the intersession immediately following the spring term of the award year. Intersessions ending during the academic year, including the intersession immediately following the spring term, are included in the academic year. The two- and four-year college and university academic year does not include summer sessions or other intersessions.

c. Beginning with the 2009-2010 academic year and thereafter, the academic year begins with the fall term of the award year and concludes with the completion of the spring term of the award year or the intersession immediately

following the spring term if such intersession ends no later than June 15, whichever is later. Any intersession or term that begins and ends during the academic year is included. The two- and four-year college and university academic year does not include other intersessions or summer sessions. See the definition of intersession below.

* * *

Intersession—

a. During the 2008-2009 academic year, an academic term between regular semesters/terms that provides credit courses to students in an intensive, condensed format.

b. Beginning with the 2009-2010 academic year, any academic term that provides credit courses to students in an intensive, condensed format that is no longer than 15 class days.

* * *

AUTHORITY NOTE: Promulgated in accordance with R.S. 17:3021-3025, R.S. 17:3042.1 and R.S. 17:3048.1.

HISTORICAL NOTE: Promulgated by the Student Financial Assistance Commission, Office of Student Financial Assistance, LR 22:338 (May 1996), repromulgated LR 24:632 (April 1998), amended LR 24:1898 (October 1998), LR 24:2237 (December 1998), LR 25:256 (February 1999), LR 25:654 (April 1999), LR 25:1458 and 1460 (August 1999), LR 25:1794 (October 1999), LR 26:65 (January 2000), LR 26:688 (April 2000), LR 26:1262 (June 2000), LR 26:1601 (August 2000), LR 26:1993, 1999 (September 2000), LR 26:2268 (October 2000), LR 26:2752 (December 2000), LR 27:36 (January 2001), LR 27:284 (March 2001), LR 27:1219 (August 2001), LR 27:1840 (November 2001), LR 27:1875 (November 2001), LR 28:45 (January 2002), LR 28:446 (March 2002), LR 28:772 (April 2002), LR 28:2330, 2331 (November 2002), LR 29:555 (April 2003), LR 29:879 (June 2003), LR 30:1159 (June 2004), LR 30:2015 (September 2004), LR 31:36 (January 2005), LR 31:3112 (December 2005), LR 33:86 (January 2007), LR 33:439 (March 2007), LR 33:1339 (July 2007), LR 33:2612 (December 2007), LR 34:234 (February 2008), LR 34:1388 (July 2008), LR 34:1884 (September 2008), LR 35:228 (February 2009), LR 35:1489 (August 2009), LR 35:1490 (August 2009), LR 36:311 (February 2010), LR 36:490 (March 2010), LR 36:2854 (December 2010), LR 37:1561 (June 2010).

George Badge Eldredge
General Counsel

1106#004

RULE

Student Financial Assistance Commission
Office of Student Finanical Assistance

Scholarship/Grant Programs—Tuition
(LAC 28:IV.301)

The Louisiana Student Financial Assistance Commission (LASFAC) has amended its Scholarship/Grant rules (R.S. 17:3021-3025, 3041.10-3041.15, 3042.1, 3048.1, 3048.5 and 3048.6). (SG11125R)

Title 28
EDUCATION
Part IV. Student Financial Assistance—Higher Education Scholarship and Grant Programs
Chapter 3. Definitions
§301. Definitions

A. Words and terms not otherwise defined in these rules shall have the meanings ascribed to such words and terms in this Section. Where the masculine is used in these rules, it includes the feminine, and vice versa; where the singular is used, it includes the plural, and vice versa.

* * *

Tuition—

a. Through the fall semester or term and winter quarter of the 2010-2011 award year, the fee charged each student by a post-secondary institution to cover the student's share of the cost of instruction, including all other mandatory enrollment fees charged to all students except for the technology fee authorized by Act 1450 of the 1997 Regular Session of the Legislature:

i. which were in effect as of January 1, 1998;

ii. any changes in the cost of instruction authorized by the legislature and implemented by the institution after that date; and

iii. for programs with alternative scheduling formats that are approved in writing by the Board of Regents after that date. Any payment for enrollment in one of these programs shall count towards the student's maximum eligibility for his award:

(a). up to the equivalent of eight full time semesters of postsecondary education in full time semesters for the TOPS Opportunity, Performance and Honors Award; or

(b). up to the equivalent of two years of postsecondary education in full time semesters and summer sessions for the TOPS Tech Award.

b. Beginning with the spring semester, quarter or term of the 2010-2011 award year:

i. the tuition and mandatory fees authorized in Subparagraph a above; or

ii. the tuition fee amount published by the postsecondary institution, whichever is greater.

* * *

AUTHORITY NOTE: Promulgated in accordance with R.S. 17:3021-3025, R.S. 17:3042.1 and R.S. 17:3048.1.

HISTORICAL NOTE: Promulgated by the Student Financial Assistance Commission, Office of Student Financial Assistance, LR 22:338 (May 1996), repromulgated LR 24:632 (April 1998), amended LR 24:1898 (October 1998), LR 24:2237 (December 1998), LR 25:256 (February 1999), LR 25:654 (April 1999), LR 25:1458 and 1460 (August 1999), LR 25:1794 (October 1999), LR 26:65 (January 2000), LR 26:688 (April 2000), LR 26:1262 (June 2000), LR 26:1601 (August 2000), LR 26:1993, 1999 (September 2000), LR 26:2268 (October 2000), LR 26:2752 (December 2000), LR 27:36 (January 2001), LR 27:284 (March 2001), LR 27:1219 (August 2001), LR 27:1840 (November 2001), LR 27:1875 (November 2001), LR 28:45 (January 2002), LR 28:446 (March 2002), LR 28:772 (April 2002), LR 28:2330, 2331 (November

2002), LR 29:555 (April 2003), LR 29:879 (June 2003), LR 30:1159 (June 2004), LR 30:2015 (September 2004), LR 31:36 (January 2005), LR 31:3112 (December 2005), LR 33:86 (January 2007), LR 33:439 (March 2007), LR 33:1339 (July 2007), LR 33:2612 (December 2007), LR 34:234 (February 2008), LR 34:1388 (July 2008), LR 34:1884 (September 2008), LR 35:228 (February 2009), LR 35:1489 (August 2009), LR 35:1490 (August 2009), LR 36:311 (February 2010), LR 36:490 (March 2010), LR 36:2854 (December 2010), LR 37:1562 (June 2011).

George Badge Eldredge
General Counsel

1106#005

RULE

Department of Environmental Quality
Office of the Secretary

Emergency Response for Solid Waste Facilities
(LAC 33:VII.115, 513, 521, 711, 713,
715, 717, 721, 723 and 725)(SW054)

Under the authority of the Environmental Quality Act, R.S. 30:2001 et seq., and in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq., the secretary has amended the Solid Waste regulations, LAC 33:VII.115, 513, 521, 711, 713, 715, 717, 721, 723 and 725 (SW054).

This Rule will allow the department to implement the revised requirements for emergency response standards at solid waste facilities, as required by Act 862 of the 2010 Legislative Session, which became effective on July 1, 2010. The revised requirements will help ensure that capabilities are in place for first responders in the event of accident, fire, explosion or other emergency at these facilities. Act 862 of the 2010 Legislative Session repealed the statutes (R.S. 2157 and 2157.1) that provided the basis for the present emergency response standards for solid waste facilities. The Act directs the secretary to promulgate new regulations prior to July 1, 2011. Under the new regulations, prospective applicants for new or renewal solid waste standard permits will be required to submit an emergency response plan to the Louisiana State Fire Marshal's Office, and obtain approval of the plan, before submitting an application to LDEQ. The basis and rationale of this Rule creates a definitive set of standards for emergency response requirements at solid waste facilities in Louisiana. This Rule meets an exception listed in R.S. 30:2019(D)(2) and R.S. 49:953(G)(3); therefore, no report regarding environmental/health benefits and social/economic costs is required.

Title 33
ENVIRONMENTAL QUALITY
Part VII. Solid Waste
Subpart 1. Solid Waste Regulations
Chapter 1. General Provisions and Definitions
§115. Definitions

A. For all purposes of these rules and regulations, the terms defined in this Section shall have the following meanings, unless the context of use clearly indicates otherwise.

* * *

Contingency Plan—Repealed.

* * *

Emergency Response Plan—an organized, planned, coordinated course of action to be followed in the event of a fire, explosion, natural disaster, or discharge or release of waste into the environment that could endanger human health or the environment.

* * *

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Solid and Hazardous Waste, Solid Waste Division, LR 19:187 (February 1993), amended LR 22:279 (April 1996), amended by the Office of Waste Services, Solid Waste Division, LR 23:1145 (September 1997), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2514, 2609 (November 2000), amended by the Office of Environmental Assessment, LR 31:1576 (July 2005), amended by the Office of the Secretary, Legal Affairs Division, LR 33:1019 (June 2007), LR 34:1023 (June 2008), LR 34:1399 (July 2008), LR 37:1563 (June 2011).

Chapter 5. Solid Waste Management System
Subchapter B. Permit Administration
§513. Permit Process for Existing Facilities and for Proposed Facilities

A. - B.2.c. …

3. The prospective applicant shall file an emergency response plan, as defined in LAC 33:VII.115.A, with the Louisiana State Fire Marshal as a special structures plan, prior to submittal of a new or renewal application for a solid waste permit. The content of the plan shall be in accord with applicable sections of LAC 33:VII.Chapter 7. A copy of the plan shall also be sent to the Office of Environmental Services. Except as provided for in LAC 33:VII.513.B.4 or 5, no application for a permit to process or dispose of solid waste shall be filed with nor accepted by the administrative authority until the plan is approved by the Louisiana State Fire Marshal. The prospective applicant shall forward a copy of the approval to the Office of Environmental Services. The approved emergency response plan shall be considered applicable to subsequent permit applications submitted by the same applicant, unless a revised plan is filed with the Louisiana State Fire Marshal. After June 20, 2011, a revised plan shall be filed with the Louisiana state fire marshal prior to submittal of a renewal application.

4. The requirements of Paragraph B.3 of this Section shall not apply if the prospective applicant can demonstrate that he has the ability to meet the emergency response requirements listed below. The prospective applicant shall provide this demonstration to the Office of Environmental Services and the Louisiana state fire marshal, at least 30 days prior to submittal of a new or renewal solid waste application.

a. Requirements for Demonstration

i. The prospective applicant shall describe arrangements (including contracts, where applicable) for providing his own emergency response services.

ii. The minimum qualification for firefighters/emergency responders shall be that of operations level responder from the National Fire Protection Association, Standard 472, or other appropriate requirement from an applicable National Fire Protection Association standard. At least one person trained to this level shall respond in any incident requiring activation of emergency response services.

iii. The demonstration shall include a list of all emergency equipment at the facility, such as fire extinguishing systems, spill control equipment, communications and alarm systems (internal and external), and decontamination equipment.

5. The requirements of Paragraph B.3 of this Section shall not apply to permit modification requests, or to applications for permits (initial or renewal), deemed technically complete prior to June 20, 2011, except as directed by the administrative authority.

C. - I. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Solid and Hazardous Waste, Solid Waste Division, LR 19:187 (February 1993), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2519 (November 2000), amended by the Office of Environmental Assessment, LR 30:2032 (September 2004), amended by the Office of the Secretary, Legal Affairs Division, LR 31:2488 (October 2005), LR 33:1037 (June 2007), LR 33:2143 (October 2007), LR 37:1563 (June 2011).

Subchapter D. Permit Application

§521. Part II: Supplementary Information, All Processing and Disposal Facilities

A. - G.1.e. …

f. procedures, equipment, and emergency response plans for protecting employees and the general public from accidents, fires, explosions, etc., and provisions for emergency response and care, should an accident occur (including proximity to a hospital, fire and emergency services, and training programs); and

G.1.g. - M. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Solid and Hazardous Waste, Solid Waste Division, LR 19:187 (February 1993), amended LR 19:1143 (September 1993), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2521 (November 2000), amended by the Office of the Secretary, Legal Affairs Division, LR 33:1040 (June 2007), LR 37:1564 (June 2011).

Chapter 7. Solid Waste Standards

Subchapter A. Landfills, Surface Impoundments, Landfarms

§711. Standards Governing Landfills (Type I and II)

A. - D.5.c. …

6. Emergency Response Plan

a. If required under LAC 33:VII.513, an emergency response plan shall be filed with the closest fire department, emergency medical services (EMS) agency, hospital or clinic, and the Office of Environmental Services, after approval by the Louisiana state fire marshal. Any significant revision of the plan shall be approved and filed in the same manner. The plans shall be reviewed by the permit holder annually, and updated if necessary, or when implementation demonstrates that a revision is needed.

b. …

c. Requirements for Emergency Response Plan

i. The emergency response plan shall describe the actions facility personnel must take in response to accident, fire, explosion, or other emergencies.

ii. If the owner or operator has already prepared an emergency response plan or contingency plan, he need only amend that plan to incorporate solid waste management provisions that are sufficient to comply with these requirements as applicable.

iii. The plan must designate those fire departments or mutual aid societies, emergency medical services agencies, and hospitals with which the facility will coordinate emergency services.

iv. For fire departments or mutual aid societies, the applicable response requirement shall be that of operations level responder from the National Fire Protection Association, Standard 472, or other appropriate requirement from an applicable National Fire Protection Association standard. At least one person trained to this level shall respond in any incident requiring activation of emergency response services.

v. For emergency medical services (EMS), the response requirement shall be that of emergency medical technician—basic, or equivalent. At least one person trained to this level shall respond in any incident requiring activation of EMS.

vi. The plan must include a list of all emergency equipment (where required) at the facility, such as fire extinguishing systems, spill control equipment, communications and alarm systems (internal and external), and decontamination equipment. This list must be kept up to date. In addition, the plan must include the location and a physical description of each item on the list and a brief outline of its capabilities.

vii. The plan shall include an evacuation plan for facility personnel. The plan must describe signals to be used to begin evacuation, evacuation routes, and alternate evacuation routes.

viii. The plan shall include emergency notification procedures required in LAC 33:I.Chapter 39.

d. The provisions of this Paragraph shall not apply if the applicant demonstrates that he meets the response requirements of the applicable sections of the National Fire Protection Association standards, in accordance with LAC 33:VII.513.B.4.

E. - F.3.d. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Solid and Hazardous Waste, Solid Waste Division, LR 19:187 (February 1993), amended LR 19:1143 (September 1993), repromulgated LR 19:1316 (October 1993), amended by the Office of the Secretary, LR 24:2251 (December 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2523 (November 2000), repromulgated LR 27:704 (May 2001), amended LR 30:1676 (August 2004), amended by the Office of Environmental Assessment, LR 30:2024 (September 2004), amended by the Office of the Secretary, Legal Affairs Division, LR 31:2492 (October 2005), LR 33:1047 (June 2007), LR 33:2145 (October 2007), LR 34:1901 (September 2008), LR 37:1564 (June 2011).

§713. Standards Governing Surface Impoundments (Type I and II)

A. - D.4. …

5. Emergency Response Plan

a. If required under LAC 33:VII.513, an emergency response plan shall be filed with the closest fire department,

emergency medical services (EMS) agency, hospital or clinic, and the Office of Environmental Services, after approval by the Louisiana State Fire Marshal. Any significant revision of the plan shall be approved and filed in the same manner. The plans shall be reviewed by the permit holder annually, and updated if necessary, or when implementation demonstrates that a revision is needed.

b. …

c. Requirements for Emergency Response Plan

i. The emergency response plan shall describe the actions facility personnel must take in response to accident, fire, explosion, or other emergencies.

ii. If the owner or operator has already prepared an emergency response plan or contingency plan, he need only amend that plan to incorporate solid waste management provisions that are sufficient to comply with these requirements as applicable.

iii. The plan must designate those fire departments or mutual aid societies, emergency medical services agencies, and hospitals with which the facility will coordinate emergency services.

iv. For fire departments or mutual aid societies, the applicable response requirement shall be that of operations level responder from the National Fire Protection Association, Standard 472, or other appropriate requirement from an applicable National Fire Protection Association standard. At least one person trained to this level shall respond in any incident requiring activation of emergency response services.

v. For emergency medical services (EMS), the response requirement shall be that of emergency medical technician—basic, or equivalent. At least one person trained to this level shall respond in any incident requiring activation of EMS.

vi. The plan must include a list of all emergency equipment (where required) at the facility, such as fire extinguishing systems, spill control equipment, communications and alarm systems (internal and external), and decontamination equipment. This list must be kept up to date. In addition, the plan must include the location and a physical description of each item on the list and a brief outline of its capabilities.

vii. The plan shall include an evacuation plan for facility personnel. The plan must describe signals to be used to begin evacuation, evacuation routes, and alternate evacuation routes.

viii. The plan shall include emergency notification procedures required in LAC 33:I.Chapter 39.

d. The provisions of this Paragraph shall not apply if the applicant demonstrates that he meets the response requirements of the applicable sections of the National Fire Protection Association standards, in accordance with LAC 33:VII.513.B.4.

E. - F.2.b.iv. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Solid and Hazardous Waste, Solid Waste Division, LR 19:187 (February 1993), repromulgated LR 19:1316 (October 1993), amended by the Office of the Secretary, LR 24:2251 (December 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2524 (November 2000), repromulgated LR 27:704 (May 2001), amended LR 30:1676 (August 2004), amended by the Office of Environmental Assessment, LR 30:2025 (September 2004), amended by the Office of the Secretary, Legal Affairs Division, LR 31:2493 (October 2005), LR 33:1053 (June 2007), LR 33:2146 (October 2007), LR 36:1241 (June 2010), LR 37:1564 (June 2011).

§715. Standards Governing Landfarms (Type I and II)

A. - D.4. …

5. Emergency Response Plan

a. If required under LAC 33:VII.513, an emergency response plan shall be filed with the closest fire department, emergency medical services (EMS) agency, hospital or clinic, and the Office of Environmental Services, after approval by the Louisiana state fire marshal. Any significant revision of the plan shall be approved and filed in the same manner. The plans shall be reviewed by the permit holder annually, and updated if necessary, or when implementation demonstrates that a revision is needed.

b. …

c. Requirements for Emergency Response Plan

i. The emergency response plan shall describe the actions facility personnel must take in response to accident, fire, explosion, or other emergencies.

ii. If the owner or operator has already prepared an emergency response plan or contingency plan, he need only amend that plan to incorporate solid waste management provisions that are sufficient to comply with these requirements as applicable.

iii. The plan must designate those fire departments or mutual aid societies, emergency medical services agencies, and hospitals with which the facility will coordinate emergency services.

iv. For fire departments or mutual aid societies, the applicable response requirement shall be that of operations level responder from the National Fire Protection Association, Standard 472, or other appropriate requirement from an applicable National Fire Protection Association standard. At least one person trained to this level shall respond in any incident requiring activation of emergency response services.

v. For emergency medical services (EMS), the response requirement shall be that of Emergency Medical Technician-.Basic, or equivalent. At least one person trained to this level shall respond in any incident requiring activation of EMS.

vi. The plan must include a list of all emergency equipment (where required) at the facility, such as fire extinguishing systems, spill control equipment, communications and alarm systems (internal and external), and decontamination equipment. This list must be kept up to date. In addition, the plan must include the location and a physical description of each item on the list and a brief outline of its capabilities.

vii. The plan shall include an evacuation plan for facility personnel. The plan must describe signals to be used to begin evacuation, evacuation routes, and alternate evacuation routes.

viii. The plan shall include emergency notification procedures required in LAC 33:I.Chapter 39.

d. The provisions of this Paragraph shall not apply if the applicant demonstrates that he meets the response requirements of the applicable sections of the National Fire Protection Association standards, in accordance with LAC 33:VII.513.B.4.

E. - F.3.b. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Solid and Hazardous Waste, Solid Waste Division, LR 19:187 (February 1993), repromulgated LR 19:1316 (October 1993), amended by the Office of the Secretary, LR 24:2251 (December 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2525 (November 2000), repromulgated LR 27:704 (May 2001), amended LR 30:1676 (August 2004), amended by the Office of Environmental Assessment, LR 30:2025 (September 2004), amended by the Office of the Secretary, Legal Affairs Division, LR 31:2493 (October 2005), LR 33:1058 (June 2007), LR 33:2147 (October 2007), LR 35:1880 (September 2009), LR 37:1565 (June 2011).

Subchapter B. Solid Waste Processors

§717. Standards Governing All Type I-A and II-A Solid Waste Processors

A. - G.4. …

5. Emergency Response Plan

a. If required under LAC 33:VII.513, an emergency response plan shall be filed with the closest fire department, emergency medical services (EMS) agency, hospital or clinic, and the Office of Environmental Services, after approval by the Louisiana state fire marshal. Any significant revision of the plan shall be approved and filed in the same manner. The plans shall be reviewed by the permit holder annually, and updated if necessary, or when implementation demonstrates that a revision is needed.

b. …

c. Requirements for Emergency Response Plan

i. The emergency response plan shall describe the actions facility personnel must take in response to accident, fire, explosion, or other emergencies.

ii. If the owner or operator has already prepared an emergency response plan or contingency plan, he need only amend that plan to incorporate solid waste management provisions that are sufficient to comply with these requirements as applicable.

iii. The plan must designate those fire departments or mutual aid societies, emergency medical services agencies, and hospitals with which the facility will coordinate emergency services.

iv. For fire departments or mutual aid societies, the applicable response requirement shall be that of operations level responder from the National Fire Protection Association, Standard 472, or other appropriate requirement from an applicable National Fire Protection Association standard. At least one person trained to this level shall respond in any incident requiring activation of emergency response services.

v. For emergency medical services (EMS), the response requirement shall be that of emergency medical technician—basic, or equivalent. At least one person trained to this level shall respond in any incident requiring activation of EMS.

vi. The plan must include a list of all emergency equipment (where required) at the facility, such as fire extinguishing systems, spill control equipment, communications and alarm systems (internal and external), and decontamination equipment. This list must be kept up to date. In addition, the plan must include the location and a physical description of each item on the list and a brief outline of its capabilities.

vii. The plan shall include an evacuation plan for facility personnel. The plan must describe signals to be used to begin evacuation, evacuation routes, and alternate evacuation routes.

viii. The plan shall include emergency notification procedures required in LAC 33:I.Chapter 39.

d. The provisions of this Paragraph shall not apply if the applicant demonstrates that he meets the response requirements of the applicable sections of the National Fire Protection Association standards, in accordance with LAC 33:VII.513.B.4.

H. - I.3. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Solid and Hazardous Waste, Solid Waste Division, LR 19:187 (February 1993), amended by the Office of the Secretary, LR 24:2252 (December 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2526, 2610 (November 2000), repromulgated LR 27:704 (May 2001), amended by the Office of Environmental Assessment, LR 30:2025 (September 2004), amended by the Office of the Secretary, Legal Affairs Division, LR 31:2494 (October 2005), LR 33:1061 (June 2007), LR 33:2148 (October 2007), LR 34:613 (April 2008), LR 35:926 (May 2009), LR 37:1566 (June 2011).

Subchapter C. Minor Processing and Disposal Facilities

§721. Standards Governing Construction and Demolition Debris and Woodwaste Landfills (Type III)

A. - C.4. ...

5. Emergency Response Plan

a. If required under LAC 33:VII.513, an emergency response plan shall be filed with the closest fire department, emergency medical services (EMS) agency, hospital or clinic, and the Office of Environmental Services, after approval by the Louisiana state fire marshal. Any significant revision of the plan shall be approved and filed in the same manner. The plans shall be reviewed by the permit holder annually, and updated if necessary, or when implementation demonstrates that a revision is needed.

b. …

c. Requirements for Emergency Response Plan

i. The emergency response plan shall describe the actions facility personnel must take in response to accident, fire, explosion, or other emergencies.

ii. If the owner or operator has already prepared an emergency response plan or contingency plan, he need only amend that plan to incorporate solid waste management provisions that are sufficient to comply with these requirements as applicable.

iii. The plan must designate those fire departments or mutual aid societies, emergency medical services agencies, and hospitals with which the facility will coordinate emergency services.

iv. For fire departments or mutual aid societies, the applicable response requirement shall be that of operations level responder from the National Fire Protection Association, Standard 472, or other appropriate requirement from an applicable National Fire Protection Association standard. At least one person trained to this level shall

respond in any incident requiring activation of emergency response services.

v. For emergency medical services (EMS), the response requirement shall be that of emergency medical technician—basic, or equivalent. At least one person trained to this level shall respond in any incident requiring activation of EMS.

vi. The plan must include a list of all emergency equipment (where required) at the facility, such as fire extinguishing systems, spill control equipment, communications and alarm systems (internal and external), and decontamination equipment. This list must be kept up to date. In addition, the plan must include the location and a physical description of each item on the list and a brief outline of its capabilities.

vii. The plan shall include an evacuation plan for facility personnel. The plan must describe signals to be used to begin evacuation, evacuation routes, and alternate evacuation routes.

viii. The plan shall include emergency notification procedures required in LAC 33:I.Chapter 39.

d. The provisions of this Paragraph shall not apply if the applicant demonstrates that he meets the response requirements of the applicable sections of the National Fire Protection Association standards, in accordance with LAC 33:VII.513.B.4.

D. - E.3. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Solid and Hazardous Waste, Solid Waste Division, LR 19:187 (February 1993), amended LR 20:1001 (September 1994), amended by the Office of the Secretary, LR 24:2252 (December 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2527 (November 2000), repromulgated LR 27:705 (May 2001), amended by the Office of Environmental Assessment, LR 30:2025 (September 2004), LR 31:1577 (July 2005), amended by the Office of the Secretary, Legal Affairs Division, LR 31:2495 (October 2005), LR 33:1067 (June 2007), LR 33:2149 (October 2007), LR 34:1901 (September 2008), LR 37:1566 (June 2011).

§723. Standards Governing Composting Facilities

A. - D.5.c. …

6. Emergency Response Plan

a. If required under LAC 33:VII.513, an emergency response plan shall be filed with the closest fire department, emergency medical services (EMS) agency, hospital or clinic, and the Office of Environmental Services, after approval by the Louisiana state fire marshal. Any significant revision of the plan shall be approved and filed in the same manner. The plans shall be reviewed by the permit holder annually, and updated if necessary, or when implementation demonstrates that a revision is needed.

b. …

c. Requirements for Emergency Response Plan

i. The emergency response plan shall describe the actions facility personnel must take in response to accident, fire, explosion, or other emergencies.

ii. If the owner or operator has already prepared an emergency response plan or contingency plan, he need only amend that plan to incorporate solid waste management provisions that are sufficient to comply with these requirements as applicable.

iii. The plan must designate those fire departments or mutual aid societies, emergency medical services agencies, and hospitals with which the facility will coordinate emergency services.

iv. For fire departments or mutual aid societies, the applicable response requirement shall be that of operations level responder from the National Fire Protection Association, Standard 472, or other appropriate requirement from an applicable National Fire Protection Association standard. At least one person trained to this level shall respond in any incident requiring activation of emergency response services.

v. For emergency medical services (EMS), the response requirement shall be that of emergency medical technician—basic, or equivalent. At least one person trained to this level shall respond in any incident requiring activation of EMS.

vi. The plan must include a list of all emergency equipment (where required) at the facility, such as fire extinguishing systems, spill control equipment, communications and alarm systems (internal and external), and decontamination equipment. This list must be kept up to date. In addition, the plan must include the location and a physical description of each item on the list and a brief outline of its capabilities.

vii. The plan shall include an evacuation plan for facility personnel. The plan must describe signals to be used to begin evacuation, evacuation routes, and alternate evacuation routes.

viii. The plan shall include emergency notification procedures required in LAC 33:I.Chapter 39.

d. The provisions of this Paragraph shall not apply if the applicant demonstrates that he meets the response requirements of the applicable sections of the National Fire Protection Association standards, in accordance with LAC 33:VII.513.B.4.

E. - E.4. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Solid and Hazardous Waste, Solid Waste Division, LR 19:187 (February 1993), amended LR 20:1001 (September 1994), amended by the Office of the Secretary, LR 24:2252 (December 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2528 (November 2000), repromulgated LR 27:705 (May 2001), amended by the Office of Environmental Assessment, LR 30:2025 (September 2004), amended by the Office of the Secretary, Legal Affairs Division, LR 31:2496 (October 2005), LR 33:1069 (June 2007), LR 33:2150 (October 2007), LR 37:1567 (June 2011).

§725. Standards Governing Separation and Woodwaste Processing Facilities (Type III)

A. - C.4. …

5. Emergency Response Plan

a. If required under LAC 33:VII.513, an emergency response plan shall be filed with the closest fire department, emergency medical services (EMS) agency, hospital or clinic, and the Office of Environmental Services, after approval by the Louisiana state fire marshal. Any significant

revision of the plan shall be approved and filed in the same manner. The plans shall be reviewed by the permit holder annually, and updated if necessary, or when implementation demonstrates that a revision is needed.

b. …

c. Requirements for Emergency Response Plan

i. The emergency response plan shall describe the actions facility personnel must take in response to accident, fire, explosion, or other emergencies.

ii. If the owner or operator has already prepared an emergency response plan or contingency plan, he need only amend that plan to incorporate solid waste management provisions that are sufficient to comply with these requirements as applicable.

iii. The plan must designate those fire departments or mutual aid societies, emergency medical services agencies, and hospitals with which the facility will coordinate emergency services.

iv. For fire departments or mutual aid societies, the applicable response requirement shall be that of operations level responder from the National Fire Protection Association, Standard 472, or other appropriate requirement from an applicable National Fire Protection Association standard. At least one person trained to this level shall respond in any incident requiring activation of emergency response services.

v. For emergency medical services (EMS), the response requirement shall be that of emergency medical technician—basic, or equivalent. At least one person trained to this level shall respond in any incident requiring activation of EMS.

vi. The plan must include a list of all emergency equipment (where required) at the facility, such as fire extinguishing systems, spill control equipment, communications and alarm systems (internal and external), and decontamination equipment. This list must be kept up to date. In addition, the plan must include the location and a physical description of each item on the list and a brief outline of its capabilities.

vii. The plan shall include an evacuation plan for facility personnel. The plan must describe signals to be used to begin evacuation, evacuation routes, and alternate evacuation routes.

viii. The plan shall include emergency notification procedures required in LAC 33:I.Chapter 39.

d. The provisions of this Paragraph shall not apply if the applicant demonstrates that he meets the response requirements of the applicable sections of the National Fire Protection Association standards, in accordance with LAC 33:VII.513.B.4.

D. - D.3. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2001 et seq.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Solid and Hazardous Waste, Solid Waste Division, LR 19:187 (February 1993), amended LR 20:1001 (September 1994), LR 22:280 (April 1996), amended by the Office of the Secretary, LR 24:2252 (December 1998), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2528 (November 2000), repromulgated LR 27:705 (May 2001), amended by the Office of Environmental Assessment, LR 30:2026 (September 2004), amended by the Office of the Secretary, Legal Affairs Division, LR 31:2496 (October 2005), LR 33:1073 (June 2007), LR 33:2151 (October 2007), LR 37:1567 (June 2011).

Herman Robinson, CPM
Executive Counsel

1106#047

RULE

Department of Environmental Quality
Office of the Secretary

$PM_{2.5}$ NSR Implementation
(LAC 33:III.504 and 509)(AQ318)

Under the authority of the Environmental Quality Act, R.S. 30:2001 et seq., and in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq., the secretary has amended the Air regulations, LAC 33:III.504 and 509 (Log #AQ318).

This Rule incorporates the provisions of the Environmental Protection Agency's (EPA) final Rule entitled "Implementation of the New Source Review (NSR) Program for Particulate Matter Less than 2.5 Micrometers ($PM_{2.5}$)", found at 73 FR 28321, May 16. 2008, into the Louisiana air quality regulations. This action also addresses concerns raised by the EPA in correspondence dated January 24, 2008. The Clean Air Act requires both major and minor NSR programs to address any pollutant for which there is a National Ambient Air Quality Standard (NAAQS) and precursors to the formation of such pollutant when identified for regulation by EPA. EPA's $PM_{2.5}$ NSR implementation Rule amends the federal NSR regulations to establish the minimum elements for state programs implementing NSR for the $PM_{2.5}$ NAAQS and requires states with SIP-approved PSD programs (like Louisiana) to "submit revised PSD programs and revised NNSR programs for $PM_{2.5}$" by May 16, 2011. By letter dated January 24, 2008, EPA submitted comments on revisions to LDEQ's Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NNSR) rules promulgated on December 20, 2005. LDEQ responded to EPA's concerns on October 6, 2008. In sum, to ensure SIP-approvability of LDEQ's PSD and NNSR regulations, the definition of "malfunctions" will be removed from LAC 33:III.504 and 509 and the reference to LAC 33:III.519 in Section 504 will be replaced with text that parallels the federal rule at 40 CFR 51.165. This Rule is also a revision to the Louisiana State Implementation Plan for air quality. The basis and rationale for this Rule are to incorporate the provisions of EPA's $PM_{2.5}$ NSR Implementation Rule into the air quality regulations and modify several existing provisions to ensure SIP-approvability. This rule meets an exception listed in R.S. 30:2019(D)(2) and R.S. 49:953(G)(3); therefore, no report regarding environmental/health benefits and social/economic costs is required.

Title 33
ENVIRONMENTAL QUALITY
Part III. Air

Chapter 5. Permit Procedures

§504. Nonattainment New Source Review (NNSR) Procedures

A. - E.5. …

F. Emission Offsets. All emission offsets approved by the department shall be surplus, permanent, quantifiable, and enforceable in accordance with LAC 33.III.Chapter 6 and shall meet the following criteria.

1. Except as specified in Subsection M of this Section, offsets shall be required at the ratio specified in Subsection L, Table 1 of this Section. All emission reductions claimed as offset credit shall be from decreases of the same regulated pollutant or pollutant class (e.g., VOC) for which the offset is required, except that direct $PM_{2.5}$ emissions or emissions of $PM_{2.5}$ precursors may be offset by reductions in direct $PM_{2.5}$ emissions or emissions of any $PM_{2.5}$ precursor, if such offsets comply with the interprecursor trading hierarchy and ratio established in the approved SIP for a particular nonattainment area.

F.2. - J.4.b. …

5. Public Participation Requirement for PALs. Procedures to establish, renew, or increase PALs for existing major stationary sources shall be consistent with 40 CFR 51.160 and 51.161. These include the requirement that the administrative authority provide the public with notice of the proposed approval of a PAL permit and at least a 30-day period for submittal of public comments. The administrative authority shall address all material comments before taking final action on the permit.

6. - 15.b. …

K. Definitions. The terms in this Section are used as defined in LAC 33:III.111 with the exception of those terms specifically defined as follows.

* * *

Malfunctions—Repealed.

* * *

Regulated Pollutant—

a. any pollutant for which a national ambient air quality standard has been promulgated or any constituent or precursor for the identified pollutant, provided that such constituent or precursor pollutant is only regulated under NNSR as part of regulation of the primary pollutant. Precursors identified by the administrative authority for purposes of NNSR include the following:

i. volatile organic compounds and nitrogen oxides are precursors to ozone in all ozone nonattainment areas;

ii. sulfur dioxide is a precursor to $PM_{2.5}$ in all $PM_{2.5}$ nonattainment areas;

iii. nitrogen oxides are presumed to be precursors to $PM_{2.5}$ in all $PM_{2.5}$ nonattainment areas, unless the administrative authority demonstrates to the administrator's satisfaction or EPA demonstrates that emissions of nitrogen oxides from sources in a specific area are not a significant contributor to that area's ambient $PM_{2.5}$ concentrations; and

iv. volatile organic compounds and ammonia are presumed not to be precursors to $PM_{2.5}$ in any $PM_{2.5}$ nonattainment area, unless the administrative authority demonstrates to the administrator's satisfaction or EPA demonstrates that emissions of volatile organic compounds or ammonia from sources in a specific area are a significant contributor to that area's ambient $PM_{2.5}$ concentrations.

b. $PM_{2.5}$ emissions and PM_{10} emissions shall include the gaseous emissions from a source or activity which condense to form particulate matter at ambient temperatures. On or after January 1, 2011, such condensable particulate matter shall be accounted for in applicability determinations and in establishing emissions limitations for $PM_{2.5}$ and PM_{10} in NNSR permits. Compliance with emissions limitations for $PM_{2.5}$ and PM_{10} issued prior to this date shall not be based on condensable particulate matter. Applicability determinations made prior to this date without accounting for condensable particulate matter shall not be considered in violation of this Section.

* * *

Significant—in reference to a net emissions increase or the potential of a source to emit any of the following pollutants, a rate of emissions that would equal or exceed the lower of any of the following rates or the applicable major modification significant net increase threshold in Subsection L, Table 1 of this Section.

Pollutant	Emission Rate
Carbon monoxide	100 tons per year (tpy)
Nitrogen oxides	40 tpy
Sulfur dioxide	40 tpy
Ozone	40 tpy of volatile organic compounds or nitrogen oxides
Lead	0.6 tpy
PM_{10}	15 tpy
$PM_{2.5}$	10 tpy of direct $PM_{2.5}$ emissions; 40 tpy of sulfur dioxide emissions; 40 tpy of nitrogen oxide[1]

[1]Nitrogen oxides are presumed to be precursors to $PM_{2.5}$ in all $PM_{2.5}$ nonattainment areas unless the administrative authority demonstrates to the administrator's satisfaction or EPA demonstrates that emissions of nitrogen oxides from sources in a specific area are not a significant contributor to that area's ambient $PM_{2.5}$ concentrations.

* * *

L. Table 1—Major Stationary Source/Major Modification Emission Thresholds

Table 1
Major Stationary Source/Major Modification Emission Thresholds

Pollutant	Major Stationary Source Threshold Values (tons/year)	Major Modification Significant Net Increase (tons/year)	Offset Ratio Minimum
Ozone VOC/NO_x		Trigger Values	
Marginal	100	40(40)[2]	1.10 to 1
Moderate	100	40(40)[2]	1.15 to 1
Serious	50	25[3](5)[4]	1.20 to 1 w/LAER or 1.40 to 1 internal w/o LAER
Severe	25	25[3](5)[4]	1.30 to 1 w/LAER or 1.50 to 1 internal w/o LAER
Extreme	10	Any increase	1.50 to 1
CO			
Moderate	100	100	>1.00 to 1
Serious	50	50	>1.00 to 1
SO_2	100	40	>1.00 to 1
PM_{10}[1]			
Moderate	100	15	>1.00 to 1
Serious	70	15	>1.00 to 1
$PM_{2.5}$[5]	100	10	>1.00 to 1
Lead	100	0.6	>1.00 to 1

Footnotes 1. - 4. …

[5] Sulfur dioxide is a precursor to $PM_{2.5}$ in all $PM_{2.5}$ nonattainment areas. Nitrogen oxides are presumed to be precursors to $PM_{2.5}$ in all $PM_{2.5}$

nonattainment areas unless the administrative authority demonstrates to the administrator's satisfaction or EPA demonstrates that emissions of nitrogen oxides from sources in a specific area are not a significant contributor to that area's ambient $PM_{2.5}$ concentrations. Volatile organic compounds and ammonia are presumed not to be precursors to $PM_{2.5}$ in any $PM_{2.5}$ nonattainment area unless the administrative authority demonstrates to the administrator's satisfaction or EPA demonstrates that emissions of volatile organic compounds or ammonia from sources in a specific area are a significant contributor to that area's ambient $PM_{2.5}$ concentrations.

VOC = volatile organic compounds
NO_X = oxides of nitrogen
CO = carbon monoxide
SO_2 = sulfur dioxide
PM_{10}= particulate matter of less than 10 microns in diameter
$PM_{2.5}$ = particulate matter of less than 2.5 microns in diameter

M. - M.3. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2054.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Radiation Protection, Air Quality Division, LR 19:176 (February 1993), repromulgated LR 19:486 (April 1993), amended LR 19:1420 (November 1993), LR 21:1332 (December 1995), LR 23:197 (February 1997), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2445 (November 2000), LR 27:2225 (December 2001), LR 30:752 (April 2004), amended by the Office of Environmental Assessment, LR 30:2801 (December 2004), amended by the Office of the Secretary, Legal Affairs Division, LR 31:2436 (October 2005), LR 31:3123, 3155 (December 2005), LR 32:1599 (September 2006), LR 33:2082 (October 2007), LR 34:1890 (September 2008), LR 37:1568 (June 2011).

§509. Prevention of Significant Deterioration

A. Applicability Procedures

1. - 5. …

B. Definitions. For the purpose of this Section, the terms below shall have the meaning specified herein as follows.

* * *

Malfunctions—Repealed.

* * *

Regulated New Source Review (NSR) Pollutant—

a. any pollutant for which a national ambient air quality standard has been promulgated or any constituent or precursor for the identified pollutant. Precursors identified by the administrative authority for purposes of PSD include the following:

i. volatile organic compounds and nitrogen oxides are precursors to ozone in all attainment and unclassifiable areas;

ii. sulfur dioxide is a precursor to $PM_{2.5}$ in all attainment and unclassifiable areas;

iii. nitrogen oxides are presumed to be precursors to $PM_{2.5}$ in all attainment and unclassifiable areas unless the administrative authority demonstrates to the administrator's satisfaction or EPA demonstrates that emissions of nitrogen oxides from sources in a specific area are not a significant contributor to that area's ambient $PM_{2.5}$ concentrations; and

iv. volatile organic compounds are presumed not to be precursors to $PM_{2.5}$ in any attainment or unclassifiable area unless the administrative authority demonstrates to the administrator's satisfaction or EPA demonstrates that emissions of volatile organic compounds from sources in a specific area are a significant contributor to that area's ambient $PM_{2.5}$ concentrations;

b. any pollutant that is subject to any standard promulgated under Section 111 of the Clean Air Act;

c. any Class I or II substance subject to a standard promulgated under or established by Title VI of the Clean Air Act;

d. any pollutant that otherwise is subject to regulation under the Clean Air Act; except that any or all hazardous air pollutants either listed in section 112 of the Clean Air Act or added to the list in accordance with section 112(b)(2) of the Clean Air Act, which have not been delisted in accordance with Section 112(b)(3) of the Clean Air Act, are not *regulated NSR pollutants* unless the listed hazardous air pollutant is also regulated as a constituent or precursor of a general pollutant listed under section 108 of the Clean Air Act; or

e. particulate matter (PM) emissions, $PM_{2.5}$ emissions, and PM_{10} emissions shall include gaseous emissions from a source or activity which condense to form particulate matter at ambient temperatures. On or after January 1, 2011, such condensable particulate matter shall be accounted for in applicability determinations and in establishing emissions limitations for PM, $PM_{2.5}$, and PM_{10} in PSD permits. Compliance with emissions limitations for PM, $PM_{2.5}$, and PM_{10} issued prior to this date shall not be based on condensable particulate matter. Applicability determinations made prior to this date without accounting for condensable particulate matter shall not be considered in violation of this Section.

* * *

Significant—

a. in reference to a net emissions increase or the potential of a source to emit any of the following pollutants, a rate of emissions that would equal or exceed any of the following rates:

Pollutant	Emission Rate
Carbon monoxide	100 tons per year (tpy)
Nitrogen oxides	40 tpy
Sulfur dioxide	40 tpy
Particulate matter	25 tpy of particulate emissions
	15 tpy of PM_{10} emissions
	10 tpy of direct $PM_{2.5}$ emissions; 40 tpy of sulfur dioxide emissions; 40 tpy of nitrogen oxide emissions[1]
Ozone	40 tpy of volatile organic compounds or nitrogen oxides
Lead	0.6 tpy
Fluorides	3 tpy
Sulfuric acid mist	7 tpy
Hydrogen sulfide (H_2S)	10 tpy
Total reduced sulfur (including H_2S)	10 tpy
Reduced sulfur compounds (including H_2S)	10 tpy
Municipal waste combustor organics[2]	0.0000035 tpy
Municipal waste combustor metals[3]	15 tpy
Municipal waste combustor acid gases[4]	40 tpy
Municipal solid waste landfills emissions[5]	50 tpy
GHGs and *GHGs* as CO_2e[6]	0 tpy and 75,000 tpy, respectively

Pollutant	Emission Rate
[1]Measured as total tetra- through octa-chlorinated dibenzo-p-dioxins and dibenzofurans. [2]Measured as particulate matter. [3]Measured as sulfur dioxide and hydrogen chloride. [4]Measured as nonmethane organic compounds. [5]Both of the following conditions must be met: (1) the net emissions increase of GHGs calculated as the sum of the six *GHGs* on a mass basis (i.e., no global warming potentials applied) equals or exceeds 0 tpy; and (2) the net emissions increase of *GHGs* calculated as the sum of the six GHGs on a basis CO_2e (i.e., global warming potentials applied) equals or exceeds 75,000 tpy CO_2e.	

b. - d.ii. …

* * *

C. - AA.15.b. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:2054.

HISTORICAL NOTE: Promulgated by the Department of Environmental Quality, Office of Air Quality and Nuclear Energy, Air Quality Division, LR 13:741 (December 1987), amended LR 14:348 (June 1988), LR 16:613 (July 1990), amended by the Office of Air Quality and Radiation Protection, Air Quality Division, LR 17:478 (May 1991), LR 21:170 (February 1995), LR 22:339 (May 1996), LR 23:1677 (December 1997), LR 24:654 (April 1998), LR 24:1284 (July 1998), repromulgated LR 25:259 (February 1999), amended by the Office of Environmental Assessment, Environmental Planning Division, LR 26:2447 (November 2000), LR 27:2234 (December 2001), amended by the Office of the Secretary, Legal Affairs Division, LR 31:2437 (October 2005), LR 31:3135, 3156 (December 2005), LR 32:1600 (September 2006), LR 32:1843 (October 2006), LR 36:2556 (November 2010), LR37:1148 (April 2011), repromulgated LR 37:1389 (May 2011), LR 37:1570 (June 2011).

Herman Robinson, CPM
Executive Counsel

1106#048

RULE

Department of Health and Hospitals
Board of Veterinary Medicine

Prescribing and Dispensing Drugs—Preceptorship Program
(LAC 46:LXXXV.705 and 1105)

The Louisiana Board of Veterinary Medicine has amended LAC 46:LXXXV.705 and 1105 in accordance with the provisions of the Administrative Procedure Act, R.S. 49:953 et seq., and the Louisiana Veterinary Practice Act, R.S. 37:1518(A)(9). The rules have been amended to implement specific requirements regarding a written prescription for a controlled drug issued by a prescribing veterinarian; to clarify the requirements for waiver of the preceptorship program necessary for licensure; and to provide administrative recourse for the board resulting from the submission of an unfavorable evaluation of a preceptee submitted by a preceptor, as well as the right to appeal a decision of the board by the preceptee.

Title 46
PROFESSIONAL AND OCCUPATIONAL STANDARDS
Part LXXXV. Veterinarians

Chapter 7. Veterinary Practice

§705. Prescribing and Dispensing Drugs

A. - K.9. ...

L. The initial prescription of a legend drug shall be communicated personally or by telephone to the pharmacy by the veterinarian. The initial prescription and any refills of a controlled drug shall be communicated personally or by telephone to the pharmacy by the veterinarian. A written prescription for a controlled drug shall be personally prepared by the prescribing veterinarian. A written prescription for a controlled drug shall be handwritten or typed, and shall contain the specific client/patient's names (or identifying information if herd, etc.) and the drug(s) prescribed with usage directions, appropriate government registration numbers, dated, and signed by the prescribing veterinarian, affixed with his signature stamp, or electronic signature thereon if transmitted electronically to a pharmacy. However, the use of a signature stamp or electronic signature will have the presumption the prescribing veterinarian knows of, and has personally provided, the prescription for the use of the patient.

M. - O.12. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1518.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Board of Veterinary Medicine, LR 6:71 (February 1980), amended by the Department of Health and Hospitals, Board of Veterinary Medicine, LR 16:225 (March 1990), LR 19:1329 (October 1993) LR 20:1381 (December 1994), LR 23:1686 (December 1997), LR 24:1932 (October 1998), LR 25:1249 (July 1999), LR 25:1627 (September 1999), LR 27:51 (January 2001), LR 30:797 (April 2004), LR 37:1571 (June 2011).

Chapter 11. Preceptorship Program

§1105. Applicants

A. - D. …

E. The board shall have the discretionary right to waive compliance with the preceptorship program when the applicant has been licensed in another state or is eligible for a license without examination, and provides written proof of employment as a licensed veterinarian in a full time, clinical practice for a minimum of 90 days for the period immediately prior to submission of the license application to the board.

F. The board shall have the discretionary right to require a preceptee, who has received an unfavorable evaluation, to repeat the preceptorship program requirement for licensure, in its entirety or partially, with another preceptor selected by the preceptee and pre-approved by the board. If the preceptee is thereafter unable to obtain a favorable evaluation, the board shall have the discretionary right to deny licensure. Any decision made by the board pursuant to this subsection shall be subject to appeal and review in accordance with LAC 46:LXXXV.105.B.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1518.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Veterinary Medicine, LR 16:232 (March 1990), amended LR 23:1686 (December 1997), LR 24:942 (May 1998), LR 27:543 (April 2001), LR 37:1571 (June 2011).

Wendy D. Parrish
Executive Director

1106#022

RULE

Department of Health and Hospitals
Bureau of Health Services Financing
and
Office of Aging and Adult Services

All Inclusive Care for the Elderly—Reimbursement Rate Reduction (LAC 50:XXIII.1301)

The Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services has amended LAC 50:XXIII.1301 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq.

The Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing amended the provisions governing the Program of All Inclusive Care for the Elderly (PACE) to: 1) remove the requirement that eligibility decisions be approved by the state administering agency; 2) revise PACE disenrollment criteria; 3) allow for service area specific rates instead of one statewide rate; and 4) clarify when the obligation for patient liability begins (*Louisiana Register*, Volume 33, Number 5).

As a result of a budgetary shortfall in state fiscal year 2011, the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services promulgated an Emergency Rule which amended the provisions governing the reimbursement methodology for PACE to reduce the capitated amounts paid to PACE organizations (*Louisiana Register*, Volume 36, Number 8). Due to a continuing budgetary shortfall in state fiscal year 2011, the department promulgated an Emergency Rule which amended the provisions governing the reimbursement methodology for PACE to further reduce the capitated amount paid to PACE organizations (*Louisiana Register,* Volume 37, Number 1). This Rule is being promulgated to continue the provisions of the August 1, 2010 and the January 1, 2011 Emergency Rules.

Title 50
PUBLIC HEALTH–MEDICAL ASSISTANCE
Part XXIII. All Inclusive Care for the Elderly
Chapter 13. Reimbursement
§1301. Payment

A. - J.3. …

K. Effective for dates of service on or after August 1, 2010, the monthly capitated amount paid to a PACE organization shall be reduced by 2 percent of the capitated amount on file as of July 31, 2010.

L. Effective for dates of service on or after January 1, 2011, the monthly capitated amount paid to a PACE organization shall be reduced by 3.09 percent of the capitated amount on file as of December 31, 2010.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254, Title XIX of the Social Security Act and 42 CFR 460 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 30:250 (February 2004), amended LR 33:850 (May 2007), amended by the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 37:1572 (June 2011).

Implementation of the provisions of this Rule may be contingent upon the approval of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), if it is determined that submission to CMS for review and approval is required.

Bruce D. Greenstein
Secretary

1106#072

RULE

Department of Health and Hospitals
Bureau of Health Services Financing

Ambulatory Surgical Centers—Reimbursement Rate Reduction (LAC 50:XI.7503)

The Department of Health and Hospitals, Bureau of Health Services Financing has amended LAC 50:XI.7503 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq.

Title 50
PUBLIC HEALTH—MEDICAL ASSISTANCE
Part XI. Clinic Services
Subpart 11. Ambulatory Surgical Centers
Chapter 75. Reimbursement
§7503. Reimbursement Methodology

A. - D. …

E. Effective for dates of service on or after August 1, 2010, the reimbursement for surgical services provided by an ambulatory surgical center shall be reduced by 4.4 percent of the fee amounts on file as of July 31, 2010.

F. Effective for dates of service on or after January 1, 2011, the reimbursement for surgical services provided by an ambulatory surgical center shall be reduced by 2 percent of the fee amounts on file as of December 31, 2010.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 35:1889 (September 2009), amended LR 36:2278 (October 2010), LR 37:1572 (June 2011).

Bruce D. Greenstein
Secretary

1106#073

RULE

Department of Health and Hospitals
Bureau of Health Services Financing

Coordinated Care Network (LAC 50:I.Chapters 31-40)

The Department of Health and Hospitals, Bureau of Health Services Financing has adopted LAC 50:I.Chapters 31-40 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq.

Title 50
PUBLIC HEALTH—MEDICAL ASSISTANCE
Part I. Administration
Subpart 3. Medicaid Coordinated Care
Chapter 31. Coordinated Care Network

§3101. Introduction

A. A coordinated care network (CCN) is an organized health care delivery system designed to improve access to care and the quality of services, as well as to promote healthier outcomes for Medicaid recipients through the establishment of a medical home system of care.

B. Coordinated care networks may be either a fee-for-service with shared savings model (CCN-S), a prepaid risk bearing managed care organization (MCO) model (CCN-P), or an alternative Medicaid managed care model that coordinates care and that the department makes available in accordance with the promulgation of administrative Rules.

1. A CCN-S is an entity that serves as a primary care case manager by providing enhanced primary care case management in addition to contracting with primary care providers (PCPs) for primary care management.

2. A CCN-P is a risk-bearing, MCO health care delivery system that is responsible for the provision of specified Medicaid State Plan services.

C. It is the department's goal to develop a health care delivery system that improves access to care and care coordination, promotes healthier outcomes, provides budget stability, and results in savings as compared to an unmanaged fee-for-service system.

D. It is the department's intent to:

1. procure the services of coordinated care networks statewide through the competitive bid process; and

a. The number of each type of coordinated care network model for each specified service area shall be no more than required to meet Medicaid enrollee capacity requirements and ensure choice for Medicaid recipients as required by federal statute.

2. provide the opportunity for an equal number of CCN-P and CCN-S models in each department designated service area, with the same minimum capacity requirements for both.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1573 (June 2011).

§3103. Recipient Participation

A. The following Medicaid recipients shall be mandatory participants in coordinated care networks:

1. categorically needy individuals:

a. children up to 19 years of age and their parents who are eligible under §1931 of the Social Security Act (hereafter referred to as the Act) as poverty-level related groups or optional groups of older children and caretaker relatives;

b. qualified pregnant women and children who are eligible under §1902 and §1905 of the Act;

c. aged, blind and disabled adults over the age of 19 who are eligible under §1619, §1634, §1902 and §1905 of the Act. These individuals may be receiving cash payments through Supplemental Security Income (SSI) or have lost SSI eligibility due to a Social Security cost-of-living adjustment (COLA) or entitlement for, or an increase in Retirement, Survivors or Disability Insurance (RSDI) benefits;

d. uninsured women under the age of 65 who have been screened through the Centers for Disease Control National Breast and Cervical Cancer Early Detection Program and identified as being in need of treatment for breast and/or cervical cancer, including pre-cancerous conditions and early stage cancer, and are not otherwise eligible for Medicaid; and

e. uninsured women who are eligible through the Louisiana Children's Health Insurance Program (LaCHIP) Prenatal Option; and

2. medically needy individuals:

a. individuals and families who have more income than is allowed for Medicaid eligibility, but who meet the standards for the Regular Medically Needy Program.

B. Voluntary Participants

1. Participation in a CCN is voluntary for:

a. individuals who are Native Americans/Alaskan Natives and members of a federally recognized tribe except when the managed care organization or primary care case management entity is:

i. the Indian Health Service; or

ii. an Indian health program or urban Indian program operated by a tribe or tribal organization under a contract, grant, cooperative agreement or compact with the Indian Health Service; and

b. children under 19 years of age who are:

i. eligible under §1902(e)(3) of the Act and receiving Supplemental Security Income (SSI);

ii. in foster care or other out-of-home placement;

iii. receiving foster care or adoption assistance;

iv. receiving services through a family-centered, community-based coordinated care system that receives grant funds under §501(a)(1)(D) of Title V, and is defined by the department in terms of either program participation or special health care needs; or

v. enrolled in the Family Opportunity Act Medicaid Buy-In Program.

NOTE: These recipients will be enrolled in a CCN pursuant to the automatic assignment protocol if they do not choose a plan after a choice period of 30 days. They may request disenrollment at any time, without cause, during the first 90 days of enrollment.

C. The enrollment broker will ensure that all participants are notified at the time of enrollment that they may request disenrollment from the CCN at any time for cause.

D. Participation Exclusion

1. The following Medicaid and/or CHIP recipients are excluded from participation in a CCN and cannot voluntarily enroll in a CCN. Individuals who:

a. receive hospice services;

b. are both Medicare and Medicaid recipients;

c. reside in a long-term care facility (nursing facility or intermediate care facility for persons with intellectual disabilities);

d. receive home and community-based waiver services;

e. are under 21 years of age and are listed on the New Opportunities Waiver Request for Services Registry (*Chisholm* class members);

f. receive services through the Program of All-Inclusive Care for the Elderly (PACE);

g. have a limited period of eligibility such as eligibility through the Spend-down Medically Needy Program or Emergency Services Only;

h. are eligible through the Louisiana Children's Health Insurance Program (LaCHIP) Affordable Plan Program;

i. are participants in the Take Charge Family Planning Waiver Program;

j. are eligible through the Tuberculosis Infected Individual Program; or

k. are enrolled in the Louisiana Health Premium Payment (LaHIPP) Program.

E. The department reserves the right to institute a medical exemption process for certain medically high risk recipients that may warrant the direct care and supervision of a non-primary care specialist on a case by case basis.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1573 (June 2011).

§3105. Enrollment Process

A. The CCN shall abide by all enrollment and disenrollment policy and procedures as outlined in the contract developed by the department.

B. The department will contract with an enrollment broker who will be responsible for the enrollment and disenrollment process for CCN participants. The enrollment broker shall be:

1. the primary contact for Medicaid recipients regarding the CCN and shall assist the recipient to enroll in a CCN;

2. the only authorized entity, other than the department, to assist a Medicaid recipient in the selection of a CCN; and

3. responsible for notifying all CCN members of their enrollment and disenrollment rights and responsibilities within the timeframe specified in the contract.

C. Enrollment Period. The annual enrollment of a CCN member shall be for a period of up to 12 months contingent upon his/her continued Medicaid and CCN eligibility. A member shall remain enrolled in the CCN until:

1. DHH or its enrollment broker approves the member's written, electronic or oral request to disenroll or transfer to another CCN for cause; or

2. the annual open enrollment period or after the lock-in period; or

3. the member becomes ineligible for Medicaid and/or the CCN program.

D. Enrollment of Newborns. Newborns of Medicaid eligible mothers who are enrolled at the time of the newborn's birth will be automatically enrolled with the mother's CCN, retroactive to the month of the newborn's birth.

1. If there is an administrative delay in enrolling the newborn and costs are incurred during that period, the member shall be held harmless for those costs and the CCN shall pay for these services.

2. The CCN and its providers shall be required to register all births through the Louisiana Electronic Event Registration System (LEERS) administered by DHH/Vital Records Registry.

E. Selection of a CCN

1. As part of the eligibility determination process, Medicaid and LaCHIP applicants shall receive information and assistance with making informed choices about the CCNs in their area of residence and the availability of choice counseling. These individuals will have the opportunity to talk with an enrollment broker who shall provide additional information to assist in choosing the appropriate CCN.

2. Each new recipient shall be given no less than 30 calendar days from the postmark date of an enrollment form mailed by the enrollment broker to select a CCN and primary care provider (PCP).

a. Recipients who fail to choose a CCN shall be automatically assigned to a CCN by the enrollment broker and the CCN shall be responsible to assign the member to a PCP if a PCP is not selected at the time of enrollment into the CCN.

3. The following provisions will be applicable for recipients who are mandatory or voluntary participants.

a. If there are two or more CCNs in a department designated service area in which the recipient resides, they shall select one.

b. If there is only one CCN in a department designated service area where the recipient resides, the recipient must choose either the CCN, Medicaid fee-for-service or an alternative Medicaid managed care program that coordinates care and which the department makes available in accordance with the promulgation of administrative Rules.

c. Recipients who fail to make a selection will be automatically assigned to a participating CCN in their area.

d. Recipients may request to transfer out of the CCN for cause and the effective date of enrollment shall be no later than the first day of the second month following the calendar month that the request for disenrollment is filed.

F. Automatic Assignment Process

1. Mandatory CCN participants that fail to select a CCN and voluntary participants that do not exercise their option not to participate in the CCN program within the minimum 30 day window, shall be automatically assigned to

a CCN by the enrollment broker in accordance with the department's algorithm/formula and the provisions of §3105.E. CCN automatic assignments shall take into consideration factors including, but not limited to:

a. the potential enrollee's geographic parish of residence;

b. assigning members of family units to the same CCN;

c. previous relationships with a Medicaid provider;

d. CCN capacity; and

e. CCN performance outcome indicators (when available).

2. Neither the MCO model nor the shared savings model will be given preference in making automatic assignments.

3. CCN automatic assignment methodology shall be available to recipients upon request to the enrollment broker prior to enrollment.

G. Selection or Automatic Assignment of a Primary Care Provider

1. As part of the Medicaid and LaCHIP application process, applicants may be given the option to indicate their preferred choice of a CCN and primary care provider.

a. If the choice of PCP is not indicated on the new enrollee file transmitted by the enrollment broker to the CCN, the CCN shall be responsible to assign the PCP.

2. The CCN is responsible to develop a PCP automatic assignment methodology in accordance with the department requirements for the assignment of a PCP to an enrollee who:

a. does not make a PCP selection after making a voluntary selection of a CCN;

b. selects a PCP within the CCN that has reached their maximum physician/patient ratio; or

c. selects a PCP within the CCN that has restrictions/limitations (e.g. pediatric only practice).

3. Members who do not proactively choose a PCP with a CCN will be automatically assigned to a PCP by the CCN. The PCP automatically assigned to the member shall be located within geographic access standards of the member's home and/or best meets the needs of the member.

4. If the enrollee does not select a PCP and is automatically assigned to a PCP by the CCN, the CCN shall allow the enrollee to change PCP, at least once, during the first 90 days from the date of assignment to the PCP. Effective the ninety-first day, a member may be locked into the PCP assignment for a period of up to nine months beginning from the original date that he/she was assigned to the CCN.

5. If a member requests to change his/her PCP for cause at any time during the enrollment period, the CCN must agree to grant the request.

H. Lock-In Period

1. Members have 90 days from the initial date of enrollment into a CCN in which they may change the CCN for any reason. Medicaid enrollees may only change CCNs without cause within the initial 90 days of enrollment in a CCN. After the initial 90-day period, Medicaid enrollees/members shall be locked into a CCN for nine additional months from the effective date of enrollment or until the annual open enrollment period, unless disenrolled under one of the conditions described in this Section.

I. Annual Open Enrollment

1. The department will provide an opportunity for all CCN members to retain or select a new CCN annually during the CCN member's open enrollment period. Prior to their annual open enrollment period, each CCN member shall receive information and the offer of assistance with making informed choices about CCNs in their area and the availability of choice counseling.

2. Members shall have the opportunity to talk with an enrollment broker representative who shall provide additional information to assist in choosing the appropriate CCN. The enrollment broker shall provide the individual with information on each CCN from which they may select.

3. During the open enrollment period, each Medicaid enrollee shall be given 60 calendar days to remain in their existing CCN or select a new CCN.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1574 (June 2011).

§3107. Disenrollment and Change of Coordinated Care Network

A. A member may request disenrollment from a CCN for cause at any time, effective the first day of the month following the month in which the member files the request.

B. A member may request disenrollment from a CCN without cause at the following times:

1. during the 90 days following the date of the member's initial enrollment with the CCN or the date the department sends the member notice of the enrollment, whichever is later;

2. at least once a year during the member's annual open enrollment period thereafter;

3. upon automatic re-enrollment if a temporary loss of Medicaid eligibility has caused the member to miss the annual open enrollment opportunity; or

4. if the department imposes the intermediate sanction against the CCN which grants enrollees the right to terminate enrollment without cause and notifies the affected enrollees of their right to disenroll.

C. All member-initiated disenrollment requests must be made to the enrollment broker.

1. Oral requests to disenroll shall be confirmed by the enrollment broker by return call with written documentation, or in writing to the requestor.

2. A member's oral or written request to disenroll must be acted on no later than the first day of the second month following the month in which the member filed the request. If not, the request shall be considered approved.

3. If the disenrollment request is denied, the member may access the state's fair hearing process as outlined in the contract.

4. The effective date of disenrollment shall be no later than the first day of the second month following the calendar month the request for disenrollment is filed.

D. Disenrollment for Cause

1. A member may initiate disenrollment or transfer from their assigned CCN after the first 90 days of enrollment for cause at any time. The following circumstances are cause for disenrollment:

a. the member moves out of the CCN's designated service area;

b. the CCN does not, because of moral or religious objections, cover the service that the member seeks;

c. the member needs related services to be performed at the same time, not all related services are available within the CCN and the member's PCP or another provider determines that receiving the services separately would subject the member to unnecessary risk;

d. the contract between the CCN and the department is terminated;

e. the member loses Medicaid eligibility;

f. the member is placed in a nursing facility or intermediate care facility for individuals with intellectual disabilities;

g. the member's eligibility changes to an excluded eligibility group;

h. to implement the decision of a hearing officer in an appeal proceeding by the member against the CCN or as ordered by a court of law; and

i. other reasons including, but not limited to:

i. poor quality of care;

ii. lack of access to services covered under the contract; or

iii. documented lack of access to providers experienced in dealing with the enrollee's health care needs.

E. Involuntary Disenrollment

1. The CCN may submit an involuntary disenrollment request to the enrollment broker, with proper documentation, for the following reasons:

a. fraudulent use of the CCN identification card. In such cases, the CCN shall report the incident to the Medicaid Program Integrity Section; or

b. the member's behavior is disruptive, unruly, abusive or uncooperative to the extent that his/her enrollment seriously impairs the CCN's ability to furnish services to either the member or other members.

2. The CCN shall promptly submit such disenrollment requests to the enrollment broker. The effective date of an involuntary disenrollment shall not be earlier than 45 calendar days after the occurrence of the event that prompted the request for involuntary disenrollment. The CCN shall ensure that involuntary disenrollment documents are maintained in an identifiable member record.

3. All requests will be reviewed on a case-by-case basis and subject to the sole discretion of the department. All decisions are final and are not subject to CCN dispute or appeal.

4. The CCN may not request disenrollment because of a member's:

a. health diagnosis;

b. adverse change in health status;

c. utilization of medical services;

d. diminished mental capacity;

e. pre-existing medical condition;

f. refusal of medical care or diagnostic testing;

g. uncooperative or disruptive behavior resulting from his or her special needs, unless it seriously impairs the CCN's ability to furnish services to either this particular member or other members as defined in this Subsection;

h. attempt to exercise his/her rights under the CCN's grievance system; or

i. attempt to exercise his/her right to change, for cause, the primary care provider that he/she has chosen or been assigned.

F. Department Initiated Disenrollment

1. The department will notify the CCN of the member's disenrollment due to the following reasons:

a. loss of Medicaid eligibility or loss of CCN enrollment eligibility;

b. death of a member;

c. member's intentional submission of fraudulent information;

d. member becomes an inmate of a public institution;

e. member moves out of state;

f. member becomes Medicare eligible;

g. member is placed in a long term care facility (nursing facility or intermediate care facility for persons with intellectual disabilities);

h. member becomes a participant in a home and community-based services waiver;

i. member elects to receive hospice services;

j. loss of CCN's participation; or

k. member enrolls in a managed care plan through third party coverage.

G. If the CCN ceases participation in a geographic service area or in the CCN Program, the CCN shall notify the department in accordance with the termination procedures described in the contract.

1. The enrollment broker will notify CCN members of the choices of CCNs in their geographic area. If there is no other CCN or other options for which they may be eligible, they will be placed in fee-for-service.

2. The CCN shall assist the department in transitioning the CCN members to another CCN or to the Medicaid fee-for-service delivery system or other program the recipient may be eligible for to ensure access to needed health care services.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1575 (June 2011).

§3109. Member Rights and Responsibilities

A. The CCN member's rights shall include, but are not limited to the right to:

1. receive information in accordance with federal regulations and as described in the contract and department issued guides;

2. receive courteous, considerate and respectful treatment provided with due consideration for the member's dignity and privacy;

3. receive information on available treatment options and alternatives in a manner appropriate to the member's condition and ability to understand;

4. participate in treatment decisions, including the right to:

a. refuse treatment;

b. complete information about their specific condition and treatment options including, but not limited to the right to receive services in a home or community setting or in an institutional setting if desired;

c. seek second opinions;

d. information about available experimental treatments and clinical trials and how such research can be accessed; and

e. assistance with care coordination from the PCP's office;

5. be free from any form of restraint or seclusion as a means of coercion, discipline, retaliation or convenience;

6. express a concern about their CCN or the care it provides, or appeal a CCN decision, and receive a response in a reasonable period of time;

7. receive a copy of their medical records, including, if the HIPAA privacy rule applies, the right to request that the records be amended or corrected as allowed in federal regulations;

8. be furnished health care services in accordance with federal regulations governing access standards;

9. implement an advance directive as required in federal regulations (applicable for CCN-P only):

a. the CCN must provide adult enrollees with written information on advanced directive policies and include a description of applicable state law. The written information must reflect changes in state law as soon as possible, but no later than 90 days after the effective date of change;

b. members have the right to file a grievance concerning noncompliance with the advance directive requirements to the department or other appropriate licensing or certification agency as allowed in federal regulations;

10. choose his/her health professional to the extent possible and appropriate in accordance with federal regulations; and

11. be furnished health care services in accordance with federal regulations.

B. Members shall have the freedom to exercise the rights described herein without any adverse affect on the member's treatment by the department or the CCN, or its contractors or providers.

C. The CCN member's responsibilities shall include, but are not limited to:

1. informing the CCN of the loss or theft of their CCN identification card;

2. presenting their identification card when using health care services;

3. being familiar with the CCN procedures to the best of his/her abilities;

4. contacting the CCN, by telephone or in writing (formal letter or electronically, including email), to obtain information and have questions clarified;

5. providing participating network providers with accurate and complete medical information;

6. following the prescribed treatment of care recommended by the provider or letting the provider know the reasons the treatment cannot be followed, as soon as possible;

7. making every effort to keep any agreed upon appointments and follow-up appointments and contacting the provider in advance if they are unable to do so; and

8. accessing preventive care services.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1576 (June 2011).

Chapter 33. Coordinated Care Network Shared Savings Model

§3301. Participation Requirements

A. In order to participate in the Medicaid Program, a coordinated care network shared savings model (CCN-S) must be a successful bidder, awarded a contract, and pass the readiness review. A CCN-S is required to comply with all of the terms and conditions set forth in the contract.

B. A CCN-S must:

1. meet the definition of a primary care case manager (PCCM) in accordance with federal regulations;

2. be a legal entity domiciled in Louisiana and registered with the Louisiana Secretary of State's Office to do business in the state;

3. have the capability to pre-process claims (with the exception of carved-out services) and transfer data to the department's fiscal intermediary or have a contract with an entity to perform these functions;

4. provide financial reports as requested by the department;

5. post a surety bond for an amount specified by the department for the at-risk portion of the enhanced care management fee;

6. post a performance bond for an amount specified by the department;

7. not have an actual or perceived conflict of interest that, in the discretion of the department, would interfere or give the appearance of possibly interfering with its duties and obligations under this Rule, the contract and any and all appropriate guides. Conflict of interest shall include, but is not limited to, being the fiscal intermediary contractor for the department; and

8. have network capacity to enroll a minimum of 75,000 Medicaid and LaCHIP eligibles into the network in each DHH designated geographic service area.

C. A CCN-S shall provide enhanced primary care case management services to recipients in specified geographic service area(s).

1. Enhanced primary care case management services shall be provided to all Medicaid recipients enrolled in the CCN-S throughout the designated geographic service area as defined by the department.

D. Upon request by the Centers for Medicare and Medicaid Services (CMS), the Office of Inspector General (OIG), the Government Accounting Office (GAO) and/or the department or its designee, a CCN-S shall make all of its records pertaining to its contract (services provided there under and payment for service) with the department available for review, evaluation and audit. The records shall include, but are not limited to the following:

1. pertinent books and documents;

2. financial records;

3. medical records and documents; and

4. provider records and documents involving financial transactions related to the contract.

E. A CCN-S shall maintain an automated management information system that collects, analyzes, integrates and reports data that complies with department and federal reporting requirements.

1. The CCN-S shall submit its emergency/contingency plan to the department for approval if the CCN-S is unable to provide the data reporting specified in the contract and department issued guides.

F. A CCN-S shall obtain insurance coverage(s) including, but not limited to, workman's compensation, commercial liability, and errors and omissions as specified in the terms of the contract. CCN-S subcontractors, if any, shall be covered under these policies or have insurance comparable to the CCN-S's required coverage.

G. A CCN-S shall maintain a minimum net worth amount as specified in the terms of the contract.

H. A CCN-S shall provide all financial reporting as specified in the terms of the contract.

I. A CCN-S shall secure and maintain performance and fidelity bonds as specified in the terms of the contract during the life of the contract.

J. In the event of noncompliance with the contract and the department's guidelines, a CCN-S shall be subject to the sanctions specified in the terms of the contract including, but not limited to:

1. corrective action plans;
2. monetary penalties;
3. temporary management; or
4. suspension and/or termination of the CCN-S' contract.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1577 (June 2011).

§3303. Shared Savings Model Responsibilities

A. The CCN-S shall be responsible for the administration and management of its requirements and responsibilities under the terms of the contract, and any and all department issued guides. This includes all subcontracts, employees, agents and anyone acting for or on behalf of the CCN-S.

1. No subcontract or delegation of responsibility shall terminate the legal responsibility of the CCN-S to the department to assure that all requirements are carried out.

B. A CCN-S shall possess the expertise and resources to ensure the delivery of enhanced primary care case management services to CCN-S members as specified in the terms of the contract.

1. A CCN-S shall have written policies and procedures governing its operation. A CCN-S shall also have a written provider network development plan which describes how the network will assure the department that the provision of services will occur according to the terms and conditions of the contract. These documents shall be furnished to the department upon request.

C. A CCN-S shall accept enrollees in the order in which they apply without restriction, up to the enrollment capacity limits set under the contract. The CCN-S shall not discriminate against enrollees on the basis of race, gender, color, national origin, age, health status or need for health care services, and shall not use any policy or practice that has the effect of discriminating on any such basis.

D. A CCN-S shall provide enhanced primary care management services and PCP care management services as defined in the Medicaid State Plan and as specified in the terms of the contract.

E. A CCN-S shall provide a chronic care management program as specified in the terms of the contract.

F. A CCN-S shall establish and implement a quality assessment and performance improvement program as specified in the terms of the contract.

G. A CCN-S shall develop and maintain a utilization management program including policies and procedures with defined structures and processes as specified in the terms of the contract.

H. A CCN-S shall develop and maintain effective continuity of care activities which ensure a continuum of care approach to providing health care services to members.

I. A CCN-S shall promote and facilitate the capacity of all participating PCP practices to meet the recognition requirements of a National Committee for Quality Assurance (NCQA) PPC®-PCMH™ as jointly defined by NCQA or Joint Commission on Accreditation of Healthcare Organizations (JCAHO) Primary Care Home Accreditation and the department.

1. Participating PCPs shall be provided with technical support and appropriate incentives to assist the practices with their transition to a patient-centered medical home as specified in the terms of the contract.

J. A CCN-S shall facilitate the data interchange between practices and the network as well as data interchange between the network and the department.

K. A CCN-S shall be responsible for conducting routine provider monitoring to ensure:

1. continued access to care for Medicaid recipients;
2. compliance with CCN-S policies and procedures; and
3. that the participating providers' practices meet or exceed the department's guidelines and timelines for implementation of patient-centered medical homes.

L. A CCN-S shall not engage the services of a provider who is in non-payment status with the department or is excluded from participation in federal health care programs (i.e., Medicare, Medicaid, or the Children's Health Insurance Program).

M. Medical records shall be maintained in accordance with the terms and conditions of the contract. These records shall be safeguarded in such a manner as to protect confidentiality and avoid inappropriate disclosure according to federal and state law.

N. A CCN-S shall provide referrals to the Women, Infants and Children (WIC) Program.

O. A CCN-S shall maintain staffing that is capable of fulfilling the requirements as specified in the terms of the contract and department issued guides.

P. A CCN-S shall participate in the department's established committees for administrative simplification and quality improvement, which will include physicians, other healthcare providers as appropriate, and at least one member of the Senate and House Health and Welfare Committees or their designees.

Q. The CCN-S shall provide both member and provider services in accordance with the terms of the contract and department issued guides.

1. The CCN-S shall submit member handbooks, provider manuals, and provider directory to the department for approval prior to distribution, annually and subsequent to any revisions.

a. The CCN-S must provide a minimum of 30 days notice to the department of any proposed material changes to the member handbooks and/or provider manuals.

b. After approval has been received from the department, the CCN-S must provide a minimum of 30 days notice to the members and/or providers of any proposed material changes to the member handbooks and/or provider manuals.

R. The member handbook shall include, but not be limited to:

1. a table of contents;
2. a general description regarding:
   a. how a coordinated care network operates;
   b. member rights and responsibilities;
   c. appropriate utilization of services including emergency room visits for non-emergent conditions;
   d. the PCP selection process; and
   e. the PCP's role as coordinator of services;
3. member rights and protections as specified in the CCN-S's contract with the department including:
   a. a member's right to disenroll from the CCN-S;
   b. a member's right to change providers within the CCN-S;
   c. any restrictions on the member's freedom of choice among CCN-S providers; and
   d. a member's right to refuse to undergo any medical service, diagnoses, or treatment or to accept any health service provided by the CCN-S if the member objects (or in the case of a child, if the parent or guardian objects)on religious grounds;
4. member responsibilities , appropriate and inappropriate behavior, and any other information deemed essential by the CCN or the department including, but not limited to:
   a. immediately notifying the department if he or she has a Workman's Compensation claim, a pending personal injury or medical malpractice law suit, or has been involved in a auto accident;
   b. reporting to the department's Medicaid Customer Service Unit if the member has or obtains another health insurance policy, including employer sponsored insurance; and
   c. a statement that the member is responsible for protecting his/her identification card and that misuse of the card, including loaning, selling or giving it to others could result in loss of the member's Medicaid eligibility and/or legal action;
5. the amount, duration, and scope of benefits available under the CCN-S's contract with the department in sufficient detail to ensure that members understand the benefits to which they are entitled including, but not limited to:
   a. information about health education and promotion programs, including chronic care management;
   b. the procedures for obtaining benefits, including prior authorization requirements and benefit limits;
   c. how members may obtain benefits, including family planning services and specialized behavioral health services, from out-of-network providers;
   d. how and where to access any benefits that are available under the Louisiana Medicaid State Plan, including information about Early and Periodic Screening, Diagnosis and Treatment (EPSDT) services;
   e. the policy on referrals for specialty care, including behavioral health services and other benefits not furnished by the member's primary care provider;
   f. for counseling or referral services that the CCN-S does not cover because of moral or religious objections, the CCN-S is required to furnish information on how or where to obtain the service;
   g. how to make, change and cancel medical appointments and the importance of canceling and/or rescheduling rather than being a "no show"; and
   h. the extent to which and how after-hour services are provided;
6. information to call the Medicaid Customer Service Unit toll free telephone number or visit a local Medicaid eligibility office to report changes in parish of residence, mailing address or family size changes;
7. a description of the CCN-S' member services and the toll-free telephone number, fax telephone number, e-mail address and mailing address to contact CCN-S' Member Services Unit;
8. instructions on how to request multi-lingual interpretation and translation services when needed at no cost to the member. This information shall be included in all versions of the handbook in English, Spanish and Vietnamese; and
9. grievance, appeal and state fair hearing procedures and time frames, as described in the CCN-S' contract with the department and department issued guide.

S. The provider manual shall include but not be limited to:

1. billing guidelines;
2. medical management/utilization review guidelines;
3. case management guidelines;
4. claims pre-processing guidelines and edits;
5. enrollee and provider grievance and appeals procedures and processes; and
6. other policies, procedures, guidelines, or manuals containing pertinent information related to operations and pre-processing claims.

T. The provider directory for members shall be developed in the following three formats:

1. a hard copy directory for members and, upon request, potential members;
2. a web-based online directory for members and the public; and
3. an electronic file of the directory for the enrollment broker.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1578 (June 2011).

§3305. Coordination of Medicaid State Plan Services

A. Core benefits and services shall be defined as those health care services and benefits required to be provided to Medicaid CCN members enrolled in the CCN-S as specified under the terms of the contract. Covered services shall be defined as those health care services and benefits to which an individual eligible for Medicaid is entitled under the Louisiana Medicaid State Plan.

B. The CCN-S shall be required to pre-process and provide service authorization, referrals, coordination, and/or assistance in scheduling medically necessary Medicaid covered services described in this Chapter, consistent with the standards as defined in the Louisiana Medicaid State Plan and the contract regarding service limits and service authorization requirements.

1. The CCN shall have policies and processes to authorize physician visits in excess of the service cap for these services as specified in the State Plan.

C. Covered services will be billed fee-for-service to the fiscal intermediary.

D. The following is a summary listing of the covered services for which the CCN-S shall pre-process and provide service authorization, referrals, coordination, and/or assistance in scheduling. These services include, but are not limited to:

1. inpatient hospital services;
2. outpatient hospital services;
3. ancillary medical services;
4. organ transplant-related services;
5. EPSDT/Well Child visits;
6. emergency medical services;
7. communicable disease services;
8. emergency medical transportation;
9. home health services;
10. family planning services as specified in 42 CFR §431.51(b)(2);
11. basic behavioral health services;
12. school-based health clinic services;
13. physician services;
14. maternity services;
15. chiropractic services; and
16. rehabilitation therapy services (physical, occupational, and speech therapies).

E. The CCN-S will be responsible for coordinating State Plan services that are medically necessary.

1. Claims will be paid fee-for-service through the Medicaid Management Information System (MMIS).

2. The CCN-S shall not implement hard limits for EPSDT services.

F. The CCN-S will not be responsible for pre-processing or providing service authorization for the following services, but shall provide any required referrals and coordination for these services:

1. EarlySteps services (specified);
2. dental services;
3. hospice services;
4. personal care services (EPSDT and long-term);
5. intermediate care facility services for persons with intellectual disabilities;
6. home and community-based waiver services;
7. behavioral health drugs;
8. school-based Individualized Education Plan (IEP) services;
9. non-emergency medical transportation;
10. nursing facility services;
11. specialized behavioral health services;
12. targeted case management;
13. durable medical equipment and certain supplies;
14. prosthetics and orthotics; and
15. non-behavioral health drugs.

G. The CCN shall implement mechanisms, as specified in the contract, to assess each Medicaid enrollee identified as having special health care needs in order to identify any ongoing special conditions of the enrollee that require a course of treatment or regular care monitoring.

1. The assessment mechanisms must use appropriate health care professionals.

2. The CCN shall have mechanisms to assess the quality and appropriateness of care furnished to enrollees with special health care needs.

H. Utilization Management

1. The CCN-S shall develop and maintain policies and procedures with defined structures and processes for a utilization management (UM) program that incorporates utilization review. The program shall include service authorization and medical necessity review and comply with the requirements set forth in this Section, the contract and department issued guides.

a. The CCN-S shall submit UM policies and procedures to the department for written approval, annually and subsequent to any revisions.

2. The UM Program policies and procedures shall, at a minimum, include the following requirements:

a. the individual(s) who is responsible for determining medical necessity, appropriateness of care, level of care needed, and denying a service authorization request or authorizing a service in amount, duration or scope that is less than requested, must meet the following requirements. The individual shall:

i. be a licensed clinical professional with appropriate clinical expertise in the treatment of a member's condition or disease;

ii. have no history of disciplinary action or sanctions, including loss of staff privileges or participation restrictions that have been taken or are pending such action by any hospital, governmental agency or unit, or regulatory body, that raise a substantial question as to the clinical peer reviewer's physical, mental, or professional competence or moral character; and

iii. attest that no adverse determination will be made regarding any medical procedure or service outside of the scope of such individual's expertise;

b. the methodology utilized to evaluate the clinical necessity, appropriateness, efficacy, or efficiency of health care services;

c. the data sources and clinical review criteria used in decision making;

d. the appropriateness of clinical review shall be fully documented;

e. the process for conducting informal reconsiderations for adverse determinations;

f. mechanisms to ensure consistent application of review criteria and compatible decisions;

g. data collection processes and analytical methods used in assessing utilization of healthcare services; and

h. provisions for assuring confidentiality of clinical and proprietary information;

3. The UM program's medical management and medical necessity review criteria and practice guidelines shall be reviewed annually and updated periodically as appropriate. The CCN-S shall use the medical necessity

definition as set forth in LAC 50:I.1101 for medical necessity determinations.

a. Medical management and medical necessity review criteria and practice guidelines shall:

i. be objective and based on valid and reliable clinical evidence or a consensus of health care professionals in the particular field;

ii. consider the needs of the members;

iii. be adopted in consultation with contracting health care professionals; and

iv. be disseminated to all affected providers, members, and potential members upon request.

b. The CCN-S must identify the source of the medical management criteria used for the review of medical necessity and for service authorization requests.

i. The vendor must be identified if the criteria are purchased.

ii. The association or society must be identified if the criteria are developed/recommended or endorsed by a national or state health care provider association or society.

iii. The guideline source must be identified if the criteria are based on national best practice guidelines.

iv. The individuals who will make medical necessity determinations must be identified if the criteria are based on the medical training, qualifications, and experience of the CCN medical director or other qualified and trained professionals.

4. The CCN-S shall ensure that only licensed clinical professionals with appropriate clinical expertise in the treatment of a member's condition or disease shall determine service authorization request denials or authorize a service in an amount, duration or scope that is less than requested.

5. The CCN-S shall ensure that compensation to individuals or entities that conduct UM activities is not structured to provide incentives for the individual or entity to deny, limit, or discontinue medically necessary covered services to any member.

I. Claims Management

1. The CCN-S must accept and pre-process claims within two business days of receipt in accordance to the requirements in the contract and department issued guides.

2. The CCN-S shall maintain a claims management system that, at a minimum, will:

a. provide service authorization approval to providers utilizing a unique authorization number as defined in the department issued guides;

b. confirm CCN-S membership as service authorization requests are submitted on the basis of the eligibility information provided by the department;

c. verify medical necessity as defined by the department;

d. identify the date that the CCN-S receives the claim;

e. provide on-line and telephone based capabilities to providers for obtaining status information;

f. obtain a submitter identification number from the department's fiscal intermediary (FI) prior to submitting claims; and

g. submit paper claims in batch form or electronic claims to the FI within two business days of receipt from providers.

3. If a claim is partially or totally denied on the basis that the provider did not submit required information or documentation with the claim, then a remittance advice or other appropriate written or electronic notice shall specifically identify all such information and documentation.

a. Resubmission of a claim with further information and/or documentation shall constitute a new claim for purposes of establishing the timeframe for claims pre-processing.

4. Pre-processed approved claims will be paid on a fee-for-service (FFS) basis by the department subject to prompt pay requirements for fee-for-service Medicaid claims.

a. The department shall not pay any claim submitted by a provider who is excluded from participation in Medicare, Medicaid, or SCHIP program pursuant to §1128 or §1156 of the Social Security Act or is otherwise not in good standing with the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1579 (June 2011).

§3307. Reimbursement Methodology

A. The department or its fiscal intermediary shall make monthly enhanced primary care case management fee payments to the CCN-S and lump sum savings payments to the CCN-S, if eligible.

B. The enhanced primary care case management fee shall be based on the enrollee's Medicaid eligibility category as specified in the contract and paid on a per member per month (PMPM) basis.

C. The enhanced primary care case management fee comprises reimbursement for enhanced primary care case management functions as specified in the terms of the contract and includes funding for the CCN-S to pay the PCPs for care management (e.g. care coordination, referrals) to Medicaid enrollees linked to each PCP as specified in the terms and conditions of the contract and department issued guides.

1. The CCN-S shall reimburse the PCP a monthly base case management fee for each enrollee assigned to the PCP. The CCN-S may reimburse an amount greater than the base case management fee, but not less than that amount.

2. In order to be eligible to receive these payments, the PCP must enter into a subcontract with the CCN-S, meet the performance measures goals, and remain in compliance with all of the provisions contained in the subcontract.

3. The CCN-S shall be subject to sanctions if it is determined that the CCN-S did not pay the base management fee to the PCPs.

a. The CCN-S shall be sanctioned an amount equal to the amount the CCN was responsible to reimburse the PCPs, plus an additional amount up to $25,000 for each event the department determines the PCP care management fee is not reimbursed.

b. The CCN-S shall be liable to reimburse the PMPM PCP care management fee owed to the PCP(s) and all costs incurred to issue payments to the PCP within the timelines specified by the department for such reimbursement or be subject to additional sanctions.

D. The department reserves the right to adjust these enhanced primary care case management fees on an as needed basis.

E. The CCN-S shall have limited risk for returning up to 50 percent of enhanced primary care case management fees advanced to the network when savings are not realized.

F. The department shall conduct a periodic reconciliation as specified in the contract to determine savings realized or refunds due to the department.

1. The reconciliation shall compare the actual aggregate cost of authorized/preprocessed services as specified in the contract and include the enhanced primary care case management fee for dates of services in the reconciliation period, to the aggregate Per Capita Prepaid Benchmark (PCPB). The PCPB will not include the PCP care management fees.

2. The PCPB will be set on the basis of health status-based risk adjustment.

a. The health risk of the Medicaid enrollees enrolled in the CCN-S will be measured using a nationally recognized risk-assessment model.

b. Utilizing this information, the PCPBs will be adjusted to account for the health risk for the enrollees in each CCN-S relative to the overall population being measured.

c. The health risk of the enrollees and associated CCN-S risk scores and the PCPBs will be updated periodically to reflect changes in risk over time.

3. Costs of the following services will not be included in the determination of the PCPB. These services include, but are not limited to:

a. nursing facilities;

b. dental services;

c. personal care services (EPSDT and Long-Term);

d. hospice;

e. specialized behavioral health drugs;

f. school-based Individualized Education Plan services provided by a school district and billed through the intermediate school district;

g. specified EarlySteps Program services;

h. specialized behavioral health services (e.g. mental health rehabilitation);

i. targeted case management;

j. non-emergency medical transportation;

k. intermediate care facilities for persons with intellectual disabilities;

l. home and community-based waiver services;

m. durable medical equipment and supplies; and

n. orthotics and prosthetics.

4. Individual member total cost for the reconciliation year in excess of an amount specified in the contract will not be included in the determination of the PCPB, nor will it be included in actual cost at the point of reconciliation so that outlier cost of certain individuals and/or services will not jeopardize the overall savings achieved by the CCN-S.

a. Application of the individual member total cost shall include:

i. when a member transitions between aid categories, claims will accumulate from zero under the new aid category;

ii. maternity claims that fall into the kick payment bucket will not be included in determining whether the catastrophic limit has been reached; and

iii. while no actual maternity kick payment is paid, a "benchmark maternity kick payment" has been calculated. This is a mechanism to protect plans with a disproportionate share of pregnant women in that the benchmark cost will increase for each additional delivery.

5. The department will perform interim and final reconciliations as of June 30 and December 31 of each year with provisions for incurred-but-not-reported (IBNR) claims included in the actual cost.

a. The department reserves the right to make interim payments of any savings for any dates of service with more than six months elapsed time.

b. A final reconciliation will be performed for any periods for which there are dates of service with more than 12 months elapsed time, at which point there should be sufficient completion of paid claims to determine total medical cost incurred by the CCN-S without the need to consider additional claims that have been incurred, but are still outstanding.

c. Final reconciliations will not be for less than 12 months of service unless determined appropriate by the department. In the first year of a CCN-S's operations, the department will exclude claims from the first 30 days of operations when calculating the reconciliation.

6. In the event the CCN-S exceeds the PCPB in the aggregate (for the entire CCN-S enrollment) as calculated in the final reconciliation, the CCN-S will be required to refund up to 50 percent of the total amount of the enhanced primary care case management fees (excluding the PCP care management fee) paid to the CCN-S during the period being reconciled.

7. The CCN-S will be eligible to receive up to 60 percent of savings if the actual aggregate costs of authorized services, including enhanced primary care case management fees advanced, are less than the aggregate PCPB (for the entire CCN-S enrollment).

a. The enhanced primary care case management fee will be reduced by the base case management fee during the reconciliation process.

b. Due to federally mandated limitations under the Medicaid State Plan, shared savings will be limited to five percent of the actual aggregate costs including the enhanced primary care case management fees paid. Such amounts shall be determined in the aggregate and not for separate enrollment types.

8. During the CCN Program's first two years of implementation, any distribution of CCN-S savings will be contingent upon the CCN meeting the established "early warning system" administrative performance measures and compliance under the contract. After the second year of implementation, distribution of savings will be contingent upon the CCN-S meeting department established clinical quality performance measure benchmarks and compliance with the contract.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1581 (June 2011).

Chapter 35. Coordinated Care Network Managed Care Organization Model

§3501. Participation Requirements

A. In order to participate in the Medicaid Program, a coordinated care network managed care organization model (CCN-P) must be a successful bidder, be awarded a contract with the department, and complete the readiness review.

B. A CCN-P must:

1. meet the federal definition of an managed care organization as defined in federal regulations;

2. meet the requirements of R.S. 22:2016 and be licensed or have a certificate of authority from the Louisiana Department of Insurance (DOI) pursuant to Title 22 of the Louisiana Revised Statues;

3. be certified by the Louisiana Secretary of State to conduct business in the state;

4. meet solvency standards as specified in federal regulations and Title 22 of the Louisiana Revised Statutes;

5. meet NCQA or URAC Health Plan Accreditation or agree to submit an application for accreditation at the earliest possible date as allowed by NCQA or URAC and once achieved, maintains accreditation through the life of this agreement;

6. have a network capacity to enroll a minimum of 75,000 Medicaid and LaCHIP eligibles into the network in each department designated geographic service area; and

7. not have an actual or perceived conflict of interest that, in the discretion of the department, would interfere or give the appearance of possibly interfering with its duties and obligations under this Rule, the contract and any and all appropriate guides. Conflict of interest shall include, but is not limited to, being the fiscal intermediary contractor for the department.

C. A CCN-P shall ensure the provision of core benefits and services to Medicaid enrollees in a department designated geographic service area as specified in the terms of the contract.

D. Upon request by the Centers for Medicare and Medicaid Services, the Office of Inspector General, the Government Accounting Office, the department or its designee, a CCN-P shall make all of its records pertaining to its contract (services provided there under and payment for services) with the department available for review, evaluation and audit. The records shall include, but are not limited to the following:

1. pertinent books and documents;

2. financial records;

3. medical records and documents; and

4. provider records and documents involving financial transactions related to the contract.

E. A CCN-P shall maintain an automated management information system that collects, analyzes, integrates and reports data that complies with department and federal reporting requirements.

1. The CCN-P shall submit to the department for approval the CCN-P's emergency/contingency plan if the CCN-P is unable to provide the data reporting specified in the contract and department issued guides.

F. A CCN-P shall obtain insurance coverage(s) including, but not limited to, workman's compensation, commercial liability, errors and omissions, and reinsurance as specified in the terms of the contract. Subcontractors, if any, shall be covered under these policies or have insurance comparable to the CCN-P's required coverage.

G. A CCN-P shall provide all financial reporting as specified in the terms of the contract.

H. A CCN-P shall secure and maintain a performance and fidelity bond as specified in the terms of the contract during the life of the contract.

I. In the event of noncompliance with the contract and the department's guidelines, a CCN-P shall be subject to the sanctions specified in the terms of the contract including, but not limited to:

1. corrective action plans;

2. monetary penalties;

3. temporary management; or

4. suspension and/or termination of the CCN-P's contract.

AUTHORITY NOTE: Promulgated in accordance with R. S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1583 (June 2011).

§3503. Managed Care Organization Model Responsibilities

A. The CCN-P shall be responsible for the administration and management of its requirements and responsibilities under the contract with the department and any and all department issued guides. This includes all subcontracts, employees, agents and anyone acting for or on behalf of the CCN-P.

1. No subcontract or delegation of responsibility shall terminate the legal obligation of the CCN-P to the department to assure that all requirements are carried out.

B. A CCN-P shall possess the expertise and resources to ensure the delivery of core benefits and services to members and to assist in the coordination of covered services, as specified in the terms of the contract.

1. A CCN-P shall have written policies and procedures governing its operation as specified in the contract and department issued guides.

C. A CCN-P shall accept enrollees in the order in which they apply without restriction, up to the enrollment capacity limits set under the contract.

1. A CCN-P shall not discriminate against enrollees on the basis of race, gender, color, national origin, age, health status or need for health care services, and shall not use any policy or practice that has the effect of discriminating on any such basis.

D. A CCN-P shall be required to provide service authorization, referrals, coordination, and/or assistance in scheduling the covered services consistent with standards as defined in the Louisiana Medicaid State Plan and as specified in the terms of the contract.

E. A CCN-P shall provide a chronic care management program as specified in the contract.

F. The CCN-P shall establish and implement a quality assessment and performance improvement program as specified in the terms of the contract and department issued guides.

G. A CCN-P shall develop and maintain a utilization management program including policies and procedures with defined structures and processes as specified in the terms of the contract and department issued guides.

H. A CCN-P shall develop and maintain effective continuity of care activities which ensure a continuum of care approach to providing health care services to members.

I. The CCN-P must have administrative and management arrangements or procedures, including a mandatory compliance plan, that are designed to guard against fraud and abuse.

1. The CCN-P shall comply with all state and federal laws and regulations relating to fraud, abuse, and waste in the Medicaid and CHIP program as well all requirements set forth in the contract and department issued guides.

J. A CCN-P shall maintain a health information system that collects, analyzes, integrates and reports data as specified in the terms of the contract and all department issued guides.

1. A CCN-P shall collect data on enrollees and provider characteristics and on services furnished to members through an encounter data system as specified in the contract and all department issued guides.

K. A CCN-P shall be responsible for conducting routine provider monitoring to ensure:

1. continued access to care for Medicaid recipients; and

2. compliance with departmental and contract requirements.

L. A CCN-P shall not engage the services of a provider who is in non-payment status with the department or is excluded from participation in federal health care programs (i.e., Medicare, Medicaid, CHIP, etc.).

M. Medical records shall be maintained in accordance with the terms and conditions of the contract. These records shall be safeguarded in such a manner as to protect confidentiality and avoid inappropriate disclosure according to federal and state law.

N. A CCN-P shall participate on the department's quality committee to provide recommendations to Medicaid on areas of standardized business process for the Coordinated Care Network Program.

O. A CCN-P shall participate on the department's established committees for administrative simplification and quality improvement, which will include physicians, hospitals, other healthcare providers as appropriate, and at least one member of the Senate and House Health and Welfare Committees or their designees.

P. The CCN-P shall provide both member and provider services in accordance with the terms of the contract and department issued guides.

1. The CCN-P shall submit member handbooks, provider manuals, and provider directory to the department for approval prior to distribution, annually and subsequent to any revisions.

a. The CCN-P must provide a minimum of 30 days notice to the department of any proposed material changes to the member handbooks and/or provider manuals.

b. After approval has been received from the department, the CCN-P must provide a minimum of 30 days notice to the members and/or providers of any proposed material changes to the member handbooks and/or provider manuals.

Q. The member handbook shall include, but not be limited to:

1. a table of contents;

2. a general description regarding:

a. how a coordinated care network operates;

b. member rights and responsibilities;

c. appropriate utilization of services including emergency room visits for non-emergent conditions;

d. the PCP selection process; and

e. the PCP's role as coordinator of services;

3. member rights and protections as specified in 42 CFR §438.100 and the CCN-P's contract with the department including, but not limited to:

a. a member's right to disenroll from the CCN-P;

b. a member's right to change providers within the CCN-P;

c. any restrictions on the member's freedom of choice among CCN-P providers; and

d. a member's right to refuse to undergo any medical service, diagnoses, or treatment or to accept any health service provided by the CCN-P if the member objects (or in the case of a child, if the parent or guardian objects)on religious grounds;

4. member responsibilities , appropriate and inappropriate behavior, and any other information deemed essential by the CCN-P or the department including, but not limited to:

a. immediately notifying the CCN-P if he or she has a Workman's Compensation claim, a pending personal injury or medical malpractice law suit, or has been involved in a auto accident;

b. reporting to the department's Medicaid Customer Service Unit if the member has or obtains another health insurance policy, including employer sponsored insurance; and

c. a statement that the member is responsible for protecting his/her identification card and that misuse of the card, including loaning, selling or giving it to others could result in loss of the member's Medicaid eligibility and/or legal action;

5. the amount, duration, and scope of benefits available under the CCN-P's contract with the department in sufficient detail to ensure that members understand the benefits to which they are entitled including, but not limited to:

a. information about health education and promotion programs, including chronic care management;

b. the procedures for obtaining benefits, including prior authorization requirements and benefit limits;

c. how members may obtain benefits, including family planning services and specialized behavioral health services, from out-of-network providers;

d. how and where to access any benefits that are available under the Louisiana Medicaid State Plan, but are not covered under the CCN-P's contract with department;

e. information about Early and Periodic Screening, Diagnosis and Treatment (EPSDT) services;

f. how transportation is provided, including how to obtain emergency and non-emergency medical transportation;

g. the post-stabilization care services rules set forth in 42 CFR 422.113(c);

h. the policy on referrals for specialty care, including behavioral health services and other benefits not furnished by the member's primary care provider;

i. for counseling or referral services that the CCN-P does not cover because of moral or religious objections, the CCN-P is required to furnish information on how or where to obtain the service;

j. how to make, change and cancel medical appointments and the importance of canceling and/or rescheduling rather than being a "no show"; and

k. the extent to which and how after-hour services are provided;

6. information to call the Medicaid Customer Service Unit toll free telephone number or visit a local Medicaid eligibility office to report changes in parish of residence, mailing address or family size changes;

7. a description of the CCN-P's member services and the toll-free telephone number, fax telephone number, e-mail address and mailing address to contact CCN-P's Member Services Unit;

8. instructions on how to request multi-lingual interpretation and translation services when needed at no cost to the member. This information shall be included in all versions of the handbook in English, Spanish and Vietnamese; and

9. grievance, appeal and state fair hearing procedures and time frames as described in 42 CFR §438.400 through §438.424 and the CCN-P's contract with the department.

R. The provider manual shall include but not be limited to:

1. billing guidelines;
2. medical management/utilization review guidelines;
3. case management guidelines;
4. claims processing guidelines and edits;
5. grievance and appeals procedures and processes; and
6. other policies, procedures, guidelines, or manuals containing pertinent information related to operations and pre-processing claims.

S. The provider directory for members shall be developed in three formats:

1. a hard copy directory for members and, upon request, potential members;
2. a web-based online directory for members and the public; and
3. an electronic file of the directory for the enrollment broker.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1583 (June 2011).

§3505 Network Access Standards and Guidelines

A. The CCN-P must maintain and monitor a provider network that is supported by written agreements and is sufficient to provide adequate access of healthcare to enrollees as required by federal law and the terms as set forth in the contract. The CCN-P shall adhere to the federal regulations governing access standards as well as the specific requirements of the contract and all department issued guides.

B. The CCN-P must provide for service delivery out-of-network for any core benefit or service not available in network for which the CCN-P does not have an executed contract for the provision of such medically necessary services. Further, the CCN-P must arrange for payment so that the Medicaid enrollee is not billed for this service.

C. The CCN shall cover all medically necessary services to treat an emergency medical condition in the same amount, duration and scope as stipulated in the Medicaid State Plan.

1. Emergency medical condition means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in the following:

a. placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy;

b. serious impairment to bodily functions; or

c. serious dysfunction of any bodily organ or part.

2. Emergency services means covered inpatient and outpatient services that are as follows:

a. furnished by a provider that is qualified to furnish these services under this Section; and

b. needed to evaluate or stabilize an emergency medical condition.

3. Post-stabilization care services means covered services, related to an emergency medical condition, that are provided after an member is stabilized in order to maintain the stabilized condition or, under the circumstances described in 42 CFR §438.114, to improve or resolve the member's condition.

D. The CCN-P must maintain a provider network and in-area referral providers in sufficient numbers, as determined by the department, to ensure that all of the required core benefits and services are available and accessible in a timely manner within the CCN-P's designated geographic service area(s) as approved by the department, in accordance with the terms and conditions in the contract and department issued guide.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1585 (June 2011).

§3507. Benefits and Services

A. Core benefits and services shall be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services furnished to enrollees under Louisiana Medicaid State Plan.

1. Core benefits and services shall be defined as those health care services and benefits required to be provided to Medicaid CCN members enrolled in the CCN-P as specified under the terms of the contract and department issued guides.

2. Covered services shall be defined as those health care services and benefits to which a Medicaid and LaCHIP eligible individual is entitled to under the Louisiana Medicaid State Plan.

B. The CCN-P:

1. shall ensure that medically necessary services, defined in LAC 50:I.1101, are sufficient in amount, duration, or scope to reasonably be expected to achieve the purpose for which the services are being furnished;

2. may not arbitrarily deny or reduce the amount, duration, or scope of a required service because of diagnosis, type of illness, or condition of the member;

3. may place appropriate limits on a service:

a. on the basis of certain criteria, such as medical necessity; or

b. for the purpose of utilization control, provided the services furnished can reasonably be expected to achieve their purpose;

4. shall provide core benefits and services as outlined and defined in the contract and shall provide medically necessary and appropriate care to Medicaid CCN Program members;

5. shall provide all of the core benefits and services consistent with, and in accordance with, the standards as defined in the Title XIX Louisiana Medicaid State Plan:

a. the CCN may exceed the limits as specified in the minimum service requirements outlined in the contract;

b. no medical service limitation can be more restrictive than those that currently exist under the Title XIX Louisiana Medicaid State Plan; and

6. shall provide pregnancy-related services that are necessary for the health of the pregnant woman and fetus, or that have become necessary as a result of being pregnant and includes, but is not limited to prenatal care, delivery, postpartum care, and family planning/interconception care services for pregnant women in accordance with federal regulations.

C. If the CCN-P elects not to provide, reimburse for, or provide coverage of a counseling or referral service because of an objection on moral or religious grounds, the CCN-P must furnish information about the services it does not cover in accordance with §1932(b)(3)(B)(ii) of the Social Security Act and federal regulations by notifying:

1. the department in its response to the department's request for proposals (RFP) or whenever it adopts the policy during the term of the contract;

2. the potential enrollees before and during enrollment in the CCN-P;

3. enrollees within 90 days after adopting the policy with respect to any particular service; and

4. members through the inclusion of the information in the member handbook.

D. The following is a summary listing of the core benefits and services that a CCN-P is required to provide:

1. inpatient hospital services;

2. outpatient hospital services;

3. ancillary medical services;

4. organ transplant-related services;

5. family planning services as specified in 42 CFR §431.51(b)(2) (not applicable to CCN operating under a moral and religious objection as specified in the contract);

6. EPSDT/Well Child visits;

7. emergency medical services;

8. communicable disease services;

9. durable medical equipment and certain supplies;

10. prosthetics and orthotics;

11. emergency and non-emergency medical transportation;

12. home health services;

13. basic behavioral health services;

14. school-based health clinic services provided by the Office of Public Health certified school-based health clinics;

15. physician services;

16. maternity services;

17. chiropractic services; and

18. rehabilitation therapy services (physical, occupational, and speech therapies).

NOTE: This overview is not all inclusive. The contract, policy transmittals, State Plan amendments, regulations, provider bulletins, provider manuals, published fee schedules, and guides issued by the department are the final authority regarding services.

E. Transition Provision. In the event a member transitions from CCN included status to a CCN excluded status before being discharged from a hospital and/or rehabilitation facility, the cost of the entire admission will be the responsibility of the CCN entity. This is only one example and does not represent all situations in which the CCN is responsible for cost of services during a transition.

F. The core benefits and services provided to the members shall include, but are not limited to, those services specified in the contract.

1. Policy transmittals, State Plan amendments, regulations, provider bulletins, provider manuals, and fee schedules, issued by the department are the final authority regarding services.

G. Excluded Services

1. The following services will continue to be reimbursed by the Medicaid Program on a fee-for-service basis. The CCN shall provide any appropriate referral that is medically necessary. The department shall have the right to incorporate these services at a later date if the PMPM rates have been adjusted to incorporate the cost of such service. Excluded services include:

a. services provided through the Early-Steps Program (IDEA Part C Program services);

b. dental services;

c. intermediate care facility services for persons with intellectual disabilities;

d. hospice services;

e. personal care services (EPSDT and Long-Term);

f. nursing facility services;

g. pharmacy services (prescription drugs);

h. school-based Individualized Education Plan services provided by a school district and billed through the intermediate school district, or school-based services funded with certified public expenditures;

i. home and community-based waiver services;

j. specialized behavioral health; and

k. targeted case management services.

H. Utilization Management

1. The CCN-P shall develop and maintain policies and procedures with defined structures and processes for a utilization management (UM) program that incorporates utilization review. The program shall include service authorization and medical necessity review and comply with the requirements set forth in this Section, the contract and department issued guides.

a. The CCN-P shall submit UM policies and procedures to the department for written approval, annually and subsequent to any revisions.

2. The UM Program policies and procedures shall, at a minimum, include the following requirements:

a. the individual(s) who is responsible for determining medical necessity, appropriateness of care, level of care needed, and denying a service authorization request or authorizing a service in amount, duration or scope that is

less than requested, must meet the following requirements. The individual shall:

i. be a licensed clinical professional with appropriate clinical expertise in the treatment of a member's condition or disease;

ii. have no history of disciplinary action or sanctions, including loss of staff privileges or participation restrictions that have been taken or are pending such action by any hospital, governmental agency or unit, or regulatory body, that raise a substantial question as to the clinical peer reviewer's physical, mental, or professional competence or moral character; and

iii. attest that no adverse determination will be made regarding any medical procedure or service outside of the scope of such individual's expertise;

b. the methodology utilized to evaluate the clinical necessity, appropriateness, efficacy, or efficiency of health care services;

c. the data sources and clinical review criteria used in decision making;

d. the appropriateness of clinical review shall be fully documented;

e. the process for conducting informal reconsiderations for adverse determinations;

f. mechanisms to ensure consistent application of review criteria and compatible decisions;

g. data collection processes and analytical methods used in assessing utilization of healthcare services; and

h. provisions for assuring confidentiality of clinical and proprietary information.

3. The UM Program's medical management and medical necessity review criteria and practice guidelines shall be reviewed annually and updated periodically as appropriate. The CCN-P shall use the medical necessity definition as set forth in LAC 50:I.1101 for medical necessity determinations.

a. Medical management and medical necessity review criteria and practice guidelines shall:

i. be objective and based on valid and reliable clinical evidence or a consensus of health care professionals in the particular field;

ii. consider the needs of the members;

iii. be adopted in consultation with contracting health care professionals; and

iv. be disseminated to all affected providers, members, and potential members upon request.

b. The CCN-P must identify the source of the medical management criteria used for the review of medical necessity and for service authorization requests.

i. The vendor must be identified if the criteria are purchased.

ii. The association or society must be identified if the criteria are developed/recommended or endorsed by a national or state health care provider association or society.

iii. The guideline source must be identified if the criteria are based on national best practice guidelines.

iv. The individuals who will make medical necessity determinations must be identified if the criteria are based on the medical training, qualifications, and experience of the CCN medical director or other qualified and trained professionals.

4. The CCN shall ensure that only licensed clinical professionals with appropriate clinical expertise in the treatment of a member's condition or disease shall determine service authorization request denials or authorize a service in an amount, duration or scope that is less than requested.

5. The CCN-P shall ensure that compensation to individuals or entities that conduct UM activities is not structured to provide incentives for the individual or entity to deny, limit, or discontinue medically necessary covered services to any member in accordance with 42 CFR §438.6(h), 42 CFR §422.208, and 42 CFR §422.210.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1585 (June 2011).

§3509. Reimbursement Methodology

A. Payments to CCN-P. The department, or its fiscal intermediary, shall make monthly capitation payments to the CCN-P based on a per member, per month rate.

1. Actuarially sound rates will be determined by the department acting on the advice of its actuaries. It is intended that rates will initially be set using historical fee-for-service data, with appropriate adjustments for the expected impact of managed care on the utilization of the various types of services (some increases and some reductions) and for the expected cost of CCN-P administration and overhead.

2. As the Coordinated Care Network Program matures and fee-for-service data is no longer available, there will be increasing reliance on encounter data and/or financial data to set future rates, subject to comparable adjustments.

3. PMPM payments will be set on the basis of health status-based risk adjustments. An initial universal PMPM rate will be set for all CCN-Ps at the beginning of each contract period and as deemed necessary by the department.

a. The health risk of the Medicaid enrollees enrolled in the CCN-P will be measured using a nationally-recognized risk-assessment model.

b. Utilizing this information, the universal PMPM rates will be adjusted to account for the health risk of the enrollees in each CCN-P relative to the overall population being measured.

c. PMPM rate risk adjustments will begin three months after the implementation date for each phase of program implementation.

d. The health risk of the members and associated CCN-P risk scores will be updated periodically to reflect changes in risk over time.

4. A CCN-P shall be reimbursed a one-time supplemental lump sum payment, hereafter referred to as a "maternity kick payment", for each obstetrical delivery in the amount determined by the department's actuary.

a. The maternity kick payment is intended to cover the cost of prenatal care, the delivery event, and post partum care. Payment will be paid to the CCN-P upon submission of satisfactory evidence of the occurrence of a delivery.

b. The hospital shall accurately input the delivery event into the Louisiana Electronic Event Registration System (LEERS) as evidence that a delivery event has taken place in order for a maternity kick payment request to be initiated to the department's fiscal intermediary for payment to the CCN-P.

c. Only one maternity kick payment will be made per delivery event. Therefore, multiple births during the same delivery will still result in one maternity kick payment being paid.

d. The maternity kick payment will be paid for both live and still births. A maternity kick payment will not be reimbursed for spontaneous or induced abortions.

B. As Medicaid is the payor of last resort, a CCN-P must agree to accept the PMPM rate as payment-in-full from the department and agree not to seek additional payment from a member for any unpaid cost.

C. The PMPM rate does not include graduate medical education payments, disproportionate share hospital payments or upper payment limit payments. These supplemental payments will be made to applicable providers outside the PMPM rate by the department according to methodology consistent with existing Rules.

D. A CCN-P shall assume 100 percent liability for any expenditure above the prepaid premium.

E. The CCN-P shall meet all financial reporting requirements specified in the terms of the contract.

F. A CCN-P shall have a medical loss ratio (MLR) for each MLR reporting calendar year of not less than 85 percent using definitions for health care services, quality initiatives and administrative cost as specified in 45 CFR Part 158.

1. A CCN-P shall provide an annual MLR report, in a format as determined by the department, by June 1 following the MLR reporting year that separately reports the CCN-P's medical loss ratio for services provided to Medicaid enrollees and payment received under the contract with the department from any other products the CCN-P may offer in the state of Louisiana.

2. If the medical loss ratio is less than 85 percent, the CCN-P will be subject to refund of the difference, within the timeframe specified, to the department by August 1. The portion of any refund due the department that has not been paid by August 1 will be subject to interest in the amount of ten percent per annum.

3. The department shall provide for an audit of the CCN's annual MLR report and make public the results within 60 calendar days of finalization of the audit.

G. Any cost sharing imposed on Medicaid members must be in accordance with the federal regulations governing cost sharing and cannot exceed the amounts reflected in the Louisiana Medicaid State Plan, but the amounts can be less than the cost sharing levels in the State Plan.

H. The department may adjust the PMPM rate, during the term of the contract, based on:

1. the health status-risk adjustment as determined by the department acting on the advice of its actuaries;

2. the inclusion of covered Medicaid services not incorporated in the applicable PMPM;

3. the implementation of federal requirements; and/or

4. legislative appropriations and budgetary constraints.

I. Any adjusted rates must continue to be actuarially sound and will require an amendment to the contract. The department will provide the CCN with three months advance notice of any major revision to the risk-adjustment methodology.

J. The CCN-P shall not assign its rights to receive the PMPM payment, or it obligation to pay, to any other entity.

1. At its option, the department may, at the request of the CCN-P, make payment to a third party administrator.

K. In the event that an incorrect payment is made to the CCN-P, all parties agree that reconciliation will occur.

1. If an error or overcharge is discovered by the department, it will be handled in accordance with the terms and conditions of the contract.

L. Network Provider Reimbursement

1. Reimbursement for covered services shall be equal to or greater than the published Medicaid fee-for-service rate in effect on the date of service. Notwithstanding, upon request by a network provider, or potential network provider, and with the prior approval of the department, exceptions may be granted.

2. The CCN-P's subcontract with the network provider shall specify that the provider shall accept payment made by the CCN as payment-in-full for core benefits and services provided and shall not solicit or accept any surety or guarantee of payment from the department or the member.

a. The term "member" shall include the patient, parent(s), guardian, spouse or any other legally responsible person of the member being served.

3. The CCN-P may enter into alternative payment arrangements with its network providers or potential providers with prior approval by the department.

a. The CCN-P shall not enter into alternative payment arrangements with federally qualified health centers or rural health clinics as the CCN-P is required to reimburse these providers according to the published FQHC/RHC Medicaid prospective payment schedule rate in effect on the date of service, whichever is applicable.

M. Out-of-Network Provider Reimbursement

1. The CCN-P is not required to reimburse more than 90 percent of the published Medicaid fee-for-service rate in effect on the date of service to out-of-network providers to whom they have made at least three documented attempts to include the provider in their network as per the terms of the contract and department issued guide.

2. If three attempts to contract with the provider prior to the delivery of the medically necessary service have not been documented, the CNN-P shall reimburse the provider the published Medicaid fee-for-service rate in effect on the date of service.

N. Reimbursement for Emergency Services for In-Network or Out-of-Network Providers

1. The CCN-P is financially responsible for ambulance services, emergency and urgently needed services and maintenance, and post-stabilization care services in accordance with provisions set forth in 42 CFR §422.113.

2. The reimbursement rate for medically necessary emergency services shall be no less than the published Medicaid fee-for-service rate in effect on the date of service, regardless of whether the provider that furnished the services has a contract with the CCN-P.

a. The CCN-P may not concurrently or retrospectively reduce a provider's reimbursement rate for these emergency services, including ancillary and diagnostic services, provided during an episode of care.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1587 (June 2011).

§3511 Prompt Pay of Claims

A. Network Providers. All subcontracts executed by the CCN-P shall comply with the terms in the contract. Requirements shall include at a minimum:

1. the name and address of the official payee to whom payment shall be made;

2. the full disclosure of the method and amount of compensation or other consideration to be received from the CCN-P; and

3. the standards for the receipt and processing of claims are as specified by the department in the CCN's contract with the department and department issued guides.

B. Network and Out-of-Network Providers

1. The CCN-P shall make payments to its network providers, and out-of-network providers, subject to conditions outlined in the contract and department issued guides.

a. The CCN-P shall pay 90 percent of all clean claims, as defined by the department, received from each provider type within 15 business days of the date of receipt.

b. The CCN-P shall pay 99 percent of all clean claims within 30 calendar days of the date of receipt.

2. The provider must submit all claims for payment no later than 12 months from the date of service.

3. The CCN-P and all providers shall retain any and all supporting financial information and documents that are adequate to ensure that payment is made in accordance with applicable federal and state laws.

a. Any such documents shall be retained for a period of at least six years or until the final resolution of all litigation, claims, financial management reviews, or audits pertaining to the contract.

4. There shall not be any restrictions on the right of the state and federal government to conduct inspections and/or audits as deemed necessary to assure quality, appropriateness or timeliness of services and reasonableness of costs.

C. Claims Management

1. The CCN shall process a provider's claims for covered services provided to members in compliance with all applicable state and federal laws, rules and regulations as well as all applicable CCN policies and procedures including, but not limited to:

a. claims format requirements;

b. claims processing methodology requirements;

c. explanation of benefits and related function requirements;

d. processing of payment errors;

e. notification to providers requirements; and

f. timely filing.

D. Provider Claims Dispute

1. The CCN shall:

a. have an internal claims dispute procedure that is in compliance with the contract and department issued guide and approved by the department;

b. contract with independent reviewers to review disputed claims;

c. systematically capture the status and resolution of all claim disputes as well as all associate documentation; and

d. Report the status of all disputes and their resolution to the department on a monthly basis as specified in the contract and department issued guides.

E. Claims Payment Accuracy Report

1. The CCN shall submit an audited claims payment accuracy percentage report to the department on a monthly basis as specified in the contract and department issued CCN-P guides.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1589 (June 2011).

Chapter 37. Enrollee Grievance and Appeal Process

Subchapter A. Coordinated Care Network Shared Savings Model

§3701. Introduction

A. A coordinated care network shared savings model (CCN-S) shall establish and maintain a procedure for the receipt and prompt internal resolution of all Medicaid enrollee grievances pursuant to applicable state and federal laws as well as the terms and conditions of the contract and all department issued guides.

1. All appeals received by the CCN-S must be logged in and directly forwarded to the state agency responsible for conducting the fair hearing process. The CCN-S must assist the department in handling appeals submitted by its members through the state fair hearing process.

2. The CCN-S shall not have any processes that impede the start of the state fair hearing process. The CCN-S shall work with the department toward simultaneous resolution of any appeals brought to their attention.

3. The CCN-S shall not create barriers to timely due process. If it is determined by the department that the CCN-S has created barriers to timely due process, the CCN-S shall be subject to sanctions for each incident and/or grievance. If the number of appeals reversed by the state fair hearing process exceeds 10 percent of the appeals received within a 12 month period, the CCN shall be subject to sanctions.

B. The CCN-S's grievance procedures and any changes thereto must be approved in writing by the department prior to their implementation and must include, at a minimum, the requirements set forth herein.

1. The CCN-S shall refer all members who are dissatisfied, in any respect, with the CCN-S or its subcontractor to the CCN-S's designee who is authorized to review and respond to grievances and to require corrective action.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1589 (June 2011).

§3703. Definitions

Action—a termination, suspension, or reduction (which includes denial of a service as specified in federal regulations) of Medicaid eligibility or covered services.

Appeal—a request for review of an action as defined in this Section.

Grievance—an expression of dissatisfaction about any matter other than an action as that term is defined in this

Section. The term is also used to refer to the overall system that includes CCN-S level grievances and access to a fair hearing. Possible subjects for grievances include, but are not limited to, the quality of care or services provided, aspects of interpersonal relationships such as rudeness of a provider or employee, or failure to respect the member's rights.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1589 (June 2011).

§3705. General Provisions

A. The CCN-S must have a system in place for members that include a grievance process and access to the fair hearing process as described in federal regulations and state laws.

B. Authority to File. A member or a representative of his/her choice may file a grievance and/or request a state fair hearing in response to an action. A CCN-S provider, acting on behalf of the member with the member's written consent, may file a grievance or request a state fair hearing on behalf of a member in response to an action.

1. Filing Timeframe. The member must be allowed 30 calendar days from the date on the CCN-S's notice of action to request a state fair hearing. Within this timeframe, the member, or a representative or provider acting on their behalf, may request a state fair hearing.

2. Filing Procedures

a. The member may file a grievance either orally or in writing with the CCN-S.

b. The member, or a representative or provider acting on the member's behalf and with the member's written consent, may file for a state fair hearing with the designated state entity either orally or in writing, unless an expedited resolution is requested. An oral request for a state fair hearing must be followed up with a written, signed appeal request in order to initiate an expedited resolution.

C. Grievance Notice and Fair Hearing Procedures

1. The CCN-S shall ensure that all members are informed of the state fair hearing process and of the CCN-S's grievance procedures.

a. The CCN-S shall provide a member handbook to each member that shall include descriptions of the CCN-S's grievance procedures.

b. Forms to file grievances, concerns or recommendations to the CCN-S shall be available through the CCN-S, and must be provided to the member upon request. The CCN-S shall make all forms easily available on its website.

D. Grievance Records

1. A copy of an oral grievance log shall be retained for six years. If any litigation, claim negotiation, audit, or other action involving the documents or records has been started before the expiration of the six year period, the records shall be retained until completion of the action and resolution of issues which arise from it or until the end of the regular six-year period, whichever is later.

E. Grievance Reports

1. The CCN-S shall provide an electronic report of the grievances it has received to the department on a monthly basis in accordance with the requirements outlined in the contract, which will include, but is not limited to:

a. the member's name and Medicaid identification number;

b. summary of grievances;

c. date of filing;

d. current status;

e. resolutions; and

f. resulting corrective action.

F. All state fair hearing requests shall be sent directly to the state designated entity. However, if the CCN-S receives a request for a state fair hearing, the CCN-S will be responsible for promptly forwarding the request to the designated state fair hearing entity.

G. The department has the right to make final decisions regarding the resolution of any grievance.

H. Information to Providers and Subcontractors

1. The CCN-S must provide the information about the grievance procedures for Medicaid enrollees to all providers and subcontractors at the time that they enter into a contract with the CCN-S as specified in the contract and the department issued guides.

I. Recordkeeping and Reporting Requirements

1. Reports of grievances and resolutions shall be submitted to the department as specified by the department. The CCN-S shall not modify its grievance procedures without the prior written approval of the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1590 (June 2011).

§3707. Enrollee Handling of Grievances and Fair Hearings

A. In handling grievances, the CCN must meet the following requirements:

1. give members any reasonable assistance in completing forms and taking other procedural steps. This includes, but is not limited to, providing interpreter services and toll-free telephone numbers that have adequate TTY/TTD and interpreter capability; and

2. acknowledge receipt of each grievance and appeal.

B. Resolution and Notification. The CCN must dispose of a grievance and provide notice, as expeditiously as the member's health conditions require, within the timeframes established in the contract and department issued guides.

1. For standard disposition of a grievance and notice to the affected parties, the established timeframe is 90 days from the day the CCN receives the grievance.

C. Extension of Timeframes. The CCN-S may extend the timeframes for disposition of a grievance up to 14 calendars days under the following circumstances:

1. the member request the extension; or

2. the CCN-S shows (to the satisfaction of the department or its designee, upon request) that there is need for additional information and how the delay is in the member's interest.

D. If the CCN-S extends the timeframes for any extension not requested by the member, it must give the member written notice of the reason for the delay.

1. The CCN shall use the method and format specified in the contract for notifying a member of the disposition of a grievance.

E. Requirements for State Fair Hearings

1. The member may request a state fair hearing within 30 days from the date of the notice of action following the resolution of the grievance.

2. The parties to the state fair hearing include the CCN-S as well as the member and his/her representative or the representative of a deceased member's estate.

F. Concurrent Appeal Review

1. The CCN-S shall conduct an internal concurrent review for each appeal for which a state fair hearing is requested. The purpose of the concurrent appeal review is to expedite the resolution of the appeal to the satisfaction of the member, if possible, prior to the state fair hearing.

2. The CCN-S shall notify the state fair hearing designated entity of concurrent appeal reviews resulting in a resolution in favor of the member.

3. The concurrent appeal review shall not delay the CCN's submission of an appeal to the state fair hearing entity, nor shall it not delay the review of the appeal in the state fair hearing.

G. Special Requirements for Appeals

1. All appeals by members or on their behalf shall be filed with the state designated entity. However, if the CCN-S receives a state fair hearing request, the request shall be forwarded directly to the designated entity that will conduct the state fair hearing.

2. The CCN-S's staff shall be educated concerning the importance of the appeal procedures and the rights of the member and providers.

3. The appropriate individual or body within the CCN-S that made the decision that is being appealed shall be identified. This individual shall prepare the summary of evidence and be available for the appeal, either in person or by telephone.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1590 (June 2011).

§3709. Notice of Action

A. Language and Format Requirements

1. The notice of action will only be sent by the CCN-S in certain circumstances as specified by the department.

2. The notice must be in writing and must meet the language and format requirements of federal regulations in order to ensure ease of understanding.

B. Content of Notice. The notice must explain the following:

1. the action the CCN-S or its subcontractor has taken or intends to take;

2. the reasons for the action;

3. the member's right to request a state fair hearing and a telephone number to call for free legal advice;

4. the procedures for exercising the rights specified in this Section;

5. the circumstances under which expedited resolution is available and how to request it;

6. the member's right to have services continue pending resolution of the appeal, the procedures to make such a request, and the circumstances under which the member may be required to pay for the costs of these services; and

7. a statement in Spanish and Vietnamese that translation assistance is available at no cost and the toll free telephone number to call to receive translation of the notice.

C. Notice Timeframes. The CCN-S must mail the notice within the following timeframes:

1. for termination, suspension, or reduction of previously authorized Medicaid-covered services, at least 10 days before the date of action (except as permitted under federal regulations);

2. for standard service authorization decisions that deny or limit services, as expeditiously as the member's health condition requires and within 14 calendar days following receipt of the request for service. A possible extension of up to 14 additional calendar days may be granted under the following circumstances:

a. the member, his/her representative or a provider acting on his/her behalf, requests an extension; or

b. the CCN-S justifies (to the department upon request) that there is a need for additional information and that the extension is in the member's interest;

3. on the date that the timeframe for service authorization expires.

D. If the CCN-S extends the timeframe in accordance with this Section, it must:

1. give the member written notice of the reason for the decision to extend the timeframe;

2. inform the member of the right to file a grievance if he/she disagrees with that decision; and

3. issue and carry out its determination as expeditiously as the member's health condition requires, but no later than the date that the extension expires.

E. For expedited service authorization decisions where a provider indicates, or the CCN-S determines, that following the standard timeframe could seriously jeopardize the member's life or health or ability to attain, maintain, or regain maximum function, the CCN-S must make an expedited authorization decision.

1. A notice must be furnished as expeditiously as the member's health condition requires, but no later than 72 hours after receipt of the request for service.

2. The CCN-S may extend the 72 hours time period by up to 14 calendar days if the member, or provider acting on behalf of the member with the member's written consent, requests an extension or if the CCN-S justifies (to the department upon request) a need for additional information and how the extension is in the member's interest.

F. The department shall conduct random reviews to ensure that members are receiving such notices in a timely manner.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1591 (June 2011).

§3711. Continuation of Services during the State Fair Hearing Process

A. If the member requests a hearing before the date of action or within 10 days from the postmark of the notice, the department may not terminate or reduce services until a decision is rendered after the hearing unless:

1. it is determined that the sole issue is one of federal or state law or policy; and

2. the department or its designee promptly informs the member in writing that services are to be terminated or reduced pending the hearing decision.

B. Member Liability for Services

1. If the final resolution of the appeal is adverse to the member, the department may recover the cost of the services furnished to the member during the pending appeal process in accordance with federal regulations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1591 (June 2011).

§3713. Effectuation of Reversed Appeal Resolutions

A. Discontinuation of Services during the State Fair Hearing Process

1. If the CCN-S or the state fair hearing entity reverses a decision to deny, limit, or delay services that were not furnished while the appeal was pending, the CCN must authorize the disputed services promptly and as expeditiously as the member's health condition requires.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1592 (June 2011).

Subchapter B. Coordinated Care Network Managed Care Organization Model

§3721. Introduction

A. A Coordinated Care Network Managed Care Organization (MCO) Model (CCN-P) must have a grievance system for Medicaid enrollees that complies with federal regulations. The CCN-P shall establish and maintain a procedure for the receipt and prompt internal resolution of all grievances and appeals in accordance with all applicable state and federal laws and as specified in the contract and all department issued guides.

B. The CCN-P's grievance and appeals procedures, and any changes thereto, must be approved in writing by the department prior to their implementation and must include, at a minimum, the requirements set forth herein.

1. The CCN-P shall refer all members who are dissatisfied, in any respect, with the CCN-P or its subcontractor to the CCN-P's designee authorized to review and respond to grievances and require corrective action.

2. The member must exhaust the CCN-P's internal grievance/appeal procedures prior to accessing the state fair hearing process or filing a grievance with the department or its designee.

C. The CCN shall not create barriers to timely due process. If the number of appeals reversed by the state fair hearing process exceeds 10 percent of appeals received within a 12 month period, the CCN shall be subject to sanctions.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1592 (June 2011).

§3723. Definitions

Action—the denial or limited authorization of a requested service, including:

1. the type or level of service;

2. reduction, suspension, or termination of a previously authorized service;

3. denial, in whole or in part, of payment for a service;

4. failure to provide services in a timely manner as specified in the contract; or

5. failure of the CCN-P to act within the timeframes provided in this Subchapter.

Appeal—a request for review of an action as the term is defined in this Section.

Grievance—an expression of dissatisfaction about any matter other than an action as that term is defined in this Section. The term is also used to refer to the overall system that includes grievances and appeals handled at the CCN-P level. Possible subjects for grievances include, but are not limited to, the quality of care or services provided, aspects of interpersonal relationships such as rudeness of a provider or employee, or failure to respect the member's rights.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1592 (June 2011).

§3725. General Provisions

A. The CCN-P must have a system in place for members that include a grievance process, an appeal process, and access to the state fair hearing process once the CCN-P's appeal process has been exhausted.

B. Filing Requirements

1. Authority to file. A member or a representative of his/her choice may file a grievance and a CCN-P level appeal. Once the CCN-P's appeals process has been exhausted, a member or his/her representative may request a state fair hearing.

a. A CCN-P provider, acting on behalf of the member and with his/her written consent, may file an appeal. A CCN-P provider may file a grievance or request a state fair hearing on behalf of a member.

2. Filing Timeframes. The member, or a representative or provider acting on the member's behalf and with his/her written consent, may file an appeal within 30 calendar days from the date on the CCN-P's notice of action.

3. Filing Procedures

a. The member may file a grievance either orally or in writing with the CCN-P.

b. The member, or a representative or provider acting on the member's behalf, may file an appeal either orally or in writing, unless an expedited resolution is requested, which must follow an oral filing with a written, signed appeal.

C. Grievance Notice and Appeal Procedures

1. The CCN-P shall ensure that all members are informed of the state fair hearing process and of the CCN-P's grievance procedures.

a. The CCN-P shall provide a member handbook to each member that shall include descriptions of the CCN-P's grievance procedures.

b. Forms to file grievances, appeals, concerns or recommendations to the CCN-P shall be available through the CCN-P, and must be provided to the member upon request. The CCN shall make all forms easily available on the CCN's website.

D. Grievance and Appeals Records

1. The CCN-P must maintain records of grievances and appeals. A copy of the grievance logs and records of the disposition of appeals shall be retained for six years. If any litigation, claim negotiation, audit, or other action involving the documents or records has been started before the expiration of the six-year period, the records shall be retained until completion of the action and resolution of issues which arise from it or until the end of the regular six-year period, whichever is later.

E. Grievance and Appeal Reports

1. The CCN-P shall provide an electronic report of the grievances and appeals to the department on a monthly basis in accordance with the requirements specified by the department, which will include, but is not be limited to:

a. the member's name and Medicaid identification number;

b. summary of grievances and appeals;

c. date of filing;

d. current status;

e. resolutions; and

f. resulting corrective action.

F. The CCN-P will be responsible for promptly forwarding any adverse decisions to the department for further review and/or action upon request by the department or the CCN-P member.

G. The department may submit recommendations to the CCN-P regarding the merits or suggested resolution of any grievance or appeal.

H. Information to Providers and Subcontractors

1. The CCN-P must provide the information about the grievance system as specified in federal regulations to all providers and subcontractors at the time they enter into a contract.

I. Recordkeeping and Reporting Requirements

1. Reports of grievances and resolutions shall be submitted to the department as specified in the contract. The CCN-P shall not modify the grievance system without the prior written approval of the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1592 (June 2011).

§3727. Handling of Enrollee Grievances and Appeals

A. In handling grievances and appeals, the CCN-P must meet the following requirements:

1. give members any reasonable assistance in completing forms and taking other procedural steps. This includes, but is not limited to, providing interpreter services and toll-free telephone numbers that have adequate TTY/TTD and interpreter capability;

2. acknowledge receipt of each grievance and appeal;

3. ensure that the individuals who make decisions on grievances and appeals are individuals who:

a. were not involved in any previous level of review or decision-making; and

b. if deciding on any of the following issues, are health care professionals who have the appropriate clinical expertise, as determined by the department, in treating the member's condition or disease:

i. an appeal of a denial that is based on lack of medical necessity;

ii. a grievance regarding denial of expedited resolution of an appeal; or

iii. a grievance or appeal that involves clinical issues.

B. Special Requirements for Appeals

1. The process for appeals must:

a. provide that oral inquiries seeking to appeal an action are treated as appeals (to establish the earliest possible filing date for the appeal) and must be confirmed in writing, unless the member or the provider requests expedited resolution;

b. provide the member a reasonable opportunity to present evidence and allegations of fact or law in person as well as in writing. The CCN-P must inform the member of the limited time available for this in the case of expedited resolution;

c. provide the member and his/her representative an opportunity, before and during the appeals process, to examine the member's case file, including medical records and any other documents and records considered during the appeals process; and

d. include, as parties to the appeal:

i. the member and his/her representative; or

ii. the legal representative of a deceased member's estate.

2. The CCN-P's staff shall be educated concerning the importance of the grievance and appeal procedures and the rights of the member and providers.

3. The appropriate individual or body within the CCN-P having decision making authority as part of the grievance and appeal procedures shall be identified.

4. Failure to Make a Timely Decision

a. Appeals shall be resolved no later than the stated time frames and all parties shall be informed of the CCN-P's decision.

b. If a determination is not made by the above time frames, the member's request will be deemed to have been approved as of the date upon which a final determination should have been made.

5. The CCN shall inform the member that he/she may seek a state fair hearing if the member is not satisfied with the CCN-P's decision in response to an appeal.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1593 (June 2011).

§3729. Notice of Action

A. Language and Format Requirements. The notice must be in writing and must meet the language and format requirements of federal regulations in order to ensure ease of understanding.

B. Content of Notice. The notice must explain the following:

1. the action the CCN-P or its subcontractor has taken or intends to take;

2. the reasons for the action;

3. the member's or the provider's right to file an appeal with the CCN;

4. the member's right to request a state fair hearing after the CCN-P's appeal process has been exhausted;

5. the procedures for exercising the rights specified in this Section;

6. the circumstances under which expedited resolution is available and the procedure to request it; and

7. the member's right to have services continue pending resolution of the appeal, the procedure to make such a request, and the circumstances under which the member may be required to pay the costs of these services.

C. Notice Timeframes. The CCN-P must mail the notice within the following timeframes:

1. for termination, suspension, or reduction of previously authorized Medicaid-covered services, at least 10 days before the date of action except as permitted under federal regulations;

2. for denial of payment, at the time of any action taken that affects the claim; or

3. for standard service authorization decisions that deny or limit services, as expeditiously as the member's health condition requires and within 14 calendar days following receipt of the request for service. A possible extension of up to 14 additional calendar days may be granted under the following circumstances:

a. the member, or his/her representative or a provider acting on the member's behalf, requests an extension; or

b. the CCN-P justifies (to the department upon request) that there is a need for additional information and that the extension is in the member's interest.

D. If the CCN-P extends the timeframe in accordance with this Section, it must:

1. give the member written notice of the reason for the decision to extend the timeframe and inform the member of the right to file a grievance if he/she disagrees with that decision; and

2. issue and carry out its determination as expeditiously as the member's health condition requires, but no later than the date the extension expires.

E. For service authorization decisions not reached within the timeframes specified in this Section, this constitutes a denial and is thus an adverse action on the date that the timeframes expire.

F. For expedited service authorization decisions where a provider indicates, or the CCN-P determines, that following the standard timeframe could seriously jeopardize the member's life or health or ability to attain, maintain, or regain maximum function, the CCN-P must make an expedited authorization decision.

1. A notice must be furnished as expeditiously as the member's health condition requires, but no later than 72 hours or as expeditiously as the member's health requires after receipt of the request for service.

2. The CCN-P may extend the 72 hour time period by up to 14 calendar days if the member or provider acting on behalf of the member requests an extension or if the CCN-P justifies (to the department upon request) that there is a need for additional information and that the extension is in the member's interest.

G. The department shall conduct random reviews to ensure that members are receiving such notices in a timely manner.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1593 (June 2011).

§3731. Resolution and Notification

A. The CCN-P must dispose of a grievance, resolve each appeal, and provide notice as expeditiously as the member's health condition requires, within the timeframes established in this Section.

B. Specific Timeframes

1. For standard disposition of a grievance and notice to the affected parties, the timeframe is established as 90 days from the day the CCN-P receives the grievance.

2. For standard resolution of an appeal and notice to the affected parties, the timeframe is established as 30 calendar days from the day the CCN-P receives the appeal.

3. For expedited resolution of an appeal and notice to affected parties, the timeframe is established as 72 hours or as expeditiously as the member's health requires after the CCN-P receives the appeal.

C. Extension of Timeframes

1. The CCN-P may extend the timeframes by up to 14 calendar days under the following circumstances:

a. the member requests the extension; or

b. the CCN-P shows to the satisfaction of the department, upon its request, that there is need for additional information and that the delay is in the member's interest.

D. If the CCN-P extends the timeframes for any extension not requested by the member, it must give the member written notice of the reason for the delay.

E. Format of Notice

1. The CCN-P shall follow the method specified in the department issued guide to notify a member of the disposition of a grievance.

2. For all appeals, the CCN-P must provide written notice of disposition.

3. For notice of an expedited resolution, the CCN-P must also make reasonable efforts to provide oral notice.

F. Content of Notice of Appeal Resolution. The written notice of the resolution must include, at a minimum, the following information:

1. the results of the resolution process and the date it was completed;

2. for appeals not resolved wholly in favor of the members:

a. the right to request a state fair hearing and the procedure to make the request;

b. the right to request to receive services during the hearing process and the procedure to make such a request; and

c. that the member may be held liable for the cost of those services if the hearing decision upholds the CCN-P's action.

G. Requirements for State Fair Hearings

1. The department shall comply with the federal regulations governing fair hearings. The CCN-P shall comply with all requirements as outlined in the contract and department issued guides.

2. If the member has exhausted the CCN-P level appeal procedures, the member may request a state fair hearing within 30 days from the date of the CCN-P's notice of resolution.

3. The parties to the state fair hearing include the CCN-P as well as the member and his/her representative or the representative of a deceased member's estate.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1594 (June 2011).

§3733. Expedited Resolution of Appeals

A. The CCN-P must establish and maintain an expedited review process for appeals when the CCN-P determines (either from a member's request or indication from the provider making the request on the member's behalf or in support of the member's request) that taking the time for a standard resolution could seriously jeopardize the member's life or health or ability to attain, maintain, or regain maximum function.

B. Punitive Action. The CCN-P must ensure that punitive action is not taken against a provider who requests an expedited resolution or supports a member's appeal.

C. If the CCN-P denies a request for expedited resolution of an appeal, it must:

1. transfer the appeal to the timeframe for standard resolution in accordance with the provisions of this Subchapter; and

2. make reasonable efforts to give the member prompt oral notice of the denial and follow up within two calendar days with a written notice.

D. This decision (i.e., the denial of a request for expedited resolution of an appeal) does not constitute an action or require a notice of action. The member may file a grievance in response to this decision.

E. Failure to Make a Timely Decision

1. Appeals shall be resolved no later than the established timeframes and all parties shall be informed of the CCN-P's decision. If a determination is not made by the established timeframes, the member's request will be deemed to have been approved as of the date upon which a final determination should have been made.

F. The CCN-P is required to follow all standard appeal requirements for expedited requests except where differences are specifically noted in the requirements for expedited resolution.

1. The member or provider may file an expedited appeal either orally or in writing. No additional follow-up may be required.

2. The CCN-P shall inform the member of the limited time available for the member to present evidence and allegations of fact or law, in person and in writing, in the case of expedited resolution.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1595 (June 2011).

§3735. Continuation of Services during the Pending CCN-P Appeal or State Fair Hearing

A. As used in this Section, the term "timely filing" means filing on or before the later of the following:

1. within 10 calendar days of the CCN-P's mailing of the notice of action; or

2. the intended effective date of the CCN-P's proposed action.

B. Continuation of Benefits. The CCN-P must continue the member's benefits if:

1. the member or the provider files the appeal timely;

2. the appeal involves the termination, suspension, or reduction of a previously authorized course of treatment;

3. the services were ordered by an authorized provider;

4. the original period covered by the original authorization has not expired; and

5. the member requests extension of benefits.

C. Duration of Continued or Reinstated Benefits

1. If, at the member's request, the CCN-P continues or reinstates the member's benefits while the appeal is pending, the benefits must be continued until one of following occurs:

a. the member withdraws the appeal;

b. 10 calendar days pass after the CCN-P mails the notice providing the resolution of the appeal against the member, unless the member has requested a state fair hearing with continuation of benefits, within the 10-day timeframe, until a state fair hearing decision is reached;

c. a state fair hearing entity issues a hearing decision adverse to the member; or

d. the time period or service limits of a previously authorized service has been met.

D. Member Liability for Services

1. If the final resolution of the appeal is adverse to the member, the CCN-P may recover from the member the cost of the services furnished to the member while the appeal is pending, to the extent that they were furnished solely because of the requirements of this Section, and in accordance with federal regulations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1595(June 2011).

§3737. Effectuation of Reversed Appeal Resolutions

A. Provision of Services during the Appeal Process

1. If the CCN-P or the state fair hearing entity reverses a decision to deny, limit, or delay services that were not furnished while the appeal was pending, the CCN-P must authorize or provide the disputed services promptly and as expeditiously as the member's health condition requires.

B. If the CCN-P or the state fair hearing entity reverses a decision to deny authorization of services, and the member received the disputed services while the appeal was pending, the CCN-P must pay for those services in accordance with the contract.

C. At the discretion of the secretary, the department may overrule a decision made by the Division of Administration, Division of Administrative Law (the state fair hearing entity).

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1595 (June 2011).

Subchapter C. Grievance and Appeals Procedures for Providers

§3743. General Provisions

A. If the provider is filing a grievance or appeal on behalf of the member, the provider shall adhere to the requirements outlined in Subchapter B of this Chapter.

B. A Coordinated Care Network must have a grievance and appeals process for claims and medical necessity and

contract disputes for providers in accordance with the contract and department issued guides.

1. The CCN shall establish and maintain a procedure for the receipt and prompt internal resolution of all provider initiated grievances and appeals as specified in the contract and all department issued guides.

2. The CCN's grievance and appeals procedures and any changes thereto, must be approved in writing by the department prior to their implementation.

3. Notwithstanding any CCN or department grievance and appeal process, nothing contained in any document, including, but not limited to Rule or contract, shall preclude a CCN provider's right to pursue relief through a court of appropriate jurisdiction.

4. The CCN shall report on a monthly basis all grievance and appeals filed and resolutions in accordance to the terms of the contract and department issued guide.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1595 (June 2011).

Chapter 39. Sanctions for Coordinated Care Networks

§3901. Sanctions

A. The CCN agrees to be subject to the sanctions specified in the terms and conditions of the contract and all department issued guides. The specific grounds for sanctions and respective sanctions shall be set forth within the contract.

1. Sanctions may include, but are not limited to:

a. corrective action plans;

b. monetary penalties;

c. temporary management; and

d. suspension and/or termination of the CCN's contract.

B. It shall be at the department's sole discretion as to the proper administrative sanction that will be imposed.

C. The department will notify the CCN through a notice of corrective action when the department or its designee determines that the CCN is deficient or non-compliant with requirements (excluding causes for intermediate sanctions and termination) of the contract.

D. The determination of deficiency and/or non-compliance with such requirements is at the sole discretion of the department.

E. The CCN shall submit a corrective action plan (CAP) to the department, within the timeframe specified in the notice, for approval. The CAP shall delineate the steps and timeline for correcting deficiencies and/or non-compliance issues identified in the notice.

F. The department shall impose monetary penalties and/or sanctions on the CCN for a deficient CAP. A CAP is deficient when it is not submitted within the notice of corrective action timeline requirements and/or when the CCN and/or its subcontractor(s) fail to implement and/or follow the CAP at the discretion of the department.

G. The department, as specified in the contract, has the right to enforce monetary penalties against the CCN for certain conduct.

1. Any and all fines collected as a result of sanctions against a CCN or any of its subcontractors, or any recoupment(s)/repayment(s) received from the CCN or any of its subcontractors, shall be placed into the Louisiana Medical Assistance Trust Fund established by R.S. 46:2623.

H. Monetary Penalties

1. The CCN may be required to pay monetary penalties to the department in the amounts specified in the contract for failure to timely and accurately comply with reporting requirements and for deficient deliverables as set forth in the contract and all department issued guides.

I. Intermediate Sanctions

1. The department may impose any of the following sanctions if it determines that the CCN has violated any provision of the contract, or the applicable statutes or Rules governing CCNs.

2. The department shall notify the CCN and CMS in writing of its intent to impose sanctions and explain the process for the CCN to employ the dispute resolution process as described in the contract. Sanctions shall be in accordance with §1932 of the Social Security Act (42 U.S.C. §1396u-2) and federal regulations and may include any of the following:

a. suspension of payment for members enrolled in the CCN after the effective date of the sanction and until CMS and/or the department is satisfied that the reason for imposition of the sanction no longer exists and is not likely to recur. This violation may result in recoupment of payments;

b. imposition of a fine of up to $25,000 for each marketing/enrollment violation, in connection with any one audit or investigation;

c. termination pursuant to the terms of the contract;

d. non-renewal of the contract;

e. suspension of auto-enrollment;

f. appointment of temporary management;

g. civil money penalties in accordance with §1932 of the Social Security Act (42 USC § 1396u-2);

h. withholding up to 30 percent of a CCN's monthly PMPM payment;

i. permitting individuals enrolled in the CCN to disenroll without cause;

j. suspension or default of all enrollment after the date that CMS or the department notifies the CCN of an occurrence under §§1903(m) or 1932(e) of the Social Security Act;

k. termination of the contract if the CCN has failed to meet requirements of §§1903(m), 1905(t)(3) or 1932(e) of the Social Security Act and offer the CCN-P's Medicaid members an opportunity to enroll with other CCNs;

l. imposition of sanctions pursuant to §1932(e)(B) of the Social Security Act if the CCN does not provide abortion services as provided under the contract;

m. imposition of a fine of up to $25,000 for each occurrence of the CCN's failure to substantially provide medically necessary items and services that are required to be provided to a member covered under the contract;

n. imposition of a fine of up to $15,000 per individual not enrolled and up to a total of $100,000 per each occurrence, when the CCN acts to discriminate among members on the basis of their health status or their requirements for health care services;

o. imposition of a fine of up to $25,000 or double the amount of the excess charges, whichever is greater, for

charging premiums/co-payments in excess of the amounts permitted under the Medicaid Program;

p. imposition of sanctions as outlined in the contract if the CCN fails to comply with the physician incentive plan requirements or other sanctions set forth in the contract or department issued guides;

q. imposition of sanctions as outlined above if the CCN misrepresents or falsifies information that it furnishes to CMS, to the state or to a member, potential member or health care provider;

r. imposition of sanctions as outlined in the contract if the CCN fails to comply with prompt payment requirements;

s. imposition of fines up to $10,000 per incident as outlined in the contract if the CCN:

i. does not maintain network adequacy for mandatory provider types included in the contract and department issued guide;

ii. does not document the required three attempts to contract with the mandatory provider type prior to the delivery of the service; and

iii. is required to provide medically necessary services through an out-of-network providers;

t. imposition of sanctions if the percentage specified in the contract of grievance decisions appealed for medical necessity to a State Fair Hearing level of recipient appeals have been reversed or otherwise resolved in favor of the member.

J. Duration of Sanction

1. Unless the duration of a sanction is specified, a sanction will remain in effect until the department is satisfied that the basis for imposing the sanction has been corrected. The department will notify CMS when a sanction has been lifted.

K. Termination for Cause

1. Issuance of Notice of Termination

a. The department may terminate the contract when it determines the CCN has failed to perform, or violates, substantive terms of the contract or the department issued guides or fails to meet applicable requirements in §§1903(m), 1905(t) or 1932 of the Social Security Act in accordance with the provisions of the contract.

b. The department will provide the CCN with a timely written Notice of Intent to Terminate notice. In accordance with federal regulations, the notice will state:

i. the nature and basis of the sanction;

ii.pre-termination hearing and dispute resolution conference rights, if applicable; and

iii. the time and place of the hearing.

c. The termination will be effective no less than 30 calendar days from the date of the notice.

d. The CCN may, at the discretion of the department, be allowed to correct the deficiencies within 30 calendar days of the date that the notice was issued, unless other provisions in this Section demand otherwise, prior to the issue of a Notice of Termination.

L. Termination Due to Serious Threat to Health of Members

1. The department may terminate the contract immediately if it is determined that actions by the CCN or its subcontractor(s) pose a serious threat to the health of members enrolled in the CCN.

2. The CCN members will be given an opportunity to enroll in another CCN (if there is capacity) or move to fee-for-service.

M. Termination for Insolvency, Bankruptcy, Instability of Funds

1. The CCN's insolvency or the filing of a bankruptcy petition by or against the CCN shall constitute grounds for termination for cause.

N. Termination for Ownership Violations

1. The CCN is subject to termination unless the CCN can demonstrate changes of ownership or control when a person with a direct or indirect ownership interest in the CCN (as defined in the contract and PE-50) has:

a. been convicted of a criminal offense as cited in §1128(a), (b)(1) or (b)(3) of the Social Security Act, in accordance with federal regulations;

b. had civil monetary penalties or assessment imposed under §1128(A) of the Social Security Act; or

c. been excluded from participation in Medicare or any state health care program.

O. CCN Requirements Prior to Termination for Cause. The CCN shall comply with all of the terms and conditions stipulated in the contract and department issued guides during the period prior to the effective date of termination. The CCN is required to meet the requirements as specified in the contract if terminated for cause.

P. Other Sanctions. The department may impose additional sanctions allowed under state statute or regulation that address areas of noncompliance.

Q. Denial of Payment While Under Sanction by CMS. Payments provided for under the contract will be denied for new members when, and for so long as, payment for those members is denied by CMS in accordance with the requirements in federal regulations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1596 (June 2011).

Chapter 40. Audit Requirements for Coordinated Care Networks

§4001. Audit of Services

A. The CCN and its subcontracts shall comply with all audit requirements specified in the contract and department issued guides.

B. The CCN and its subcontractor shall maintain supporting financial information and documents that are adequate to ensure that payment is made in accordance with applicable federal and state requirements, and are sufficient to ensure the accuracy and validity of claims.

1. Such documents, including all original claim forms, shall be maintained and retained by the CCN and or its subcontractors for a period of six years after the contract expiration date or until the resolution of all litigation, claim, financial management review or audit pertaining to the contract, whichever is longer.

2. The CCN or its subcontractors shall provide any assistance that such auditors and inspectors reasonably may require to complete with such audits or inspections.

C. There shall be no restrictions on the right of the state and federal government to conduct inspections and audits as deemed necessary to assure quality, appropriateness or timeliness of services and reasonableness of their costs.

D. Upon reasonable notice, the CCN and its subcontractors shall provide the officials and entities identified in the contract and department issued guides with prompt, reasonable, and adequate access to any records, books, documents, and papers that are related to the performance of the contract.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1597 (June 2011).

Implementation of the provisions of this Rule may be contingent upon the approval of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), if it is determined that submission to CMS for review and approval is required.

Bruce D. Greenstein
Secretary

1106#074

RULE

Department of Health and Hospitals
Bureau of Health Services Financing

Early and Periodic Screening, Diagnosis and Treatment—Dental Program—Covered Services and Reimbursement Rate Reduction
(LAC 50:XV.6903 and 6905)

The Department of Health and Hospitals, Bureau of Health Services Financing has amended LAC 50:XV.6903 and §6905 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq.

Title 50
PUBLIC HEALTH—MEDICAL ASSISTANCE
Part XV. Services for Special Populations
Subpart 5. Early and Periodic Screening, Diagnosis and Treatment
Chapter 69. Dental Services
§6903. Covered Services

A. - D. …

E. Effective August 1, 2010, the prefabricated esthetic coated stainless steel crown-primary tooth dental procedure shall be included in the service package for coverage under the EPSDT Dental Program.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 29:175 (February 2003), amended LR 30:252 (February 2004), LR 31:667 (March 2005), LR 33:1138 (June 2007), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 35:1889 (September 2009), amended LR 37:1598 (June 2011).

§6905. Reimbursement

A. - D.3. …

E. Effective for dates of service on or after August 1, 2010, the reimbursement fees for EPSDT dental services shall be reduced to the following percentages of the 2009 National Dental Advisory Service Comprehensive Fee Report seventieth percentile, unless otherwise stated in this Chapter:

1. 69 percent for the following oral evaluation services:
   a. periodic oral examination;
   b. oral examination—patients under three years of age; and
   c. comprehensive oral examination—new patient;
2. 65 percent for the following annual and periodic diagnostic and preventive services:
   a. radiographs—periapical, first film;
   b. radiograph—periapical, each additional film;
   c. radiograph—panoramic film;
   d. prophylaxis—adult and child;
   e. topical application of fluoride—adult and child (prophylaxis not included); and
   f. topical fluoride varnish, therapeutic application for moderate to high caries risk patients (under 6 years of age);
3. 50 percent for the following diagnostic and adjunctive general services:
   a. oral/facial images;
   b. non-intravenous conscious sedation; and
   c. hospital call; and
4. 58 percent for the remainder of the dental services.

F. Removable prosthodontics and orthodontic services are excluded from the August 1, 2010 rate reduction.

G. Effective for dates of service on and after January 1, 2011, the reimbursement fees for EPSDT dental services shall be reduced to the following percentages of the 2009 National Dental Advisory Service Comprehensive Fee Report seventieth percentile, unless otherwise stated in this Chapter:

1. 67.5 percent for the following oral evaluation services:
   a. periodic oral examination;
   b. oral Examination-patients under 3 years of age; and
   c. comprehensive oral examination-new patients;
2. 63.5 percent for the following annual and periodic diagnostic and preventive services:
   a. radiographs-periapical, first film;
   b, radiographs-periapical, each additional film;
   c. radiographs-panoramic film;
   d. diagnostic casts;
   e. prophylaxis-adult and child;
   f. topical application of fluoride, adult and child (prophylaxis not included); and
   g. topical fluoride varnish, therapeutic application for moderate to high caries risk patients (under 6 years of age);
3. 73.5 percent for accession of tissue, gross and microscopic examination, preparation and transmission of written report;
4. 70.9 percent for accession of tissue, gross and microscopic examination, including assessment of surgical margins for presence of disease, preparation and transmission of written report;
5. 50 percent for the following diagnostic and adjunctive general services:
   a. oral/facial image;

b. non-intravenous conscious sedation; and
c. hospital call; and
6. 57 percent for the remainder of the dental services.

H. Removable prosthodontics and orthodontic services are excluded from the January 1, 2011 rate reduction.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 33:1138 (June 2007), amended LR 34:1032 (June 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 35:1890 (September 2009), amended LR 36:2040 (September 2010), LR 37:1598 (June 2011).

Bruce D. Greenstein
Secretary

1106#075

RULE

Department of Health and Hospitals
Bureau of Health Services Financing

Early and Periodic Screening, Diagnosis and Treatment—Health Services—EarlySteps Reimbursement Rate Reduction (LAC 50:XV.7107)

The Department of Health and Hospitals, Bureau of Health Services Financing has amended LAC 50:XV.7107 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq.

Title 50
PUBLIC HEALTH-MEDICAL ASSISTANCE
Part XV. Services to Special Populations
Subpart 5. Early and Periodic Screening, Diagnosis and Treatment
Chapter 71. Health Services
§7107. EarlySteps Reimbursement

A. - B.2.e. …

C. Effective for dates of service on or after January 1, 2011, the reimbursement for certain Medicaid-covered health services rendered in the EarlySteps Program shall be reduced by 2 percent of the rate in effect on December 31, 2010.

1. The following services rendered in the natural environment shall be reimbursed at the reduced rate:
a. audiology services;
b. speech pathology services;
c. occupational therapy;
d. physical therapy; and
e. psychological services.

2. Services rendered in special purpose facilities/inclusive child care and center-based special purpose facilities shall be excluded from this rate reduction.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 30:800 (April 2004), amended LR 31:2030 (August 2005), LR 35:69 (January 2009), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1599 (June 2011).

Bruce D. Greenstein
Secretary

1106#076

RULE

Department of Health and Hospitals
Bureau of Health Services Financing

End Stage Renal Disease Facilities—Reimbursement Rate Reduction (LAC 50:XI.6901 and 6903)

The Department of Health and Hospitals, Bureau of Health Services Financing has amended LAC 50:XI.6901 and §6903 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq.

Title 50
PUBLIC HEALTH—MEDICAL ASSISTANCE
Part XI. Clinic Services
Subpart 9. End Stage Renal Disease Facilities
Chapter 69. Reimbursement
§6901. General Provisions

A. End stage renal disease (ESRD) facilities are reimbursed a hemodialysis composite rate. The composite rate is a comprehensive payment for the complete hemodialysis treatment in which the facility assumes responsibility for providing all medically necessary routine dialysis services.

B. - D. …

E. Effective for dates of service on or after August 1, 2010, the reimbursement to ESRD facilities shall be reduced by 4.6 percent of the rates in effect on July 31, 2010.

F. Effective for dates of service on or after January 1, 2011, the reimbursement to ESRD facilities shall be reduced by 2 percent of the rates in effect on December 31, 2010.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 30:1022 (May 2004), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 35:1891 (September 2009), LR 36:2040 (September 2010), LR 37:1599 (June 2011).

§6903. Medicare Part B Claims

A. - D. …

E. Effective for dates of service on or after August 1, 2010, the reimbursement to ESRD facilities for Medicare Part B claims shall be reduced by 4.6 percent of the rates in effect on July 31, 2010.

F. Effective for dates of service on or after January 1, 2011, the reimbursement to ESRD facilities for Medicare Part B claims shall be reduced by 2 percent of the rates in effect on December 31, 2010.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR

35:1891 (September 2009), amended LR 36:2040 (September 2010), LR 37:1599 (June 2011).

Bruce D. Greenstein
Secretary

1106#077

RULE

Department of Health and Hospitals
Bureau of Health Services Financing

Family Planning Clinics—Reimbursement Rate Reduction
(LAC 50:XI.3501)

The Department of Health and Hospitals, Bureau of Health Services Financing has amended LAC 50:XI.3501 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq.

Title 50
PUBLIC HEALTH—MEDICAL ASSISTANCE
Part XI. Clinic Services
Subpart 5. Family Planning
Chapter 35. Reimbursement
§3501. Reimbursement Methodology

A. The reimbursement for family planning clinics is a flat fee for each covered service as specified on the established Medicaid fee schedule. Fee schedule rates are based on a percentage of the Louisiana Medicare Region 99 allowable for a specified year.

1. - 2. Repealed.

B. Effective for dates of service on or after August 1, 2010, the reimbursement rates for family planning clinic services shall be 75 percent of the 2009 Louisiana Medicare Region 99 allowable or billed charges, whichever is the lesser amount minus any third party liability coverage.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 30:1022 (May 2004), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1600 (June 2011).

Bruce D. Greenstein
Secretary

1106#078

RULE

Department of Health and Hospitals
Bureau of Health Services Financing

Outpatient Hospital Services—Duration of Outpatient Status
(LAC 50:V.5107)

The Department of Health and Hospitals, Bureau of Health Services Financing has adopted LAC 50:V.5107 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq.

Title 50
PUBLIC HEALTH—MEDICAL ASSISTANCE
Part V. Hospitals
Subpart 5. Outpatient Hospitals
Chapter 51. General Provisions
§5107. Duration of Outpatient Status

A. The Medicaid Program will reimburse medically necessary services rendered to a recipient in outpatient status up to a time period not to exceed 30 hours.

B. This time period is used by the physician to observe the recipient and to determine the need for the following actions:

1. further treatment;
2. admission to inpatient status; or
3. discharge.

C. It is the responsibility of the physicians providing the recipient's outpatient hospital care to determine whether he/she should be admitted to inpatient status.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1600 (June).

Implementation of the provisions of this Rule may be contingent upon the approval of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), if it is determined that submission to CMS for review and approval is required.

Bruce D. Greenstein
Secretary

1106#079

RULE

Department of Health and Hospitals
Bureau of Health Services Financing

Prosthetics and Orthotics—Osteogenic Bone Growth Stimulators
(LAC 50:XVII.10501-10505)

The Department of Health and Hospitals, Bureau of Health Services Financing has adopted LAC 50:XV.10501-10505 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq.

Title 50
PUBLIC HEALTH—MEDICAL ASSISTANCE
Part XVII. Prosthetics and Orthotics
Subpart 5. Orthotic DevicesChapter 105. Osteogenic Bone Growth Stimulators
§10501. General Provisions

A. Osteogenic bone growth stimulators are used to augment bone repair associated with either a healing fracture or bone fusion.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1600 (June 2011).

§10503. Medical Necessity

A. Spinal noninvasive electrical bone growth stimulators may be considered:

1. when a minimum of nine months has elapsed since the patient has had fusion surgery which has resulted in a failed spinal fusion;

2. when there is a history of a previously failed spinal fusion at the same site following spinal fusion surgery and more than nine months has elapsed since fusion surgery was performed at the same level which is being fused again. As long as nine months has passed since the failed fusion surgery, this repeated fusion attempt requires no minimum passage of time for the application of the device; or

3. following a multi-level spinal fusion (i.e., involving three or more contiguous vertebrae, such as L3-L5 or L4-S1). There is no minimum time for application after this surgery.

B. Nonspinal noninvasive ultrasonic bone growth stimulators may be considered for nonunion fractures when a minimum of two sets of radiographs, one before treatment and a second separated by 90 days, are obtained. These radiographs shall include multiple views and be accompanied by a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the two sets of radiographs.

C. Nonspinal noninvasive electrical bone growth stimulators may be considered:

1. when long bone fractures have failed to heal and a period of six months from the initial date of treatment has elapsed;

2. when a long bone fusion has failed and a period of nine months from the initial date of treatment has elapsed; or

3. for the treatment of congenital pseudoarthroses. There is no minimal time requirement after this diagnosis.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1601 (June 2011).

§10505. Reimbursement Methodology

A. Medicaid coverage shall be limited to reimbursement for noninvasive types of bone growth stimulators only. Medicaid will not provide reimbursement for invasive types of bone growth stimulators.

B. Noninvasive types of bone growth stimulators shall be reimbursed on an item-by-item basis. Reimbursement amounts may be based on:

1. invoiced costs to providers;

2. comparative prices of providers;

3. manufacturer's suggested retail prices; or

4. a flat fee negotiated between the department and the provider.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:1601 (June 2011).

Implementation of the provisions of this Rule may be contingent upon the approval of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), if it is determined that submission to CMS for review and approval is required.

Bruce D. Greenstein
Secretary

1106#080

RULE

Department of Health and Hospitals
Licensed Professional Couselors Board of Examiners

License of Title for Marriage and Family Therapy
(LAC 46:LX. 3303, 3305, 3309 and 3311)

In accordance with R.S. 49:950 et seq., of the Louisiana Administrative Procedure Act, as well as R.S. 37:1101 and 37:1122, the Licensed Professional Counselors Board of Examiners has amended its existing rules and regulations, by revising LAC 46:LX.Chapter 31, relative to the License of Title for Marriage and Family Therapy. These revisions are necessary to implement Act 613 of the 2010 Regular Session of the Louisiana Legislature.

Specifically, the Licensed Professional Counselors Board of Examiners has revised Sections 3303, 3305, 3309 and 3311, relative to this Chapter, to prescribe academic requirements for marriage and family therapist license of title.

Title 46
PROFESSIONAL AND OCCUPATIONAL STANDARDS
Part LX. Licensed Professional Counselors Board of Examiners
Subpart 2. Professional Standards for Licensed Marriage and Family Therapists
Chapter 33. Requirements for Licensure

§3303. Definitions

* * *

Supervision—the professional relationship between a supervisor and supervisee that promotes the development of responsibility, skill, knowledge, and ethical standards in the practice of marriage and family therapy. In addition to monitoring the student's supervised face-to-face therapy with individuals, couples, families, and/or groups from a systemic/relational perspective, the supervisor provides regular, face-to-face guidance and instruction. *Supervision* may include, without being limited to, the review of case presentations, audiotapes, videotapes, and direct observation. *Supervision* will be distinguishable from psychotherapy and teaching.

AUTHORITY NOTE: Promulgated in accordance with R. S. 37:1101-1122.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Licensed Professional Counselors Board of Examiners, LR 29:155 (February 2003), amended LR 29:2784 (December 2003), LR 35:1113 (June 2009), LR 37:1601 (June 2011).

§3305. General Licensing Requirements

A. Each person desiring to obtain a license as a practicing marriage and family therapist shall make

application to the board upon such forms and completed in such manner as the board prescribes, accompanied by such fee prescribed. An applicant shall furnish evidence satisfactory to the board and the advisory committee that such person:

1. is of good moral character;

2. is not engaged or has not engaged in any practice or conduct that would be grounds for refusing to issue a license;

3. is qualified for licensure pursuant to the requirements provided for in this Subpart.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1101-1122.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Licensed Professional Counselors Board of Examiners, LR 29:155 (February 2003), amended LR 37:1601 (June 2011).

§3309. Academic Requirements for MFT Licensure

A. The advisory committee and board have determined that "meets the standards" as provided in R.S. 37:1101(12) means:

1. a master's or doctoral degree in marriage and family therapy from a program accredited by the Commission on Accreditation for Marriage and Family Therapy Education (COAMFTE) in a regionally accredited educational institution or a certificate in marriage and family therapy from a post-graduate training institute accredited by COAMFTE; or

2. a master's or doctoral degree in marriage and family therapy or marriage and family counseling from a program accredited by the Council for Accreditation of Counseling and Related Educational Programs (CACREP) in a regionally accredited educational institution with a minimum of 6 graduate courses in marriage and family therapy including coursework on the AAMFT Code of Ethics and a minimum of 500 supervised direct client contact hours, with a minimum of 250 hours of these 100 hours with couples and families, and a minimum of 100 hours of face-to-face supervision. The training of the supervisor must be equivalent to that of an AAMFT approved supervisor or AAMFT supervisor candidate.

B. The board upon recommendation of the advisory committee shall register a person for MFT Internship who applies on the required application forms, completed as the board prescribes and accompanied by the required fee. Additionally, applicants must meet one of the following academic options:

1. Option 1—a master's degree or a doctoral degree in marriage and family therapy from a program in a regionally accredited educational institution accredited by the Commission on Accreditation for Marriage and Family Therapy Education (COAMFTE) or a certificate from a postgraduate training institute in marriage and family therapy accredited by COAMFTE; or

2. Option 2—a master's or doctoral degree in marriage and family therapy or a related clinical mental health field from a regionally accredited institution of higher education with coursework that includes practicum and internship in marriage and family therapy determined by the advisory committee to be substantially equivalent to a graduate degree in marriage and family therapy from a program accredited by COAMFTE. To be considered substantially equivalent, qualifying degrees must include a minimum of 60 semester hours of coursework; or

3. Option 3—a certificate from a postgraduate training institute in marriage and family therapy with coursework that includes practicum and internship in marriage and family therapy determined by the advisory committee to be substantially equivalent to a graduate certificate from a program accredited by COAMFTE. To be considered substantially equivalent, qualifying certificates must include the equivalent of 60 semester hours of coursework; or

4. Option 4—a masters degree or a doctoral degree in marriage and family therapy from a regionally accredited institution of higher education whose program and curriculum was approved by the board through the advisory committee at anytime prior to July 1, 2010, and the applicant for licensure has at least five hundred hours of face-to-face client contact, and the client contact shall include both of the following:

(a). 250 hours of relational therapy. As used herein, "relational therapy" shall mean therapy with couples or families present in the therapy room;

(b). 100 hours in which the applicant has been subjected to qualified supervision as is defined in R.S. 37:1103(11);

5. Required coursework for Options 2 and 4 may be completed during the qualifying master's or doctoral degree programs, or may be taken as post-graduate work at a regionally accredited college, university, or postgraduate marriage and family therapy training institute.

AUTHORITY NOTE: Promulgated in accordance with R. S. 37:1101-1122.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Licensed Professional Counselors Board of Examiners, LR 37:1602 (June 2011).

§3311. Coursework and Academic Supervision Requirements, for Options 2, 3, and 4

A. General Requirements for Qualifying Coursework and Academic Supervision

1. Undergraduate level courses will not meet academic requirements unless the applicant's official transcript clearly shows that the course was given graduate credit.

2. Only coursework taken for credit and receiving a passing grade will be accepted. Coursework taken outside of a program of study for which a degree was granted must receive an "A," "B," or "pass."

3. One course is defined as three semester credits, four quarter credits, or 45 didactic contact hours in a postgraduate training program.

4. An applicant may not use a course for more than one of the seven coursework areas described in Subsection B of this Section.

5. If titles of academic courses are not self-explanatory, their content and relevance must be substantiated by the applicant through course descriptions in official school catalogs, bulletins, syllabi, or by other means approved by the advisory committee.

6. The burden is on the applicant to prove by a preponderance of the evidence that the coursework is equivalent to the requirements in Subsections A and B of this Section.

7. Degrees and coursework obtained at foreign universities shall be acceptable only if determined to be

equivalent as defined in Subsections A and B of this Section as determined by the advisory committee.

B. Specific Coursework Requirements—Options 2 and 3

1. The applicant must document as determined by the advisory committee that all required graduate and postgraduate coursework was presented from a family systems perspective. Coursework will specify how marriage and family therapists apply psychotherapeutic and family systems theories and techniques in the delivery of professional psychotherapeutic services to individuals, couples, families, and groups for the purpose of assessment, treatment planning, and treatment of mental, intellectual, emotional, or behavioral disorders and apply family systems theories, assessment, and techniques in their professional consultation work with organizations.

2. Academic Course Content. An applicant with a master's or doctoral degree in marriage and family therapy or a related clinical mental health field from programs not accredited by the COAMFTE or with a certificate from a postgraduate training institute in marriage and family therapy not accredited by the COAMFTE must have the specified coursework in each of the following areas (one course equals three semester hours or its equivalent as defined in Paragraph A.3 of this Section.

a. Theoretical Knowledge of Marriage and Family Therapy—minimum of two courses. Courses in this area shall provide academic instruction in the historical development, empirical foundations, and contemporary conceptual directions of the field of marriage and family therapy. Coursework shall provide a comprehensive survey and substantive understanding of the systems paradigm, family therapy theory, and the major models of marriage, couple, and family therapy practice. Overview courses in which systems theory is surveyed equally as one of several theories do not qualify for this area.

b. Clinical Knowledge of Marriage and Family Therapy—minimum of four courses. Courses in this area shall provide academic instruction in clinical intervention as it relates to family systems theory. Coursework shall highlight clinical practice in couples and family therapy in relation to cultural and racial diversity, gender, sexual functioning/orientation, violence, addiction, abuse and other relevant issues. Coursework shall focus on the treatment of individuals, couples, and families from a systemic/relational perspective and in response to a wide variety of presenting problems.

c. Assessment and Treatment in Marriage and Family Therapy—minimum of two courses. One course must be in psychopathology. Courses in this area shall provide academic instruction from a systemic/relational perspective in psychopharmacology, physical health and illness, traditional psycho diagnostic categories including the use of the Diagnostic and Statistical Manual of Mental Disorders and the assessment and treatment planning for the treatment of mental, intellectual, emotional, or behavioral disorders within the context of marriage and family systems.

d. Individual, Couple, and Family Development—minimum of one course. Courses in this area shall provide academic instruction in individual, couple, and family development across the lifespan.

e. Professional Identity and Ethics—minimum of one course. Courses in this area shall provide academic instruction in the development of professional identity, ethical and legal issues, scope of practice, professional membership, certification, and licensure. Coursework shall focus on ethical and legal issues related to the practice of marriage and family therapy, including but not limited to the AAMFT Code of Ethics, confidentiality, legal responsibilities and liabilities of clinical practice and research, family law, record keeping, reimbursement, the business aspects of practice, and familiarity with regional and federal laws as they relate to the practice of individual, couple and family therapy. Generic courses in ethics do not meet this standard.

f. Research—minimum of one course. Courses in this area shall provide academic instruction in the understanding and performance of research. Coursework shall focus on content such as research methodology, data analysis, research evaluation, and quantitative and qualitative research.

g. Additional Learning—minimum of one course. Courses in this area will augment students' specialized interest and background in individual, couple, and family therapy and may be chosen from coursework offered in a variety of disciplines.

2. Academic Supervision—as part of their degree program, an applicant must have completed 500 supervised face-to face direct client contact hours with individuals, couples, families, and/or groups from a systemic/relational perspective with 100 hours of face-to-face supervision. At least 250 of these hours must be with couples or families present in the therapy room. If a student is simultaneously being supervised and having direct client contact, the time may be counted as both supervision time and direct client contact time.

AUTHORITY NOTE: Promulgated in accordance with R. S. 37:1101-1122.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Licensed Professional Counselors Board of Examiners, LR 37:1602 (June 2011).

Gloria Bockrath
Board Chair

1106#031

RULE

Department of Health and Hospitals
Office of Aging and Adult Services

Louisiana Physician Order for Scope of Treatment
(LAC 48:I.Chapter 2)

The Department of Health and Hospitals, Office of Aging and Adult Services has amended LAC 48 to provide for the Louisiana Physician Order for Scope of Treatment program as authorized by R.S. 40:1299.64.1-1299.64.6. This Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq.

During the 2010 Regular Session of the Louisiana Legislature, Act 954 authorized the Louisiana Department of Health and Hospitals to establish the Louisiana Physician Order for Scope of Treatment (LaPOST) Program, which allows for a means by which a person may convert his or her wishes concerning life-sustaining treatment into a standing

medical order. Act 954 also provided for specific requirements for the structure and language of the LaPOST form. This Rule is being promulgated to adopt standards to provide for the LaPOST program and form.

Title 48
PUBLIC HEALTH—General
Part I. General Administration
Subpart 1. General

Chapter 2. Louisiana Physician Order for Scope of Treatment

§201. Statement of Policy

A. The Department of Health and Hospitals is committed to the following.

1. It is important for people to make health care decisions before a medical crisis presents itself.

2. Health care planning is a process, rather than a single decision, that helps individuals to consider the kind of care they would want if they become seriously ill or incapacitated, and encourages them to talk to their family members or legal representative about such issues.

3. The Louisiana Physician Order for Scope of Treatment "LaPOST" form documents the wishes of a qualified patient in a physician order.

4. The hallmarks of the LaPOST form are the following:

a. immediately actionable, signed physician orders on a standardized form;

b. orders that address a range of life-sustaining interventions as well as the patient's preferred treatment for each intervention;

c. a brightly colored, clearly identifiable form;

d. a form that is recognized, adopted, and honored across treatment settings.

B. The provisions of this rule are permissive and voluntary. The completion of the Louisiana Physician Order for Scope of Treatment form merely illustrates a means of documenting a decision of a patient relative to withholding or withdrawal of medical treatment or life-sustaining procedures.

1. Nothing in this rule shall be construed to require the completion of a Louisiana physician order for scope of treatment form.

2. Nothing in this rule shall be construed to be the exclusive means by which life-sustaining procedures may be withheld or withdrawn, nor shall this rule be construed to require the application of medically inappropriate treatment or life-sustaining procedures to any patient.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1299.64.1-1299.64.6.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Aging and Adult Services, LR 37:1604 (June 2011).

§203. Definitions

The definitions found in R.S. 40:1299.64.2 apply to this Rule.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1299.64.1-1299.64.6.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Aging and Adult Services, LR 37:1604 (June 2011).

§205. LaPOST Form

A. An individual who desires to execute a LaPOST form must use the form created by the Department of Health and Hospitals. The form may not be altered in layout or style, without the express written permission of the Department of Health and Hospitals.

B. The form to be used for the Louisiana physician order scope of treatment, as provided in R.S. 40:1299.64.1-64.6, can be found at www.La-POST.org.

C. The LaPOST form found at www.La-POST.org is the exclusive form that shall be used to document the wishes of a qualified patient in a physician order for scope of treatment under this Rule.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1299.64.1-1299.64.6.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Aging and Adult Services, LR 37:1604 (June 2011).

§207. Execution of the LaPOST Form

A. A LaPOST form can only be executed by a competent adult patient or if the patient is incompetent or otherwise lacks capacity, a personal health care representative.

B. The LaPOST form must be completed by a physician based on patient preferences and medical indications.

C. The LaPOST form shall:

1. list the qualified patient's last name, first name and middle initial, and date of birth;

2. list the qualified patient's life-limiting and irreversible condition;

3. check all physician orders that apply. Any section not completed implies full treatment for that section;

4. indicate with whom the physician discussed summary of goals and the basis for the orders;

5. contain the physician's signature;

6. contain the patient or personal health care representative's signature and date.

D. The LaPOST form can be executed on behalf of a qualified patient by a personal health care representative only if the patient is incompetent to make their own decisions or lacks capacity.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1299.64.1-1299.64.6

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Aging and Adult Services, LR 37:1604 (June 2011).

§209. Review of the LaPOST Form

A. The LaPOST form should be reviewed periodically by the physician and the patient, including, but not limited to, when:

1. the patient is transferred from one care setting to another;

2. there is a substantial change in the person's health care status; or

3. the patient's treatment preferences change.

B. A new LaPOST form should be completed if the patient wishes to make a substantive change to their treatment goal (eg., reversal of prior directive).

C. When completing a new LaPOST form, the old LaPOST form must be properly voided and retained in the medical chart. A notation that a new form has been executed should be stated on the old LaPOST form.

D. To void a LaPOST form, a line should be drawn through the "Physician's Orders" section of the LaPOST form and "VOID" should be written in large letters. The notation should be signed and dated by the physician.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1299.64.1-1299.64.6.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Aging and Adult Services, LR 37:1604 (June 2011).

§211. Revocation of the LaPOST Form

A. The LaPOST form may be revoked at any time by the patient or his/her personal health care representative by expressing his/her intent verbally, in writing, or by destroying the LaPOST form.

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:1299.64.1-1299.64.6.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Aging and Adult Services, LR 37:1605 (June 2011).

Bruce Greenstein
Secretary

1106#044

RULE

Office of the Governor
Crime Victims Reparations Board

Compensation to Victims
(LAC 22:XIII. 103, 301, and 503)

In accordance with the provisions of R.S. 49:950 et seq., which is the Administrative Procedure Act, and R.S. 46:1801 et seq., which is the Crime Victims Reparations Act, the Crime Victims Reparations Board promulgates rules and regulations regarding the awarding of compensation to applicants.

Title 22
CORRECTIONS, CRIMINAL JUSTICE AND LAW ENFORCEMENT
Part XIII. Crime Victims Reparations Board

Chapter 1. Authority and Definitions

§103. Definitions

A. …

* * *

Pecuniary Loss—amount of expense reasonably and necessarily incurred by reason of personal injury as a consequence of death, or a catastrophic property loss, and includes:

a. for personal injury:

i. ...

ii. actual loss of past earnings and anticipated loss of future earnings because of a disability resulting from the personal injury; or the receipt of medically indicated services for a minor child related to the personal injury;

iii. care of a child or dependent;

iv. counseling or therapy for the parent(s) or sibling(s) of a child who is the victim of a sexual crime;

v. Loss of support for a child victim of a sexual crime not otherwise compensated for as a pecuniary loss for personal injury;

b. as a consequence of death:

i. - v. ...

vi. crime scene cleanup;

c. - d. ...

* * *

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:1801 et seq.

HISTORICAL NOTE: Promulgated by the Office of the Governor, Crime Victims Reparations Board, LR 20:538 (May 1994), amended LR 22:709 (August 1996), LR 23:861 (July 1997), LR 24:327 (February 1998), LR 37:1605 (June 2011).

Chapter 3. Eligibility and Application Process

§301. Eligibility

A. To be eligible for compensation, an individual must have suffered personal injury, death or catastrophic property loss as a result of a violent crime.

1. Victim Conduct and Behavior

a. The Crime Victims Reparations Board may vote to deny or reduce an award to a claimant who is a victim, or who files an application on behalf of a victim, when any of the following occurs.

i. The victim was assisting, attempting, or engaging in an illegal activity that substantially caused the injuries that are the basis for the claim.

ii. The victim committed a felony offense or was serving a sentence for a felony offense committed within five years prior to the date of victimization or five years subsequent to serving the sentence.

iii. The victim contributed to or provoked the offense through his/her own misconduct.

b. Safety Belt Use by Vehicle Occupants

i. As Louisiana requires all vehicle occupants to use seat belts, victims not wearing a safety belt and injured or killed by a driver in violation of R.S. 14:98 (DWI), hit and run, or other intentional acts will have their award reduced, if found eligible otherwise.

ii. The total maximum award allowed under current policy will be reduced by 50 percent.

2. - 3.g. ...

AUTHORITY NOTE: Promulgated in accordance with R. S. 46:1801 et seq.

HISTORICAL NOTE: Promulgated by the Office of the Governor, Crime Victims Reparations Board, LR 20:538 (May 1994), amended LR 22:709 (August 1996), LR 31:2009 (August 2005), LR 35:65 (January 2009), LR 36:2278 (October 2010), LR 37:1605 (June 2011).

Chapter 5. Awards

§503. Limits on Awards

A. - M.2. ...

N. Crime Scene Cleanup

1. Crime scene cleanup means the removal or attempted removal of blood, stains, odors, broken glass, impurities or other debris caused by the crime or the processing of the crime scene where the crime occurred.

2. Expenses for crime scene cleanup may not exceed total costs of $2500.

3. Types of allowable expenses for clean up include:

a. equipment rental;

b. disinfecting and cleaning supplies;

c. professional cleaning services insured for that purpose.

4 Expenses for crime scene cleanup cannot be used for:

a. property repair;

b. replacement of personal property;

c. costs not directly billed to victim and/or claimant.

O. Loss of Support for Child Victim in Sexual Crimes

1. Loss of support may be paid on behalf of a child victim of a sexual offense if the offender was providing support through employment or a benefits program before the date the crime was committed.

2. Claimant qualifications:

a. must be a parent, or legal guardian of the minor child(ren);

b. must provide documented proof that offender supported the home and minor child victim;

c. is only eligible if the offender is incarcerated.

3. The board may award loss of support up to:

a. $7500 maximum per victim;

b. maximum amount per week for loss of support is the same authorized for lost wages in §503.D.4.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:1801 et seq.

HISTORICAL NOTE: Promulgated by the Office of the Governor, Crime Victims Reparations Board, LR 20:539 (May l994), amended LR 22:710 (August l996), LR 24:328 (February 1998), LR 25:26 (January 1999), LR 26:1019 (May 2000), LR 29:577 (April 2003), LR 31:1330 (June 2005), LR 32:242 (February 2006), LR 35:65 (January 2009), LR:37:1605 (June 2011).

Lamarr Davis
Chairman

1106#030

RULE

Office of the Governor
Commission on Law Enforcement and Administration of Criminal Justice

Peace Officer Training (LAC 22:III.4703 and 4750)

In accordance with the provision of R.S. 40:2401 et seq., the Peace Officer Standards and Training Act, and R.S. 40:905 et seq., which is the Administrative Procedure Act, the Peace Officer Standards and Training Council hereby promulgates rules and regulations relative to the training of peace officers.

Title 22
CORRECTIONS, CRIMINAL JUSTICE AND LAW ENFORCEMENT
Part III. Commission on Law Enforcement and Administration of Criminal Justice
Subpart 4. Peace Officers
Chapter 47. Standards and Training
§4703. Basic Certification

A. - C.3. ...

D. When a basic student injures themselves during a basic training course, the student must have the nature of the injury immediately documented. Should the injury later prevent the student from being tested on a basic training course requirement, then upon written request of the agency head, the student will have eight weeks from the time of the medical release to take and pass those course requirements, unless the time between the academy graduation and medical release exceeds a one year period. In that case, the student will be required to complete another basic training course.

AUTHORITY NOTE: Promulgated in accordance with R.S. 15:1204 and R.S. 15:1207.

HISTORICAL NOTE: Promulgated by the Office of the Governor, Commission on Law Enforcement and Administration of Criminal Justice, LR 13:434 (August 1987), amended LR 25:663 (April 1999), LR 27:49 (January 2001), LR 28:475 (March 2002), LR 31:2008 (August 2005), LR 35:1235 (July 2009), LR 36:992 (May 2010), LR 37:1606 (June 2011).

§4750. In Service Training & Certification

A. Firearms

1. Annual Requalification

a. To maintain firearm certification, an officer shall be required to requalify yearly on the POST firearms qualification course, demonstrating at least 80 percent proficiency. Scores shall be computed and verified by a POST certified firearms instructor.

b. If the period between qualifying exceeds 13 months for any reason, the officer will be required to successfully complete the pre-academy firearms course conducted by a POST certified firearms instructor, unless the officer had been in the military for more than five years and was exercising his veteran reemployment rights.

AUTHORITY NOTE: Promulgated in accordance with R.S. 15:1204 and R.S. 15:1207.

HISTORICAL NOTE: Promulgated by the Office of the Governor, Commission on Law Enforcement and Administration of Criminal Justice, LR:37:1606 (June 2011).

Joey Watson
Executive Director

1106#029

RULE

Office of the Governor
Department of Veterans Affairs

Military Family Assistance Program (LAC 4:VII.961-987)

The Louisiana Department of Veterans Affairs has adopted rules and regulations pertaining to the Military Family Assistance Board and the Military Family Assistance Fund, in accordance with the provisions of Act 676 of the 2008 Regular Legislative Session and Act 256 of the 2010 Regular Legislative Session.

Title 4
ADMINISTRATION
Part VII. Governor's Office
Chapter 9. Veterans Affairs
Subchapter D. Military Family Assistance Program
§961. Authority

A. Rules and regulations are hereby established by the Military Family Assistance Board by order of the Military Family Assistance Act, R. S. 46: 120 et seq., Act 151 of the 2005 Louisiana Legislature and amended by Act 676 of the 2008 Louisiana Legislature and Act 256 of the 2010 Louisiana Legislature.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:121 et seq.

HISTORICAL NOTE: Promulgated by the Office of the Governor, Department of Veterans Affairs, LR 37:1606 (June 2011).

§963. Construction of Regulations; Severability

A. Nothing contained in these rules shall be so construed as to conflict with any provision of the Act or any other

applicable statute. If any provision of any rule or regulation is held invalid by any state or federal court in Louisiana, such provision shall be deemed severed from the rule and the court's finding shall not be construed to invalidate any of the other provisions of the rules.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:121 et seq.

HISTORICAL NOTE: Promulgated by the Office of the Governor, Department of Veterans Affairs, LR 37:1606 (June 2011).

§965. Definitions

A. The following terms as used in these regulations, unless the context otherwise requires or unless redefined by a particular part hereof, shall have the following meanings.

Activated Military Personnel or *Activated Military Person*—a person domiciled in Louisiana for civilian purposes, names Louisiana as home of residence (HOR) for military purposes, and who is a member of a reserve component of the United States Army, Navy, Air Force, Marine Corps, or Coast Guard, including the Louisiana National Guard, and called to active federal service in excess of 30 days or who is a member of the Louisiana National Guard and called to active state service pursuant to Louisiana R.S. 29:7.

Application—a written request for financial assistance from the Military Family Assistance Program made on the form captioned Military Family Assistance Program Request Form, together with documents related thereto.

Approval Authority—the third party administrator for all need-based claims of $1500 or less; the fund committee for all need-based claims of greater than $1500 up to $2500; and the board for all need-based claims of greater than $2500. The fund committee and the board are the approval authority for all claims for one-time lump sum payments and all claims appealed by an eligible applicant.

Board—the Louisiana Military Family Assistance Board.

Claimant—an eligible applicant.

Eligible Applicant—activated military personnel or a family member of activated military personnel.

Family Member of Activated Military Personnel—the primary next of kin or an immediate family member.

Final Appeal—an appeal to the Louisiana Military Family Assistance Board.

Fund Committee—the committee comprised of three board members appointed by the chairman of the board to assist in administering the Louisiana Military Family Assistance Program which committee shall also serve as an appellate body for all claims of $1500 or less before a final appeal is made to the full board.

Immediate Family Member—with respect to an activated military person:

a. spouse;

b. a natural child, adopted child, step child, or illegitimate child, if acknowledged by the person or parenthood has been established by a court of competent jurisdiction, except that if such child has not attained the age of 18 years, the term means a surviving parent or legal guardian of such child;

c. any other person claimed as a dependent on the federal income tax of the activated military person;

d. a biological or adoptive parent, unless legal custody of the person by the parent has been previously terminated by reason of a court decree or otherwise under law and not restored;

e. a brother or sister of the person, if such brother or sister has attained the age of 18 years; or

f. any other person, if such person was given sole legal custody of the person by a court decree or otherwise under law before the person attained the age of 18 years and such custody was not subsequently terminated before that time.

Outreach—activities directed at improving or strengthening veteran initiatives, activities or problems.

Third Party Administrator—the Louisiana Department of Veterans Affairs Benefits Division.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:121 et seq.

HISTORICAL NOTE: Promulgated by the Office of the Governor, Department of Veterans Affairs, LR 37:1607 (June 2011).

§967. Eligibility

A. To be eligible for a grant from the Louisiana Military Family Assistance Program, an individual must be either an activated military person or the family member of an activated military person.

B. The activated military person must have served in excess of 30 consecutive days of active duty since September 11, 2001, before the activated military person or any family member may submit an application for assistance to the Louisiana Military Family Assistance Program.

C. The Military Family Assistance Program is a payer of last resort. All applicants shall seek assistance from other available sources prior to making application to the Military Family Assistance Program. Other available sources include, but are not limited to, Army Emergency Relief, Air Force Aid Society, Navy-Marine Corps Relief Society, Coast Guard Mutual Assistance, Salvation Army, American Red Cross, and Veterans' Emergency Assistance.

D. The approval authority may, in its sole discretion, waive the requirement to seek assistance from other available sources when unusual or exigent circumstances make such application impractical or unlikely to produce results in a timely manner or when the applicant shows that the circumstances are such that other potential sources of funds are inapplicable to the particular circumstances.

E. Requests for assistance from the Military Family Assistance Fund shall not be bifurcated.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:121 et seq.

HISTORICAL NOTE: Promulgated by the Office of the Governor, Department of Veterans Affairs, LR 37:1607 (June 2011).

§969. Application Process

A. Eligible Applicant Responsibilities

1. All requests for assistance shall be made through a completed Louisiana Military Family Relief Assistance Program Request Form.

2. An application is not complete unless it is signed by the applicant and contains all information requested by the form.

3. All applicants shall provide all additional information requested by the Military Family Assistance Board, the fund committee, or the third party administrator. Failure to provide additional requested information may result in the denial of the application.

4. Applications for assistance from the Military Family Assistance Program shall include copies of applications for other types of assistance filed by the applicant.

5. Applications, together with all supporting documents, shall be mailed to: Department of Veterans Affairs, Attn: MFA Third Party Administrator, P.O. Box 94095, Baton Rouge, LA 70804-9095.

6. To expedite the application process, applications and supporting documents may be sent by facsimile transmission to MFA third party administrator. If the application and supporting documents are faxed, an application with the applicant's original signature must also be mailed, along with all supporting documents, to the third party administrator. The approval authority shall not approve or pay a request for assistance until an original application is received.

7. An application for assistance from the Military Family Assistance Fund shall be considered made as of the date that it is received by the third party administrator, provided that for all applications received by facsimile transmission, an application with the applicant's original signature is subsequently received by the third party administrator.

8. If an individual acts on behalf of an eligible applicant in preparing and submitting the application, a copy of a fully executed power of attorney authorizing the individual preparing and submitting the application to act on the eligible applicant's behalf must be submitted as an attachment to the application.

9. The deadline to file an application for assistance from the Military Family Assistance Fund is six months from the date of discharge from active duty.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:121 et seq.

HISTORICAL NOTE: Promulgated by the Office of the Governor, Department of Veterans Affairs, LR 37:1607 (June 2011).

§971. Types of Grants; Restrictions on Awards

A. Three types of grants may be made by the Military Family Assistance Fund:

1. grants for need-based assistance;
2. grants for one-time lump sum awards; and
3. grants for transportation and other related costs as authorized by the board.

B. No request shall be approved by the board, the fund committee, or the third party administrator that does not meet the requirements of the law or the rules.

C. The request of an eligible applicant may be denied if the activated military personnel is not in good standing with the appropriate military unit at the time the application is submitted or the time payment is made.

D. The board may disapprove a request for assistance if the board determines that the grant of an award under the facts and circumstances of a particular case is not be in the best interests of the board or the state of Louisiana.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:121 et seq.

HISTORICAL NOTE: Promulgated by the Office of the Governor, Department of Veterans Affairs, LR 37:1608 (June 2011).

§973. Award Amounts

A. The maximum dollar amount that may be awarded on behalf of an activated military person for a need-based claim per 12 month period is $10,000.

B. The maximum dollar amount for need-based claims shall apply per active duty order.

C. One uniform maximum dollar amount that may be awarded on behalf of an activated military person for a one-time lump sum award shall be $700. With respect to one-time lump sum awards, the following shall apply.

1. An eligible applicant may be awarded an additional one-time lump sum award for cost directly related to a service related death or an injury with a greater than 50 percent residual disability.

2. One-time lump sum awards are addition to, and not in lieu of, need-based awards.

3. A one-time lump sum award may be made only when extenuating circumstances are present. Extenuating circumstances include, but are not limited to:

a. the circumstance in which the injured military person is recuperating in a location away from home that necessitates travel by family members to visit with the injured military person. Costs associated with transportation, lodging, meals, and other related matters not covered by any other source to enable family members to visit an activated military person with a service related injury with a greater than fifty percent residual disability, whether the extent of the disability has been determined at the time application is made or is reasonably anticipated to result in a greater than fifty percent residual disability at the time application is made, may be requested;

b. the circumstance in which the funeral of an activated military person necessitates travel by family members to attend the funeral. Costs associated with transportation, lodging, meals, and other related matters not covered by any other source to enable family members to attend the funeral of an activated military person may be requested;

c. the circumstance in which the absence of family members to visit the injured activated military person or attend the funeral of the activated military person creates financial needs for the care of a home, pets, children, or others when the financial need is not covered by any other source;

d. such other extenuating circumstances as may be determined on a case-by-case basis by the fund committee.

4. Family members of activated military personnel who are listed as missing in action or prisoner of war by the U.S. Department of Defense shall be eligible for the lump sum award. The activated military person must be listed as missing in action or a prisoner of war on or after September 11, 2001.

D. With respect to grants for transportation and other related costs of activated military personnel, the following shall apply.

1. One transportation request shall be approved per person per period of mobilization, and pay no greater than $500 per applicant.

2. The utilization of the lowest cost fare and group rates with other applicants, where practicable, shall be encouraged.

3. The awarded amount shall be subtracted from the maximum dollar amount of $10,000 per applicant per 12-month period.

4. Consideration for assistance will be limited to activated military personnel whose deployment is for overseas only.

5. Requests for assistance must have the approval from the adjutant general and/or commanding officer.

6. The rank of the applicant will be considered.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:121 et seq.

HISTORICAL NOTE: Promulgated by the Office of the Governor, Department of Veterans Affairs, LR 37:1608 (June 2011).

§975. Minimum Funding Levels; Reserve Level; Calculation of Funds Available for Payment of One-Time Lump Sum Awards

A. The Military Family Assistance Fund shall have a minimum of $150,000 on deposit for the Military Family Assistance Program to become operational.

B. At all times the fund shall have a reserve of a minimum of $15,000.

C. For fiscal year 2006/2007, the maximum percentage of the Military Family Assistance Fund that may be directed to one-time lump sum awards shall not exceed five percent. The percentage shall be based on the amount of funds on deposit in the Military Family Assistance Fund as of the date of the approval of these rules.

D. For fiscal year 2007/2008 and each succeeding fiscal year, the maximum percentage of the Military Family Assistance Fund that may be directed to one-time lump sum awards shall not exceed 20 percent. This percentage shall be based on the amount of funds on deposit in the Military Family Assistance Fund as of the first day of the fiscal year.

E. Award amounts directed to transportation and other related costs of activated military personnel shall not exceed 30 percent of the funds on deposit in the Military Family Assistance Fund on the first day of the fiscal year.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:121 et seq.

HISTORICAL NOTE: Promulgated by the Office of the Governor, Department of Veterans Affairs, LR 37:1609 (June 2011).

§977. Third Party Administrator

A. The third party administrator shall receive all need-based applications, all applications for one-time lump sum assistance, and all applications for transportation and other related costs assistance.

B. The third party administrator is authorized to review, process, approve and remit payment on all need-based applications of $1500 and less. In no event shall the third party administrator remit payment on any request that exceeds $1500 without the prior express written approval of the board or the fund committee.

C. The third party administrator is authorized to disapprove need-based applications for $1500 or less if the eligible applicant fails to show that all requirements set forth in the law and the rules are met. The eligible applicant has the right to appeal such disapproval to the fund committee.

D. With respect to need-based applications of $1500 and less, the third party administrator is authorized to approve the claim in part and disapprove the claim in part. The eligible applicant has the right to appeal the third party administrator's disapproval of any part of its need-based claim to the fund committee.

E. For all need-based applications received, regardless of the dollar amount of the request, the third party administrator shall make a determination on the following issues:

1. that all awards are on behalf of activated military personnel;

2. that all awards are made pursuant to a claim that is made by an eligible applicant;

3. that all awards are need-based. The third party administrator may consider a claim need-based if all of the following apply:

a. the funds are requested for necessary expenses incurred or to be incurred;

b. the necessary expenses created or will create an undue hardship on the activated military person or family member;

c. the undue hardship is directly related to the activation of the military person;

d. the activated military person or family member does not have reasonable and timely access to any other funding source;

e. payment of the claim does not supplant other available public or private funds; and

f. the Louisiana Military Family Assistance Fund is the eligible applicant's last resort.

F. For all one-time lump sum applications, the third party administrator shall make an initial determination of whether extenuating circumstances exist that support approval of the application.

G. After making the determinations set forth above, the third party administrator shall, for all need-based applications requesting assistance in an amount greater than $1500 and for all one-time lump sum applications, forward the application together with all supporting documents and the determination to the fund committee for further review and processing, approval or disapproval, and payment by the third party administrator in the event of approval.

H. If the third party administrator approves a request of $1500 or less, it shall determine when the claim shall be paid, the amount of payment, to whom the payment shall be made, and such other matters as it deems necessary and appropriate.

I. The third party administrator shall make a written determination on all applications for assistance as soon as possible.

1. In no event shall the time period between receipt of the completed application by the third party administrator and release of the written determination by the third party administrator exceed 30 calendar days.

2. The written determination shall be:

a. to approve the claim;

b. to disapprove the claim;

c. to request additional information or documentation regarding the claim; or

d. to schedule a meeting with the eligible applicant to discuss the claim.

J. If the third party administrator schedules a meeting, it shall make a determination within 15 days following the date that such meeting actually takes place. The determination shall be to either approve or disapprove the claim.

K. If the third party administrator fails to make a written determination within the time periods set forth in these rules, the claim shall be considered disapproved. The eligible applicant may then lodge an appeal within the time delays set forth by statute.

L. The third party administrator shall determine that sufficient funds are on deposit for the payment of all approved claims.

M. The third party administrator shall notify the fund committee and the board in writing any time approved applications will cause the Military Family Assistance Fund's unobligated balance to drop to within $15,000 of its minimum reserve level.

N. With respect to any application that creates a conflict of interest for the third party administrator, the third party administrator shall refer the application to the fund committee for consideration and action.

O. The third party administrator shall notify the board if it appears that an application is submitted in violation the law and these rules.

P. The third party administrator shall submit such reports to the Fund Committee and the board as are requested.

Q. The third party administrator may refer need-based requests for assistance to the fund committee for determination if the third party administrator suspects that the grant of an award under the facts and circumstances of a particular case may not be in the best interests of the Board or the state of Louisiana.

R. The third party administrator's expenses in the administration of the program shall be paid from the balance of the Military Family Assistance Fund, but shall not exceed 5 percent of the total amount deposited into the fund in the previous fiscal year.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:121 et seq.

HISTORICAL NOTE: Promulgated by the Office of the Governor, Department of Veterans Affairs, LR 37:1609 (June 2011).

§979. Fund Committee

A. The Fund Committee shall receive determinations from the third party administrator and make decisions on all need-based applications of greater than $1500 up to $2500 and all applications for one-time lump sum assistance.

B. The fund committee shall sit as a board of appeals for the third party administrator's disapproval of all or any part of a need-based application for $1500 or less. If the fund committee disapproves the eligible applicant's request for assistance, the eligible applicant may appeal the fund committee's disapproval to the military family assistance board.

C. The board chairman shall designate the members of the fund committee and shall select alternates to act on their behalf.

D. The fund committee shall receive the third party administrator's monthly report on applications received and claims paid. The fund committee shall determine the payment of claims when the Military Family Assistance Fund falls to within $15,000 of its minimum funding level.

E. The fund committee shall instruct the third party administrator with respect to the receipt and processing of all applications for assistance from the fund if the fund falls to within $15,000 of its minimum funding level.

F. The fund committee may refer need-based requests for assistance and requests for one-time lump sum awards to the board for determination if the Fund Committee suspects that the grant of an award under the facts and circumstances of a particular case may not be in the best interests of the board or the state of Louisiana.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:121 et seq.

HISTORICAL NOTE: Promulgated by the Office of the Governor, Department of Veterans Affairs, LR 37:1610 (June 2011).

§981. The Board and Chairman of the Board

A. If the board suspects that an application is submitted in violation of the provisions of the law and these rules, it shall refer such application to the appropriate district attorney's office.

B. The board shall provide an annual report to the Joint Legislative Committee on the Budget on the overall activities of the program and any recommendations for consideration.

C. The chairman of the board shall appoint three board members and alternates to serve on the fund committee.

D. The board shall sit as a final board of appeals for all applications disapproved by the fund committee. An eligible applicant shall have no right to appeal the final decision of the board to any other court, tribunal, or hearing body.

E. The board shall make determinations on requests for assistance brought before the board.

F. The board shall exercise oversight of the activities of the third party administrator and the fund committee.

G. The chairman of the board shall provide for state administration of the program, the cost of which shall be paid from the balance of the Military Family Assistance Fund, not to exceed 5 percent of the total amount deposited into the fund in the previous fiscal year.

H. The Secretary of the Louisiana Department of Veterans Affairs may direct up to 10 percent of the total amount deposited into the fund in the previous fiscal year to be spent toward veteran outreach activities.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:121 et seq.

HISTORICAL NOTE: Promulgated by the Office of the Governor, Department of Veterans Affairs, LR 37:1610 (June 2011).

§983. Appeals

A. An eligible applicant may appeal the third party administrator's disapproval of all or any part of the request for assistance to the fund committee within thirty days of the receipt of the written determination disapproving the claim.

B. The fund committee is authorized by these rules to decline to consider any appeal that is not timely filed.

C. An eligible applicant may appeal the fund committee's disapproval of claim to the board within 30 days of the receipt of the written determination disapproving the claim.

D. The board is authorized by these rules to decline to consider any appeal that is not timely filed.

E. The decision of the board on a request for assistance shall be final. The third party administrator, the fund committee, and the eligible applicant shall not have a right to appeal the final decision of the board to any court, tribunal, or hearing body of any kind.

F. The eligible applicant may request reconsideration of a disapproval of claim by the third party administrator, the fund committee, or the board. The request for reconsideration shall be made within 30 days of the date of the eligible applicant's receipt of the written determination disapproving the claim. The request for reconsideration shall be made to the approval authority that disapproved the request for assistance.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:121 et seq.

HISTORICAL NOTE: Promulgated by the Office of the Governor, Department of Veterans Affairs, LR 37:1610 (June 2011).

§985. Withdrawal of Applications

A. An eligible applicant and anyone properly acting on behalf of an eligible applicant shall have the right to withdraw the application at any time prior to final disposition of the application by the third party administrator, the fund committee or the board.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:121 et seq.

HISTORICAL NOTE: Promulgated by the Office of the Governor, Department of Veterans Affairs, LR 37:1611 (June 2011).

§987. Waivers

A. Prior to the approval of a claim, applications and the identity of eligible applicants and their related military personnel shall be confidential unless expressly waived by the eligible applicant in writing. The filing of an appeal before the fund committee or the board shall be considered a waiver of the identity of eligible applicants and their related military personnel.

B. Once a claim is approved, the identity of the eligible applicant, related activated military personnel, and any person filing the application on behalf of the eligible applicant, and the amount approved shall be public record.

C. Applications, the identify of applicants and their related military personnel, and all records of the board, the fund committee and the third party administrator related thereto, shall be available prior to any approval of the application, to necessary parties including but not limited to, the legislative auditor, the legislative oversight committee for rules and annual reports, and such other parties as necessary for prudent administration of the Military Family Assistance Program and verification of elements of the application.

D. The board, the fund committee, and the third party administrator are expressly authorized to make public data concerning the number of applications received, the amount of claims approved, the geographic areas of the state from which such applications are received and approved, the number of disapproved applications, and the amount of funds in the Louisiana Family Military Assistance Fund.

AUTHORITY NOTE: Promulgated in accordance with R.S. 46:121 et seq.

HISTORICAL NOTE: Promulgated by the Office of the Governor, Department of Veterans Affairs, LR 37:1611 (June 2011).

Lane A. Carson
Secretary

1106#021

RULE

Office of the Governor
Office of Financial Institutions

Broker-Dealer and Investment Adviser Recordkeeping Requirements (LAC 10:XIII.Chapter 17)

In accordance with the Louisiana Securities Law, R.S. 51:701 et seq., and particularly R.S. 51:703(I), as amended, and the Administrative Procedure Act, R.S. 49:950 et seq., the Commissioner of Financial Institutions hereby adopts LAC10:XIII.Chapter 17, a Rule to place a requirement on broker-dealers and investment advisers registered or notice filed with the commissioner to maintain such books and records as set out in §§1701 and 1703 below.

Title 10
FINANCIAL INSTITUTIONS, CONSUMER CREDIT, INVESTMENT SECURITIES AND UCC
Part XIII. Investment Securities
Subpart 1. Securities
Chapter 17. Dealer and Investment Adviser Recordkeeping Requirements

§1701. Broker-Dealer Requirements

A. Unless otherwise provided by order of the Securities and Exchange Commission (hereinafter "SEC"), each broker-dealer registered or required to be registered pursuant to R.S. 51:703(A)(1) shall make, maintain and preserve books and records in compliance with SEC Rules 17a-3 (17 CFR 240.17a-3), 17a-4 (17 CFR 240.17a-4), and 15c2-11 (17 CFR 240.15c2-11), which are adopted and incorporated herein by reference.

B. To the extent that the SEC promulgates changes to the above referenced rules, broker-dealers in compliance with such rules as amended shall not be subject to enforcement action by the commissioner for violation of this rule to the extent that the violation results solely from the broker-dealer's compliance with the amended rule.

AUTHORITY NOTE: Promulgated in accordance with R.S. 51:703(I).

HISTORICAL NOTE: Promulgated by the Office of the Governor, Office of Financial Institutions, LR 37:1611 (June 2011).

§1703. Investment Adviser Requirements

A. Except as provided in Subsection C, unless otherwise provided by order of the SEC, each investment adviser registered or required to be registered pursuant to R.S. 51:703(A)(2) or notice filed pursuant to R.S. 51:703(D)(2) shall make, maintain and preserve books and records in compliance with SEC Rule 204-2 (17 CFR 275.204-2), which is adopted and incorporated by reference, notwithstanding the fact that such investment adviser is not registered or required to be registered under Section 203 of the Investment Advisers Act of 1940.

B. To the extent that the SEC promulgates changes to the above-referenced rules, investment advisers in compliance with such rules as amended shall not be subject to enforcement action by the commissioner for violation of this rule to the extent that the violation results solely from the investment adviser's compliance with the amended rule.

C. Every investment adviser that has its principal place of business in a state other than this state shall be exempt from the requirements of Subsection A, provided the investment adviser is licensed or registered in such state and is in compliance with such state's recordkeeping requirements.

AUTHORITY NOTE: Promulgated in accordance with R.S. 51:703(I).

HISTORICAL NOTE: Promulgated by the Office of the Governor, Office of Financial Institutions, LR 37:1611 (June 2011).

§1705. Cessation of Business

A. Before ceasing to conduct or discontinuing business, each broker-dealer and investment adviser shall arrange for and be responsible for the preservation of the books and records required to be maintained and preserved by this Rule for the remainder of the period specified.

B. Each broker-dealer and investment adviser shall notify the commissioner in writing of the exact address where such books and records will be maintained during such period. The filing with the Central Registration Depository of a Form BD-W by a broker-dealer or a Form ADV-W by an investment adviser shall satisfy this notice requirement.

AUTHORITY NOTE: Promulgated in accordance with R.S. 51:703(I).

HISTORICAL NOTE: Promulgated by the Office of the Governor, Office of Financial Institutions, LR 37:1612 (June 2011).

John Ducrest
Commissioner

1106#012

RULE

Office of the Governor
Used Motor Vehicle Commission

Editor's Note: This Rule is being printed in its entirety to correct an error upon submission. The original Rule may be viewed in the May 20, 2011 edition of the *Louisiana Register* on page 1405.

Licensure and Established Place of Business
(LAC 46:V.2905 and 2907)

Notice is hereby given in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq., and through the authority granted in R.S. 32:783(E), that the Louisiana Used Motor Vehicle Commission has amended LAC 46:V.2905 in order to better facilitate the requirements to become a used motor vehicle dealer. The Louisiana Used Motor Vehicle Commission also amended LAC 46:V.2907 by adding a paragraph in order to better facilitate an established place of business.

Title 46
PROFESSIONAL AND OCCUPATIONAL STANDARDS
Part V. Automotive Industry
Subpart 2. Used Motor Vehicles
Chapter 29. Licenses to be issued by the Used Motor Vehicle Commission

§2905. Qualifications and Eligibility for Licensure

A. The commission, in determining the qualifications and eligibility of an applicant for a dealer's license, shall verify:

1. the applicant has an established place of business properly zoned in the municipality, provide a suitable office, have a permanently affixed sign, clearly visible from the street or roadway at a minimum of 16 square feet and subject to local zoning laws, in front of the establishment which denotes that vehicles are offered for sale at the location to which the sign is affixed. Existing signs prior to adoption of this rule will not have to meet the new requirements. If two or more dealers share a location, each dealer must display his own sign. Applicant must have an installed telephone listed in the business name at the established place of business, the telephone number shall be listed on the application for license;

2. the applicant has the required garage liability insurance policy on all vehicles offered for sale or used in any other capacity in demonstrating or utilizing the streets and roadways in accordance with the financial responsibility laws of the state and for those dealers who conduct the business of daily vehicle rentals, a separate renter's policy is in effect;

3. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 32:791.

HISTORICAL NOTE: Promulgated by the Department of Commerce, Used Motor Vehicle and Parts Commission, LR 11:1062 (November 1985), amended by the Department of Economic Development, Used Motor Vehicle and Parts Commission LR 15:258 (April 1989), LR 15:375 (May 1989), LR 24:1682 (September 1998), LR 25:245 (February 1999), amended by the Office of the Governor, Used Motor Vehicle Commission, LR 30:436 (March 2004), amended but the Office of the Governor, Recreational and Used Motor Vehicle Commission, LR 30:2480 (November 2004), LR 33:1635 (August 2007), amended by the Office of the Governor, Used Motor Vehicle Commission, LR 37:1405 (May 2011), LR 37:1612 (June 2011).

§2907. Established Place of Business

A. …

B. A dealer licensed by the Commission to conduct auctions at an established place of business may conduct a public or retail auction for a specified period of time at a location other than the dealer's established place of business after receipt of a license for the other location. A licensed dealer which conducts a public or retail auction at a location other than the dealer's established place of business shall include the address and telephone number of dealer's established place of business together with a telephone number to be used during the auction on all signs and bills of sale and shall obtain a public retail auction license for the auction location prior to advertising the auction.

AUTHORITY NOTE: Promulgated in accordance with R.S. 32:791.

HISTORICAL NOTE: Promulgated by the Department of Commerce, Used Motor Vehicle and Parts Commission, LR 11:1063 (November 1985), amended by the Office of the Governor, Recreational and Used Motor Vehicle Commission, LR 33:1635 (August 2007), amended by the Office of the Governor, Used Motor Vehicle Commission, LR 37:1405 (May 2011), LR 37:1612 (June 2011).

Derek Parnell
Executive Director

1106#011

RULE

Department of Public Safety and Corrections
Office of State Police
Transportation and Environmental Safety Section

Federal Motor Carrier Regulations
(LAC 33:V.10303)

The Department of Public Safety and Corrections, Office of State Police, in accordance with R.S. 49:950 et seq., and R.S. 32:1501 et seq., hereby amends its rules regulating motor carrier safety and hazardous materials by updating the revision date of the adopted federal motor carrier regulations to January 1, 2011.

Title 33
ENVIRONMENTAL QUALITY
Part V. Hazardous Wastes and Hazardous Materials
Subpart 2. Department of Public Safety and Corrections—Hazardous Materials
Chapter 103. Motor Carrier Safety and Hazardous Materials
§10303. Federal Motor Carrier Safety and Hazardous Materials

A. The following federal motor carrier safety regulations and hazardous materials regulations promulgated by the United States Department of Transportation, revised as of January 1, 2011, and contained in the following Parts of 49 CFR as now in effect or as hereafter amended, are made a part of this Chapter.

Hazardous Material Regulations	
Part 107	Hazardous Materials Program Procedures
Part 171	General Information, Regulations, and Definitions
Part 172	Hazardous Materials Table, Special Provisions, and Hazardous Materials Communications, Emergency Response Information, and Training Requirements
Part 173	Shippers—General Requirements for Shipments and Packagings
Part 177	Carriage by Public Highways
Part 178	Specifications for Packagings
Part 180	Continuing Qualification and Maintenance of Packagings
Motor Carrier Safety Regulations	
Part 355	Compatibility of State Laws and Regulations Affecting Interstate Motor Carrier Operations
Part 360	Fees for Motor Carrier Registration and Insurance
Part 365	Rules Governing Applications for Operating Authority
Part 367	Standards for Registration with States
Part 373	Receipts and Bills
Part 374	Passenger Carrier Regulations
Part 375	Transportation of Household Goods in Interstate Commerce: Consumer Protection Regulations
Part 376	Lease and Interchange of Vehicles
Part 379	Preservation of Records
Part 382	Controlled Substances and Alcohol Use and Testing
Part 383	Commercial Driver's License Standards; Requirements and Penalties
Part 384	State Compliance with Commercial Driver's License Program
Part 385	Safety Fitness Procedures
Part 386	Rules of Practice for Motor Carrier, Broker, Freight Forwarder and Hazardous Materials Proceedings
Part 387	Minimum Levels of Financial Responsibility for Motor Carriers
Part 388	Cooperative Agreements with States
Part 389	Rulemaking Procedures-Federal Motor Carrier Safety
Part 390	Federal Motor Carrier Safety Regulations; General
Part 391	Qualifications of Drivers
Part 392	Driving of Commercial Motor Vehicles
Part 393	Parts and Accessories Necessary for Safe Operation
Part 395	Hours of Service of Drivers
Part 396	Inspection, Repair, and Maintenance
Part 397	Transportation of Hazardous Materials; Driving and Parking Rules

AUTHORITY NOTE: Promulgated in accordance with R.S. 32: 1501 et seq.

HISTORICAL NOTE: Promulgated by the Department of Public Safety and Corrections, Office of State Police, LR 14:31 (January 1988), amended LR 17:1115 (November 1991), LR 19:351 (March 1993), LR 20:58 (January 1994), LR 24:956 (May 1998), LR 24:2321 (December 1998), LR 29:711 (May 2003), LR 30:447 (March 2004), LR 32:641 (April 2006), LR 34:882 (May 2008), amended by the Department of Public Safety and Corrections, Office of State Police, Transportation and Environmental Safety Section, LR 37:1613 (June 2011).

Jill P. Boudreaux
Undersecretary

1106#016

RULE

Department of Revenue
Policy Services Division

Electronic Filing Requirements for Oil or Gas Severance Tax (LAC 61:III.1525)

Under the authority of R.S. 47:1511, which authorizes the Secretary of the Department of Revenue to prescribe rules and regulations to carry out the purposes of Title 47 of the Louisiana Revised Statutes of 1950 and the purposes of any other statutes or provisions included under the secretary's authority, and, in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq., the Department of Revenue, Policy Services Division, has amended LAC 61:III.1525 to mandate electronic filing of the applications for certification of wells for reduced oil or gas severance tax rates.

The Rule provides information relative to the electronic filing mandate. Specifically, the Rule provides that, beginning with the filing of the July 2011 production month application due September 25, 2011, the secretary of revenue will require the gas severance tax application for certification of incapable wells, Form G-2, and the oil severance tax application for certification of stripper/incapable wells, Form O-2, to be electronically filed with the Department of Revenue on or before the twenty-

fifth day of the second month following the production month in which the reduced tax rate(s) is applicable.

Title 61
REVENUE AND TAXATION
Part III. Administrative Provisions and Miscellaneous
Chapter 15. Mandatory Electronic Filing of Tax Returns and Payment
§1525. Severance Tax—Oil or Gas

A. R.S. 47:1520(A)(1)(b) authorizes the secretary of revenue to require electronic filing of tax returns or reports by persons severing oil or gas from the soil or water from the state that are required to file reports under R.S. 47:635(A)(2) or 640(A)(2).

B. R.S. 47:635(A)(2) requires every person severing oil or gas from the soil or water of the state to submit, on or before the twenty-fifth day of the second month following the month to which the tax is applicable, a statement on forms approved by the department, of the business conducted by the severer during the month, showing the gross quantity of oil or gas severed or produced, the names of the owners at the time of severance, the portion owned by each, the location and place(s) where the oil or gas was produced or severed from the soil or water and any other reasonable and necessary information pertaining thereto that the secretary may require.

C. R.S. 47:640(A)(2) requires purchasers and other persons dealing in oil or gas severed from the soil or water in Louisiana to submit, on or before the twenty-fifth day of the second month following the month to which the tax is applicable, to the Department of Revenue a monthly statement on forms approved by the department, showing the names and addresses of all persons from whom they have purchased oil or gas during that month, together with the total quantity of, and gross price paid for the oil or gas, and, at the time the report is made, pay the amount of tax deducted or withheld, or that may be due.

D. Effective with the July 2010 filing period, severers of oil or gas that are required to file reports under R.S. 47:635(A)(2) and 640(A)(2) shall be required to file the tax returns or report electronically with the Department of Revenue using the electronic format prescribed by the department.

E. R.S. 47:633(7)(b) and 633(7)(c)(i)(aa) provide reduced severance tax rates on oil produced from wells that have been certified by the Department of Revenue as "incapable wells" and "stripper wells" on or before the twenty-fifth day of the second month following the month of production.

F. R.S. 47:633(9)(b) and 633(9)(c) provide reduced severance tax rates on gas produced from wells that have been determined by the secretary of revenue to be "incapable oil wells" and "incapable gas wells."

G. Beginning with the July 2011 production month application that is due September 25, 2011, Form G-2, Application for Certification of Incapable Wells, and Form O-2, Application for Certification of Stripper/Incapable Wells, must be filed electronically with the Department of Revenue on or before the twenty-fifth day of the second month following the production month in which the reduced tax rate(s) is applicable. If the due date falls on a weekend or holiday, the application and electronic filing thereof is due on the next business day.

H. Failure to comply with these electronic filing requirements will result in the assessment of a penalty of $100 or five percent of the tax, whichever is greater, as provided by R.S. 47:1520(B).

1. If it is determined that the failure to comply is attributable, not to the negligence of the taxpayer, but to other cause set forth in written form and considered reasonable by the secretary, the secretary may remit or waive payment of the whole or any part of the penalty.

2. If the penalty exceeds $25,000, it may be waived by the secretary only after approval by the Board of Tax Appeals.

3. If the taxpayer can prove electronic filing of a tax return, report, or application for certification would create an undue hardship, the secretary may exempt the taxpayer from filing the return, report, or application electronically.

AUTHORITY NOTE: Promulgated in accordance with R.S. 47:1511, 47:1520, 47:635(A)(2), 47:640(A)(2), 47:633(7)(b), 47:633(7)(c)(i)(aa),. 47:633(9)(b), and 47:633(9)(c).

HISTORICAL NOTE: Promulgated by the Department of Revenue, Policy Services Division, LR 36:1271 (June 2010), amended by the Department of Revenue, Policy Services Division, LR 37:1614 (June 2011).

Cynthia Bridges
Secretary

1106#010

RULE

Department of the Treasury
Board of Trustees of the Louisiana State Employees' Retirement System

Election to the Board of Trustees
(LAC 58:I.Chapters 3, 4, and 5)

The Department of the Treasury, Board of Trustees of the Louisiana State Employees' Retirement System ("LASERS") has amended LAC 58:I.Chapters 3 and 5 and adopted Chapter 4 regarding the election of active and retired persons to the LASERS Board of Trustees. The rule changes consolidate rule duplication into a single common chapter, provide clarification where needed, and update the election process to reflect experience gained in previous elections. These rule changes comply with and are enabled by R.S. 11:515. These Rules will completely supplant Chapters 3 and 5 and create Chapter 4 within Title 58 of the *Louisiana Administrative Code*.

Title 58
RETIREMENT
Part I. Louisiana State Employees' Retirement System
Chapter 3. Election of Active Member Trustees
§301. Eligible Candidates
[Formerly LAC 58:I.303.A]

A. An active member candidate for a position on the board of trustees must be an active member of the system with at least 10 years of credited service (excluding any military service credit) as of the date on which nominations close. Optional retirement plan participants do not acquire service credit and are prohibited from running for trustee positions by §307 of this Chapter.

B. A participant in the Deferred Retirement Option Plan who has not yet terminated state service and who is still employed by the state is eligible to run as an active member candidate for election to the board of trustees, so long as he qualifies under Subsection A of this Section.

C. A rehired retiree who has selected Option 2 of R.S. 11:416 or Option 2 of R.S. 11:416.1 is eligible to run as an active member candidate for election to the board of trustees, so long as he qualifies under Subsection A of this Section.

D. A disability retiree who has returned to work under either R.S. 11:224 or R.S. 11:225 is eligible to run as an active member candidate for election to the board of trustees, so long as he qualifies under subsection A of this Section.

AUTHORITY NOTE: Promulgated in accordance with R.S. 11:511 and R.S. 11:515.

HISTORICAL NOTE: Promulgated by the Department of Treasury, Board of Trustees of the State Employees' Retirement System, LR 22:373 (May 1996), amended LR 23:996 (August 1997), LR 25:1278 (July 1999), LR 26:2633 (November 2000), LR 31:946 (April 2005), LR 34:446 (March 2008), LR 37:1614 (June 2011).

§303. Nomination Process
[Formerly LAC 58:I.303.A]

A. The board of trustees shall accept the name and final four digits of the Social Security number of every candidate nominated by petition of 25 or more active members of the system and shall place the name of such candidates on the ballot, provided each such candidate meets the requirements for trustee. Those active members signing the petition shall also supply the final four digits of their Social Security number. When returning the nominating petition, the candidate should include his qualifications, platform and photograph for inclusion in the election brochure circulated by LASERS. In years where a special election is held, a candidate shall clearly state in his petition whether he is running for a four-year term or for the unexpired portion of the term that is the subject of the special election.

B. The printed name of those persons signing the nominating petition must be legible for purposes of verification. Unverifiable signatories shall not count toward the required total of 25 and may disqualify the petition.

C. In years where a special election is held, a candidate shall clearly state in his petition whether he is running for a four-year term or for the unexpired portion of the term that is the subject of the special election.

AUTHORITY NOTE: Promulgated in accordance with R.S. 11:511 and R.S. 11:515.

HISTORICAL NOTE: Promulgated by the Department of Treasury, Board of Trustees of the State Employees' Retirement System, LR 22:373 (May 1996), amended LR 23:996 (August 1997), LR 25:1278 (July 1999), LR 26:2633 (November 2000), LR 31:946 (April 2005), LR 34:446 (March 2008), LR 37:1615 (June 2011).

§305. Vacancies; Special Elections

A. The board shall appoint a member to fill any active member vacancy created on the board. The appointee shall possess the necessary qualifications under R.S. 11:511 for the active member position. The board may give due consideration to the runners-up in the previous election, if those members are willing to serve and the appointment does not violate law or these regulations.

B. The appointment shall be valid only until January 1 of the year following the next election.

C. When the unexpired term for the vacancy is greater than two years, a special election shall be held to fill the vacancy simultaneous with the election ordinarily held in odd number years. The ballot for the special election may be the same as that used in the regular election. Candidates for four year terms may not also be candidates to complete unexpired terms.

D. The deadlines and procedures for special elections shall be identical to those for elections normally held in years ending with odd numbers.

AUTHORITY NOTE: Promulgated in accordance with R.S. 11:511, R.S. 11:512 and R.S. 11:515.

HISTORICAL NOTE: Promulgated by the Department of the Treasury, Board of Trustees of the State Employees' Retirement System, LR 22:373 (May 1996), amended LR 23:997 (August 1997), LR 35:271 (February 2009), LR 37:1615 (June 2011).

§307. Optional Retirement Plan Participants

A. Because optional retirement plan participants do not acquire service credit for purposes of determining eligibility under R.S. 11:511(4), these participants are not eligible to vote in the trustee elections or run for a position on the board of trustees.

AUTHORITY NOTE: Promulgated in accordance with R.S. 11:511 and R.S. 11:515.

HISTORICAL NOTE: Promulgated by the Department of Treasury, Board of Trustees of the State Employees' Retirement System, LR 26:2633 (November 2000), LR 37:1615 (June 2011).

Chapter 4. Rules Common to the Election of Both Active and Retired Member Trustees

§401. General Schedule of Elections
[Formerly LAC 58:I.301.B and LAC 58:I.501.B]

A. Elections shall be held in years ending with an odd number.

1. Three active member trustees shall be chosen in each election and shall serve a four-year term.

2. Beginning in 1995 and continuing thereafter every four years, two retired member trustees shall be chosen in an election and shall serve a four year term. Beginning in 1997 and continuing thereafter every four years, a single retired trustee shall be chosen in an election and shall serve a four year term.

B. The schedule for elections shall be as follows:

1. first day in March: nominations shall be opened;

2. second Tuesday in July: nominations shall be closed. All nominating petitions must be received by the close of business (4:30 p.m. central time);

3. Friday following second Tuesday in July: a drawing shall be held to determine candidate positions on a ballot;

4. fourth Friday in September: the final day that information on candidates and ballots may be mailed;

5. fourth Friday in October: all ballots or electronic votes must be received by the close of business (4:30 p.m. central time). No faxed ballots shall be accepted;

6. Wednesday following fourth Friday in October: all ballots and electronic votes shall be tallied and verified;

7. regular November meeting: the board shall be presented with the certified ballot count, and if it is accepted, shall authorize publication of results;

8. January following election: newly elected members receive orientation; oaths shall be taken prior to the regular January meeting.

C. In order to facilitate the election process, in the event of a disaster or emergency declared by executive order or proclamation of the governor, the executive director may change the election schedule. Such a schedule change shall be in effect for a single election cycle only, after which the schedule shall return to that set forth in Subsection B of this Section.

AUTHORITY NOTE: Promulgated in accordance with R.S. 11:511 and R.S. 11:515.

HISTORICAL NOTE: Promulgated by the Department of Treasury, Board of Trustees of the State Employees' Retirement System, LR 22:373 (May 1996), amended LR 23:996, 997 (August 1997), LR 25:1278 (July 1999), LR 26:2633 (November 2000), LR 33:1151 (June 2007), LR 34:446, 447 (March 2008), LR 37:1615 (June 2011).

§403. Receipt of Nominating Petitions

A. Signed nominating petitions will be accepted if received by facsimile or emailed by the date nominations are closed so long as original nominating petitions are received by 4:30 p.m. central time on the first Friday following the close of nominations. If originals are not received by that deadline, the person in whose name they are submitted shall not be qualified as a candidate.

AUTHORITY NOTE: Promulgated in accordance with R.S. 11: 511 and R.S. 11:515.

HISTORICAL NOTE: Promulgated by the Department of Treasury, Board of Trustees of the State Employees' Retirement System, LR 37:1616 (June 2011).

§405. Election Process
[Formerly LAC 58:I.303.C-I and LAC 58:I.503.C-J]

A. Active Members—ballots or election brochures shall be distributed to each active member by the fourth Friday in September. This includes active members appearing on the June monthly retirement reports and participants in the DROP program who have not terminated service.

B. Retired Members—ballots or election brochures shall be distributed to each retired member appearing on the June Retiree Master List by the fourth Friday in September.

C. There shall be a drawing at 11 a.m. central time on the Friday following the second Tuesday in July, in the retirement systems building, 8401 United Plaza Boulevard, Baton Rouge, LA, to determine the position each candidate shall have on the ballot or election brochure. All candidates may attend or send a representative to the drawing.

D. Each active member may vote for three candidates.

E. Each retiree may vote for two candidates during the election when two retiree members are up for election, but may only vote for one candidate during the election where only one retiree member is up for election. If electronic voting methods are utilized, members shall follow the instructions on the election brochure for registering their votes.

F. If electronic voting methods are utilized, members shall follow the instructions on the election brochure for registering their votes. Votes shall be confidential. Ballots or electronic votes received after the close of business on the fourth Friday in October (4:30 p.m. central time) shall be rejected. Ballots must be returned to the address set forth in the instructions on the election brochure.

G. All valid ballots shall be tallied on Wednesday following the fourth Friday in October.

H. The executive director shall submit a written report of the election results to the board of trustees no later than the regular November meeting of the board of trustees.

I. Upon receipt of the results of the election, the board of trustees shall timely promulgate the election and notify the successful candidates of their election and the secretary of state, so as to allow the candidates sufficient time to take and file the oath of office with the Secretary of State within the time specified by law.

AUTHORITY NOTE: Promulgated in accordance with R.S. 11:511 and R.S. 11:515.

HISTORICAL NOTE: Promulgated by the Department of Treasury, Board of Trustees of the State Employees' Retirement System, LR 22:373 (May 1996), amended LR 23:996, 997 (August 1997), LR 25:1278 (July 1999), LR 26:1490 (July 2000), LR 26:2633 (November 2000), LR 31:946, 947 (April 2005), LR 34:446, 447 (March 2008), LR 37:1616 (June 2011).

§407. Winning Candidates
[Formerly LAC 58:I.303.B and G, LAC 58:I.501.A and LAC 58:I.503.H]

A.1. Active Members—the three candidates who receive the most votes shall be declared successful candidates and presented to the board.

2. Retired Members—beginning in 1995 and continuing thereafter every four years, the two retired member candidates who receive the most votes shall be declared successful candidates and presented to the board. Beginning in 1997 and continuing thereafter every four years, the retired member candidate who receives the most votes shall be declared the successful candidate and presented to the board.

B. Ties affecting elected positions shall be decided by a coin toss held by the executive director in the presence of the candidates affected or the representative they designate.

C. No department in the executive branch of state government may have more than two trustees serving on the board at the same time.

AUTHORITY NOTE: Promulgated in accordance with R.S. 11:511 and R.S. 11:515.

HISTORICAL NOTE: Promulgated by the Department of Treasury, Board of Trustees of the State Employees' Retirement System, LR 22:373 (May 1996), amended LR 23:996 (August 1997), LR 25:1278 (July 1999), LR 26:2633 (November 2000), LR 31:946 (April 2005), LR 34:446 (March 2008), LR 37:1616 (June 2011).

§409. Candidates Withdrawing Prior to Election

A. A candidate may withdraw his candidacy at any time. If he withdraws prior to the deadline for voting, all votes cast for him shall not be counted.

AUTHORITY NOTE: Promulgated in accordance with R.S. 11:511 and R.S. 11:515.

HISTORICAL NOTE: Promulgated by the Department of Treasury, Board of Trustees of the State Employees' Retirement System, LR 37:1616 (June 2011).

§411. No Solicitation
[Formerly LAC 58:I.303.J and LAC 58:I.503.K]

A. Candidates for election to the LASERS board of trustees shall not solicit employees of LASERS to participate in their campaigns, and LASERS' employees cannot participate, or give assistance to any member who is running for election or re-election to the board. Candidates shall not solicit or have contact with any vendor or employee

of a vendor who is providing LASERS with products or services related to elections of the LASERS board of trustees. LASERS employees are free to sign nominating petitions.

AUTHORITY NOTE: Promulgated in accordance with R.S. 11:511 and R.S. 11:515.

HISTORICAL NOTE: Promulgated by the Department of Treasury, Board of Trustees of the State Employees' Retirement System, LR 22:373 (May 1996), amended LR 23:996 (August 1997), LR 25:1278 (July 1999), LR 26:2633 (November 2000), LR 31:946 (April 2005), LR 34:446 (March 2008), LR 37:1616 (June 2011).

Chapter 5. Election of Retired Member Trustees

§501. Eligible Candidates
[Formerly LAC 58:I.503.A]

A. A candidate for a position of retired member trustee on the board of trustees must be a retired member of the system who has been on retired status (not including retired status under the Deferred Retirement Option Plan) by the date on which nominations close.

B. A rehired retiree who selected either Option 1 or Option 3 of R.S. 11:416 or Option 1, Option 3 or Option 4 of R.S. 11:416.1 is eligible to run as a candidate for a position of retired member trustee on the board of trustees.

C. A participant in the Deferred Retirement Option Plan who has not yet terminated state service and who is still employed by the state is not eligible to run for board election as a retired member candidate.

D. A disability retiree who has returned to work under either R.S. 11:224 or R.S. 11:225 is not eligible to run as a retired member candidate for election to the board of trustees.

AUTHORITY NOTE: Promulgated in accordance with R.S. 11:511 and R.S. 11:515.

HISTORICAL NOTE: Promulgated by the Department of Treasury, Board of Trustees of the State Employees' Retirement System, LR 22:373 (May 1996), amended LR 23:997 (August 1997), LR 25:1278 (July 1999), LR 26:1490 (July 2000), LR 26:2633 (November 2000), LR 31:947 (April 2005), LR 34:447 (March 2008), LR 37:1617 (June 2011).

§503. Nomination Process

A. The board of trustees shall accept the name and final four digits of the Social Security number of every candidate nominated by petition of 25 or more retired members of the system and shall place the name of such candidates on the ballot, provided each such candidate meets the requirements for trustee. Those retired members signing the petition shall also supply the final four digits of their Social Security number. When returning the nominating petition, the candidate should include his qualifications, platform and photograph for inclusion in the election brochure circulated by LASERS.

B. The printed name of those persons signing the nominating petition must be legible for purposes of verification. Unverifiable signatories shall not count toward the required total of 25 and may disqualify the petition.

C. In years where a special election is held, a candidate shall clearly state in his petition whether he is running for a four-year term or for the unexpired portion of the term that is the subject of the special election.

AUTHORITY NOTE: Promulgated in accordance with R.S. 11:511 and R.S. 11:515.

HISTORICAL NOTE: Promulgated by the Department of Treasury, Board of Trustees of the State Employees' Retirement System, LR 22:373 (May 1996), amended LR 23:997 (August 1997), LR 25:1278 (July 1999), LR 26:1490 (July 2000), LR 26:2633 (November 2000), LR 31:947 (April 2005), LR 34:447 (March 2008), LR 37:1617 (June 2011).

§505. Vacancies; Special Elections
[Formerly LAC 58:I.507]

A. The Executive Board of the Retired State Employees Association shall appoint a member to fill any retired member vacancy created on the board. The appointee shall possess the necessary qualifications under R.S. 11:511 for the retired member position.

B. The appointment shall be valid only until January 1 of the year following the next election.

C. When the unexpired term for the vacancy is greater than two years, a special election shall be held to fill the vacancy simultaneously with the election ordinarily held in odd number years. The ballot for the special election may be the same as that used in the regular election.

D. The deadlines and procedures for special elections shall be identical to those for elections normally held in years ending with odd numbers.

AUTHORITY NOTE: Promulgated in accordance with R.S. 11:511, R.S. 11:512 and R.S. 11:515.

HISTORICAL NOTE: Promulgated by the Department of the Treasury, Board of Trustees of the State Employees' Retirement System, LR 23:998 (August 1997), amended LR 37:1617 (June 2011).

Cindy Rougeou
Executive Director

1106#033

RULE

Department of the Treasury
Deferred Compensation Commission

Public Employees Deferred Compensation Plan
(LAC 32:VII.101, 301, 305, 317, 323,
709,721, 723, and 1107)

The Louisiana Deferred Compensation Commission (the "LDCC"), in accordance with R.S. 49:950 et seq., and R.S. 42:1303-1303.1, has amended the Louisiana Public Employees Deferred Compensation Plan. The Rule updates the plan for IRS compliance and references the appropriate sections of the Internal Revenue Code.

Title 32
EMPLOYEE BENEFITS
Part VII. Public Employee Deferred Compensation
Subpart 1. Deferred Compensation Plan

Chapter 1. Administration

§101. Definitions

Account Balance—

1. the bookkeeping account maintained with respect to each participant which reflects the value of the deferred compensation credited to the participant, including:

a. the participant's total amount deferred;

b. the earnings or loss of the fund (net of fund expenses) allocable to the participant;

c. any transfers for the participant's benefit; and

d. any distribution made to the participant or the participant's beneficiary:

i. if a participant has more than one beneficiary at the time of the participant's death, then each beneficiary's share of the account balance shall be treated as a separate account for each beneficiary;

2. the *account balance* includes:

a. any account established under §505 for rollover contributions and plan-to-plan transfers made for a participant;

b. the account established for a beneficiary after a participant's death; and

c. any account or accounts established for an alternate payee [as defined in Code §414(p)(8)].

Administrator or *Plan Administrator*—the person, persons or entity appointed by the Louisiana Deferred Compensation Commission to administer the plan pursuant to LAC 32:VII.103.A, if any.

Age 50 or Older Catch-Up—the deferred amount described pursuant to LAC 32:VII.303.C.

Alternate Payee—the spouse, former spouse, child or other dependent of a participant who has acquired an interest in the participant's account pursuant to a Qualified Domestic Relations Order (QDRO) pursuant to §1503. Alternate payees shall be treated as beneficiaries for all purposes under the plan except that alternate payees shall be allowed to request a distribution of all or a portion of their account balance at any time, subject to the terms of the QDRO.

Beneficiary—the person, persons or entities designated by a participant pursuant to §301.A.5 who is entitled to receive benefits under the plan after the death of a participant.

Commission—the Louisiana Deferred Compensation Commission, as established in accordance with R.S. 42:1302, which shall be comprised of the state treasurer, the commissioner of administration, the commissioner of insurance, the commissioner of financial institutions (or their designees), and three participant members (elected by the participants).

Compensation—all payments paid by the employer to an employee or independent contractor as remuneration for services rendered, including salaries and fees, and, to the extent permitted by treasury regulations or other similar guidance, accrued vacation and sick leave pay paid within 2 and 1/2 months of participant's severance from employment so long as the employee would have been able to use the leave if employment had continued.

Custodial Account—the account established with a bank or trust company meeting the provisions of Internal Revenue Code (IRC) §401(f), that the commission has elected to satisfy the trust requirement of IRC §457(g) by setting aside plan assets in a custodial account.

Custodian—the bank or trust company or other person, if any selected by the commission to hold plan assets in a custodial account in accordance with regulations pursuant to IRC §457(g) and 401(f).

Deferred Compensation—the amount of compensation not yet earned, which the participant and the commission mutually agree, shall be deferred.

Employee—any individual who is employed by the employer, either as a common law employee or an independent contractor, including elected or appointed individuals providing personal services to the employer. Any *employee* who is included in a unit of employees covered by a collective bargaining agreement that does not specifically provide for participation in the plan shall be excluded.

Includible Compensation—an employee's actual wages in Box 1 of Form W-2 for a year for services to the employer, but subject to a maximum of $200,000 [or such higher maximum as may apply under Code §401(a)(17)] and increased (up to the dollar maximum) by any compensation reduction election under Code §§125, 132(f), 401(k), 403(b), or 457(b) [for purposes of the limitation set forth in §303.A, compensation for services performed for the employer as defined in IRC §457(e)(5)].

Independent Contractor—an individual (not a corporation, partnership, or other entity), who is receiving compensation for services rendered to or on behalf of the employer in accordance with a contract between such individual and the employer.

Interest or *Interest in Deferred Compensation*—under the plan, the aggregate of:

1. a participant's deferred compensation for his or her entire period of participation in the plan; and

2. the earnings or losses allocable to such amount. Such interest represents an accounting entry only and does not constitute an ownership interest, right or title in the assets so invested.

Investment Product—any form of investment designated by the commission for the purpose of receiving funds under the plan.

IRC—the *Internal Revenue Code* of 1986, as amended, or any future United States Internal Revenue law. References herein to specific section numbers shall be deemed to include treasury regulations thereunder and Internal Revenue Service guidance thereunder and to corresponding provisions of any future United States internal revenue law. All citations to sections of the Code are to such sections as they may from time to time be amended or renumbered.

Limited Catch-Up—the deferred amount described in LAC 32:VII.305.A.

Non-Elective Employer Contribution—any contribution made by an employer for the participant with respect to which the participant does not have the choice to receive the contribution in cash or property. Such term may also include an employer matching contribution.

Normal Retirement Age—

1. the age designated by a participant, which age shall be between:

a. the earliest date on which such participant is entitled to retire under the public retirement system of which that participant is a member without actuarial reduction in his or her benefit; and

b. age 70 1/2, provided, however, that if a participant continues in the employ of the employer beyond 70 1/2, *normal retirement age* means the age at which the participant severs employment;

2. if the participant is not a member of a defined benefit plan in any public retirement system, the participant's normal retirement age may not be earlier than age 65, and may not be later than age 70 1/2. A special rule shall apply to qualified police or firefighters under the plan, if any. Any qualified police or firefighter, as defined under §415(b)(2)(H)(ii)(I), who is participating in the plan may choose a normal retirement age that is not earlier than age 40 nor later than age 70 1/2;

3. if a participant continues to be employed by employer after attaining age 70 1/2, not having previously elected an alternate normal retirement age, the participant's alternate normal retirement age shall not be later than the mandatory retirement age, if any, established by the employer, or the age at which the participant actually severs employment with the employer if the employer has no mandatory retirement age.

Participant—an individual who is eligible to defer compensation under the plan, and has executed an effective deferral authorization. *Participant* also includes an employee or independent contractor who has severance from employment but has not received a complete distribution of his or her interest in deferred compensation under the plan.

Participation Agreement—the agreement executed and filed by an individual who is eligible to defer compensation under the plan, and has executed an effective deferral authorization.

Pay Period—a regular accounting period designated by the employer for the purpose of measuring and paying compensation earned by an employee or independent contractor.

Plan—the State of Louisiana Public Employees Deferred Compensation Plan established by this document and any applicable amendment.

Plan Year—the calendar year.

Qualified Domestic Relations Order or *QDRO*—as specified in LAC 32:VII.1503.B.

Qualified Military Service—any service in the uniformed service (as defined in Chapter 43 of Title 38 of the United States Code as in effect as of December 12, 1994) by any individual if such individual is entitled to reemployment rights under such Chapter with respect to such service.

Section 3121 Participant—an individual who is using the Plan as a retirement system providing FICA replacement benefits pursuant to IRC §3121(b)(7)(F) and the regulations thereunder.

Separation from Service or *Separates from Service*—

1. with respect to an employee, the permanent severance of the employment relationship with the employer on account of such employee's:

a. retirement;

b. discharge by the employer;

c. resignation;

d. layoff; or

e. in the case of an employee who is an appointed or elected officer, the earlier of:

i. the taking of the oath of office of such officer's successor; or

ii. the cessation of the receipt of compensation

2. if an employee incurs a break in service for a period of less than 30 days or transfers among various Louisiana governmental entities, such break or transfer shall not be considered a separation from service;

3. with respect to an independent contractor, *separation from service* means that the expiration of all contracts pursuant to services performed for or on behalf of the employer.

Severance from Employment or *Severs Employment*—

1. the date the employee dies, retires, or otherwise has a severance from employment with the employer, as determined by the administrator (and taking into account guidance issued under the Code). An employee whose employment is interrupted by qualified military service under Code §414(u) shall be deemed severed from employment until such time as he or she is reemployed following the term of duty. A participant shall be deemed to have severed employment with the employer for purposes of this plan when both parties consider the employment relationship to have terminated and neither party anticipates any future employment of the participant by the employer. In the case of a participant who is an independent contractor, severance from employment shall be deemed to have occurred when:

a. the participant's contract for services has completely expired and terminated;

b. there is no foreseeable possibility that the employer shall renew the contract or enter into a new contract for services to be performed by the participant; and

c. it is not anticipated that the participant shall become an employee of the employer;

2. with respect to an employee, the permanent severance of the employment relationship with the employer on account of such employee's:

a. retirement;

b. discharge by the employer;

c. resignation;

d. layoff; or

e. in the case of an employee who is an appointed or elected officer, the earlier of:

i. the taking of the oath of office of such officer's successor; or

ii. the cessation of the receipt of compensation;

3. if an employee incurs a break in service for a period of less than 30 days or transfers among various Louisiana governmental entities, such break or transfer shall not be considered a severance from employment.

Total Amount Deferred—with respect to each participant, the sum of all compensation deferred under the plan (plus investment gains and/or losses thereon, including amounts determined with reference to life insurance policies) calculated in accordance with the method designated in the participant's participation agreement(s) under which such compensation was deferred and any subsequent election(s) to change methods, less the amount of any expenses or distributions authorized by this plan.

Trustee—the commission or such other person, persons or entity selected by the commission who agrees to act as *trustee*. This term also refers to the person holding the assets of any custodial account or holding any annuity contract described in LAC 32:VII.317.

Unforeseeable Emergency—

1. severe financial hardship of a participant or beneficiary resulting from:

a. an illness or accident of the participant or beneficiary, the participant's or beneficiary's spouse, or the participant's or beneficiary's dependent (as defined in IRC §152, and without regard to IRC §152(b)(1), (b)(2), and (d)(1)(B));

b. loss of the participant's or beneficiary's property due to casualty (including the need to rebuild a home following damage to a home not otherwise covered by homeowner's insurance, such as damage that is the result of a natural disaster); or

c. other similar extraordinary and unforeseeable circumstances arising as a result of events beyond the control of participant or beneficiary;

2. the definition of *unforeseeable emergency* does not include either the purchase of a home or the payment of college tuition;

3. The definition of *unforeseeable emergency* includes, but is not limited to, the following:

a. payment of mortgage payments or rent due to imminent foreclosure of or eviction from the participant's or beneficiary's primary residence;

b. the need to pay for medical expenses, including non-refundable deductibles, as well as for the cost of prescription drug medication; and

c. the need to pay for funeral expenses of a spouse or dependent (as defined above) of a participant or beneficiary.

AUTHORITY NOTE: Promulgated in accordance with IRC §457 and R.S. 42:1301-1308.

HISTORICAL NOTE: Promulgated by the Department of the Treasury, Deferred Compensation Commission, LR 24:1962 (October 1998), amended LR 28:1494 (June 2002), LR 32:118 (January 2006), LR 37:1617 (June 2011).

Chapter 3. Plan Participation, Options and Requirements

§301. Enrollment in the Plan

A. The following applies to compensation deferred under the plan.

1. - 3. ...

4. Notwithstanding §301.A.1, to the extent permitted by applicable law, the administrator may establish procedures whereby each employee becomes a participant in the plan (automatic enrollment) and, as a term or condition of employment, elects to participate in the plan and consents to the deferral by the employer of a specified amount for any payroll period for which a participation agreement is not in effect. In the event such procedures are in place, a participant may elect to defer a different amount of compensation per payroll period, including zero, by entering into a participation agreement.

a. Within a reasonable period of time before each plan year, the commission shall give to each employee to whom an automatic enrollment arrangement described in §301.A.4 applies for such year notice of the employee's rights under such arrangement.

b. The notice provided for in §301.A.4.a above shall provide an explanation of the employee's rights and obligations under the arrangement, including the right to elect not to have contributions made on the employee's behalf or to have such contributions made at a different percentage. The notice shall also provide an explanation of how contributions made under the arrangement will be invested in the absence of any investment election by the employee.

5. - 6. ...

AUTHORITY NOTE: Promulgated in accordance with IRC §457 and R.S. 42:1301-1308.

HISTORICAL NOTE: Promulgated by the Department of the Treasury, Deferred Compensation Commission, LR 24:1964 (October 1998), amended LR 28:1495 (June 2002), LR 32:119 (January 2006), LR 37:1620 (June 2011).

§305. Limited Catch-Up

A. - A.1. …

2. the sum of:

a. an amount equal to the aggregate limit determined by §303A. of this Plan for the current year and any prior calendar years beginning after December 31, 2001, during which the participant was eligible to participate in this Plan, minus the aggregate amount of compensation that the participant deferred under this Plan during such years, plus

b. an amount equal to the aggregate limit referred to in IRC §457(b)(2) for each prior calendar year beginning after December 31, 1978, and before January 1, 2002, during which the participant was an employee, minus the aggregate contributions made by the participant to pre-2002 coordination plans for such years.

B. - C.2. …

AUTHORITY NOTE: Promulgated in accordance with IRC §457 and R.S. 42:1301-1308.

HISTORICAL NOTE: Promulgated by the Department of the Treasury, Deferred Compensation Commission, LR 24:1965 (October 1998), amended LR 28:1496 (June 2002), LR 32:120 (January 2006), LR 37:1620 (June 2011).

§317. Custody of Plan Assets

A. - A.2. …

3. All amounts deferred under the Plan shall be transferred by the employer to the Commission for investment through an account described in §317.A.1 or 2 above within 15 business days following the month in which such amounts would have otherwise been paid to the participant.

AUTHORITY NOTE: Promulgated in accordance with IRC §457 and R.S. 42:1301-1308.

HISTORICAL NOTE: HISTORICAL NOTE: Promulgated by the Department of the Treasury, Deferred Compensation Commission, LR 24:1966 (October 1998), LR 37:1620 (June 2011).

§323. Section 3121 Participants

A. Notwithstanding any other provisions in this plan to the contrary, the following shall apply to all section 3121 participants:

1. annual allocations to each section 3121 participant's account must be equal to at least 7.5 percent of the participant's annual compensation;

2. all amounts deferred by a section 3121 participant shall be held in a non-forfeitable account. Such account shall be credited with earnings at a rate that is reasonable under all the facts and circumstances or employees' accounts are held in a separate trust that is subject to general fiduciary standards and are credited with actual net earnings on the trust fund, in accordance with IRS Treas. reg. §31.3121(b)(7)-2(e)(2)(iii);

3. no distributions from the Plan shall be made to a section 3121 participant before such Participant severs employment.

B. In the event a section 3121 participant no longer intends to use the plan as a retirement system providing FICA replacement benefits pursuant to IRC §3121(b)(7)(F) and the regulations thereunder, the participant may transfer any amounts being held pursuant to this Subsection to an account described in §505 of the plan.

AUTHORITY NOTE: Promulgated in accordance with IRC §457 and R.S. 42:1301-1308.

HISTORICAL NOTE: Promulgated by the Department of the Treasury, Deferred Compensation Commission, LR 37:1620 (June 2011).

Chapter 7. Distributions

§709. Unforeseeable Emergency

A. - A.4. ...

B. The following events are not considered unforeseeable emergencies under the Plan:

1. enrollment of a child in college;
2. purchase of a house;
3. purchase or repair of an automobile, except due to a casualty loss or other similar extraordinary and unforeseeable circumstances arising as a result of events beyond the control of the participant or beneficiary;
4. repayment of loans (unless the loan was the direct result of an unforeseeable emergency, as defined in section 101 of the plan);
5. payment of income taxes, back income taxes, or fines associated with back income taxes (except for income taxes which result from a distribution made in connection with an unforeseeable emergency, as defined in section 101 of the plan);
6. marital separation or divorce; or
7. bankruptcy (except when bankruptcy resulted directly from an unforeseeable emergency, as defined in section 101 of the plan).

AUTHORITY NOTE: Promulgated in accordance with IRC §457 and R.S. 42:1301-1308.

HISTORICAL NOTE: Promulgated by the Department of the Treasury, Deferred Compensation Commission, LR 24:1968 (October 1998), amended LR 28:1498 (June 2002), LR 32:122 (January 2006), LR 37:1621 (June 2011).

§721. Transfers and Rollovers

A. - B. …

C. Section 3121 Participant Transfers. If a participant was formerly a section 3121 participant, then the plan shall accept assets representing amounts deferred under §323 of this plan, provided the participant remains an employee.

D. Rollovers to the Plan

1. The plan shall accept a rollover contribution on behalf of a participant or employee who may become a participant. A rollover contribution, for purposes of this Subsection, is an eligible rollover contribution (as defined in IRC §402(f)(2)) from any:

a. plan qualified under IRC §401(a) or 403(a);

b. tax-sheltered annuity or custodial account described in IRC §403(b);

c. individual retirement account or annuity described in IRC §408;

d. eligible deferred compensation plan described in IRC §457(b).

2. Prior to accepting any rollover contribution, the commission must reasonably conclude, after a good faith effort, that the amount to be rolled over to the plan is a valid rollover within the meaning of the Internal Revenue Code. A participant's rollover contribution shall be held in a separate rollover account or accounts, as the commission shall determine from time to time. If, at any time, a rollover contribution is determined to be invalid, the commission shall distribute to the participant any such amount determined to be invalid within a reasonable period of time after such a determination is made.

AUTHORITY NOTE: Promulgated in accordance with IRC §457 and R.S. 42:1301-1308.

HISTORICAL NOTE: Promulgated by the Department of the Treasury, Deferred Compensation Commission, LR 24:1969 (October 1998), amended LR 28:1499 (June 2002), LR 37:1621 (June 2011).

§723. Eligible Rollover Distributions

A. …

B. Notice. The commission shall, within a reasonable period of time before making an eligible rollover distribution, provide a written explanation to the distributee explaining the following, as amended from time to time by applicable changes to the law:

1. the provisions under which the distributee may have the distribution directly transferred to an eligible retirement plan and that the automatic distribution by direct transfer applies to certain distributions in accordance with §401(a)(31)(B) of the Internal Revenue Code;
2. the provision which requires the withholding of tax on the distribution if it is not directly transferred to an eligible retirement plan;
3. the provisions under which the distribution will not be subject to tax if transferred to an eligible retirement plan within 60 days after the date on which the recipient received the distribution;
4. the provisions under which distributions from the eligible retirement plan receiving the distribution may be subject to restrictions and tax consequences which are different from those applicable to distributions from the plan making such distribution.

C. Definitions. For purposes of this §723, the following definitions shall apply.

Direct Rollover—a payment by the plan to the eligible retirement plan specified by the distributee.

Distributee—includes an employee or former employee, the employee's or former employee's surviving spouse and the employee's or former employee's spouse or former spouse who is the alternate payee under a *qualified domestic relations order*, as defined in IRC §414(p), are distributees with regard to the interest of the spouse or former spouse.

Eligible Retirement Plan—an eligible retirement plan is an individual retirement account described in IRC §408(a), an individual retirement annuity described in IRC §408(b), an annuity plan described in IRC §403(a) that accepts the distributee's eligible rollover distribution, a qualified trust described in IRC §401(a) (including §401(k)) that accepts the distributee's eligible rollover distribution, a tax-sheltered annuity described in IRC §403(b) that accepts the distributee's eligible rollover distribution, or another eligible deferred compensation plan described in IRC §457(b) that accepts the distributee's eligible rollover distribution. However, in the case of an eligible rollover distribution to the surviving spouse, an eligible retirement plan is an individual retirement account or individual retirement annuity.

Eligible Rollover Distribution—any distribution of all or any portion of the balance to the credit of the distribute, except that an eligible rollover distribution does not include any distribution that is one of a series of substantially equal periodic payments (not less frequently than annually) made

for the life (or life expectancy) of the distributee or the joint lives (or joint life expectancies and the distributee's designated beneficiary, or for:

a. a specified period of 10 years or more;

b. any distribution to the extent such distribution is required under IRC §401(a)(9);

c. any distribution that is a deemed distribution under the provisions of IRC §72(p);

d. the portion of any distribution that is not includable in gross income; and

e. any hardship distribution or distribution on account of unforeseeable emergency.

Reasonable Period of Time—shall have the meaning assigned to it under §401(a)(31) of the Internal Revenue Code and the regulations thereunder.

AUTHORITY NOTE: Promulgated in accordance with R.S. 42:1301-1308 and IRC §457.

HISTORICAL NOTE: Promulgated by the Department of the Treasury, Deferred Compensation Commission, LR 24:1969 (October 1998), amended LR 28:1499 (June 2002), LR 32:123 (January 2006), LR 37:1621 (June 2011).

Chapter 11. Participant Loans

§1107. Loan Terms and Conditions

A. - A.9.c. …

10. Loans shall not be available for a period of 30 days following the repayment of a previous loan from the plan.

AUTHORITY NOTE: Promulgated in accordance with R.S. 42:1301-1308 and IRC §457.

HISTORICAL NOTE: Promulgated by the Department of the Treasury, Deferred Compensation Commission, LR 24:1969 (October 1998), amended LR 28:1499 (June 2002), LR 32:123 (January 2006), LR 37:1622 (June 2011).

Emery Bares
Chairman

1106#023

RULE

Department of Wildlife and Fisheries
Wildlife and Fisheries Commission

Methods of Payment for Commercial Licenses and Oyster Tags (LAC 76:VII.413)

The Wildlife and Fisheries Commission does hereby promulgate rules and regulations relative to credit card or business checks purchases. Authority to establish such rules and regulations is vested in the Wildlife and Fisheries Commission by R.S. 56:642(C).

Title 76
WILDLIFE AND FISHERIES
Part VII. Fish and Other Aquatic Life

Chapter 4. License and License Fees

§413. Methods of Payment for Commercial Licenses and Oyster Tags

A. Commercial licenses and oyster tags may be purchased using the following forms of payment:

1. cash;
2. money order;
3. cashier's check;
4. business checks certified by the issuing bank; and
5. credit cards (MasterCard, American Express, or Discover only).

B. Payment by credit card will be allowed only by the card holder at the Baton Rouge Licensing location with the credit card present at the time of purchase.

C. No other forms of payment will be accepted.

AUTHORITY NOTE: Promulgated in accordance with R.S. 56:642(C).

HISTORICAL NOTE: Promulgated by the Department of Wildlife and Fisheries, Wildlife and Fisheries Commission, LR 37:1622 (June 2011).

Robert J. Barham
Secretary

1106#019

RULE

Department of Wildlife and Fisheries
Wildlife and Fisheries Commission

Oyster Leases (LAC 76:VII.501)

The Wildlife and Fisheries Commission does hereby amend the rules on oyster leases.

Title 76
WILDLIFE AND FISHERIES
Part VII. Fish and Other Aquatic Life

Chapter 5. Oysters

§501. Oyster Leases

A. Office Policies and Procedures

1. Office hours will be from 8 a.m. to 4:30 p.m., Monday through Friday excluding state holidays.

2. No one is to go into the lease document or quadrangle files, or application registration without permission of and accompaniment by designated office personnel.

B. Oyster Lease Applications

1. All applicants must appear in person at the Oyster Lease Section office to apply for an oyster lease, or provide power of attorney to agents to act in their behalf.

a. No application for new area will be accepted from any person not of the full age of majority (18 years).

2. An applicant will be required to outline on a department map the area for which he wishes to apply. Pursuant to R.S. 56:427(A), each element of the verbal description written on the application must be met by the survey plat. Additionally, the survey plat must conform completely to the map outline attached to and made a part of the application; provided, however, that deviations from the map outline (but not the verbal written description) are permitted when such a deviation would not encroach on a neighboring lease or application, or when the signed, written consent of the leaseholder or applicant whose lease or application would be affected, has been granted. In no case will an applicant survey outside of his verbal written description, except as provided in Clause 2.a.ii below.

a. In the event of department error which results in an application being taken in an area where there is a prior undisclosed application or lease which prevents the applicant from taking the full amount of acreage applied for in the area described, the following procedure shall apply. The applicant shall have the option of:

i. taking all available remaining acres within the originally described area in a lease; or

ii. taking all applied-for acres in one lease outside of the originally described area but in the nearest unencumbered water bottom; or

iii. if neither of the above options is acceptable to the applicant, the applicant may have his original application cancelled and receive a full refund of the application fee.

b. The applicant shall have 30 days, from the date of notification by certified letter of the conflict, to exercise the above options.

c. If the applicant exercises the option as set out in Clause 2.a.ii above he shall be held to the amount of acres in his original application plus 10 percent.

d. In all such cases, the department shall have final approval of all relocations.

e. Before having the relocation area surveyed, it shall be necessary for the applicant to submit a new application for the area of relocation. This application shall be identified as a "relocation" application and shall indicate the old application by number for which it is being substituted and shall also be approved in writing by the Administrator of the Fisheries Division of the department. There will be no charge for the relocation application.

f. All relocations shall follow this procedure. No survey shall proceed until the properly completed relocation application has been submitted, accepted and approved. No survey is authorized without the above procedure being followed nor shall the department be responsible for the cost of any survey performed prior to final approval of the relocated application.

3. Where distances between oyster leases or between oyster leases and the shoreline are 200 feet or less, no applications or leases shall be taken or issued except that the intervening space may be shared equally by the existing leases or applicants if properly applied for and leased in accordance with existing policies and practices.

4. No new application will be taken or lease issued whose length exceeds its narrowest width by more than a factor of three except as follows:

a. between existing leases where all available water bottoms are taken;

b. in bayous (or similar configurations, connections or cuts between bays, lakes and ponds, etc.) where all available water bottoms are taken with a subservient clause prohibiting an impedance of reasonable navigation.

5. Any application for an oyster lease may be contoured to follow the shoreline.

6. Upon death of an applicant the estate will have 180 days to appoint a representative to deal with the applications. If the department has not been notified within 180 days the application will be cancelled and fees will be retained.

7. No application for lease shall be transferrable.

8. An application will automatically be cancelled unless an applicant submits a complete survey, meeting department specifications, no later than 1.5 years after the date of submission of the lease application.

C. Application Fees

1. Application fees for new leases will be $40.

2. Application fees on leases expiring by 15-year limitation will be $30.

D. Private Surveyors Surveying Oyster leases for Oyster Farmer

1. Surveyor to be charged the basic rate for copies of documents needed.

2. All corners of oyster lease surveys to be referenced to the Louisiana State Plane Coordinate System, South Zone, NAD83, Survey Feet.

3. Surveyors to plot on the survey plat any land, any existing structures or improvements within or adjacent to the application boundary.

4. Survey plats to be drawn in black ink on standard oyster lease plats furnished by the Louisiana Department of Wildlife and Fisheries Oyster Lease Section and original to become the property of same. Surveyors to provide a formatted ascii file of the coordinates for each corner of the survey that complies with the Oyster Lease Section's geographic information system.

5. The acreage of all surveys, even though calculated to tenth or hundredth of acre, to be rounded up to the next highest acre.

6. Application number and ownership to be shown on all survey plats as indicated on the original application.

7. No land area to be included in survey.

8. Use standard signs and symbols.

9. If a private surveyor repeatedly surveys over an existing lease, application or land area, that private surveyor will be reported to the Louisiana State Board of Professional Engineers and Land Surveyors.

10. Noncompliance with any requirement established by law or by these rules, after 30-day notification from the department by certified mail, shall result in cancellation of the application or lease and forfeiture of all fees to the department.

E. Office Procedures and Fees

1. If any survey of existing leases shows an overlap, the department will abstract the leases involved and eliminate the overlap, giving the area to the longest continuously uninterrupted lease and shall notify the lessees of the action.

2. Annual rental notices will be mailed to lessees at least 30 days in advance of due date which is January 1 of each year.

3. A fee of $10 per lease will be charged for transfer of an oyster lease.

4. A fee for all extra maps, leases, plats or documents, will be charged as follows.

All maps	$ 10 per copy
Plats	$ 5 per copy
Lease Documents	$ 5 per copy
Other materials	$ 1 per copy
Computations	$ 2 per point
(State Plane to Latitude/Longitude)	

F. Oyster Lease Posting Requirements. In an effort to comply with R.S. 56:430(B), and to keep within the constraints of R.S. 14:63 dealing with criminal trespassing, the following are the posting oyster lease requirements.

1. The oyster lessee or person seeking to post the oyster lease shall place and maintain signs along the boundaries of the property or area to be posted. These signs shall be written in the English language.

2. The signs shall have letters at least three inches in height and shall be of sufficient size and clarity to give notice to the public of the location and boundary of the oyster lease. The signs shall be placed and maintained at intervals of not more than one-fifth of a mile and shall be at least 3 to 12 feet above the water level.

3. At the main entrance to the property and at no less than all corners along the boundary of said property, the party seeking to post same shall include his name, initials, or lease number.

4. In marsh areas and canals, posted signs shall also be placed at all major points of ingress and egress.

5. In open waters all signs are to be placed facing outward.

G. Policy to Comply with Laws Concerning Default in Payment of Rent on Oyster Leases (Noncompliance R.S. 56:429)

1. On the first working day in February of each year, the Survey Section will compile a list of leases that are in default (R.S. 56:429). After compiling the list each owner will be notified by certified mail that his lease is in default and will be offered at public auction on the last Tuesday in March. He will also be notified that all works, improvements, betterments, and oysters on the leased area are the property of the state and that the Enforcement Division of the Louisiana Department of Wildlife and Fisheries has been so notified.

2. On the first working day following the last day of February all leases still in default will be advertised in a newspaper in the parish in which the lease is located. After the placement of the advertisement, advertisement cost will be added to the lease rent plus 10 percent. Up to and including the second Monday in March, the leases may be reinstated by payment of the rent due plus 10 percent and the advertising cost if applicable.

3. On the last Tuesday in March the auction will be held at a place to be designated by the Louisiana Department of Wildlife and Fisheries. The auctioneer will be the chief surveyor or his designee. The opening bid for each lease will be the rent due plus 10 percent and advertising cost. All sales must be paid for in cash or by check. The auction will start with the lowest numbered lease and continue numerically until complete.

4. Any leases not sold at auction will be removed from the Oyster Lease Section maps. The area will be open and may be taken by application.

H. Procedures to Comply with R.S. 56:432

1. The Oyster Lease Section will keep an indexing system to determine the acreage held by all oyster lease holders.

2. No application will be accepted that will cause an applicant to exceed a total of 2,500 acres under lease and application. Reference R.S. 56:432.

3. An oyster lease applicant will be given 30 days to reduce lease acreage prior to cancellation of any application that would cause his lease acreage to exceed 2,500 acres. If the reduction is not made within 30 days the application will be cancelled and all fees retained by the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 56:6(10) and R.S. 56:422.

HISTORICAL NOTE: Promulgated by the Department of Wildlife and Fisheries, Wildlife and Fisheries Commission, LR 10:470 (June 1984), amended LR 12:844 (December 1986), LR 15:197 (March 1989), LR 17:808 (August 1991), LR 37:1622 (June 2011).

Robert J. Barham
Secretary

1106#017

RULE

Department of Wildlife and Fisheries
Wildlife and Fisheries Commission

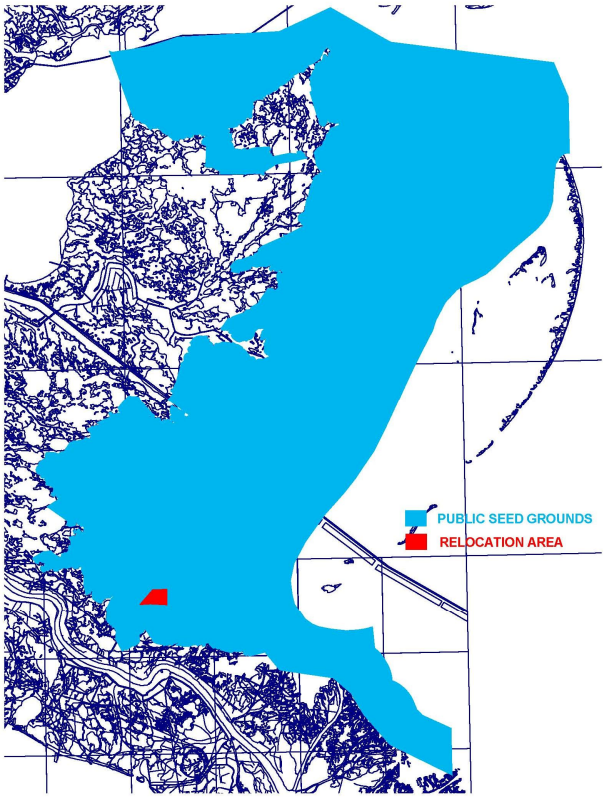
Public Seed Grounds East of the Mississippi River and Oyster Lease Relocation (LAC 76:VII.511 and 531)

The Wildlife and Fisheries Commission does hereby establish the following administrative rules to modify the public oyster seed grounds east of the Mississippi River and for the efficient and effective relocation of oyster leases which were not renewed due to such leases being wholly contained within a public oyster seed ground. Authority to designate public oyster seed grounds is vested in the Wildlife and Fisheries Commission by Louisiana Revised Statutes (R.S.) 56:434. Authority to develop rules for oyster lease relocation is vested in the Wildlife and Fisheries Commission by Act 265 of the 2010 Regular Legislative Session.

Title 76
WILDLIFE AND FISHERIES
Part VII. Fish and Other Aquatic Life
Chapter 5. Oysters
§511. Public Oyster Seed Grounds East of the Mississippi River

A. The public oyster seed grounds east of the Mississippi River are described as that portion of state water bottoms hatched on the map below, except for that portion as described in Louisiana Administrative Code (LAC) 76:VII.531.B (Oyster Lease Relocation) and more particularly described as that area within the following coordinates (North American Datum 1983):

1. 89 degrees 27 minutes 49.74 seconds W
   29 degrees 27 minutes 48.91 seconds N;
2. 89 degrees 26 minutes 36.54 seconds W
   29 degrees 27 minutes 48.89 seconds N;
3. 89 degrees 26 minutes 36.47 seconds W
   29 degrees 26 minutes 38.48 seconds N;
4. 89 degrees 28 minutes 04.69 seconds W
   29 degrees 26 minutes 43.66 seconds N;
5. 89 degrees 28 minutes 58.49 seconds W
   29 degrees 26 minutes 41.69 seconds N.



AUTHORITY NOTE: Promulgated in accordance with R.S. 56:434.

HISTORICAL NOTE: Promulgated by the Department of Wildlife and Fisheries, Office of Coastal and Marine Resources, LR 14:716 (October 1988), amended by the Department of Wildlife and Fisheries, Wildlife and Fisheries Commission, LR 37:1624 (June 2011).

§531. Oyster Lease Relocation

A. Eligibility. Those leases which are currently located wholly within a public oyster seed ground, and any former leases which were determined by the Department of Wildlife and Fisheries to have been non-renewed since 1998 due to the fact that such leases were wholly contained within a public oyster seed ground, shall be eligible for relocation.

B. Area of Relocation. The below described area, recommended by the Department of Wildlife and Fisheries and approved by the Office of Coastal Protection and Restoration, in consultation with the Louisiana Oyster Task Force, is hereby set aside from the Public Oyster Seed Grounds east of the Mississippi River, as described in Louisiana Administrative Code (LAC) 76:VII.511. This area is more particularly described as that area within the following coordinates (North American Datum 1983):

1. 89 degrees 27 minutes 49.74 seconds W
   29 degrees 27 minutes 48.91 seconds N;
2. 89 degrees 26 minutes 36.54 seconds W
   29 degrees 27 minutes 48.89 seconds N;
3. 89 degrees 26 minutes 36.47 seconds W
   29 degrees 26 minutes 38.48 seconds N;
4. 89 degrees 28 minutes 04.69 seconds W
   29 degrees 26 minutes 43.66 seconds N;
5. 89 degrees 28 minutes 58.49 seconds W
   29 degrees 26 minutes 41.69 seconds N.

C. Amount Lease Acreage Available. Any new lease issued under this relocation program shall be for an amount of acreage not to exceed the acreage of the lease which is being relocated.

D. Notification and Application Process. The Department of Wildlife and Fisheries shall notify the leaseholder of an affected existing lease, or the leaseholder of record for a lease that was previously not renewed, of the option to relocate the lease. The affected leaseholder or leaseholder of record shall have 60 days from the date of notification to appear in person at the LDWF Oyster Lease Survey Section office to apply for a relocation lease. Applications shall be on application forms provided by the department and shall be processed by the department in the order in which they are received by the department.

E. Deceased Leaseholders. Any person or entity desiring to exercise the relocation rights of an otherwise eligible deceased applicant must present a valid "letter of administration" or "judgment of possession" in order to exercise the relocation rights provided in this Section.

F. Partitioning of Leases. Any qualifying leasehold person or entity who requests to have his rights in a qualifying lease partitioned into two or more leases within the relocation area shall provide to the LDWF Oyster Lease Survey Section a valid court order designating such persons or entities, and their respective percentage of lease relocation rights.

G. Issuance of Relocated Leases. Relocated leases shall be issued pursuant to LAC 76:VII.501 and 503.

H. Expiration Date. This Rule shall expire on January 1, 2013.

AUTHORITY NOTE: Promulgated in accordance with Act 265 of the 2010 Regular Legislative Session.

HISTORICAL NOTE: Promulgated by the Department of Wildlife and Fisheries, Wildlife and Fisheries Commission, LR 37:1625 (June 2011).

Robert J. Barham
Secretary

1106#018

RULE

Workforce Commission
Office of Workers' Compensation

Hearing Rules (LAC 40:I.5501-6627)

Notice is hereby given, in accordance with R.S. 49:950 et seq., that the Louisiana Workforce Commission, Office of Workers' Compensation, pursuant to the authority vested in the director of the Office of Workers' Compensation by R.S. 23:1310.1 and in accordance with applicable provisions of the Administrative Procedure Act, has amended rules governing the procedure before the workers' compensation court, LAC 40:I, Subpart 2, Chapters 55 through 66 to provide for the procedural rules for the workers' compensation court. The enactment is set forth in the attached documents.

Title 40
LABOR AND EMPLOYMENT
Part I. Workers' Compensation Administration
Subpart 3. Hearing Rules
Chapter 55. General Provisions
Subchapter A. Definitions
§5501. Purpose; Definitions

A. - B. …

* * *

Judicial District—as referred to in R.S. 1310.4, any of the 10 locations of a workers' compensation district office, i.e. Shreveport, Monroe, Alexandria, Lake Charles, Lafayette, Baton Rouge, Covington, New Orleans, Harahan, Houma, and the parishes each encompass.

* * *

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1310.1.

HISTORICAL NOTE: Promulgated by the Department of Labor, Office of Workers' Compensation Administration, LR 25:265 (February 1999), amended LR 25:1859 (October 1999), amended by the Louisiana Workforce Commission, Office of Workers' Compensation, LR 37:1626 (June 2011).

Subchapter C. Commencement
§5507. Commencement of a Claim

A. - B. …

C. Any party aggrieved by the R.S. 23:1203.1(J) determination of the medical director may seek judicial review by filing a Form LWC-WC-1008 in a workers' compensation district office within 15 days of the date said determination is mailed to the parties. A party filing an appeal under this Section must simultaneously notify the other party and the medical director that an appeal of the medical director's decision has been filed. Upon receipt of the appeal, the workers' compensation judge shall immediately set the matter for an expedited hearing to be held not less than 15 days nor more than 30 days after the receipt of the appeal by the office. The workers' compensation judge shall provide notice of the hearing date to the parties at the same time and in the same manner.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1310.1.

HISTORICAL NOTE: Promulgated by the Department of Labor, Office of Workers' Compensation Administration, LR 25:265 (February 1999) amended LR 25:1860 (October 1999), LR 33:652 (April 2007), amended by the Louisiana Workforce Commission, Office of Workers' Compensation, LR 37:1626 (June 2011).

§5511. Service

A. Service of process in a workers' compensation claim shall be as provided for in R.S. 23:1310.3(C).

B. Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1310.1.

HISTORICAL NOTE: Promulgated by the Department of Labor, Office of Workers' Compensation Administration, LR 25:265 (February 1999) amended LR 25:1860 (October 1999), LR 33:652 (April 2007), amended by the Louisiana Workforce Commission, Office of Workers' Compensation, LR 37:1626 (June 2011).

Subchapter D. Venue
§5515. Proper Venue

A. Proper venue in a workers' compensation claim shall be governed by R.S. 23:1310.4. When a claim has been filed in a district of improper venue, the judge shall, by written order and in the interest of justice, transfer the claim to a district of proper venue.

B. When the claimant or his dependent is not a party to the disputed claim, the petitioner shall have the right to select the venue of necessary hearings by the workers' compensation judge as provided in the Code of Civil Procedure.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1310.1.

HISTORICAL NOTE: Promulgated by the Department of Labor, Office of Workers' Compensation Administration, LR 25:265 (February 1999), amended LR 25:1860 (October 1999), LR 33:652 (April 2007), amended by the Louisiana Workforce Commission, Office of Workers' Compensation, LR 37:1626 (June 2011).

Subchapter E. Recusal
§5525. Procedure for Recusal of a Workers' Compensation Judge

A. …

B. A workers' compensation judge may recuse himself, prior to a judgment being rendered, whether a motion for his recusation has been filed by a party or not, in any cause in which a ground for recusation exists.

C. …

D. On written application of a workers' compensation judge, the chief judge shall immediately reassign the matter to another workers' compensation judge in either the same workers' compensation district office or another workers' compensation district office.

E. Any party to a workers' compensation claim may file a written motion for recusal of the judge to whom the matter is assigned specifying the grounds for recusal. This motion shall be filed prior to trial or hearing unless the party discovers the facts constituting the ground for recusal thereafter. In such case, the motion shall be filed immediately after the facts are discovered, but in no case after judgment. If a valid ground for recusation is set forth in the motion, the judge shall either recuse himself or refer the matter to the chief judge. Upon receipt of the motion the chief judge shall either try the motion or assign it to another workers' compensation judge for trial. Trial of the motion shall be held in an expedited manner and in no event later than 14 days following filing of the motion.

F. If a valid ground for recusation is not set forth in the motion, the judge shall deny the motion and proceed with the trial of the cause. Any party aggrieved by any denial may file an appeal in accordance with the provisions of R.S. 23:1310.5.

G. Consolidated cases are to be considered as one case within the meaning of this Section.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1310.1.

HISTORICAL NOTE: Promulgated by the Department of Labor, Office of Workers' Compensation Administration, LR 25:1860 (October 1999), amended LR 33:652 (April 2007), amended by the Louisiana Workforce Commission, Office of Workers' Compensation, LR 37:1626 (June 2011).

§5529. Recusation on Court's Own Motion

Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1310.1.

HISTORICAL NOTE: Promulgated by the Department of Labor, Office of Workers' Compensation Administration, LR 25:266 (February 1999), amended LR 25:1860 (October 1999), LR

33:653 (April 2007), repealed by the Louisiana Workforce Commission, Office of Workers' Compensation, LR 37:1626 (June 2011).

Subchapter F. Power and Authority

§5533. General

A. …

B. All workers' compensation judges shall be subject to the Code of Judicial Conduct, Civil Service Rules, the Louisiana Code of Governmental Ethics and the Louisiana State Bar Association Code of Professional Conduct.

C. All workers' compensation mediators shall be subject to the Civil Service Rules, the Louisiana Code of Governmental Ethics, and the Louisiana State Bar Association Code of Professional Conduct.

D. A workers' compensation judge or mediator shall not refer any claimant to an attorney for representation in a workers' compensation matter except under the following circumstances:

1. when ordered to appoint an attorney for an unrepresented party by a court of competent jurisdiction;

2. except as provided in §5709.B of these rules; or

3. when the judge has a reasonable belief that the unrepresented party lacks capacity to represent himself.

F. The court shall have available a list of attorneys, compiled by the director, who have indicated a willingness to handle workers' compensation matters.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1310.1.

HISTORICAL NOTE: Promulgated by the Department of Labor, Office of Workers' Compensation Administration, LR 25:266 (February 1999), amended LR 25:1860 (October 1999), LR 33:653 (April 2007), amended by the Louisiana Workforce Commission, Office of Workers' Compensation, LR 37:1627 (June 2011).

Subchapter G. Clerks

§5539. District Clerk; Pleadings Filed; Docket Books

A. - B. …

C. The manager of the records management division shall be the custodian of all records and documents for that district or offices and no such records, documents, or paper shall be withdrawn.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1310.1.

HISTORICAL NOTE: Promulgated by the Louisiana Department of Labor, Office of Workers' Compensation Administration, LR 25:266 (February 1999), amended LR 25:1861 (October 1999), amended by the Louisiana Workforce Commission, Office of Workers' Compensation, LR 37:1627 (July 2011).

Subchapter H. Bailiffs

§5541. Security

A. …

B. The bailiff may in his discretion, or as ordered by the judge, inspect any object carried by any person entering the premises. No one shall enter or remain in the premises without submitting to such an inspection if requested to do so.

C. - E. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1310.1.

HISTORICAL NOTE: Promulgated by the Department of Labor, Office of Workers' Compensation Administration, LR 25:266 (February 1999), amended LR 25:1861 (October 1999), LR 33:653 (April 2007), amended by the Louisiana Workforce Commission, Office of Workers' Compensation, LR 37:1627 (June 2011).

Chapter 57. Actions

Subchapter A. General Provisions

§5701. Prescription; Filing Procedure

A. …

B. All pleadings filed with the court may be filed by facsimile transmission or electronic transmission (with verified signature) to the assigned facsimile number or electronic address of the district of proper venue. A facsimile or electronic transmission (with verified signature), when filed, has the same force and effect as the original. If the party fails to comply with the requirements of Paragraph C of this Section, a facsimile filing shall have no force or effect.

C.1. Within five days, exclusive of legal holidays, after the district office or the records management division has received a facsimile transmission, the party filing the document shall forward the following to the district office or records manager:

a. - b. …

c. a transmission fee of $5 for the first 10 pages and $1 for each page thereafter.

2. Repealed.

D. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1310.1.

HISTORICAL NOTE: Promulgated by the Department of Labor, Office of Workers' Compensation Administration, LR 25:267 (February 1999), amended LR 25:1862 (October 1999), LR 33:654 (April 2007), amended by the Louisiana Workforce Commission, Office of Workers' Compensation, LR 37:1627 (June 2011).

§5705. Abandonment

A. A claim may be dismissed without prejudice after contradictory hearing properly noticed by the court on the judge's own motion or on ex parte motion of a party for the following reasons:

1. where no service of process has occurred within 60 days after the Form LWC-WC-1008 has been filed. This provision shall not apply if the claim is awaiting action by the workers' compensation court;

2. where no responsive pleadings have been filed and no default has been entered within 60 days after service of process;

3. …

4. where a claimant fails to appear for any properly noticed conference or hearing;

5. where an attorney or pro se litigant fails to keep the workers' compensation court apprised of an address change or when a notice is returned to the workers' compensation court for the reason of an incorrect address and no correction is made to the address for a period of 60 days.

B. …

C. Any order of dismissal shall allow for reinstatement of the action within 30 days for good cause shown.

D. The workers' compensation judge may order the claim dismissed, with prejudice, after a contradictory hearing, when it is shown that more than 90 days has elapsed since a claim was dismissed for any reason listed in Subsection A of this Section and no good cause has been shown for reinstatement.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1310.1.

HISTORICAL NOTE: Promulgated by the Department of Labor, Office of Workers' Compensation Administration, LR 25:268 (February 1999), amended LR 25:1862 (October 1999), LR 33:654 (April 2007), amended by the Louisiana Workforce Commission, Office of Workers' Compensation, LR 37:1627 (June 2011).

Subchapter B. Settlement

§5709. Joint Petition Settlements

A.1.A lump sum or compromise settlement shall be presented to the presiding judge in a pending disputed claim or to any judge in an undisputed claim for approval on Form LWC-WC-1011 and upon joint petition of the parties.

A.2. - B. ….

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1310.1.

HISTORICAL NOTE: Promulgated by the Department of Labor, Office of Workers' Compensation Administration, LR 25:268 (February 1999), amended LR 25:1863 (October 1999), LR 33:654 (April 2007), amended by the Louisiana Workforce Commission, Office of Workers' Compensation, LR 37:1628 (June 2011).

Chapter 58. Pleadings

Subchapter B. Supplemental/Amended Pleadings

§5805. Amendment of Claim and Answer

A. Amendment of a claim and answer shall be governed by Code of Civil Procedure Article 1151 et seq.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1310.1.

HISTORICAL NOTE: Promulgated by the Louisiana Department of Labor, Office of Workers' Compensation Administration, LR 25:268 (February 1999), amended LR 25:1863 (October 1999), amended by the Louisiana Workforce Commission, Office of Workers' Compensation, LR 37:1628 (June 2011).

Subchapter C. Forms

§5809. Forms

A. The Office of Workers' Compensation Administration shall prepare and adopt such forms for use in matters before the Office of Workers' Compensation Administration as it may deem necessary or advisable. Whenever Office of Workers' Compensation Administration forms are prescribed and are applicable, they shall be used. A photo ready copy of any form may be procured upon request to any district office, the office of the director, or from the website, www.laworks.net.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1310.1.

HISTORICAL NOTE: Promulgated by the Department of Labor, Office of Workers' Compensation Administration, LR 25:269 (February 1999), amended LR 25:1863 (October 1999), LR 33:654 (April 2007), amended by the Louisiana Workforce Commission, Office of Workers' Compensation, LR 37:1628 (June 2011).

Subchapter D. Mediation

§5813. Mediation Conference

A. Parties who have a workers' compensation dispute as defined by R.S. 23:1310.3(A) and who desire to engage the services of a Louisiana Workforce Commission, Office of Workers' Compensation Administration mediator, may make a joint written request for a mediation conference to any Office of Workers' Compensation mediator selected by mutual agreement of the parties. The parties shall forward to the selected mediator, along with the written request, a confidential position statement, not to exceed 10 pages, outlining the issues in dispute and the respective position of the parties. Upon receipt of the joint written request, the selected mediator shall schedule a mediation conference and provide notice in the same manner and at the same time to all parties of the date and time of the conference. Notice of any scheduled mediation conference may be given by telephone, but shall be confirmed by United States Mail, facsimile transmission, or electronic transmission. The location of the mediation conference shall be in the assigned district office of the selected mediator.

B. A mediation conference may also be scheduled upon order of a presiding workers' compensation judge in any pending workers' compensation disputed claim (Form LWC-WC-1008). If the parties select an Office of Workers' Compensation mediator, the court-ordered mediation conference shall be conducted in the district office in which the selected mediator is assigned.

C. On the scheduled date of the mediation conference, each party shall provide a representative to participate in the mediation conference, either in person or via telephone, who has been provided with authority to enter into negotiations in a good faith effort to resolve the issue(s) in dispute. The attorneys for the parties may participate in the mediation conference via telephone only upon mutual consent of the parties. No stenographic report shall be taken at any mediation conference and no witnesses shall be called. All statements made at any mediation conference shall be privileged and shall not be admissible in any subsequent status conference, pretrial conference, hearing, or trial. Any party to the claim and/or their representative may request a copy of the Form LWC-WC-1008 filed in the claim prior to the scheduled mediation conference. No such request shall be denied by any employee of the Office of Workers' Compensation Administration. If the parties agree, the mediator may schedule additional mediation conferences when deemed appropriate.

D. Nothing in this rule shall prohibit parties from requesting the services of an Office of Workers' Compensation mediator prior to the filing of a disputed claim for compensation (Form LWC-WC-1008). Said request shall be made by the parties in the same manner as provided for in Subsection A of this Section. However, neither the request nor the participation in a pre-1008 mediation conference shall interrupt the running of prescription.

E. Nothing in this rule shall prohibit the parties from engaging the services of a private mediator to conduct a mediation conference at a location mutually agreeable to the parties. Within five days of the conclusion of said private mediation, the parties shall certify to the court that a private mediation has occurred and the results thereof. Said certification shall be provided by the parties via United States mail, electronic transmission, or facsimile transmission.

F. - G. Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1310.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers' Compensation Administration, LR 25:1863 (October 1999), LR 33:654 (April 2007), amended by the Louisiana Workforce Commission, Office of Workers' Compensation, LR 37:1628 (June 2011).

§5815. Pretrial Mediation

Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1310.1.

HISTORICAL NOTE: Promulgated by the Department of Labor, Office of Workers' Compensation Administration, LR 33:655 (April 2007), repealed by the Louisiana Workforce Commission, Office of Workers' Compensation, LR 37:1629 (June 2011).

§5817. Conclusion of Mediation Conferences held by an Office of Workers' Compensation Mediator

A. When it becomes apparent during the course of a pre-1008 mediation conference that an agreement on all issues cannot be reached, the Office of Workers' Compensation mediator shall issue a report stating the result of the conference. The report shall be issued to the parties immediately following the conference by facsimile transmission, by electronic transmission or by mail within five days thereof.

B. When it becomes apparent during the course of a post-1008 mediation conference that agreement on all issues cannot be reached, the Office of Workers' Compensation mediator shall issue a report stating the results of the conference. The report shall be issued immediately following the conference to the parties and to the judge where the claim was filed. The report shall be issued in person, by facsimile transmission, by electronic transmission, or by mail within five days thereof.

C. Following a mediation conference, at which agreement is reached on all issues in dispute, a report embodying the agreement shall be issued to the parties in person, by facsimile transmission, by electronic transmission, or by mail within five days thereof. The mediator shall file the original report with the judge presiding over the district where the claim was filed or in the case of a pre-1008 mediation conference, with the judge presiding over the district situated within the parish of the claimant's domicile. The report may require dismissal of the claim or the filing of an LWC Form 1011 within 30 days.

D. Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1310.1.

HISTORICAL NOTE: Promulgated by the Department of Labor, Office of Workers' Compensation Administration, LR 25:269 (February 1999), amended LR 25:1864 (October 1999), LR 33:655 (April 2007), amended by the Louisiana Workforce Commission, Office of Workers' Compensation, LR 37:1629 (June 2011).

§5819. Failure to Attend; Sanctions

A. If any party fails to appear at a mediation conference ordered by the judge or requested by the parties, after proper notice and without just cause, the presiding workers' compensation judge, upon request of a party , may fine the delinquent party an amount not to exceed $500, which shall be payable to the Office of Workers' Compensation Administrative Fund. In addition, the presiding workers' compensation judge may assess against the party failing to attend, costs and reasonable attorney's fees incurred by any other party in connection with the conference. The penalties provided for in this Section shall be assessed by the presiding workers' compensation judge only after a contradictory hearing which shall be held prior to the hearing on the merits of the dispute.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1310.1.

HISTORICAL NOTE: Promulgated by the Department of Labor, Office of Workers' Compensation Administration, LR 25:1864 (October 1999), amended LR 33:655 (April 2007), amended by the Louisiana Workforce Commission, Office of Workers' Compensation, LR 37:1629 (June 2011).

Chapter 59. Production of Evidence

Subchapter D. Depositions

§5925. Depositions in Advance of Hearing; Perpetuation of Testimony

A. …

B. Any party seeking to offer the testimony of a witness at trial by deposition may take a deposition to perpetuate the trial testimony of such witness at any time prior to trial. Such deposition may be offered by any party and shall be admissible upon consent of the parties or as otherwise provided by these rules, the Code of Evidence and the Code of Civil Procedure.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1310.1.

HISTORICAL NOTE: Promulgated by the Louisiana Department of Labor, Office of Workers' Compensation Administration, LR 25:273 (February 1999), amended LR 25:1866 (October 1999), amended by the Louisiana Workforce Commission, Office of Workers' Compensation, LR 37:1629 (July 2011).

Chapter 60. Pretrial Procedure

§6001. Scheduling Conferences

A. - E. …

F. If the parties agree, discovery may be conducted after the date set in the scheduling order for the completion of discovery and the parties shall notify the court.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1310.1.

HISTORICAL NOTE: Promulgated by the Department of Labor, Office of Workers' Compensation Administration, LR 25:1867 (October 1999), amended LR 33:657 (April 2007), amended by the Louisiana Workforce Commission, Office of Workers' Compensation, LR 37:1629 (June 2011).

§6003. Conferences or Hearings by Telephone

Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1310.1.

HISTORICAL NOTE: Promulgated by the Department of Labor, Office of Workers' Compensation Administration, LR 25:276 (February 1999), amended LR 25:1868 (October 1999), LR 33:657 (April 2007), repealed by the Louisiana Workforce Commission, Office of Workers' Compensation, LR 37:1629 (June 2011).

§6005. Pretrial Conference

A. - B. …

C. The pretrial conference will be held by telephone, unless in the judge's discretion, attendance in person at the conference is necessary.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1310.1.

HISTORICAL NOTE: Promulgated by the Department of Labor, Office of Workers' Compensation Administration, LR 25:277 (February 1999), amended LR 25:1868 (October 1999), LR 33:657 (April 2007), amended by the Louisiana Workforce Commission, Office of Workers' Compensation, LR 37:1629 (June 2011).

Chapter 61. Hearings
Subchapter B. Continuance and Stays
§6103. General

A. - C. …

D.1. If all parties are represented by counsel and the motion is uncontested, the moving party shall certify to the court that he has spoken to opposing counsel, that no opposition exists and that all witnesses have been timely notified of the continuance. Only one uncontested motion must be granted. A new trial date shall be established by mutual agreement of the parties.

2. Subsequent uncontested motions for continuance by represented parties may be granted at the discretion of the workers' compensation judge and when the workers' compensation judge believes it is in the best interest of the parties.

E. If any of the parties are unrepresented, the uncontested motion may be granted if there are good grounds therefore and if the workers' compensation judge believes it is in the best interest of the parties.

F. The request for continuance shall state the reasons the continuance is necessary, that all parties have been notified of the request, and whether all parties agree to the continuance.

G. Joint requests for continuance of a pre-1008 or post-1008 mediation conference held by an Office of Workers' Compensation mediator shall be submitted to the selected mediator in writing.

H. Joint requests for continuance of a court-ordered mediation conference may be permitted for good cause shown by written motion to the judge where the claim was filed no later than three business days prior to the scheduled conference. The request shall state the reasons why the continuance is necessary, that all parties have been notified of the request and that all parties agree to the continuance.

I. Contradictory motions for continuance of a court-ordered mediation conference shall be submitted by written motion to the judge where the claim was filed no later than five business days prior to the scheduled mediation. The judge may entertain such motion by telephone status conference with all parties participating. Such telephone status conference shall be initiated by the party requesting the continuance.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1310.1.

HISTORICAL NOTE: Promulgated by the Department of Labor, Office of Workers' Compensation Administration, LR 25:277 (February 1999), amended LR 25:1868 (October 1999), LR 33:658 (April 2007), amended by the Louisiana Workforce Commission, Office of Workers' Compensation, LR 37:1630 (June 2011).

§6104. Stays

A. Upon motion of a party and for good cause shown, or at the discretion of the court in the interest of justice, the workers' compensation judge may order a stay of the claim.

B. When a stay is granted, a telephone status conference shall be set at such intervals as directed by the workers' compensation judge but at least every six months.

C. Section 5705.A of these rules shall not apply to any matter subject to a stay order as long as such order is in effect.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1310.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers' Compensation Administration, LR 37:1630 (June 2011).

Chapter 65. Special Disputes
Subchapter B. Social Security Offset
§6507. Offset

A. …

B. A request for offsets pursuant to R.S. 23:1225(A) made in connection with a claim not in dispute may be made by motion on Form LWC-WC-1005(A) or by letter, filed in the appropriate district office. When properly filed, the motion or letter requesting an offset may be granted ex parte from date of filing. Such offsets shall not be taken unless the social security offset has been removed. No fee shall be charged in connection with a request made under this Subsection.

C. - E. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1310.1.

HISTORICAL NOTE: Promulgated by the Department of Labor, Office of Workers' Compensation Administration, LR 25:281 (February 1999), amended LR 25:1871 (October 1999), LR 33:659 (April 2007), amended by the Louisiana Workforce Commission, Office of Workers' Compensation, LR 37:1630 (June 2011).

Subchapter C. Financial and Compliance Hearings
§6509. Financial and Compliance Hearings

A. Any party may request a mediation conference which shall be held within 15 days of the filing of an appeal for financial and compliance matters.

B. - C. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1310.1.

HISTORICAL NOTE: Promulgated by the Department of Labor, Office of Workers' Compensation Administration, LR 25:281 (February 1999), amended LR 25:1871 (October 1999), LR 33:659 (April 2007), amended by the Louisiana Workforce Commission, Office of Workers' Compensation, LR 37:1630 (June 2011).

Chapter 66. Miscellaneous
Subchapter A. General
§6605. Fees

A. …

1. filing of 1008-$30; filing of 1011 where no 1008 has been filed -$30;

2. - 4. …

5. filing by facsimile transmission−$5 for the first 10 pages and $1 for each page thereafter;

6. - 7. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1310.1.

HISTORICAL NOTE: Promulgated by the Louisiana Department of Labor, Office of Workers' Compensation Administration, LR 25:281 (February 1999), amended LR 25:1871 (October 1999), amended by the Louisiana Workforce Commission, Office of Workers' Compensation, LR 37:1630 (June 2011).

Curt Eysink
Executive Director

1106#027

RULE

Workforce Commission
Office of Workers' Compensation

Medical Guidelines (LAC 40:I.Chapters 20-23)

In accordance with R.S. 49:950 et seq., that the Louisiana Workforce Commission, Office of Workers' Compensation, pursuant to authority vested in the Director of the Office of Workers' Compensation by R.S. 23:1310.1 and in accordance with applicable provisions of the Administrative Procedure Act, has enacted LAC 40:I., Subpart 2, Chapters 20-23 to add the following:

Chapter 20 (Spine Medical Treatment Guidelines): Sections 2001 through 2012 (Cervical Spine Injury), Sections 2013 through 2024 (Low Back Pain);

Chapter 21 (Pain Medical Treatment Guidelines): Sections 2101 through 2116 (Chronic Pain Disorder), Sections 2117 through 2136 (Complex Regional Pain Syndrome/Reflex Sympathetic Dystrophy);

Chapter 22 (Neurological and Neuromuscular Disorder Medical Treatment Guidelines): Sections 2201 through 2214 (Carpal Tunnel Syndrome), Sections 2215 through 2228 (Thoracic Outlet Syndrome);

Chapter 23 (Upper and Lower Extremities Medical Treatment Guidelines): Sections 2301 through 2314 (Lower Extremities), Sections 2315 through 2328 (Shoulder Injuries).

The contents of the new chapters are relative to medical treatment guidelines for the delivery of medical treatment in workers compensation cases, which are being promulgated in accordance with the directives of R.S. 23:1203.1. The proposed enactment is set forth in the attached documents.

Title 40
LABOR AND EMPLOYMENT
Part I. Workers' Compensation Administration
Subpart 2. Medical Guidelines
Chapter 20. Spine Medical Treatment Guidelines
§2001. Subchapter A. Cervical Spine Injury

A. This document has been prepared by the Louisiana Workforce Commission, Office of Workers' Compensation and should be interpreted within the context of guidelines for physicians/providers treating individuals qualifying under Louisiana's Workers' Compensation Act as injured workers with cervical spine injuries. These guidelines are enforceable under the Louisiana Workers Compensation Act. All medical care, services, and treatment owed by the employer to the employee in accordance with the Louisiana Workers' Compensation Act shall mean care, services, and treatment in accordance with these guidelines. Medical care, services and treat Medical care, services, and treatment that varies from these guidelines shall also be due by the employer when it is demonstrated to the medical director of the office by a preponderance of the scientific medical evidence, that a variance from these guidelines is reasonably required to cure or relieve the injured worker from the effects of the injury or occupational disease given the circumstances. Therefore, these guidelines are not relevant as evidence of a provider's legal standard of professional care. To properly utilize this document, the reader should not skip nor overlook any sections.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1631 (June 2011).

§2003. General Guideline Principles

A. The principles summarized in this section are key to the intended implementation of all Office of Workers' Compensation guidelines and critical to the reader's application of the guidelines in this document.

1. Application of Guidelines. The OWCA provides procedures to implement medical treatment guidelines and to foster communication to resolve disputes among the provider, payer, and patient through the Office of Worker's Compensation.

2. Education. Education of the patient and family, as well as the employer, insurer, policy makers and the community should be the primary emphasis in the treatment of cervical spine injuries and disability. Currently, practitioners often think of education last, after medications, manual therapy, and surgery. Practitioners must develop and implement an effective strategy and skills to educate patients, employers, insurance systems, policy makers, and the community as a whole. An education-based paradigm should always start with inexpensive communication providing reassuring information to the patient. More in-depth education currently exists within a treatment regime employing functional restorative and innovative programs of prevention and rehabilitation. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of facilitating self-management of symptoms and prevention.

3. Treatment Parameter Duration. Time frames for specific interventions commence once treatments have been initiated, not on the date of injury. Obviously, duration will be impacted by patient compliance, as well as availability of services. Clinical judgment may substantiate the need to accelerate or decelerate the time frames discussed in this document. Such deviation shall be in accordance with La. R.S. 23:1203.1.

4. Active Interventions. Emphasizing patient responsibility, such as therapeutic exercise and/or functional treatment, are generally emphasized over passive modalities, especially as treatment progresses. Generally, passive interventions are viewed as a means to facilitate progress in an active rehabilitation program with concomitant attainment of objective functional gains.

5. Active Therapeutic Exercise Program. Exercise program goals should incorporate patient strength, endurance, flexibility, coordination, and education. This includes functional application in vocational or community settings.

6. Positive Patient Response. Positive results are defined primarily as functional gains that can be objectively measured. Standard measurement tools, including outcome measures, should be used. Objective functional gains include, but are not limited to, positional tolerances, range-of-motion (ROM), strength, and endurance, activities of daily living, cognition, psychological behavior, and efficiency/velocity measures that can be quantified. Subjective reports of pain and function should be considered and given relative weight when the pain has anatomic and

physiologic correlation. Anatomic correlation must be based on objective findings.

7. Re-Evaluation Treatment Every three to four Weeks. If a given treatment or modality is not producing positive results within three to four weeks, the treatment should be either modified or discontinued. Reconsideration of diagnosis should also occur in the event of poor response to a seemingly rational intervention.

8. Surgical Interventions. Surgery should be contemplated within the context of expected functional outcome and not purely for the purpose of pain relief. The concept of "cure" with respect to surgical treatment by itself is generally a misnomer. All operative interventions must be based upon positive correlation of clinical findings, clinical course, and diagnostic tests. A comprehensive assimilation of these factors must lead to a specific diagnosis with positive identification of pathologic conditions.

9. Six-Month Time Frame. The prognosis drops precipitously for returning an injured worker to work once he/she has been temporarily totally disabled for more than six months. The emphasis within these guidelines is to move patients along a continuum of care and return-to-work within a six-month time frame, whenever possible. It is important to note that time frames may not be pertinent to injuries that do not involve work-time loss or are not occupationally related.

10. Return To Work. Return to work is therapeutic, assuming the work is not likely to aggravate the basic problem or increase long-term pain. The practitioner must provide specific written physical limitations and the patient should never be released to "sedentary" or "light duty." The following physical limitations should be considered and modified as recommended: lifting, pushing, pulling, crouching, walking, using stairs, bending at the waist, awkward and/or sustained postures, tolerance for sitting or standing, hot and cold environments, data entry and other repetitive motion tasks, sustained grip, tool usage and vibration factors. Even if there is residual chronic pain, return-to-work is not necessarily contraindicated. The practitioner should understand all of the physical demands of the patient's job position before returning the patient to full duty and should request clarification of the patient's job duties. Clarification should be obtained from the employer or, if necessary, including, but not limited to, an occupational health nurse, occupational therapist, vocational rehabilitation specialist, or an industrial hygienist.

11. Delayed Recovery. Delayed recovery strongly considers a psychological evaluation, if not previously provided, as well as initiating interdisciplinary rehabilitation treatment and vocational goal setting, for those patients who are failing to make expected progress 6 to 12 weeks after an injury. The OWCA recognizes that 3 to 10 percent of all industrially injured patients will not recover within the timelines outlined in this document despite optimal care. Such individuals may require treatments beyond the limits discussed within this document, but such treatment will require clear documentation by the authorized treating practitioner focusing on objective functional gains afforded by further treatment and impact upon prognosis.

12. Guideline Recommendations and Inclusion of Medical Evidence. Guidelines are recommendations based on available evidence and/or consensus recommendations. When possible, guideline recommendations will note the level of evidence supporting the treatment recommendation. When interpreting medical evidence statements in the guideline, the following apply:

a. *Consensus* means the opinion of experienced professionals based on general medical principles. Consensus recommendations are designated in the guideline as generally well accepted, generally accepted, acceptable/accepted, or well-established.

b. *Some* means the recommendation considered at least one adequate scientific study, which reported that a treatment was effective.

c. *Good* means the recommendation considered the availability of multiple adequate scientific studies or at least one relevant high-quality scientific study, which reported that a treatment was effective.

d. *Strong* means the recommendation considered the availability of multiple relevant and high quality scientific studies, which arrived at similar conclusions about the effectiveness of a treatment.

A. All recommendations in the guideline are considered to represent reasonable care in appropriately selected cases, regardless of the level of evidence or consensus statement attached to it. Those procedures considered inappropriate, unreasonable, or unnecessary are designated in the guideline as "not recommended."

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1631 (June 2011).

§2005. Initial Diagnostic Procedures

A. The OWCA recommends the following diagnostic procedures be considered, at least initially, the responsibility of the workers' compensation carrier to ensure that an accurate diagnosis and treatment plan can be established. Standard procedures, that should be utilized when initially diagnosing a work-related cervical spine complaint, are listed below.

1. History-taking and physical examination (Hx and PE). These are generally accepted, well-established and widely used procedures that establish the foundation/basis for and dictate subsequent stages of diagnostic and therapeutic procedures. When findings of clinical evaluations and those of other diagnostic procedures are not complementing each other, the objective clinical findings should have preference. The medical records should reasonably document the following.

a. History of Present Injury: A detailed history, taken in temporal proximity to the time of injury, should primarily guide evaluation and treatment. The history should include:

i. Mechanism of Injury. This includes details of symptom onset and progression. The mechanism of injury should include a detailed description of the incident and the position of the body before, during, and at the end of the incident. Inclusion of normal work body postures, frequency during the workday and lifting/push/pull requirements, should be included in the absence of a known specific incident;

ii. Location of pain, nature of symptoms, and alleviating/exacerbating factors (e.g. sleep positions). Of particular importance, is whether raising the arm over the head alleviates radicular-type symptoms. The history should

include both the primary and secondary complaints (e.g., primary neck pain, secondary arm pain, headaches, and shoulder girdle complaints). The use of a patient completed pain drawing, Visual Analog Scale (VAS) is highly recommended, especially during the first two weeks following injury to assure that all work related symptoms are being addressed;

iii. presence and distribution of upper and/or lower extremity numbness, paresthesias, or weakness, especially if precipitated by coughing or sneezing;

iv. presence and distribution of upper and/or lower extremity numbness, paresthesias, or weakness, especially if precipitated by coughing or sneezing;

v. ability to perform job duties and activities of daily living;

b. Past History

i. past medical history includes neoplasm, arthritis, and diabetes;

ii. review of systems includes neoplasm, arthritis, and diabetes;

iii. smoking history;

iv. vocational and recreational pursuits;

v. history of depression, anxiety, or other psychiatric illness.

c. Physical Examination should include accepted tests and exam techniques applicable to the area being examined, including:

i. visual inspection, including posture;

ii. cervical range-of-motion, quality of motion, and presence of muscle spasm. Motion evaluation of specific joints may be indicated. Range-of-motion should not be checked in acute trauma cases until fracture and instability have been ruled out on clinical examination, with or without radiographic evaluation;

iii. examination of thoracic spine;

iv. palpation of spinous processes, facets, and muscles noting myofascial tightness, tenderness, and trigger points;

v. motor and sensory examination of the upper muscle groups with specific nerve root focus, as well as sensation to light touch, pin prick, temperature, position and vibration. More than 2 cm difference in the circumferential measurements of the two upper extremities may indicate chronic muscle wasting; and

vi. Deep tendon reflexes. Asymmetry may indicate pathology. Inverted reflexes (e.g. arm flexion or triceps tap) may indicate nerve root or spinal cord pathology at the tested level. Pathologic reflexes include wrist, clonus, grasp reflex, and Hoffman's sign.

d. Relationship to Work: This includes a statement of the probability that the illness or injury is work-related. If further information is necessary to determine work relatedness, the physician should clearly state what additional diagnostic studies or job information is required.

e. Spinal Cord Evaluation: In cases where the mechanism of injury, history, or clinical presentation suggests a possible severe injury, additional evaluation is indicated. A full neurological examination for possible spinal cord injury may include:

i. Sharp and light touch, deep pressure, temperature, and proprioceptive sensory function;

ii. strength testing;

iii. anal sphincter tone and/or perianal sensation;

iv. presence of pathological reflexes of the upper and lower extremities; or

v. evidence of an Incomplete Spinal Cord Injury Syndrome:

(a). Anterior Cord Syndrome is characterized by the loss of motor function and perception of pain and temperature below the level of the lesion with preservation of touch, vibration, and proprioception. This is typically seen after a significant compressive or flexion injury. Emergent CT or MRI is necessary to look for a possible reversible compressive lesion requiring immediate surgical intervention. The prognosis for recovery is the worst of the incomplete syndromes.

(b). Brown-Sequard Syndrome is characterized by ipsilateral motor weakness and proprioceptive disturbance with contralateral alteration in pain and temperature perception below the level of the lesion. This is usually seen in cases of penetrating trauma or lateral mass fracture. Surgery is not specifically required, although debridement of the open wound may be.

(c). Central Cord Syndrome is characterized by sensory and motor disturbance of all limbs, often upper extremity more than lower, and loss of bowel and bladder function with preservation of perianal sensation. This is typically seen in elderly patients with a rigid spine following hyperextension injuries. Surgery is not usually required.

(d). Posterior Cord Syndrome, a rare condition, is characterized by loss of sensation below the level of the injury, but intact motor function.

vi. Spinal cord lesions should be classified according to the American Spine Injury Association (ASIA) impairment scale.

Asia Impairment Scale
A=Complete: No motor or sensory function is preserved in the sacral segments S4-S5
B=Incomplete: Sensory but not motor function is preserved below the neurological level and includes the sacral segments S4-S5
C=Incomplete: Motor function is preserved below the neurological level, and more than half of key muscles below the neurological level have a muscle grade less than 3
D=Incomplete: Motor function is preserved below the neurological level, and at least half of key muscles below the neurological level have a grade of 3 or more
E= Normal: motor and sensory function are normal

vii. A worksheet which details dermatomes and muscle testing required is available from ASIA.

f. Soft Tissue Injury Evaluation. Soft tissue injuries are traumatic injuries to the muscles, ligaments, tendons, and/or connective tissue. The most common mechanism is sudden hyperextension and/or hyperflexion of the neck. Acceleration/deceleration on the lateral plane may also result in one of these syndromes. A true isolated cervical strain is not associated with focal neurological symptoms. The signs and pathophysiology of these injuries are not well understood. Soft tissue injuries may include cervical strain, myofascial syndromes, somatic dysfunction, and fractures. The Quebec Classification is used to categorize soft tissue and more severe cervical injuries.

i. Grade I—neck complaints of pain, stiffness, or tenderness only, without physical signs. Lesion not serious

enough to cause muscle spasm. Includes whiplash injury, minor cervical sprains, or strains.

ii. Grade II—neck complaints with musculoskeletal signs, such as limited range-of-motion. Includes muscle spasm related to soft tissue injury, whiplash, cervical sprain, and cervicalgia with headaches, sprained cervical facet joints and ligaments.

iii. Grade III—neck complaints, such as limited range-of-motion, combined with neurologic signs. Includes whiplash, cervicobrachialgia, herniated disc, cervicalgia with headaches.

iv. Grade IV—neck complaints with fracture or dislocation.

2. Imaging of the cervical spine is a generally accepted, well-established and widely used diagnostic procedure. Basic views are the anteroposterior (AP), lateral, right, and left obliques, swimmer's, and odontoid. CT scans may be necessary to visualize C7 and odontoid in some patients. Lateral flexion and extension views are done to evaluate instability but may have a limited role in the acute setting. MRI or CT is indicated when spinal cord injury is suspected. The mechanism of injury and specific indications for the imaging should be listed on the request form to aid the radiologist and x-ray technician. Alert, non-intoxicated patients, who have isolated cervical complaints without palpable midline cervical tenderness, neurologic findings, or other acute or distracting injuries elsewhere in the body, may not require imaging. The following suggested indications are:

a. history of significant trauma, especially high impact motor vehicle accident, rollover, ejection, bicycle, or recreational vehicle collision or fall from height greater than one meter;

b. age over 65 years;

c. suspicion of fracture, dislocation, instability, or neurologic deficit—Quebec Classification Grade III and IV;

d. unexplained or persistent cervical pain for at least 6 weeks or pain that is worse with rest;

e. localized pain, fever, constitutional symptoms, suspected tumor, history of cancer, or suspected systemic illness such as a rheumatic/rheumatoid disorder or endocrinopathy;

3. Laboratory Testing. Laboratory tests are generally accepted, well-established and widely used procedures. They are, however, rarely indicated at the time of initial evaluation, unless there is suspicion of systemic illness, infection, neoplasia, or underlying rheumatologic disorder, connective tissue disorder, or based on history and/or physical examination. Laboratory tests can provide useful diagnostic information. Tests include, but are not limited to:

a. complete blood count (CBC) with differential can detect infection, blood dyscrasias, and medication side effects;

b. erythrocyte sedimentation rate (ESR), rheumatoid factor (RF), anti-nuclear antigen (ANA), human leukocyte antigen (HLA), and C-reactive protein (CRP), can be used to detect evidence of a rheumatologic, infection, or connective tissue disorder;

c. serum calcium, phosphorous, uric acid, alkaline phosphatase, and acid phosphatase can detect metabolic bone disease; and;

d. liver and kidney function may be performed for prolonged anti-inflammatory use or other medications requiring monitoring.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1632 (June 2011).

§2007. Follow-Up Diagnostic Imaging and Testing Procedures

A. One diagnostic imaging procedure may provide the same or distinctive information as does another procedure. Therefore, prudent choice of a single diagnostic procedure, a complement of procedures, or a sequence of procedures will optimize diagnostic accuracy, and maximize cost effectiveness (by avoiding redundancy), and minimize potential adverse effects to patients.

B. All imaging procedures have a degree of specificity and sensitivity for various diagnoses. No isolated imaging test can assure a correct diagnosis. Clinical information obtained by history taking and physical examination should form the basis for selecting an imaging procedure and interpreting its results.

C. Magnetic resonance imaging (MRI), myelography, or computed axial tomography (CT) scanning following myelography may provide useful information for many spinal disorders. When a diagnostic procedure, in conjunction with clinical information, provides sufficient information to establish an accurate diagnosis, the second diagnostic procedure will become a redundant procedure. At the same time, a subsequent diagnostic procedure can be a complementary diagnostic procedure if the first or preceding procedures, in conjunction with clinical information, cannot provide an accurate diagnosis. Usually, preference of a procedure over others depends upon availability, a patient's tolerance, and/or the treating practitioner's familiarity with the procedure.

1. Imaging studies are generally accepted, well-established and widely used diagnostic procedures. In the absence of myelopathy, progressive neurological changes or incapacitating pain, imaging usually is not appropriate until conservative therapy has been tried and failed. Six to eight weeks of treatment are usually an adequate period of time before an imaging procedure is in order, but the clinician should use judgment in this regard. When the findings of the diagnostic imaging and testing procedures are not consistent with the clinical examination, clinical findings should have preference. There is good evidence that in the over 40 asymptomatic population, the prevalence of disc degeneration is greater than 50 percent. Disc degeneration, seen as loss of signal intensity on MRI, may be due to age-related biochemical changes rather than structural deterioration, and may not have pathological significance. Disc bulging and posterior disc protrusion, while not rare, is more commonly symptomatic in the cervical spine than in the lumbar spine due to the smaller cervical spinal canal. Mild reduction in the cross-sectional area of the spinal cord may be seen without myelopathy in patients older than 40, therefore, clinical correlation is required. The studies below are listed in frequency of use, not importance.

a. Magnetic Resonance Imaging (MRI) is the imaging study of choice for most abnormalities of the

cervical spine. MRI is useful in suspected nerve root compression, in myelopathy to evaluate the spinal cord and/or masses, infections such as epidural abscesses or disc space infection, bone marrow involvement by metastatic disease, and/or suspected disc herniation or cord contusion following severe neck injury. MRI should be performed immediately if there is a question of infection or metastatic disease with cord compression. MRI is contraindicated in patients with certain implanted devices.

b. In general, the high field, conventional, MRI provides better resolution. A lower field scan may be indicated when a patient cannot fit into a high field scanner or is too claustrophobic despite sedation. Inadequate resolution on the first scan may require a second MRI using a different technique. All questions in this regard should be discussed with the MRI center and/or radiologist. Specialized MRI Scans:

i. MRI with 3-dimensional reconstruction. On rare occasions, MRI with 3-dimensional reconstruction views may be used as a pre-surgical diagnostic procedure to obtain accurate information of characteristics, location, and spatial relationships among soft tissue and bony structures;

ii. Dynamic-kinetic MRI of the spine. Dynamic-kinetic MRI of the spine uses an MRI unit configured with a top-front open design which enables upright, weight-bearing patient positioning in a variety of postures not obtainable with the recumbent images derived from conventional, closed unit MRI systems. Imaging can be obtained in flexion, extension, and rotation of the spine, as well as in erect positioning. There is a theoretical advantage to imaging sequences obtained under more physiologic conditions than in the supine position. There is currently ongoing research to establish whether the theoretical advantages of positional and kinetic MRI result in improved sensitivity and specificity in detecting spine pathology. Currently it remains investigational, and is not recommended until the correlation with clinical syndromes is firmly established.

c. Computed Axial Tomography (CT) provides excellent visualization of bone and is used to further evaluate bony masses and suspected fractures not clearly identified on radiographic evaluation. It may sometimes be done as a complement to MRI scanning to better delineate bony osteophyte formation in the neural foramen. CT is usually utilized for suspected cervical spine fracture in a patient with negative plain films, or to further delineate a cervical fracture. CT scanning is also quite useful for congenital anomalies at the skull base and at the C1-2 levels. Plain CT scanning is poor for the C6-7 or C7-T1 levels because of shoulder artifact. Instrument-scatter reduction software provides better resolution when metallic artifact is of concern.

d. Myelography is the injection of radiopaque material into the spinal subarachnoid space, with x-rays then taken to define anatomy. It may be used as a diagnostic procedure to obtain accurate information of characteristics, location, and spatial relationships among soft tissue and bony structures. Myelography is an invasive procedure with complications including nausea, vomiting, headache, convulsion, arachnoiditis, CSF leakage, allergic reactions, bleeding, and infection. Therefore, myelography should only be considered when CT and MRI are unavailable, for morbidly obese patients or those who have undergone multiple operations, and when other tests prove non-diagnostic. The use of small needles and a less toxic, water-soluble, nonionic contrast is recommended.

e. CT Myelogram provides more detailed information about relationships between neural elements and surrounding anatomy and is appropriate in patients with multiple prior operations or tumorous conditions.

f. Single Photon Emission Computerized Tomography (SPECT) A scanning technique which may be helpful to localize facet joint pathology and is useful in determining which patients are likely to have a response to facet injection. SPECT combines bone scans & CT Scans in looking for facet joint pathology.

g. Bone Scan (Radioisotope Bone Scanning) is generally accepted, well-established and widely used. Bone scanning is more sensitive but less specific than MRI. 99MTechnetium diphosphonate uptake reflects osteoblastic activity and may be useful in diagnosing metastatic/primary bone tumors, stress fractures, osteomyelitis, and inflammatory lesions, but cannot distinguish between these entities. In the cervical spine, the usual indication is to evaluate for neoplastic conditions. Other indications include occult fracture or infection.

h. Other Radioisotope Scanning Indium and gallium scans are generally accepted, well-established, and widely used procedures, usually to help diagnose lesions seen on other diagnostic imaging studies. 67Gallium citrate scans are used to localize tumor, infection, and abscesses. 111Indium-labeled leukocyte scanning is utilized for localizing infection or inflammation and is usually not used for the cervical spine.

i. Dynamic [Digital] Fluoroscopy Dynamic [Digital] Fluoroscopy of the cervical spine measures the motion of intervertebral segments using a videofluoroscopy unit to capture images as the subject performs cervical flexion and extension, storing the anatomic motion of the spine in a computer. Dynamic Fluoroscopy may be used in state-designated trauma centers to evaluate the cervical spine. Its superiority over MRI has not been established. If performed, full visualization of the cervical spine (C1 - T1), in accordance with §2005.A.2. (Initial Diagnostic Procedures-Imaging), should be accomplished prior to the procedure. In the post-acute setting in some rare cases, Dynamic [Digital] Fluoroscopy may be used but is primarily an investigational tool and therefore, requires prior authorization in the post-acute setting. No studies have yet demonstrated predictive value in terms of standard operative and non-operative therapeutic outcomes.

2. Other Tests. The following diagnostic procedures are listed in alphabetical order, not by importance.

a. Electrodiagnostic Testing

i. Electromyography (EMG), and Nerve Conduction Studies. (NCS). These are generally accepted, well-established and widely used diagnostic procedures. EMG and NCS, when performed and interpreted by a trained physician/electrophysiologist, may be useful for patients with suspected neural involvement whose symptoms are persistent or unresponsive to initial conservative treatments. They are used to differentiate peripheral neural deficits from radicular and spinal cord neural deficits and to rule out concomitant myopathy. However, F-Wave Latencies are not diagnostic for radiculopathy.

ii. In general, EMG and NCS are complementary to imaging procedures such as CT, MRI, and/or myelography or diagnostic injection procedures. Electrodiagnostic studies may provide useful, correlative neuropathophysiological information that would be otherwise unobtainable from the radiologic studies discussed above.

iii. Portable Automated Electrodiagnostic Device (also known as Surface EMG) this is not a substitute for conventional diagnostic testing in clinical decision-making and therefore, is not recommended.

iv. Somatosensory Evoked Potential (SSEP) is useful for the evaluation of myelopathy. It is not recommended to identify radiculopathy.

v. Current Perception Threshold Evaluation (CPT) may be useful as a screening tool, but its diagnostic efficacy in the evaluation of cervical spine pain has not been determined. Therefore, CPT is not recommended as a diagnostic tool

b. Injections—Diagnostic

i. Description Diagnostic cervical injections are generally accepted well-established procedures. These injections may be useful for localizing the source of pain, and may have added therapeutic value when combined with injection of therapeutic medication(s). Each diagnostic injection has inherent risks, and risk versus benefit should always be evaluated when considering injection therapy.

ii. Since these procedures are invasive, less invasive or non-invasive procedures should be considered first. Selection of patients, choice of procedure, and localization of the level for injection should be determined by clinical information indicating strong suspicion for pathologic condition(s) and the source of pain symptoms. Because injections are invasive with an inherent risk, the number of diagnostic procedures should be limited in any individual patient to those most likely to be primary pain generators. Patients should not receive all of the diagnostic blocks listed merely in an attempt to identify 100 percent of the pain generators.

iii. The interpretation of the test results are primarily based on functional change, symptom report, and pain response (via a recognized pain scale before and at an appropriate time after the injection). The diagnostic significance of the test result should be evaluated in conjunction with clinical information and the results of other diagnostic procedures. Injections with local anesthetics of differing duration may be used to support a diagnosis. In some cases, injections at multiple levels may be required to accurately diagnose cervical conditions. Refer to Injections – Therapeutic for information on specific injections.

iv. It is obligatory that sufficient data be accumulated by the examiner performing this procedure such that the diagnostic value of the procedure is evident to other reviewers. This entails, at a minimum, documentation of patient response immediately following the procedure with details of any symptoms with a response and the degree of response. Additionally, a log must be recorded as part of the medical records which documents response, if any, on an hourly basis for, at a minimum, the expected duration of local anesthetic phase of the procedure. Responses must be identified as to specific body part (e.g., neck, arm pain). The practitioner must identify the local anesthetic used and the expected duration of response for diagnostic purposes.

v. Multiple injections provided at the same session without staging may seriously dilute the diagnostic value of these procedures. Practitioners must carefully weigh the diagnostic value of the procedure against the possible therapeutic value.

vi. Special Requirements for Diagnostic Injections. Since multi-planar fluoroscopy during procedures is required to document technique and needle placement, an experienced physician should perform the procedure. Permanent images are required to verify needle placement. The subspecialty disciplines of the physicians performing the injections may be varied, including, but not limited to: anesthesiology, radiology, surgery, or physiatry. The practitioner should have completed fellowship training in pain medicine with interventional training, or its equivalent. They must also be knowledgeable in radiation safety.

vii. Complications. General complications of diagnostic injections may include transient neurapraxia, nerve injury, infection, headache, vasovagal effects, as well as epidural hematoma, permanent neurologic damage, dural perforation and CSF leakage, and spinal meningeal abscess. Severe complications are remote but can include spinal cord damage, quadriplegia, and/or death. Injections at a C2-C3 level frequently cause temporary neuritis with ataxia.

viii. Contraindications. Absolute contraindications to diagnostic injections include:

(a). bacterial infection—systemic or localized to region of injection;

(b). bleeding diatheses;

(c). hematological conditions and

(d). possible pregnancy.

ix. Relative contraindications to diagnostic injections may include: allergy to contrast, poorly controlled Diabetes Mellitus, and hypertension.

x. Drugs affecting coagulation may require restriction from use. Anti-platelet therapy and anti-coagulations should be addressed individually by a knowledgeable specialist. It is recommended to refer to the American Society of Regional Anesthesia for anticoagulation guidelines.

xi. Specific Diagnostic Injections. In general, relief should last for at least the duration of the local anesthetic used and should significantly relieve pain and result in functional improvement. Refer to "Injections—Therapeutic" for information on specific therapeutic injections.

(a). Medial branch blocks are generally-accepted diagnostic injections, used to determine whether a patient is a candidate for radiofrequency medial branch neurotomy (also known as facet rhizotomy). The International Spine Intervention Society (ISIS) suggests controlled blocks—using either placebo or an anesthetic with a varying length of activity (i.e., bupivacaine longer than lidocaine). To be a positive diagnostic block, the patient should report a reduction of pain of 50 percent or greater from baseline for the length of time appropriate for the local anesthetic used. In almost all cases, this will mean a reduction of pain to 1 or 2 on the Visual Analog Scale (VAS) 10-point scale correlated with functional improvement. The patient should

also identify activities of daily living (which may include measurements of range-of-motion) that are impeded by their pain and can be observed to document functional improvement in the clinical setting. Ideally, these activities should be assessed throughout the observation period for function. The observer should not be the physician who performed the procedure. It is suggested that this be recorded on a form similar to ISIS recommendations.

(b). A separate comparative block on a different date may be performed to confirm the level of involvement. A comparative block uses anesthetics with varying lengths of activity. Medial Branch blocks are probably not helpful to determine the likelihood of success for spinal fusion.

(i). Frequency and Maximum Duration May be repeated once for comparative blocks. Limited to four levels / five medial branches.

c. Atlanto-Axial and Atlanto-Occipital injections are generally accepted for diagnosis and treatment but do not lend themselves to denervation techniques owing to variable neuroanatomy. Injection of this articulation is complicated by the proximity of the vertebral artery, which may be tortuous at the level of the C1 joint. Inadvertent injection of the vertebral artery may cause respiratory arrest, seizure, stroke, or permanent neurological sequelae. Only practitioners skilled in these injections should perform them.

i. Frequency and Maximum Duration: Once per side

d. Transforaminal injections / Spinal selective nerve root blocks are generally accepted and useful in identifying spinal pathology. When performed for diagnosis, small amounts of local anesthetic should be used to determine the level of nerve root irritation. A positive diagnostic block should result in a positive diagnostic functional benefit and a 50 percent reduction in nerve-root generated pain appropriate for the anesthetic used as measured by accepted pain scales (such as a VAS).

i. Time to Produce Effect: less than 30 minutes for local anesthesia; corticosteroids up to 72 hours for most patients.

ii. Frequency and Maximum Duration: once per suspected level. limited to two levels

e. Zygapophyseal (Facet) Blocks. Facet blocks are generally accepted but should not be considered diagnostic blocks for the purposes of determining the need for a rhizotomy (radiofrequency medial branch neurotomy), nor should they be done with medial branch blocks.

f. These blocks should not be considered a definitive diagnostic tool. They may be used diagnostically to direct functional rehabilitation programs. A positive diagnostic block should result in a positive diagnostic functional benefit and a 50 percent reduction in pain appropriate for the anesthetic used as measured by accepted pain scales (such as a VAS). They then may be repeated per the therapeutic guidelines when they are accompanied by a functional rehabilitation program. (Refer to Therapeutic Spinal Injections.)

i. Time to Produce Effect: Less than 30 minutes for local anesthesia; corticosteroids up to 72 hours for most patients.

ii. Frequency and Maximum Duration: Once per suspected level, limited to two levels.

g. Personality/ Psychological/ Psychiatric/ Psychosocial Evaluation: These are generally accepted and well-established diagnostic procedures with selective use in the upper extremity population, but have more widespread use in subacute and chronic upper extremity populations. Diagnostic testing procedures may be useful for patients with symptoms of depression, delayed recovery, chronic pain, recurrent painful conditions, disability problems, and for preoperative evaluation. Psychological/psychosocial and measures have been shown to have predictive value for postoperative response, and therefore should be strongly considered for use pre-operatively when the surgeon has concerns about the relationship between symptoms and findings, or when the surgeon is aware of indications of psychological complication or risk factors for psychological complication (e.g. childhood psychological trauma). Psychological testing should provide differentiation between pre-existing conditions versus injury caused psychological conditions, including depression and posttraumatic stress disorder. Psychological testing should incorporate measures that have been shown, empirically, to identify comorbidities or risk factors that are linked to poor outcome or delayed recovery.

i. Formal psychological or psychosocial evaluation should be performed on patients not making expected progress within 6 to 12 weeks following injury and whose subjective symptoms do not correlate with objective signs and test results. In addition to the customary initial exam, the evaluation of the injured worker should specifically address the following areas:

(a). employment history;

(b). interpersonal relationships-both social and work;

(c). patient activities;

(d). current perception of the medical system;

(e). current perception/attitudes toward employer/job

(f). results of current treatment

(g). risk factors and psychological comorbidities that may influence outcome and that may require treatment

(h). childhood history, including history of childhood psychological trauma, abuse and family history of disability.

ii. Personality/ psychological/ psychosocial evaluations consist of two components, clinical interview and psychological testing. Results should help clinicians with a better understanding of the patient in a number of ways. Thus the evaluation result will determine the need for further psychosocial interventions; and in those cases, Diagnostic and Statistical Manual of Mental Disorders (DSM) diagnosis should be determined and documented. The evaluation should also include examination of both psychological comorbidities and psychological risk factors that are empirically associated with poor outcome and/or delayed recovery. An individual with a Ph.D., Psy.D, or psychiatric M.D./D.O. credentials should perform initial evaluations, which are generally completed within one to two hours. A professional fluent in the primary language of the patient is preferred. When such a provider is not available, services of a professional language interpreter should be provided.

iii. Frequency: one-time visit for the clinical interview. If psychometric testing is indicated as a part of the initial evaluation, time for such testing should not exceed an additional two hours of professional time.

h. Provocation Discography

i. Description. Discography is an accepted, but rarely indicated, invasive diagnostic procedure to identify or refute a discogenic source of pain for patients who are surgical candidates. Discography should only be performed by physicians who are experienced and have been proctored in the technique. Discograms have a significant false positive rate. It is essential that all indications, preconditions, special considerations, procedures, reporting requirements, and results, are carefully and specifically followed. Results should be interpreted judiciously. Fewer studies have been published on cervical and thoracic discography than on lumbar discography.

ii. Indications. Discography may be indicated when a patient has a history of functionally limiting, unremitting cervical pain of greater than four months duration, with or without arm pain, which has been unresponsive to all conservative interventions. A patient who does not desire operative therapeutic intervention is not a candidate for an invasive non-therapeutic intervention, such as provocation discography.

iii. Discography may prove useful for the evaluation of the pre-surgical spine, discogenic pain at levels above or below a prior spinal fusion, annular tear, or internal disc disruption.

iv. Discography may show disc degeneration and annular disruption in the absence of cervical pain. Discography may also elicit concordant pain in patients with mild and functionally inconsequential neck pain. Because patients with mild neck pain should not be considered for invasive treatment, discography should not be performed on these patients. The presence of an annular tear does not necessarily identify the tear as a pain generator.

v. Discography is not useful in previously operated discs. Discography may prove useful in evaluating the number of cervical spine levels that might require fusion. CT Discography provides further detailed information about morphological abnormalities of the disc and possible lateral disc herniations.

vi. Preconditions for provocation discography include all of the following:

(a). A patient with functionally limiting, unremitting neck and/or arm pain of greater than four months duration in whom conservative treatment has been unsuccessful and in whom the specific diagnosis of the pain generator has not been made apparent on the basis of other noninvasive imaging studies (e.g., MRI, CT, plain films, etc.). It is recommended that discography be reserved for use in patients with equivocal MRI findings, especially at levels adjacent to clearly pathological levels. Discography may be more sensitive than MRI or CT in detecting radial annular tears. However, radial tears must always be correlated with clinical presentation.

(b). Psychosocial evaluation has been completed. There is some evidence that false positives and complaints of long-term pain arising from the procedure itself occur more frequently in patients with somatoform disorders. Therefore, discograms should not be performed on patients with non-anatomic symptoms consistent with somatoform disorders.

(c). Patients who are considered surgical candidates (e.g., symptoms are of sufficient magnitude and the patient has been informed of the possible surgical options that may be available based upon the results of discography). Discography should never be the sole indication for surgery.

(d). Informed consent regarding the risks and potential diagnostic benefits of discography has been obtained.

vii. Complications include, but are not limited to, discitis, nerve damage, retropharyngeal abscess, chemical meningitis, pain exacerbation, and anaphylaxis. Therefore, prior to consideration of discography, the patient should undergo other diagnostic modalities in an effort to define the etiology of the patient's complaint including psychological evaluation, myelography, CT and MRI.

viii. Contraindications include:

(a) active infection of any type or continuing antibiotic treatment for infection; and/or

(b) bleeding diathesis or pharmaceutical anticoagulation with warfarin, etc.; and/or

(c) significant spinal stenosis at the level being studied as visualized by MRI, myelography or CT scan; and/or

(d) presence of clinical myelopathy; and/or

(e) effacement of the cord, thecal sac or circumferential absence of epidural fat; and

(f) known allergic reactions.

ix. Special Considerations

(a). Discography should not be performed by the physician expected to perform the therapeutic procedure. The procedure should be carried out by an experienced individual who has received specialized training in the technique of provocation discography.

(b). Discography should be performed in a blinded format that avoids leading the patient with anticipated responses. The procedure should always include one or more disc levels thought to be normal or nonpainful in order to serve as an internal control. The patient should not know what level is being injected in order to avoid spurious results. Adjacent discs may be identified as pain generators in more than half of cases in which discogenic pain is identified at one level. Because surgery is likely to fail in multi-level discogenic pain, injection of as many levels as feasible can prevent many operative failures. Abnormal disc levels may be repeated to confirm concordance.

(c). Sterile technique must be utilized.

(d). Judicious use of light sedation during the procedure is acceptable, represents the most common practice nationally at the current time, and is recommended by most experts in the field. The patient must be awake and able to accurately report pain levels during the provocation portion of the procedure.

(e). CT or MRI should establish cervical spinal dimensions and ruled out spinal stenosis.

(f). Intradiscal injection of local anesthetic may be carried out after the provocation portion of the examination and the patient's response.

(g). It is recommended that a post-discogram CT be considered as it frequently provides additional useful information about disc morphology or other pathology.

x. Reporting of Discography. In addition to a narrative report, the discography report should contain a standardized classification of disc morphology and the pain response. All results should be clearly separated in the report from the narrative portion. Asymptomatic annular tears are common and the concordant pain response is an essential finding for a positive discogram.

xi. When discography is performed to identify the source of a patient's neck pain, both a concordant pain response and morphological abnormalities must be present at the pathological level prior to initiating any treatment directed at that level. The patient must be awake during the provocation phase of the procedure; therefore, sedative medication must be carefully titrated.

xii. Caution should be used when interpreting results from discography. One study using asymptomatic volunteers reported pain in the majority of discs injected, but no subjects reported pain exceeding 6/10 on a pain scale in a normal disc.

i. Reporting disc morphology as visualized by the post-injection CT scan (when available) should follow the Modified Dallas Discogram Scale where

i. Grade 0 = Normal Nucleus.

ii. Grade 1 = Annular tear confined to inner one-third of annulus fibrosis.

iii. Grade 2 = Annular tear extending to the middle third of the annulus fibrosis.

iv. Grade 3 = Annular tear extending to the outer one-third of the annulus fibrosis.

v. Grade 4 = A grade 3 tear plus dissection within the outer annulus to involve more than 30 degrees of the disc circumference.

vi. Grade 5 = Full thickness tear with extra-annular leakage of contrast, either focal or diffuse.

j. Reporting of pain response should be consistent with the operational criteria of the International Spine Intervention Society Guidelines (ISIS). The report must include the level of concordance for neck and arm pain separately using a 10-point VAS, or similar quantitative assessment. It should be noted that the change in the VAS score before and after provocation is more important than the number reported.

k. The diagnosis of discogenic pain is less likely when there are more discs with dissimilar pain and fewer with no pain. At least two discs with no pain on stimulation and one disc with concordant pain registering at least 7 on a 10-point VAS or equivalent should be present to qualify for a diagnosis of discogenic pain. The VAS score prior to the discogram should be taken into account when interpreting the VAS score reported by the patient during the discogram.

l. Time parameters for provocation discography are as follows:

i. Frequency: One time only.

ii. Maximum: Repeat Discography is rarely indicated

m. Thermography is an accepted and established procedure, but has no use as a diagnostic test for cervical pain. It may be used to diagnose regional pain disorders and in these cases, refer to the Complex Regional Pain Syndrome/Reflex Sympathetic Dystrophy Medical Treatment Guidelines.

3. Special tests are generally well-accepted tests and are performed as part of a skilled assessment of the patients' capacity to return-to-work, his/her strength capacities, and physical work demand classifications and tolerance. The procedures in this subsection are listed in alphabetical order, not by importance.

a. Computer-Enhanced Evaluations may include isotonic, isometric, isokinetic and/or isoinertial measurement of movement, range-of-motion, endurance, or strength. Values obtained can include degrees of motion, torque forces, pressures, or resistance. Indications include determining validity of effort, effectiveness of treatment and demonstrated motivation. These evaluations should not be used alone to determine return-to-work restrictions.

i. Frequency: One time for evaluation. Can monitor improvements in strength every three to four weeks up to a total of six evaluations.

b. Functional Capacity Evaluation (FCE): is a comprehensive or modified evaluation of the various aspects of function as they relate to the worker's ability to return to work. Areas such as endurance, lifting (dynamic and static), postural tolerance, specific range-of-motion, coordination and strength, worker habits, employability, as well as psychosocial, cognitive, and sensory perceptual aspects of competitive employment may be evaluated. Components of this evaluation may include: musculoskeletal screen; cardiovascular profile/aerobic capacity; coordination; lift/carrying analysis; job-specific activity tolerance; maximum voluntary effort; pain assessment/psychological screening; non-material and material handling activities cognitive; visual; and sensory perceptual factors.

i. When an FCE is being used to determine return to a specific jobsite, the provider is responsible for fully understanding the job duties. A jobsite evaluation is frequently necessary. FCEs cannot be used in isolation to determine work restrictions. The authorized treating physician must interpret the FCE in light of the individual patient's presentation and medical and personal perceptions. FCEs should not be used as the sole criteria to diagnose malingering.

ii. Full FCEs are sometimes not necessary. If Partial FCEs are performed, it is recognized that all parts of the FCE that are not performed are considered normal. In many cases, a work tolerance screening will identify the ability to perform the necessary job tasks.

c. Frequency: Can be used initially to determine baseline status. Additional evaluations can be performed to monitor and assess progress and aid in determining the endpoint for treatment.

d. Job site evaluation is a comprehensive analysis of the physical, mental and sensory components of a specific job. These components may include, but are not limited to; postural tolerance (static and dynamic); aerobic requirements; range-of-motion; torque/force; lifting/carrying; cognitive demands; social interactions; visual perceptual; sensation; coordination; environmental requirements of a job; repetitiveness; and essential job functions.

i. Job descriptions provided by the employer are helpful but should not be used as a substitute for direct

observation. A jobsite evaluation may include observation and instruction of how work is done, what material changes (desk, chair) should be made, and determination of readiness to return-to-work.

ii. Requests for a jobsite evaluation should describe the expected goals for the evaluation. Goals may include, but are not limited to the following.

(a). to determine if there are potential contributing factors to the person's condition and/or for the physician to assess causality;

(b). to make recommendations for, and to assess the potential for ergonomic changes;

(c). to determine the essential demands of the job. To provide a detailed description of the physical and cognitive job requirements;

(d). to assist the patient in their return-to-work by educating them on how they may be able to do their job more safely and in a more bio-mechanically appropriate manner;

(e). to give detailed work/activity restrictions.

iii. Frequency: One time with additional visits as needed for follow-up per jobsite.

f. Vocational Assessment. The vocational assessment should provide valuable guidance in the determination of future rehabilitation program goals. It should clarify rehabilitation goals, which optimize both patient motivation and utilization of rehabilitation resources. If prognosis for return to former occupation is determined to be poor, except in the most extenuating circumstances, vocational assessment should be implemented within 3 to 12 months post-injury. Declaration of MMI should not be delayed solely due to lack of attainment of a vocational assessment.

i. Frequency: One time with additional visits as needed for follow-up

g. Work Tolerance Screening: is a determination of an individual's tolerance for performing a specific job based on a job activity or task and may be used when a full Functional Capacity Evaluation is not indicated. It may include a test or procedure to specifically identify and quantify work-relevant cardiovascular, physical fitness and postural tolerance. It may also address ergonomic issues affecting the patient's return-to-work potential. Full job description should include a physical assessment of the job requirements

i. Frequency: One time for initial screen. May monitor improvements in strength every 3 to 4 weeks up to a total of 6 visits.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1634 (June 2011).

§2009. Therapeutic Procedures—Non-Operative

A. Before initiation of any therapeutic procedure, the authorized treating provider, employer, and insurer must consider these important issues in the care of the injured worker.

B. First, patients undergoing therapeutic procedure(s) should be released or returned to modified or restricted duty during their rehabilitation at the earliest appropriate time. Refer to "Return-to-Work" in this section for detailed information.

C. Second, cessation and/or review of treatment modalities should be undertaken when no further significant subjective or objective improvement in the patient's condition is noted. If patients are not responding within the recommended duration periods, alternative treatment interventions, further diagnostic studies or consultations should be pursued.

D. Third, providers should provide and document education to the patient. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of facilitating self-management of symptoms

E. Lastly, formal psychological or psychosocial evaluation should be performed on patients not making expected progress within 6 to 12 weeks following injury and whose subjective symptoms do not correlate with objective signs and tests.

F. Home therapy is an important component of therapy and may include active and passive therapeutic procedures as well as other modalities to assist in alleviating pain, swelling, and abnormal muscle tone.

G. The following procedures are listed in alphabetical order.

1. Acupuncture is an accepted and widely used procedure for the relief of pain and inflammation, and there is some scientific evidence to support its use. The exact mode of action is only partially understood. Western medicine studies suggest that acupuncture stimulates the nervous system at the level of the brain, promotes deep relaxation, and affects the release of neurotransmitters. Acupuncture is commonly used as an alternative or in addition to traditional Western pharmaceuticals. While it is commonly used when pain medication is reduced or not tolerated, it may be used as an adjunct to physical rehabilitation and/or surgical intervention to hasten the return of functional activity. Acupuncture should be performed by licensed practitioners.

a. Acupuncture is the insertion and removal of filiform needles to stimulate acupoints (acupuncture points). Needles may be inserted, manipulated, and retained for a period of time. Acupuncture can be used to reduce pain, reduce inflammation, increase blood flow, increase range-of-motion, decrease the side effect of medication-induced nausea, promote relaxation in an anxious patient, and reduce muscle spasm. Indications include joint pain, joint stiffness, soft tissue pain and inflammation, paresthesia, post-surgical pain relief, muscle spasm, and scar tissue pain.

b. Acupuncture with Electrical Stimulation: is the use of electrical current (micro-amperage or milli-amperage) on the needles at the acupuncture site. It is used to increase effectiveness of the needles by continuous stimulation of the acupoint. Physiological effects (depending on location and settings) can include endorphin release for pain relief, reduction of inflammation, increased blood circulation, analgesia through interruption of pain stimulus, and muscle relaxation.

i. It is indicated to treat chronic pain conditions, radiating pain along a nerve pathway, muscle spasm, inflammation, scar tissue pain, and pain located in multiple sites.

c. Total Time Frames for Acupuncture and Acupuncture with Electrical Stimulation: Time frames are

not meant to be applied to each of the above sections separately. The time frames are to be applied to all acupuncture treatments regardless of the type or combination of therapies being provided.

i. Time to Produce Effect: three to six treatments
ii. Frequency: one to three times per week.
iii. Optimum Duration: one to two months.
iv. Maximum Duration: 14 treatments.

2. Any of the above acupuncture treatments may extend longer if objective functional gains can be documented or when symptomatic benefits facilitate progression in the patient's treatment program. Treatment beyond 14 treatments must be documented with respect to need and ability to facilitate positive symptomatic or functional gains. Such care should be re-evaluated and documented with each series of treatments.

a. Other Acupuncture Modalities: Acupuncture treatment is based on individual patient needs and therefore treatment may include a combination of procedures to enhance treatment effect. Other procedures may include the use of heat, soft tissue manipulation/massage, and exercise. Refer to Active Therapy (Therapeutic Exercise) and Passive Therapy sections (Massage and Superficial Heat and Cold Therapy) for a description of these adjunctive acupuncture modalities and time frames.

3. Biofeedback is a form of behavioral medicine that helps patients learn self-awareness and self-regulation skills for the purpose of gaining greater control of their physiology, such as muscle activity, brain waves, and measures of autonomic nervous system activity. Electronic instrumentation is used to monitor the targeted physiology and then displayed or fed back to the patient visually, auditorially, or tactilely, with coaching by a biofeedback specialist. Biofeedback is provided by clinicians certified in biofeedback and/or who have documented specialized education, advanced training, or direct or supervised experience qualifying them to provide the specialized treatment needed (e.g., surface EMG, EEG, or other).

a. Treatment is individualized to the patient's work-related diagnosis and needs. Home practice of skills is required for mastery and may be facilitated by the use of home training tapes. The ultimate goal of biofeedback treatment is to normalize the physiology to the pre-injury status to the extent possible, and involves transfer of learned skills to the workplace and daily life. Candidates for biofeedback therapy or training must be motivated to learn and practice biofeedback and self-regulation techniques.

b. Indications for biofeedback include individuals who are suffering from musculoskeletal injury in which muscle dysfunction or other physiological indicators of excessive or prolonged stress response affects and/or delays recovery. Other applications include training to improve self-management of emotional stress/pain responses such as anxiety, depression, anger, sleep disturbance, and other central and autonomic nervous system imbalances. Biofeedback is often used in conjunction with other treatment modalities.

i. Time to Produce Effect: three to four sessions.
ii. Frequency: one to two times per week.
iii. Optimum Duration: five to six sessions.
iv. Maximum Duration: 10 to 12 sessions. Treatment beyond 12 sessions must be documented with respect to need, expectation, and ability to facilitate positive functional gains.

4. Injections—Therapeutic

a. Therapeutic Spinal Injections. Therapeutic spinal injections may be used after initial conservative treatments, such as physical and occupational therapy, medication, manual therapy, exercise, acupuncture, have been undertaken. Therapeutic injections should be used only after imaging studies and diagnostic injections have established pathology. Injections are invasive procedures that can cause catastrophic complications; thus clinical indications and contraindications should be closely adhered to. The purpose of spinal injections is to facilitate active therapy by providing short-term relief through reduction of pain and inflammation. All patients should continue appropriate exercise with functionally directed rehabilitation. Active treatment, which patients should have had prior to injections, will frequently require a repeat of the sessions previously ordered (Refer to Active Therapy). Injections, by themselves, are not likely to provide long-term relief. Rather, active rehabilitation with modified work achieves long-term relief by increasing active ROM, strength, and stability. Subjective reports of pain response (via a recognized pain scale) and function should be considered and given relative weight when the pain has anatomic and physiologic correlation. Anatomic correlation must be based on objective findings

b. Special Considerations—for all injections (excluding trigger point and occipital nerve blocks) multi-planar fluoroscopy, during procedures is required to document technique and needle placement, and should be performed by a physician experienced in the procedure. Permanent images are required to verify needle placement. The subspecialty disciplines of the physicians performing injections may be varied, including, but not limited to: anesthesiology, radiology, surgery, neurology or physiatry. The practitioner should have completed fellowship training in pain medicine with interventional training, or its equivalent. They must also be knowledgeable in radiation safety.

c. Complications. Appropriate medical disclosures with regard to potential complications should be provided to the patient as deemed appropriate by the treating physician.

d. Contraindications. Absolute contraindications to therapeutic injections include: (a) bacterial infection – systemic or localized to region of injection, (b) bleeding diatheses, (c) hematological conditions, and (d) possible pregnancy.

i. Relative contraindications to diagnostic injections may include: allergy to contrast, poorly controlled Diabetes Mellitus and hypertension.

(a). Drugs affecting coagulation may require restriction from use. Anti-platelet therapy and anti-coagulations should be addressed individually by a knowledgeable specialist. It is recommended to refer to American Society of Regional Anesthesia for anticoagulation guidelines.

(b). Cervical Epidural Steroid Injection (ESI)

(i). Description. Cervical ESIs are injections of corticosteroid into the epidural space. The purpose of ESI is to reduce pain and inflammation in the acute or subacute phases of injury, restoring range-of-

motion, and thereby, facilitating progress in more active treatment programs.

(ii). Needle placement. Multi-planar fluoroscopic imaging is required for all epidural steroid injections. Contrast epidurograms allow one to verify the flow of medication into the epidural space. Permanent images are required to verify needle placement.

(iii). Indications. Cervical ESIs are useful in patients with symptoms of cervical radicular pain syndromes. They have less defined usefulness in non-radicular pain. There is some evidence that epidural steroid injections are effective for patients with radicular pain or radiculopathy (sensory or motor loss in a specific dermatome or myotome). In one study, 53 percent of patients had 50 percent or greater relief of pain at 6 months with only 20 percent having similar relief at 12 months. There is some evidence to suggest that epidural injections are not effective for cervical axial pain; however, it is an accepted intervention. Only patients who have:

[a]. pain affected by activity; and

[b]. annular tears verified by appropriate imaging may have injections for axial pain.

(iv). There is some evidence in studies of the lumbar spine that patients who smoke or who have pain unaffected by rest or activity are less likely to have a successful outcome from ESIs. This may also apply to the cervical spine although there are currently no studies to verify this finding. MRI or CT scans are required prior to thoracic and cervical ESIs, to assure that adequate epidural space is present.

(c). Time to Produce Effect: Local anesthetic, less than 30 minutes; corticosteroid, 48 to 72 hours for 80 percent of patients and 72 hours to 2 weeks for 20 percent of patients.

ii. Frequency: One or more divided levels can be injected in one session. Whether injections are repeated depends upon the patient's response to the previous injection. Subsequent injections may occur after one to two weeks if there is a positive patient response. Positive patient response results are defined primarily as functional gains that can be objectively measured. Objective functional gains include, but are not limited to, positional tolerances, range of motion (ROM), strength, endurance, activities of daily living, cognition, psychological behavior, and efficiency/velocity measures that can be quantified. Subjective reports of pain response (via a recognized pain scale) and function should be considered and given relative weight when the pain has anatomic and physiologic correlation. Anatomic correlation must be based on objective findings.

(a). Injections can be repeated after a hiatus of six months if the patient has demonstrated functional gain and pain returns or worsens. If the first injection does not provide a diagnostic response with temporary and sustained pain relief (at least two to six weeks) substantiated by accepted pain scales (i.e., 50 percent pain reduction as measured by tools such as VAS), and improvement in function, similar injections should not be repeated.

(b). Optimal Duration: Usually one to three injection(s), over a period of six months depending upon each patient's response and functional gain.

(c). Maximum Duration: Two sessions consisting of up to three injections each may be done in one year, as per the patient's response to pain and function. Patients should be reassessed after each injection for a 50 percent improvement in pain (as measured by accepted pain scales) and evidence of functional improvement.

e. Zygapophyseal (Facet) Injection

i. Description. A generally accepted intra-articular or pericapsular injection of local anesthetic and corticosteroid. There is conflicting evidence to support long-term therapeutic effect using facet injections. There is no justification for a combined facet and medial branch block.

ii. Indications. Patients with pain 1) suspected to be facet in origin based on exam findings and 2) affecting activity; OR, patients who have refused a rhizotomy; OR, patients who have facet findings with a thoracic component. In these patients, facet injections may be occasionally useful in facilitating a functionally-directed rehabilitation program and to aid in identifying pain generators. Patients with recurrent pain should be evaluated with more definitive diagnostic injections, such as medial nerve branch injections, to determine the need for a rhizotomy. Because facet injections are not likely to produce long-term benefit by themselves and are not the most accurate diagnostic tool, they should not be performed at more than two levels.

iii. Facet injections may be repeated if they result in increased documented functional benefit for at least 4 to 6 weeks and at least a 50 percent initial improvement in pain scales as measured by accepted pain scales (such as VAS).

(a). Time to Produce Effect: Up to 30 minutes for local anesthetic; corticosteroid up to 72 hours.

(b). Frequency: 1 injection per level with a diagnostic response. If the first injection does not provide a diagnostic response of temporary and sustained pain relief substantiated by accepted pain scales, (i.e., 50 percent pain reduction substantiated by tools such as VAS), and improvement in function, similar injections should not be repeated. At least four to six weeks of functional benefit should be obtained with each therapeutic injection.

(c). Optimum Duration: two to three injections for each applicable joint per year. Not to exceed two joint levels.

(d). Maximum Duration: four per level per year. Prior authorization must be obtained for injections beyond two levels.

f. Intradiscal Steroid Therapy: Intradiscal Steroid Therapy consists of injection of a steroid preparation into the intervertebral disc under fluoroscopic guidance at the time of discography. There is good evidence that it is not effective in the treatment of suspected discogenic low back pain. There is no support for its use in the cervical spine and its use is not recommended.

g Radio Frequency (RF) Medial Branch Neurotomy/ Facet Rhizotomy:

i. Description. A procedure designed to denervate the facet joint by ablating the corresponding sensory medial branches. Continuous percutaneous radio-frequency is the method generally used.

ii. There is good evidence to support this procedure in the cervical spine but benefits beyond one year are not yet established. Radio-frequency medial branch

neurotomy is the procedure of choice over alcohol, phenol, or cryoablation. Precise positioning of the probe under fluoroscopic guidance is required since the maximum effective diameter of the device is a 5 x 8 millimeter oval. Permanent images should be recorded to verify placement of the device.

iii. Indications. Those patients with proven, significant, facetogenic pain. This procedure is not recommended for patients with multiple pain generators or involvement of more than three medial branch nerves.

iv. Individuals should have met the following indications: pain of well-documented facet origin, unresponsive to active and/or passive therapy, manual therapy, and in which a psychosocial screening has been performed (e.g., pain diagram, thorough psychosocial history, screening questionnaire). It is generally recommended that this procedure not be performed until three months of active therapy and manual therapy have been completed. All patients should continue appropriate exercise with functionally directed rehabilitation. Active treatment, which patients will have had prior to the procedure, will frequently require a repeat of the sessions previously ordered (Refer to Active Therapy).

v. All patients should have a successful response to a diagnostic medial nerve branch block and a separate comparative block. ISIS suggests controlled blocks-using either placebo or anesthetics with varying lengths of activity (i.e., bupivacaine longer than lidocaine). To be a positive diagnostic block the patient should report a reduction of pain of 50 percent or greater from baseline for the length of time appropriate for the local anesthetic used. In almost all cases this will mean a reduction of pain to 1 or 2 on the VAS 10-point scale correlated with functional improvement. The patient should also identify activities of daily living (which may include measurements of range-of-motion) that are impeded by their pain and can be observed to document functional improvement in the clinical setting. Ideally, these activities should be assessed throughout the observation period for function. The observer should not be the physician who performed the procedure. It is suggested that this be recorded on a form similar to ISIS recommendations.

vi. A separate comparative block may be performed on a different date to confirm the level of involvement. A comparative block uses anesthetics with varying lengths of activity.

vii. Complications. Appropriate medical disclosures should be provided to the patient as deemed necessary by the treating physician.

viii. Post-Procedure Therapy. Active therapy. Implementation of a gentle reconditioning program within the first post-procedure week is recommended, barring complications. Instruction and participation in a long-term home-based program of ROM, cervical, scapular, and thoracic strengthening, postural or neuromuscular re-education, endurance, and stability exercises should be accomplished over a period of four to ten visits post-procedure.

ix. Requirements for repeat RF neurotomy (or additional level RF neurotomies). In some cases pain may recur [ISIS]. Successful rhizotomy usually provides from six to eighteen months of relief.

x. Before a repeat RF neurotomy is done, a confirmatory medial branch injection should be performed if the patient's pain pattern presents differently than in the initial evaluation. In occasional patients, additional levels of RF neurotomy may be necessary. The same indications and limitations apply.

h. Occipital Nerve Block

i. Description. Occipital nerve blocks are generally accepted injections used both diagnostically and therapeutically in the treatment of occipital neuralgia. The greater occipital nerve is the target.

ii. Indications. Diagnosis and treatment of occipital neuralgia/cephalgia. Peripheral block of the greater occipital nerve may be appropriate as initial treatment. It may be indicated in patients unresponsive to peripheral nerve block or those patients in need of additional diagnostic information.

iii. Complications. Bleeding, infection, neural injury. Post procedural ataxia is common and usually lasts 30 minutes post procedure. Because the occipital artery runs with the occipital nerve, inadvertent intravascular injection is a risk of this procedure and may lead to systemic toxicity and/or seizures.

(a). Time to Produce Effect: Approximately 30 minutes for local anesthetic; 48 to 72 hours for corticosteroid.

(b). Optimal Duration: one to three sessions for each nerve

(c). Maximum Duration: Continue up to three injections if progressive symptomatic and functional improvement can be documented.

(e). Trigger Point Injections and Dry Needling Treatment

iv. Description. Trigger point injections are a generally accepted treatment. Trigger point treatment can consist of dry needling or injection of local anesthetic with or without, corticosteroid into highly localized, extremely sensitive bands of skeletal muscle fibers that produce local and referred pain when activated. Medication is injected in a four-quadrant manner in the area of maximum tenderness. Injection efficacy can be enhanced if injections are immediately followed by myofascial therapeutic interventions, such as vapo-coolant spray and stretch, ischemic pressure massage (myotherapy), specific soft tissue mobilization and physical modalities. There is conflicting evidence regarding the benefit of trigger point injections. A truly blinded study comparing dry needle treatment of trigger points is not feasible. There is no evidence that injection of medications improves the results of trigger-point injections. Needling alone may account for some of the therapeutic response.

v. There is no indication for conscious sedation for patients receiving trigger point injections. The patient must be alert to help identify the site of the injection.

vi. Indications. Trigger point injections may be used to relieve myofascial pain and facilitate active therapy and stretching of the affected areas. They are to be used as an adjunctive treatment in combination with other treatment modalities such as functional restoration programs. Trigger point injections should be utilized primarily for the purpose of facilitating functional progress. Patients should continue

in an aggressive aerobic and stretching therapeutic exercise program as tolerated throughout the time period they are undergoing intensive myofascial interventions. Myofascial pain is often associated with other underlying structural problems and any abnormalities need to be ruled out prior to injection.

vii. Trigger point injections are indicated in those patients where well circumscribed trigger points have been consistently observed, demonstrating a local twitch response, characteristic radiation of pain pattern and local autonomic reaction, such as persistent hyperemia following palpation. Generally, these injections are not necessary unless consistently observed trigger points are not responding to specific, noninvasive, myofascial interventions within approximately a six-week time frame.

viii. Complications. Potential but rare complications of trigger point injections include infection, pneumothorax, anaphylaxis, neurapraxia, and neuropathy. If corticosteroids are injected in addition to local anesthetic, there is a risk of local myopathy developing. Severe pain on injection suggests the possibility of an intraneural injection, and the needle should be immediately repositioned.

(a). Time to Produce Effect: Local anesthetic 30 minutes; no anesthesia 24 to 48 hours

(b). Frequency: Weekly, suggest no more than four injection sites per session per week to avoid significant post-injection soreness

(c). Optimal Duration: four Weeks

(d). Maximum Duration: eight weeks. Occasional patients may require two to four repetitions of trigger point injection series over a one to two year period.

(f). Prolotherapy: also known as sclerotherapy consists of a series of injections of hypertonic dextrose, with or without glycerine and phenol, into the ligamentous structures of the neck. There is no evidence that Prolotherapy is effective in cervical pain. The injections are invasive, may be painful to the patient, and are not generally accepted or widely used. Therefore, the use of Prolotherapy for cervical pain is not recommended.

(g). Epiduroscopy and Epidural Lysis of Adhesions: is not recommended in the cervical spine secondary to the potential for dural puncture, hematoma, and spinal cord injury.

5. Medications used in the treatment of cervical injuries is appropriate for controlling acute and chronic pain and inflammation. Use of medications will vary widely due to the spectrum of injuries from simple strains to post-surgical healing. All drugs should be used according to patient needs. A thorough medication history, including use of alternative and over the counter medications, should be performed at the time of the initial visit and updated periodically. Treatment for pain control is initially accomplished with acetaminophen and/or NSAIDs. The patient should be educated regarding the interaction with prescription and over-the-counter medications as well as the contents of over-the-counter herbal products. The following are listed in alphabetical order:

a. Acetaminophen: is an effective analgesic with antipyretic but not anti-inflammatory activity. Acetaminophen is generally well tolerated, causes little or no gastrointestinal irritation, and is not associated with ulcer formation. Acetaminophen has been associated with liver toxicity in overdose situations or in chronic alcohol use. Patients may not realize that many over-the-counter preparations may contain acetaminophen. The total daily dose of acetaminophen is recommended not to exceed 2250 mg per 24-hour period from all sources, including narcotic-acetaminophen combination preparations. Higher doses may result in liver toxicity.

i. Optimum Duration: 7 to 10 days.

ii. Maximum Duration: Chronic use as indicated on a case-by-case basis. Use of this substance long-term for three days per week or greater may be associated with rebound pain upon cessation.

b. Muscle Relaxants: are appropriate for muscle spasm with pain. There is strong evidence that muscle relaxants are more effective than placebo for providing short-term pain relief in acute low back pain. Similar effects can be expected for cervical pain. When prescribing these agents, physicians must seriously consider side effects of drowsiness or dizziness, and the fact that benzodiazepines may be habit-forming.

i. Optimum Duration: one week.

ii. Maximum Duration: two weeks (or longer if used only at night)

c. Narcotics should be primarily reserved for the treatment of severe cervical pain. In mild-to-moderate cases of cervical pain, narcotic medication should be used cautiously on a case-by-case basis. Adverse effects include respiratory depression, the development of physical and psychological dependence, and impaired alertness.

d. Narcotic medications should be prescribed with strict time, quantity, and duration guidelines, and with definitive cessation parameters. Pain is subjective in nature and should be evaluated using a scale to rate effectiveness of the narcotic prescribed. Any use beyond the maximum should be documented and justified based on the diagnosis and/or invasive procedures.

i. Optimum Duration: three to seven days.

ii. Maximum Duration: two weeks. Use beyond two weeks is acceptable in appropriate cases. Refer to Chronic Pain Guidelines which gives a detailed discussion regarding medication use in chronic pain management.

e. Nonsteroidal Anti-Inflammatory Drugs (NSAIDs): are useful for pain and inflammation. In mild cases, they may be the only drugs required for analgesia. There are several classes of NSAIDs, and the response of the individual injured worker to a specific medication is unpredictable. For this reason, a range of NSAIDs may be tried in each case with the most effective preparation being continued. Patients should be closely monitored for adverse reactions. The US Food and Drug Administration advise that many NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. Naproxen sodium does not appear to be associated with increased risk of vascular events. Administration of proton pump inhibitors, histamine 2 blockers, or prostaglandin analog misoprostol along with these NSAIDs may reduce the risk of duodenal and gastric ulceration but do not impact possible cardiovascular complications. Due to the cross-reactivity between aspirin and NSAIDs, NSAIDs should not be used in aspirin-sensitive patients, and should be used with caution in all asthma patients. NSAIDs are associated with abnormal renal

function, including renal failure, as well as abnormal liver function. Certain NSAIDs may have interactions with various other medications. Individuals may have adverse events not listed above. Intervals for metabolic screening are dependent upon the patient's age, general health status and should be within parameters listed for each specific medication. Complete blood count (CBC), and liver and renal function should be monitored at least every six months in patients on chronic NSAIDs and initially when indicated.

i. Non-selective Nonsteroidal Anti-Inflammatory Drugs

(a). Includes NSAIDs and acetylsalicylic acid (aspirin). Serious GI toxicity, such as bleeding, perforation, and ulceration can occur at any time, with or without warning symptoms in patients treated with traditional NSAIDs. Physicians should inform patients about the signs and/or symptoms of serious gastrointestinal toxicity and what steps to take if they occur. Anaphylactoid reactions may occur in patients taking NSAIDs. NSAIDs may interfere with platelet function. Fluid retention and edema have been observed in some patients taking NSAIDs.

(i). Optimal Duration: one week

(ii). Maximum Duration: one year Use of these substances long-term for (three days per week or greater) is associated with rebound pain upon cessation.

ii. Selective Cyclo-oxygenase-2 (COX-2) Inhibitors

(a). Selective cyclo-oxygenase-2 (COX-2) inhibitors are more recent NSAIDs and differ in adverse side effect profiles from the traditional NSAIDs. The major advantages of selective COX-2 inhibitors over traditional NSAIDs are that they have less gastrointestinal toxicity and no platelet effects. COX-2 inhibitors can worsen renal function in patients with renal insufficiency, thus renal function may need monitoring.

(b). COX-2 inhibitors should not be first-line for low risk patients who will be using an NSAID short term but are indicated in select patients for whom traditional NSAIDs are not tolerated. Serious upper GI adverse events can occur even in asymptomatic patients. Patients at high risk for GI bleed include those who use alcohol, smoke, are older than 65, take corticosteroids or anti-coagulants, or have a longer duration of therapy. Celecoxib is contraindicated in sulfonamide allergic patients.

(i). Optimal Duration: 7 to 10 days.

(ii). Maximum Duration: Chronic use is appropriate in individual cases. Use of these substances long-term (for three days per week or greater) is associated with rebound pain upon cessation.

f. Oral Steroids: have limited use but are accepted in cases requiring potent anti-inflammatory drug effect and should not be routinely recommended.

g. Intravenous Steroids: The risks of permanent neurological damage from acute spinal cord compression generally outweigh the risks of pharmacologic side effects of steroids in an emergent situation.

h. Psychotropic/Anti-anxiety/Hypnotic Agents: may be useful for treatment of mild and chronic pain, dysesthesias, sleep disorders, and depression. Antidepressant medications, such as tricyclics and Selective Serotonin Reuptake Inhibitors (SSRIs), are useful for affective disorder and chronic pain management. Tricyclic antidepressant agents, in low dose, are useful for chronic pain but have more frequent side effects.

i. Anti-anxiety medications should generally be limited to short-term use. Combinations of the above agents may be useful.

ii. As a general rule, providers (physicians or medical psychologist) should access the patient's prior history of substance abuse or depression prior to prescribing any of these agents. Due to the habit-forming potential of the benzodiazepines and other drugs found in this class, they are not routinely recommended. Refer to the Chronic Pain Guidelines which give a detailed discussion regarding medication use in chronic pain management.

(a). Optimum Duration: one to six months.

(b). Maximum Duration: 6 to 12 months, with monitoring.

i. Tramadol: is useful in relief of pain and has been shown to provide pain relief equivalent to that of commonly prescribed NSAIDs. Although Tramadol may cause impaired alertness, it is generally well tolerated, does not cause gastrointestinal ulceration, or exacerbate hypertension or congestive heart failure. Tramadol should be used cautiously in patients who have a history of seizures or who are taking medication that may lower the seizure threshold, such as monoamine oxidase (MAO) inhibitors, SSRIs, and tricyclic antidepressants. This medication has physically addictive properties and withdrawal may follow abrupt discontinuation and is not recommended for those with prior opioid addiction.

i. Optimal Duration: three to seven days

ii. Maximum Duration: two weeks. Use beyond two weeks is acceptable in appropriate cases.

6. Occupational Rehabilitation Programs

a. Non-Interdisciplinary. These generally accepted programs are work-related, outcome-focused, individualized treatment programs. Objectives of the program include, but are not limited to, improvement of cardiopulmonary and neuro-musculoskeletal functions (strength, endurance, movement, flexibility, stability, and motor control functions), patient education, and symptom relief. The goal is for patients to gain full or optimal function and return to work. The service may include the time-limited use of passive modalities with progression to active treatment and/or simulated/real work.

i. Work Conditioning

(a). These programs are usually initiated once reconditioning has been completed but may be offered at any time throughout the recovery phase. It should be initiated when imminent return of a patient to modified or full duty is not an option, but the prognosis for returning the patient to work at completion of the program is at least fair to good.

(i). Length of Visit: one to two hours per day.

(ii). Frequency: two to five visits per week.

(iii). Optimum Duration: two to four weeks.

(iv). Maximum Duration: six weeks. Participation in a program beyond six weeks must be documented with respect to need and the ability to facilitate positive symptomatic or functional gains.

ii. Work Simulation

(a). Work simulation is a program where an individual completes specific work-related tasks for a

particular job and return to work. Use of this program is appropriate when modified duty can only be partially accommodated in the work place, when modified duty in the work place is unavailable, or when the patient requires more structured supervision. The need for work place simulation should be based upon the results of a Functional Capacity Evaluation and/or Jobsite Analysis.

(i). Length of Visit: two to six hours per day.

(ii). Frequency: two to five visits per week.

(iii). Optimum Duration: two to four weeks.

(iv). Maximum Duration: six weeks. Participation in a program beyond six weeks must be documented with respect to need and the ability to facilitate positive symptomatic or functional gains.

b. Interdisciplinary—programs are well-established treatment for patients with sub-acute and functionally impairing cervical spine pain. They are characterized by a variety of disciplines that participate in the assessment, planning, and/or implementation of an injured workers program with the goal for patients to gain full or optimal function and return to work. There should be close interaction and integration among the disciplines to ensure that all members of the team interact to achieve team goals. Programs should include cognitive-behavioral therapy as there is good evidence for its effectiveness in patients with chronic low back pain and it is probably effective in cervical spine pain. These programs are for patients with greater levels of disability, dysfunction, deconditioning and psychological involvement. For patients with chronic pain, refer to the Chronic Pain Disorder Medical Treatment Guidelines.

i. Work Hardening

(a). Work Hardening is an interdisciplinary program addressing a patient's employability and return to work. It includes a progressive increase in the number of hours per day that a patient completes work simulation tasks until the patient can tolerate a full workday. This is accomplished by addressing the medical, psychological, behavioral, physical, functional, and vocational components of employability and return-to-work.

(b). This can include a highly structured program involving a team approach or can involve any of the components thereof. The interdisciplinary team should, at a minimum, be comprised of a qualified medical director who is board certified with documented training in occupational rehabilitation; team physicians having experience in occupational rehabilitation; occupational therapy; physical therapy; case manager; and psychologist. As appropriate, the team may also include: chiropractor, RN, vocational specialist or Certified Biofeedback Therapist.

(i). Length of Visit: up to eight hours/day.

(ii). Frequency: two to five visits per week.

(iii). Optimal Duration: two to four weeks.

(iv). Maximum Duration: six weeks. Participation in a program beyond six weeks must be documented with respect to need and the ability to facilitate positive symptomatic or functional gains.

ii. Spinal Cord Programs

(a). Spinal Cord Systems of Care provide coordinated, case-managed, and integrated service for people with spinal cord dysfunction, whether due to trauma or disease. The system includes an inpatient component in an organization licensed as a hospital and an outpatient component. Each component endorses the active participation and choice of the persons served throughout the entire program. The Spinal Cord System of Care also provides or formally links with key components of care that address the lifelong needs of the persons served.

(b). This can include a highly structured program involving a team approach or can involve any of the components thereof. The interdisciplinary team should, at a minimum, be comprised of a qualified medical director who is board certified and trained in rehabilitation, a case manager, occupational therapy, physical therapy, psychologist, rehabilitation RN and MD, and therapeutic recreation specialist. As appropriate, the team may also include: rehabilitation counselor, respiratory therapist, social worker, or speech-language pathologist.

(c). Timeframe durations for any spinal cord program should be determined based upon the extent of the patient's injury and at the discretion of the rehabilitation physician in charge.

7. Orthotics. Primary principles and objectives of the application of cervical orthosis include, control of the position through the use of control forces; application of corrective forces to abnormal curvatures; aid in spinal stability when soft tissues or osteoligamentous structures cannot sufficiently perform their role as spinal stabilizers; and restrict spinal segment movement after acute trauma or surgical procedure. In cases of traumatic cervical injury, the most important objective is the protection of the spinal cord and nerve root.

a. Cervical Collars

i. Soft Collars are well-tolerated by most patients but may not significantly restrict motion in any plane and are associated with delayed recovery. There is no evidence that their use promotes recovery from cervical sprain. In acute strain/sprain type injuries, use of cervical collars may prolong disability, limit early mobilization, promote psychological dependence, and limit self-activity. There is some evidence that patients encouraged to continue usual activity have less neck stiffness and headache than patients placed in cervical collars following motor vehicle crashes.

ii. Rigid Collars, such as a Philadelphia Orthosis, are useful post-operative or in emergency situations. These collars restrict flexion and extension motion, and to a lesser degree, lateral bending and rotation. Duration of wear post-surgery is dependent upon the surgeon and degree of cervical healing but is generally not used beyond eight weeks.

b. Poster Appliances: such as the Miami brace, restrict flexion and extension motion to about the same degree as a Philadelphia collar, and to a greater degree, lateral bending and rotation. Not recommended in sprain or strain injuries.

c. Cervicothoracic Orthosis: such as Yale and sternal occipital mandibular immobilization (SOMI) type braces, restrict flexion and extension motion to a fuller degree than the Philadelphia collar and to a better degree lateral bending and rotation. Not recommended in sprain or strain type injuries.

d. Halo Devices: are used in the treatment of cervical fracture, dislocation, and instability at the discretion

of the treating surgeon. Refer to Halo Devices in the Operative Treatment section.

e. Other Orthosis Devices and Equipment: Special orthosis or equipment may have a role in the rehabilitation of a cervical injury such as those injuries to a cervical nerve root resulting in upper extremity weakness or a spinal cord injury with some degree of paraparesis or tetraparesis. Use of such devices would be in a structured rehabilitation setting as part of a comprehensive rehabilitation program.

8. Patient education. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of prolonging the beneficial effects of treatment, as well as, facilitating self-management of symptoms and injury prevention. The patient should be encouraged to take an active role in the establishment of functional outcome goals. They should be educated on their specific injury, assessment findings, and plan of treatment. Instruction on proper body mechanics and posture, positions to avoid, self-care for exacerbation of symptoms, and home exercise should also be addressed.

a. Time to Produce Effect: Varies with individual patient.

b. Frequency: Should occur at each visit.

9. Personality/psychological/psychiatric/ psychosocial intervention is a generally accepted, widely used, and well-established intervention. This group of therapeutic and diagnostic modalities includes, but is not limited to; individual counseling, group therapy, stress management, psychosocial crises intervention, hypnosis and meditation. Any evaluation or diagnostic workup should clarify and distinguish between pre-existing versus aggravated versus purely causative psychological conditions. Psychosocial intervention is recommended as an important component in the total management program that should be implemented as soon as the problem is identified. This can be used alone or in conjunction with other treatment modalities. Providers treating patients with chronic pain should refer to the Chronic Pain Disorder Medical Treatment Guidelines.

a. Time to Produce Effect: two to four weeks.

b. Frequency: one to three times weekly for the first four weeks (excluding hospitalization, if required), decreasing to one to two times per week for the second month. Thereafter, two to four times monthly.

c. Optimum Duration: six weeks to three months.

d. Maximum Duration: 3 to 12 months. Counseling is not intended to delay but to enhance functional recovery. For select patients, longer supervised treatment may be required, and if further counseling beyond three months is indicated, extensive documentation addressing which pertinent issues are preexisting versus aggravated versus causative, as well as projecting a realistic functional prognosis, should be provided by the authorized treating practitioner every four to six weeks during treatment.

10. Restriction of activities. There is some evidence to support the continuation of normal daily activities as the recommended treatment for acute and chronic cervical injuries without neurologic symptoms. Complete work cessation should be avoided, if possible, since it often further aggravates the pain presentation. Modified return-to-work is almost always more efficacious and rarely contraindicated in the vast majority of injured workers with cervical spine injuries.

11. Return-to-work: Early return-to-work should be a prime goal in treating occupational injuries given the poor return-to-work prognosis for an injured worker who has been out of work for more than six months. It is imperative that the patient be educated regarding the benefits of return-to-work, restrictions, and follow-up if problems arise. When attempting to return a patient to work after a specific injury, clear objective restrictions of activity level should be made. An accurate job description with detailed physical duty descriptions is often necessary to assist the physician in making return-to-work recommendations. This may require a jobsite evaluation.

a. Employers should be prepared to offer transitional work. This may consist of temporary work in a less demanding position, return to the regular job with restrictions, or gradual return to the regular job. Company policies which encourage return-to-work with positive communication are most likely to have decreased worker disability.

b. Return-to-work is defined as any work or duty that the patient is able to perform safely. It may not be the patient's regular work. Due to the large spectrum of injuries of varying severity and varying physical demands in the work place, it is not possible to make specific return-to-work guidelines for each injury. Therefore, the OWCA recommends the following.

i. Establishment of a Return-To-Work Status: Ascertaining a return-to-work status is part of medical care, should be included in the treatment and rehabilitation plan, and addressed at every visit. A description of daily activity limitations is part of any treatment plan and should be the basis for restriction of work activities. In most non-surgical cases, the patient should be able to return to work in some capacity or in an alternate position consistent with medical treatment within several days unless there are extenuating circumstances. Injuries requiring more than two weeks off work should be thoroughly documented.

ii. Establishment of Activity Level Restrictions: Communication is essential between the patient, employer, and provider to determine appropriate restrictions and return-to-work dates. It is the responsibility of the physician to provide clear concise restrictions, and it is the employer's responsibility to determine if temporary duties can be provided within the restrictions. For cervical spine injuries, the following should be addressed when describing the patient's activity level:

(a). Total body position including upper trunk, especially rotation and flexion. To include duration and frequency.

(b). Upper extremity requirements including reaching above the shoulder, repetitive motions, pushing, pulling, and lifting or carrying requirements. Duration and frequency should be included.

(c). Sitting duration and frequency with regard to posture, work height(s), and movements of the head and neck.

(d). Visual field requirements in respect to limitations in head and neck movements and tolerance to looking upward and downward.

(e). Use of adaptive devices or equipment for proper office ergonomics or to enhance capacities can be included.

iii. Compliance with Activity Restrictions: In some cases, compliance with restriction of activity levels may require a complete jobsite evaluation, a functional capacity evaluation (FCE), or other special testing. Refer to the "Special Tests" section of this guideline.

12. Therapy—Active. The following active therapies are widely used and accepted methods of care for a variety of work-related injuries. They are based on the philosophy that therapeutic exercise and/or activity are beneficial for restoring flexibility, strength, endurance, function, range-of-motion, and can alleviate discomfort. Active therapy requires an internal effort by the individual to complete a specific exercise or task. This form of therapy requires supervision from a therapist or medical provider such as verbal, visual, and/or tactile instruction(s). At times, the provider may help stabilize the patient or guide the movement pattern but the energy required to complete the task is predominately executed by the patient.

a. Patients should be instructed to continue active therapies at home as an extension of the treatment process in order to maintain improvement levels. Follow-up visits to reinforce and monitor progress and proper technique are recommended. Home exercise can include exercise with or without mechanical assistance or resistance and functional activities with assistive devices.

b. The following active therapies are listed in alphabetical order:

c. Activities of Daily Living (ADL)~~:~~ : are well-established interventions which involve instruction, active-assisted training, and/or adaptation of activities or equipment to improve a person's capacity in normal daily activities such as self-care, work re-integration training, homemaking, and driving.

i. Time to Produce Effect: four to five treatments.

ii. Frequency: three to five times per week.

iii. Optimum Duration: four to six weeks.

iv. Maximum Duration: six weeks.

d. Aquatic Therapy: is a well-accepted treatment which consists of the therapeutic use of aquatic immersion for therapeutic exercise to promote strengthening, core stabilization, endurance, range-of-motion, flexibility, body mechanics, and pain management. Aquatic therapy includes the implementation of active therapeutic procedures in a swimming or therapeutic pool. The water provides a buoyancy force that lessens the amount of force gravity applies to the body. The decreased gravity effect allows the patient to have a mechanical advantage and more likely have a successful trial of therapeutic exercise. The therapy may be indicated for individuals who:

i. Cannot tolerate active land-based or full-weight bearing therapeutic procedures;

ii. Require increased support in the presence of proprioceptive deficit;

iii. Are at risk of compression fracture due to decreased bone density;

iv. Have symptoms that are exacerbated in a dry environment;

v. Would have a higher probability of meeting active therapeutic goals than in a dry environment;

vi. The pool should be large enough to allow full extremity range-of-motion and fully erect posture. Aquatic vests, belts, and other devices may be used to provide stability, balance, buoyancy, and resistance.

(a). Time to Produce Effect: four to five treatments

(b). Frequency: three to five times per week.

(c). Optimum Duration: four to six weeks.

(d). Maximum Duration: eight weeks.

(e). A self-directed program is recommended after the supervised aquatics program has been established, or, alternatively a transition to a self-directed dry environment exercise program.

(f). Functional Activities: are well-established interventions which involve the use of therapeutic activities to enhance mobility, body mechanics, employability, coordination, balance, and sensory motor integration.

(i). Time to Produce Effect: four to five treatments

(ii). Frequency: three to five times per week

(iii). Optimum Duration: four to six weeks

(iv). Maximum Duration: six weeks

(g). Functional Electrical Stimulation: is an accepted treatment in which the application of electrical current to elicit involuntary or assisted contractions of atrophied and/or impaired muscles. It may be indicated for muscle atrophy due to radiculopathy.

(i). Time to Produce Effect: two to six treatments.

(ii). Frequency: three times per week.

(iii). Optimum Duration: eight weeks.

(iv). Maximum Duration: eight weeks. If beneficial, provide with home unit.

(h). Neuromuscular Re-education: is a generally accepted treatment. It is the skilled application of exercise with manual, mechanical, or electrical facilitation to enhance strength, movement patterns, neuromuscular response, proprioception, kinesthetic sense, and coordination, education of movement, balance, and posture. Indications include the need to promote neuromuscular responses through carefully timed proprioceptive stimuli, to elicit and improve motor activity in patterns similar to normal neurologically developed sequences, and improve neuromotor response with independent control.

(i). Time to Produce Effect: two to six treatments.

(ii). Frequency: three times per week.

(iii). Optimum Duration: four to eight weeks.

(iv). Maximum Duration: eight weeks.

(i). Spinal Stabilization: is a generally accepted treatment. The goal of this therapeutic program is to strengthen the spine in its neural and anatomic position. The stabilization is dynamic which allows whole body movements while maintaining a stabilized spine. It is the ability to move and function normally through postures and activities without creating undue vertebral stress.

(i). Time to Produce Effect: four to eight treatments.

(ii). Frequency: three to five times per week.

(iii). Optimum Duration: four to eight weeks.

(iv). Maximum Duration: eight weeks.

(j). Therapeutic Exercise: is a generally well-accepted treatment. Therapeutic exercise with or without mechanical assistance or resistance, may include isoinertial, isotonic, isometric and isokinetic types of exercises. Indications include the need for cardiovascular fitness, reduced edema, improved muscle strength, improved connective tissue strength and integrity, increased bone density, promotion of circulation to enhance soft tissue healing, improvement of muscle recruitment, improved proprioception and coordination, increased range-of-motion and are used to promote normal movement patterns. Therapeutic exercise can also include complementary/alternative exercise movement therapy (with oversight of a physician or appropriate healthcare professional).

(i). Time to Produce Effect: two to six treatments.

(ii). Frequency: three to five times per week.

(iii). Optimum Duration: four to eight weeks.

(iv). Maximum Duration: eight weeks.

13. Therapy—Passive. Most of the following passive therapies and modalities are generally accepted methods of care for a variety of work-related injuries. Passive therapy includes those treatment modalities that do not require energy expenditure on the part of the patient. They are principally effective during the early phases of treatment and are directed at controlling symptoms such as pain, inflammation and swelling and to improve the rate of healing soft tissue injuries. They should be used adjunctively with active therapies such as postural stabilization and exercise programs to help control swelling, pain, and inflammation during the active rehabilitation process. Please refer to General Guideline Principles, Active Interventions. Passive therapies may be used intermittently as a therapist deems appropriate or regularly if there are specific goals with objectively measured functional improvements during treatment.

a. On occasion, specific diagnoses and post-surgical conditions may warrant durations of treatment beyond those listed as "maximum". Factors such as exacerbation of symptoms, re-injury, interrupted continuity of care and co-morbidities may also extend durations of care. Specific goals with objectively measured functional improvement during treatment must be cited to justify extended durations of care. It is recommended that, if no functional gain is observed after the number of treatments under "time to produce effect" has been completed alternative treatment interventions, further diagnostic studies or further consultations should be pursued.

i. The following passive therapies are listed in alphabetical order:

(a). Electrical Stimulation (Unattended): is an accepted treatment. Once applied, unattended electrical stimulation requires minimal on-site supervision by the physical therapist, occupational therapist, or other provider. Indications include pain, inflammation, muscle spasm, atrophy, decreased circulation, and the need for osteogenic stimulation. A home unit should be purchased if treatment is effective and frequent use is recommended.

(i). Time to Produce Effect: two to four treatments.

(ii). Frequency: Varies, depending upon indication, between two to three times/day to 1 time/week. A home unit should be purchased if treatment is effective and frequent use is recommended.

(iii). Optimum Duration: four treatments for clinic use.

(iv). Maximum Duration: eight treatments for clinic use.

(b). Iontophoresis: is an accepted treatment which consists of the transfer of medication, including, but not limited to, steroidal anti-inflammatories and anesthetics, through the use of electrical stimulation. Indications include pain (Lidocaine), inflammation (hydrocortisone, salicylate), edema (mecholyl, hyaluronidase, salicylate), ischemia (magnesium, mecholyl, iodine), muscle spasm (magnesium, calcium), calcific deposits (acetate), scars, and keloids (sodium chloride, iodine, acetate). There is no proven benefit for this therapy in the cervical spine.

(i). Time to Produce Effect: one to four treatments.

(ii). Frequency: 3 times per week with at least 48 hours between treatments.

(iii). Optimum Duration: four to six weeks.

(iv). Maximum Duration: six weeks.

(c). Manipulation: is a generally accepted, well-established, and widely used therapeutic intervention for cervical pain. Manipulative treatment (not therapy) is defined as the therapeutic application of manually guided forces by an operator to improve physiologic function and/or support homeostasis that has been altered by the injury or occupational disease, and has associated clinical significance.

(i). High velocity, low amplitude (HVLA) technique, chiropractic manipulation, osteopathic manipulation, muscle energy techniques, counter strain, and non-force techniques are all types of manipulative treatment. This may be applied by osteopathic physicians (D.O.), chiropractors (D.C.), properly trained physical therapists (P.T.), properly trained occupational therapists (O.T.), or properly trained medical physicians. Under these different types of manipulation exist many subsets of different techniques that can be described as a) direct- a forceful engagement of a restrictive/pathologic barrier, b) indirect- a gentle/non-forceful dis-engagement of a restrictive/pathologic barrier, c) the patient actively assisting in the treatment and d) the patient relaxing, allowing the practitioner to move the body tissues. When the proper diagnosis is made and coupled with the appropriate technique, manipulation has no contraindications and can be applied to all tissues of the body. Pre-treatment assessment should be performed as part of each manipulative treatment visit to ensure that the correct diagnosis and correct treatment is employed.

(ii). High velocity, low amplitude (HVLA) manipulation is performed by taking a joint to its end range of motion and moving the articulation into the zone of accessory joint movement, well within the limits of anatomical integrity. There is good scientific evidence to suggest that HVLA manipulation can be effective for relieving pain and decreasing muscle spasm to improve

function for patients with cervical pain. There is some evidence to show that manipulation of the cervical spine with exercise may be effective prophylactic treatment for cervicogenic headaches. Contraindications to HVLA manipulation include joint instability, fractures, severe osteoporosis, infection, metastatic cancer, active inflammatory arthritides, and signs of progressive neurologic deficits, myelopathy, vertebrobasilar insufficiency, or carotid artery disease. Relative contraindications include stenosis, spondylosis, and disc herniation.

b. Manipulation / Grade I - V

i. Time to produce effect for all types of manipulative treatment: one to six treatments.

ii. Frequency: Up to three times per week for the first four weeks as indicated by the severity of involvement and the desired effect, then up to two treatments per week for the next four weeks. For further treatments, twice per week or less to maintain function.

iii. Optimum Duration: 8 to 12 weeks.

iv. Maximum Duration: three months. Extended durations of care beyond what is considered "maximum" may be necessary in cases of re-injury, interrupted continuity of care, exacerbation of symptoms, and in those patients with comorbidities. Refer to the Chronic Pain Guidelines for care beyond three months.

c. Manipulation under General Anesthesia (MUA) refers to manual manipulation of the cervical spine in combination with the use of a general anesthetic or conscious sedation. It is intended to improve the success of manipulation when pain, muscle spasm, guarding, and fibrosis appear to be limiting its application in patients otherwise suitable for its use. There have been no high quality studies to justify MUAs benefits. Given the risks of general anesthetic and conscious sedation, it is not recommended.

d. Manipulation under Joint Anesthesia (MUJA) refers to manipulation of the cervical spine in combination with a fluoroscopically guided injection of anesthetic with or without corticosteroid agents into the facet joint at the level being manipulated. There are no controlled clinical trials to support its use. It is not recommended.

e. Massage. Manual or Mechanical. Massage is a generally well-accepted treatment consisting of manipulation of soft tissue with broad ranging relaxation and circulatory benefits. This may include stimulation of acupuncture points and acupuncture channels (acupressure), application of suction cups and techniques that include pressing, lifting, rubbing, pinching of soft tissues by or with the practitioner's hands. Indications include edema (peripheral or hard and non-pliable edema), muscle spasm, adhesions, the need to improve peripheral circulation and range-of-motion, or to increase muscle relaxation and flexibility prior to exercise.

i. As with all passive therapies, massage must be accompanied by exercise and patient education.

ii. Mobilization—Grade I - V

(a). Time to Produce Effect: Immediate

(b). Frequency: one to two times per week

(c). Optimum Duration: six weeks

(d). Maximum Duration: two months

f. Mobilization (Joint) is a generally well-accepted treatment consisting of passive movement involving oscillatory motions to the vertebral segment(s). The passive mobility is performed in a graded manner (I, II, III, IV, or V), which depicts the speed and depth of joint motion during the maneuver. For further discussion on Level V joint mobilization please see section on HVLA manipulation [Section 12. c.]. It may include skilled manual joint tissue stretching. Indications include the need to improve joint play, segmental alignment, improve intracapsular arthrokinematics, or reduce pain associated with tissue impingement. Mobilization should be accompanied by active therapy. For Level V mobilization, contraindications include joint instability, fractures, severe osteoporosis, infection, metastatic cancer, active inflammatory arthritis, and signs of progressive neurologic deficits, myelopathy, vertebrobasilar insufficiency, or carotid artery disease. Relative contraindications include stenosis, spondylosis, and disc herniation.

i. Time to Produce Effect: six to nine treatments.

ii. Frequency: Up to three times per week.

iii. Optimum Duration: four to six weeks.

iv. Maximum Duration: six weeks.

g. Mobilization (Soft Tissue): is a generally well-accepted treatment. Mobilization of soft tissue is the skilled application of muscle energy, strain/counter strain, myofascial release, manual trigger point release, and other manual therapy techniques designed to improve or normalize movement patterns through the reduction of soft tissue pain and restrictions. These can be interactive with the patient participating or can be with the patient relaxing and letting the practitioner move the body tissues. Indications include muscle spasm around a joint, trigger points, adhesions, and neural compression. Mobilization should be accompanied by active therapy.

i. Time to Produce Effect: four to nine treatments.

ii. Frequency: Up to three times per week.

iii. Optimum Duration: four to six weeks.

iv. Maximum Duration: six weeks.

h. Short-Wave Diathermy is an accepted treatment which involves the use of equipment that exposes soft tissue to a magnetic or electrical field. Indications include enhanced collagen extensibility before stretching, reduced muscle guarding, reduced inflammatory response, and enhanced reabsorption of hemorrhage/hematoma or edema.

i. Time to Produce Effect: two to four treatments

ii. Frequency: two to three times per week up to three weeks

iii. Optimum Duration: three to five weeks

iv. Maximum Duration: five weeks

i. Superficial Heat and Cold Therapy (Excluding Infrared Therapy~~):~~ is a generally accepted treatment. Superficial heat and cold are thermal agents applied in various manners that lower or raise the body tissue temperature for the reduction of pain, inflammation, and/or effusion resulting from injury or induced by exercise. It includes application of heat just above the surface of the skin at acupuncture points. Indications include acute pain, edema and hemorrhage, need to increase pain threshold, reduce muscle spasm, and promote stretching/flexibility. Cold and heat packs can be used at home as an extension of therapy in the clinic setting.

i. Time to Produce Effect: Immediate

ii. Frequency: two to five times per week

iii. Optimum Duration: three weeks as primary or intermittently as an adjunct to other therapeutic procedures up to two months

iv. Maximum Duration: two months

j. Traction-Manual—is an accepted treatment and an integral part of manual manipulation or joint mobilization. Indications include decreased joint space, muscle spasm around joints, and the need for increased synovial nutrition and response. Manual traction is contraindicated in patients with tumor, infection, fracture, or fracture dislocation.

i. Time to Produce Effect: one to three sessions

ii. Frequency: two to three times per week

iii. Optimum Duration: 30 days

iv. Maximum Duration: one month

k. Traction. Mechanical: is a generally accepted treatment and most commonly used for patients with radicular findings. It is sometimes used to treat symptoms from decreased joint space and muscle spasm around the joints. If successful it should be shifted to home traction. Traction modalities are contraindicated in patients with tumor, infections, fracture, or fracture dislocation. Non-oscillating inversion traction methods are contraindicated in patients with glaucoma or hypertension. A home cervical traction unit may be purchased if therapy proves effective.

i. Time to Produce Effect: 1 to 3 sessions up to 30 minutes. If response is negative after 3 treatments, discontinue this modality

ii. Frequency: two to three times per week. A home cervical traction unit may be purchased if therapy proves effective.

iii. Optimum Duration: four weeks.

iv. Maximum Duration: four weeks.

l. Transcutaneous Electrical Nerve Stimulation (TENS) is a generally accepted treatment which should include at least one instructional session for proper application and use. Indications include muscle spasm, atrophy, and decreased circulation and pain control. Minimal TENS unit parameters should include pulse rate, pulse width and amplitude modulation. Consistent, measurable, functional improvement must be documented prior to the purchase of a home unit.

i. Time to Produce Effect: Immediate

ii. Frequency: Variable

iii. Optimum Duration: three sessions

iv. Maximum Duration: three sessions. Purchase or provide with home unit if effective.

m. Ultrasound (Including Phonophoresis) is an accepted treatment which uses sonic generators to deliver acoustic energy for therapeutic thermal and/or non-thermal soft tissue effects. Indications include scar tissue, adhesions, collagen fiber and muscle spasm, and the need to extend muscle tissue or accelerate the soft tissue healing. Ultrasound with electrical stimulation is concurrent delivery of electrical energy that involves dispersive electrode placement. Indications include muscle spasm, scar tissue, pain modulation, and muscle facilitation.

i. Phonophoresis is the transfer of medication through the use of sonic generators to the target tissue to control inflammation and pain. These topical medications include, but are not limited to, steroidal anti-inflammatory and anesthetics.

(a). Time to Produce Effect: 6 to 15 treatments

(b). Frequency: three times per week

(c). Optimum Duration: four to eight weeks

(d). Maximum Duration: eight weeks

14. Vocational Rehabilitation is a generally accepted intervention. Initiation of vocational rehabilitation requires adequate evaluation of patients for quantification highest functional level, motivation, and achievement of maximum medical improvement. Vocational rehabilitation may be as simple as returning to the original job or as complicated as being retrained for a new occupation.

a. It may also be beneficial for full vocational rehabilitation to be started before MMI if it is evident that the injured worker will be unable to return to his/her previous occupation. A positive goal and direction may aid the patient in decreasing stress and depression and promote optimum rehabilitation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1640 (June 2011).

§2011. Therapeutic Procedures—Operative

A. All operative interventions should be based on a positive correlation with clinical findings, the natural history of the disease, the clinical course, and diagnostic tests. A comprehensive assimilation of these factors should have led to a specific diagnosis with positive identification of the pathologic condition(s). It is imperative for the clinician to rule out non-physiologic modifiers of pain presentation, or non-operative conditions mimicking radiculopathy or instability (peripheral compressive neuropathy, chronic soft tissue injuries, and psychological conditions), prior to consideration of elective surgical intervention. Early intervention may be required in acute incapacitating pain or in the presence of progressive neurological deficits. Patients who are not candidates for or refuse surgical treatment should be treated with non-operative therapy as indicated.

B. Operative treatment is indicated when the natural history of surgically treated lesions is better than the natural history for non-operatively treated lesions. All patients being considered for surgical intervention should first undergo a comprehensive neuromusculoskeletal examination to identify mechanical pain generators that may respond to non-surgical techniques, or may be refractory to surgical intervention.

C. In situations requiring the possible need for re-surgery, a second opinion may be necessary. Psychological evaluation is strongly encouraged when surgery is being performed for isolated axial pain to determine if the patient will likely benefit from the treatment.

D. Interdisciplinary interventions should be strongly considered post-operatively in patients not making functional progress within expected time frames (Refer to Interdisciplinary Programs).

E. Return to work activity restrictions should be specific according to the recommendations in Return to Work. Most cervical non-fusion surgical patients can return to a limited level of duty between three to six weeks. Full activity is generally achieved between six weeks to six months, depending on the procedure and healing of the individual.

1. Acute fractures and dislocations: Decisions regarding the need for surgery in acute traumatic injury will depend on the specific injury type and possibility of long-term neurologic damage. Acute disc herniations may occur in the presence of traumatic injury.

a. Halo Immobilization

i. Description. Intervention that restricts flexion-extension motion. Halo vest will provide significant but not complete rotational control and is the most effective device for treating unstable injuries to the cervical spine.

ii. Complications. May include pin infection, pin loosening, and palsy of the sixth cranial nerve.

iii. Surgical Indications. Cervical fractures requiring the need for nearly complete restriction of rotational control, and to prevent graft dislodgment, spine mal-alignment, or pseudarthrosis. Decision for use of halo is at the discretion of the surgeon based upon the patients' specific injury. Not indicated for unstable skull fractures or if skin overlying pin sites is traumatized.

iv. Operative Treatment. Placement of the pins and apparatus.

v. Post-Operative Therapy. Traction may be required for re-alignment and or fracture reduction (amount to be determined by surgeon), active and/or passive therapy, pin care.

b. Anterior or Posterior Decompression with Fusion

i. Description—to provide relief of pressure on the cervical spinal cord and nerve roots, and alignment and stabilization of the spine. May involve the use of bone grafts, sometimes combined with metal devices, to produce a rigid connection between two or more adjacent vertebrae.

ii. Complications—appropriate medical disclosures should be provided to the patient as deemed necessary by the treating physician.

iii. Surgical Indications—when a significant or progressive neurological deficit exists in the presence of spinal canal compromise. Whether early decompression and reduction of neural structures enhances neurological recovery continues to be debated. Currently, a reasonable approach would be to treat non-progressive neurological deficits on a semi-urgent basis, when the patient's systemic condition is medically stable.

iv. Operative Treatment—both anterior and posterior surgical decompression of the cervical spine are widely accepted. The approach is guided by location of the compressive pathology as well as the presence of other concomitant injuries. Posterior stabilization and fusion alone may be indicated for patients who have been realigned with traction and do not have significant canal compromise. The anterior approach is acceptable if there is disc and/or vertebral body anteriorly compromising the canal. The posterior approach may be indicated in radiculopathy in the absence of myelopathy and with evidence of pseudarthrosis on radiographs, or if the compression pathology is arising posteriorly.

(a). The number of levels involved in the fracture pattern determines the choice between the use of wire techniques versus spinal plates. In injuries treated with an anterior decompression procedure, anterior bone grafting alone does not provide immediate internal fixation and an anterior cervical plate is significantly beneficial. Patients who undergo surgery for significant fracture dislocations of the spine (three level injury) with canal compromise are best managed with anterior cervical decompression, fusion, and plating but in some cases posterior stabilization and fusion are also considered.

(b). Recombinant Human Bone Morphogenetic Protein (rhBMP-2) is a member of a family of cytokines capable of inducing bone formation. It is produced from genetically modified cell lines using molecular cloning techniques. Use of rhBMP-2 in the cervical spine may carry a risk of swelling and ectopic bone formation which can encroach on neurovascular structures and on the esophagus. BMP usage in the anterior cervical spine is generally not indicated.

v. Post-Operative Treatment. Cervical bracing may be appropriate (usually 6-12 weeks with fusion). Home programs with instruction in ADLs, sitting, posture, and a daily walking program should be an early part of the rehabilitation process. Referral to a formal rehabilitation program, with emphasis on cervical, scapular, and thoracic strengthening, and restoration of ROM, is appropriate once the fusion is solid and without complication. Active treatment, which patients should have had prior to surgery, will frequently require a repeat of the sessions previously ordered. The goals of the therapy program should include instruction in a long-term home-based exercise program. (Refer to Active Therapy).

2. Disc herniation and other cervical conditions. Operative treatment is indicated only when the natural history of an operatively treatable problem is better than the natural history of the problem without operative treatment. All patients being considered for surgical intervention should undergo a comprehensive neuromuscular examination to identify pain generators that may respond to nonsurgical techniques or may be refractory to surgical intervention. Timely decision making for operative intervention is critical to avoid deconditioning, and increased disability of the cervical spine.

a. General Recommendations. There is some evidence to suggest that recovery from cervical radiculopathy in patients without clinical signs of spinal cord compression at one year is similar with one-level fusion, physical therapy, or rigid cervical collar use. For patients with whiplash injury (Quebec Classification Grade Levels I or II), there is no evidence of any beneficial effect of operative treatment. Refer to (Soft Tissue Injury Evaluation), for Discussion on Quebec Classification Levels.

b. If cervical fusion is being considered, it is recommended that the injured worker refrain from smoking for at least six weeks prior to surgery and during the time of healing. Because smokers have a higher risk of non-union and higher post-operative costs, it is recommended that insurers cover a smoking cessation program peri-operatively.

c. General Indications for Surgery. Operative intervention should be considered and a consultation obtained when improvement of symptoms has plateaued and the residual symptoms of pain and functional disability are unacceptable at the end of six weeks of treatment, or at the end of longer duration of non-operative intervention for debilitated patients with complex problems. Choice of hardware instrumentation is based on anatomy, the patient's pathology, and surgeon's experience and preference.

i. Specific Indications include

(a). for Patients with Myelopathy immediate surgical evaluation and treatment is indicated;

(b). for Patients with Cervical Radiculopathy.

(i). early intervention may be required for acute incapacitating pain or in the presence of progressive neurological deficits;

(ii). persistent or recurrent arm pain with functional limitations, unresponsive to conservative treatment after six weeks; or

(iii). progressive functional neurological deficit; or

(iv). static neurological deficit associated with significant radicular pain; and

(v). confirmatory imaging studies consistent with clinical findings.

(c). For Patients with Persistent Non-radicular Cervical Pain—in the absence of a radiculopathy, it is recommended that a decisive commitment to surgical or nonsurgical interventions be made within four to five months following injury. The effectiveness of three-level cervical fusion for non-radicular pain has not been established. In patients with non-radicular cervical pain for whom fusion is being considered, required pre-operative indications include all of the following.

(i). In general, if the program of non-operative treatment fails, operative treatment is indicated when:

[a]. improvement of the symptoms has plateaued, and the residual symptoms of pain and functional disability are unacceptable at the end of 6 to 12 weeks of active treatment, or at the end of longer duration of non-operative programs for debilitated patients with complex problems; and/or

[b]. frequent recurrences of symptoms cause serious functional limitations even if a non-operative active treatment program provides satisfactory relief of symptoms, and restoration of function on each recurrence;

[c]. mere passage of time with poorly guided treatment is not considered an active treatment program;

(ii). all pain generators are adequately defined and treated; and

(iii). all physical medicine and manual therapy interventions are completed; and

(iv). x-ray, MRI, or CT/discography demonstrating disc pathology or spinal instability; and

(v). spine pathology limited to two levels; and

(vi). psychosocial evaluation for confounding issues addressed;

(vii). for any potential surgery, it is recommended that the injured worker refrain from smoking for at least six weeks prior to surgery and during the period of healing. Because smokers have a higher risk of non-union and higher post-operative costs, it is recommended that insurers cover a smoking cessation program peri-operatively.

ii. Surgical Procedures include

(a). Cervical Discectomy with or without Fusion

(i). Description. Procedure to relieve pressure on one or more nerve roots or spinal cord. It may be performed with or without the use of a microscope.

(ii). Complications. Appropriate medical disclosures should be provided to the patient as deemed necessary by the treating physician.

(iii). Surgical Indications. Radiculopathy from ruptured disc or spondylosis, spinal instability, or patients with non-radicular neck pain meeting fusion criteria. There is no evidence that discectomy with fusion versus discectomy without fusion has superior long-term results. Discectomy alone is generally considered in patients with pure radicular symptoms from their herniated disc and who have sufficiently large foramen that disc space collapse is unlikely to further compromise the nerve root. Failure rates increase with disease at more than two levels.

(iv). Operative Treatment. Cervical plating may be used to prevent graft dislodgment especially for multi-level disease.

(a). Recombinant Human Bone Morphogenetic Protein (rhBMP-2) is a member of a family of cytokines capable of inducing bone formation. It is produced from genetically modified cell lines using molecular cloning techniques. Use of rhBMP-2 in the cervical spine may carry a risk of swelling and ectopic bone formation which can encroach on neurovascular structures and on the esophagus. BMP usage in the anterior cervical spine is generally not indicated.

(v). Post-Operative Therapy. Cervical bracing may be appropriate (usually 6 - 12 weeks with fusion). Home programs with instruction in ADLs, sitting, posture, and a daily walking program should be an early part of the rehabilitation process. Referral to a formal rehabilitation program, with emphasis on cervical, scapular, and thoracic strengthening and restoration of ROM is appropriate, once fusion is solid and without complication. Active treatment, which patients should have had prior to surgery, will frequently require a repeat of the sessions previously ordered. The goals of the therapy program should include instruction in a long-term home-based exercise program. (Refer to Active Therapy).

(b). Cervical Corpectomy

(i). Description. Removal of a portion or the entire vertebral body from the front of the spine. May also include removal of the adjacent discs. Usually involves fusion.

(ii). Complications. Appropriate medical disclosures should be provided to the patient as deemed necessary by the treating physician.

(iii). Surgical Indications. Single or two-level spinal stenosis, spondylolisthesis, or severe kyphosis, with cord compression.

(iv). Operative Treatment. Neural decompression, fusion with instrumentation, or halo vest placement to maintain cervical position. Hemicorpectomy may be done when only a portion of the vertebral body needs to be resected. Allografts may be used for single bone graft fusion; however, autografts are generally preferable for multi-level fusions unless a large strut graft is required.

(v). Post-Operative Therapy — Dependent upon number of vertebral bodies involved, healing time may be longer than discectomy. Halo vest care is required. Home programs with instruction in ADLs, sitting, posture, and a daily walking program should be an early part of the rehabilitation process. Referral to a formal rehabilitation

program with emphasis on cervical, scapular, and thoracic strengthening is appropriate for most patients once the cervical spine is deemed stable and without complication. The goals of the therapy program should include instruction in a long-term home-based exercise program. (Refer to Active Therapy).

(c). Cervical Laminectomy with or without Foraminotomy or Fusion:

(i). Description. Surgical removal of the posterior portion of a vertebrae in order to gain access to the spinal cord or nerve roots with or without stabilization fusion. /instrumentation.

(ii). Complications. May include perineural fibrosis, kyphosis in fractures without fusion or with failed fusion, nerve injury, post surgical instability (with foraminotomies), CSF leak, infection, in-hospital mortality, non-union of fusion, donor site pain (autograft only).

(iii). Surgical Indications. Neural compression.

(iv). Operative Treatment. Laminotomy, partial discectomy, and nerve root decompression.

(v). Post-Operative Therapy. Cervical bracing may be appropriate (usually 6 to 12 weeks with fusion). Home programs with instruction in ADLs, sitting, posture, and a daily walking program should be an early part of the rehabilitation process. Referral to a formal rehabilitation program with emphasis on cervical, scapular, and thoracic strengthening and restoration of ROM is appropriate for most patients once the cervical spine is deemed stable and without complication. The goals of the therapy program should include instruction in a long-term home-based exercise program. (Refer to Active Therapy).

(d). Cervical Laminoplasty

(i). Description. Technique that increases anterior or posterior dimensions of the spinal canal while leaving posterior elements partially intact. It may be performed with or without the use of a microscope.

(ii). Complications. Loss of cervical motion, especially extension.

(iii). Surgical Indications. Multi-level disease: cervical spinal stenosis or spondylitic myelopathy. Not indicated in cervical kyphosis.

(iv). Operative Treatment. Posterior approach, with or without instrumentation.

(v). Post-Operative Therapy. May include 4 to 12 weeks of cervical bracing. Home programs with instruction in ADLs, sitting, posture, and daily walking program should be an early part of the rehabilitation process. Referral to a formal rehabilitation program with emphasis on cervical, scapular, and thoracic strengthening and restoration of ROM is appropriate once the cervical spine is stable and without complication. Active treatment which patients should have had prior to surgery will frequently require a repeat of the sessions previously ordered. The goals of the therapy program should include instruction in a long-term, home-based exercise program. (Refer to Active Therapy).

(e). Percutaneous Discectomy:

(i). Description. An invasive operative procedure to accomplish partial removal of the disc through a needle which allows aspiration of a portion of the disc trocar under imaging control.

(ii). Complications include, but are not limited to, injuries to the nerve or vessel, infection, and hematoma.

(iii). Surgical Indications. Percutaneous discectomy is indicated only in cases of suspected septic discitis in order to obtain diagnostic tissue. The procedure is not recommended for contained disc herniations or bulges with associated radiculopathy due to lack of evidence to support long-term improvement.

(iv). Operative Treatment—partial discectomy

3. Artificial cervical disc replacement involves the insertion of an FDA approved prosthetic device into the cervical intervertebral space with the goal of maintaining physiologic motion at the treated cervical segment. The use of artificial discs in motion-preserving technology should be based on the surgeon's skill and training.

4. Percutaneous radiofrequencey disc decompression of the cervical spine is an investigational procedure which introduces a 19 gauge cannula under local anesthesia and fluoroscopic guidance into the nucleus pulposus of a contained herniated disc, using radiofrequency energy to dissolve and remove disc material. Pressure inside the disc is lowered as a result. There have been no randomized clinical trials of this procedure at this time. It is not recommended.

5. Epiduroscopy and epidural lysis of adhesions. Refer to Therapeutic Injections.

6. Intraoperative monitoring is a common intraoperative electrodiagnostic technique that may include somatosensory evoked potentials (SSEP), motor evoked potentials (MEP), or pedicle screw monitoring. The monitoring procedure may be used at the discretion of the surgeon. The use of intraoperative monitoring can be anticipated to become more common as percutaneous spinal procedures gain greater acceptance.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1651 (June 2011).

§2012. LWC-WC 1009. Disputed Claim for Medical Treatment

Mail to:
OWCA—Medical Services
ATTN: Medical Director
P.O. Box 94040
Baton Rouge, LA 70804

1. Social Security No. __-__-__
2. Date of Injury/Illness __-__-__
3. Parts of Body Injury_____
4. Date of Birth __-__-__
5. Date of This Request __-__-__
6. Claim Number _____

DISPUTED CLAIM FOR MEDICAL TREATMENT

NOTE: THIS REQUEST WILL NOT BE HONORED UNLESS THE INSURER HAS ISSUED A DENIAL FOR THE MEDICAL SERVICES IN DISPUTE AS PER R.S. 23:1203.1 J.

GENERAL INFORMATION
Claimant files this dispute with the Office of Workers' Compensation – Medical Services Director. This office must be notified immediately in writing of changes in address. An employee may be represented by an attorney, but it is not required.

7. This request is submitted by
___ Employee ___ Employer __ Insurer ___ Health Care Provider ___ Other ___

A. Copies of all relevant medical records must be included with this request.

B. A copy of the denial letter issued by the insurance carrier must be attached to this request.

EMPLOYEE
8. Name _____
Street or Box _____
City _____
State _____ Zip _____
Phone (____) _____

EMPLOYEE'S ATTORNEY
9. Name _____
Street or Box _____
City _____
State _____
Phone (____) _____
Fax (____) _____

EMPLOYER
10. Name _____
Street or Box _____
City _____
State _____ Zip _____
Phone (____) _____
Fax (____) _____

INSURER/ADMINISTRATOR
(circle one)
11. Name _____
Street or Box _____
City _____
State _____
Phone (____) _____
Fax (____) _____

EMPLOYER/INSURER'S ATTORNEY
12. Name _____
Street or Box _____
City _____
State _____ Zip _____
Phone (____) _____
Fax (____) _____

TREATING/REQUESTING PHYSICIAN
13. Name _____
Street or Box _____
City _____
State _____
Phone (____) _____
Fax (____) _____

LWC-WC 1009
11/2010

14. PLEASE PROVIDE A SUMMARY OF THE DETAILS REGARDING THE ISSUE AT DISPUTE:
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

You may attach a letter or petition with additional information with this disputed claim.
The information given above is true and correct to the best of my knowledge and belief.

_____ _____
SIGNATURE OF REQUESTING PARTY DATE

LWC-WC 1009
11/2010

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1654 (June 2011).

Subchapter B. Low Back Pain

§2013. Introduction

A. This document has been prepared by the Louisiana Workforce Commission, Office of Workers' Compensation (OWCA) and should be interpreted within the context of guidelines for physicians/providers treating individuals qualifying under Louisiana Workers' Compensation Act as injured workers with low back pain. The guidelines are enforceable under the Louisiana Workers Compensation Act. All medical care, services, and treatment owed by the employer to the employee in accordance with the Louisiana Workers' Compensation Act shall mean care, services, and treatment in accordance with these guidelines. Medical care, services, and treatment that varies from these guidelines shall also be due by the employer when it is demonstrated to the medical director of the office by a preponderance of the scientific medical evidence, that a variance from these guidelines is reasonably required to cure or relieve the injured worker from the effects of the injury or occupational disease given the circumstances. Therefore, these guidelines are not relevant as evidence of a provider's legal standard of professional care. To properly utilize this document, the reader should not skip nor overlook any sections.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1655 (June 2011).

§2015. General Guideline Principles

A. The principles summarized in this section are key to the intended implementation of all Office of Workers' Compensation guidelines and critical to the reader's application of the guidelines in this document.

1. Application of Guidelines. The OWCA provides procedures to implement medical treatment guidelines and to foster communication to resolve disputes among the provider, payer, and patient through the Office of Workers Compensation.

2. Education. Education of the patient and family, as well as the employer, insurer, policy makers and the community should be the primary emphasis in the treatment of low back pain. Currently, practitioners often think of education last, after medications, manual therapy, and surgery. Practitioners must develop and implement an effective strategy and skills to educate patients, employers, insurance systems, policy makers, and the community as a whole. An education-based paradigm should always start with inexpensive communication providing reassuring information to the patient. More in-depth education currently exists within a treatment regime employing functional restorative and innovative programs of prevention and rehabilitation. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of facilitating self-management of symptoms and prevention.

3. Treatment Parameter Duration—time frames for specific interventions commence once treatments have been initiated, not on the date of injury. Obviously, duration will be impacted by patient compliance, as well as availability of services. Clinical judgment may substantiate the need to accelerate or decelerate the time frames discussed in this document. Such deviation shall be in accordance with La. R.S. 23:1203.1.

4. Active Interventions—emphasizing patient responsibility, such as therapeutic exercise and/or functional treatment, are generally emphasized over passive modalities, especially as treatment progresses. Generally, passive interventions are viewed as a means to facilitate progress in an active rehabilitation program with concomitant attainment of objective functional gains.

5. Active Therapeutic Exercise Program. Exercise program goals should incorporate patient strength, endurance, flexibility, coordination, and education. This includes functional application in vocational or community settings.

6. Positive Patient Response. Positive results are defined primarily as functional gains that can be objectively measured. Standard measurement tools, including outcome measures, should be used.

a. Objective functional gains include, but are not limited to, positional tolerances, range-of-motion (ROM), strength, and endurance, activities of daily living, cognition, psychological behavior, and efficiency/velocity measures that can be quantified. Subjective reports of pain and function should be considered and given relative weight when the pain has anatomic and physiologic correlation. Anatomic correlation must be based on objective findings.

7. Re-Evaluation Treatment Every Three to Four Weeks. If a given treatment or modality is not producing positive results within three to four weeks, the treatment should be either modified or discontinued. Reconsideration of diagnosis should also occur in the event of poor response to a seemingly rational intervention.

8. Surgical Interventions. Surgery should be contemplated within the context of expected functional outcome and not purely for the purpose of pain relief. The concept of "cure" with respect to surgical treatment by itself is generally a misnomer. All operative interventions must be based upon positive correlation of clinical findings, clinical course, and diagnostic tests. A comprehensive assimilation of these factors must lead to a specific diagnosis with positive identification of pathologic conditions.

9. Six-Month Time Frame. The prognosis drops precipitously for returning an injured worker to work once he/she has been temporarily totally disabled for more than six months. The emphasis within these guidelines is to move patients along a continuum of care and return-to-work within a six-month time frame, whenever possible. It is important to note that time frames may not be pertinent to injuries that do not involve work-time loss or are not occupationally related.

10. Return-to-Work. Return to Work is therapeutic, assuming the work is not likely to aggravate the basic problem or increase long-term pain. The practitioner must provide specific written physical limitations and the patient should never be released to "sedentary" or "light duty." The following physical limitations should be considered and modified as recommended: lifting, pushing, pulling, crouching, walking, using stairs, bending at the waist, awkward and/or sustained postures, tolerance for sitting or standing, hot and cold environments, data entry and other repetitive motion tasks, sustained grip, tool usage and vibration factors. Even if there is residual chronic pain, return-to-work is not necessarily contraindicated. The practitioner should understand all of the physical demands of the patient's job position before returning the patient to full duty and should request clarification of the patient's job duties. Clarification should be obtained from the employer or, if necessary, including, but not limited to, an occupational health nurse, occupational therapist, vocational rehabilitation specialist, or an industrial hygienist.

11. Delayed Recovery. Strongly consider a psychological evaluation, if not previously provided, as well as initiating interdisciplinary rehabilitation treatment and vocational goal setting, for those patients who are failing to make expected progress 6 to 12 weeks after an injury. The OWCA recognizes that 3 to 10 percent of all industrially injured patients will not recover within the timelines outlined in this document despite optimal care. Such individuals may require treatments beyond the limits discussed within this document, but such treatment will require clear documentation by the authorized treating practitioner focusing on objective functional gains afforded by further treatment and impact upon prognosis.

12. Guideline Recommendations and Inclusion of Medical Evidence. Guidelines are recommendations based on available evidence and/or consensus recommendations. When possible, guideline recommendations will note the level of evidence supporting the treatment recommendation. When interpreting medical evidence statements in the guideline, the following apply.

a. *Consensus* means the opinion of experienced professionals based on general medical principles. Consensus recommendations are designated in the guideline as "generally well accepted," "generally accepted," "acceptable/accepted," or "well-established."

b. *Some*—the recommendation considered at least one adequate scientific study, which reported that a treatment was effective.

c. *Good*—the recommendation considered the availability of multiple adequate scientific studies or at least one relevant high-quality scientific study, which reported that a treatment was effective.

d. *Strong*—the recommendation considered the availability of multiple relevant and high quality scientific studies, which arrived at similar conclusions about the effectiveness of a treatment.

B. All recommendations in the guideline are considered to represent reasonable care in appropriately selected cases, regardless of the level of evidence or consensus statement attached to it. Those procedures considered inappropriate, unreasonable, or unnecessary are designated in the guideline as "not recommended."

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1655 (June 2011).

§2017. Initial Diagnostic Procedures

A. The OWCA recommends the following diagnostic procedures be considered, at least initially, the responsibility of the workers' compensation carrier to ensure that an accurate diagnosis and treatment plan can be established. Standard procedures, that should be utilized when initially diagnosing a work-related low back pain complaint, are listed below.

1. History-taking and physical examination (Hx and PE) are generally accepted, well-established and widely used procedures that establish the foundation/basis for and dictates subsequent stages of diagnostic and therapeutic procedures. When findings of clinical evaluations and those

of other diagnostic procedures are not complementing each other, the objective clinical findings should have preference. The medical records should reasonably document the following.

a. History of Present Injury—a detailed history, taken in temporal proximity to the time of injury should primarily guide evaluation and treatment. The history should include pertinent positive and negative information regarding the following:

i. mechanism of injury. This includes details of symptom onset and progression. The mechanism of injury should include a detailed description of the incident and the position of the body before, during, and at the end of the incident. Inclusion of normal work body postures, frequency during the workday, and lifting/push/pull requirements should be included in the absence of a known specific incident;

ii. location of pain, nature of symptoms, and alleviating/exacerbating factors (e.g., sitting tolerance). The history should include both the primary and secondary complaints (e.g., primary low back pain, secondary hip, groin). The use of a patient completed pain drawing, Visual Analog Scale (VAS), is highly recommended, especially during the first two weeks following injury to assure that all work related symptoms are addressed;

iii. presence and distribution of lower extremity numbness, paresthesias, or weakness, especially if precipitated by coughing or sneezing;

iv. alteration in bowel, bladder, or sexual function; and for female patients, alteration in their menstrual cycle;

v. prior occupational and non-occupational injuries to the same area including specific prior treatment, chronic or recurrent symptoms, and any functional limitations; Specific history regarding prior motor vehicle accidents may be helpful; and

vi. ability to perform job duties and activities of daily living.

b. Past History—

i. past medical includes neoplasm, gout, arthritis, hypertension, kidney stones, and diabetes;

ii. review of systems includes symptoms of rheumatologic, neurologic, endocrine, neoplastic, infectious, and other systemic diseases;

iii. smoking history;

iv. vocational and recreational pursuits; and

v. history of depression, anxiety, or other psychiatric illness.

c. Physical Examination—should include accepted tests and exam techniques applicable to the area being examined, including:

i. general inspection, including stance and gait;

ii. visual inspection;

iii. palpation;

iv. lumbar range of motion, quality of motion, and presence of muscle spasm. Motion evaluation of specific joints may be indicated;

v. examination of thoracic spine and pelvis;

vi. nerve tension testing;

vii. sensory and motor examination of the lower extremities with specific nerve root focus;

viii. deep tendon reflexes with or without Babinski's;

ix. if applicable to injury, anal sphincter tone and/or perianal sensation; and,

x. if applicable, abdominal examination, vascular examination, circumferential lower extremity measurements, or evaluation of hip or other lower extremity abnormalities;

xi. If applicable, Waddell Signs, which include five categories of clinical signs tenderness; superficial and non-anatomic, pain with simulation: axial loading and rotation; regional findings: sensory and motor, inconsistent with nerve root patterns; distraction/inconsistency in straight leg raising findings, and over-reaction to physical examination maneuvers. Significance may be attached to positive findings in three out of five of these categories, but not to isolated findings. Waddell advocates considering Waddell's signs prior to recommending a surgical procedure. These signs should be measured routinely to identify patients requiring further assessment (i.e., biopsychosocial) prior to undergoing back surgery.

(a). It is generally agreed that Waddell Signs are associated with decreased functional performance and greater subjective pain levels, though they provide no information on the etiology of pain. Waddell Signs cannot be used to predict or diagnose malingering. Their presence of three out of five signs may most appropriately be viewed as a "yellow flag", or screening test, alerting clinicians to those patients who require a more comprehensive approach to their assessment and care plan. Therefore, if three out of five Waddell Signs are positive in a patient with subacute or chronic back pain, a psychosocial evaluation should be part of the total evaluation of the patient. Refer to Personality/Psychological/Psychosocial Evaluation.

d. Relationship To Work. This includes a statement of the probability that the illness or injury is work-related. If further information is necessary to determine work relatedness, the physician should clearly state what additional diagnostic studies or job information is required.

2. Radiographic imaging of the lumbosacral spine is a generally accepted, well-established and widely used diagnostic procedure when specific indications based on history and/or physical examination are present. There is some evidence that early radiographic imaging without clear indications is associated with prolonged care, but no difference in functional outcomes. Therefore, it should not be routinely performed without indications. The mechanism of injury and specific indications for the radiograph should be listed on the request form to aid the radiologist and x-ray technician. Suggested indications include:

a. history of significant trauma, especially blunt trauma or fall from a height;

b. age over 55 years;

c. unexplained or persistent low back pain for at least 6 weeks or pain that is worse with rest;

d. localized pain, fever, constitutional symptoms, or history or exam suggestive of intravenous drug abuse, prolonged steroid use, or osteomyelitis;

e. suspected lesion in the lumbosacral spine due to systemic illness such as a rheumatic/rheumatoid disorder or endocrinopathy. Suspected lesions may require special views;

f. past medical history suggestive of pre-existing spinal disease, osteoporosis, spinal instrumentation, or cancer; and

g. prior to high-velocity/low amplitude manipulation or Grade IV to V mobilization.

3. Laboratory Testing. Laboratory tests are generally accepted, well-established and widely used procedures. They are, however, rarely indicated at the time of initial evaluation, unless there is suspicion of systemic illness, infection, neoplasia, or underlying rheumatologic disorder, connective tissue disorder, or based on history and/or physical examination. Laboratory tests can provide useful diagnostic information. Tests include, but are not limited to:

a. complete blood count (CBC) with differential can detect infection, blood dyscrasias, and medication side effects;

b. erythrocyte sedimentation rate (ESR), rheumatoid factor (RF), antinuclear antigen (ANA), human leukocyte antigen (HLA), and C-reactive protein (CRP), can be used to detect evidence of a rheumatologic, infectious, or connective tissue disorder;

c. serum calcium, phosphorous, uric acid, alkaline phosphatase, and acid phosphatase can detect metabolic bone disease;

d. urinalysis for bacteria (usually with culture and sensitivity), calcium, phosphorus, hydroxyproline, or hematuria; and,

e. liver and kidney function may be performed for prolonged anti-inflammatory use or other medications requiring monitoring.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1656 (June 2011).

§2019. Follow-Up Diagnostic Imaging and Testing Procedures

A. One diagnostic imaging procedure may provide the same or distinctive information as does another procedure. Therefore, the prudent choice of a single diagnostic procedure, a complement of procedures or a sequence of procedures will optimize diagnostic accuracy; maximize cost effectiveness (by avoiding redundancy), and minimize potential adverse effects to patients.

B. All imaging procedures have a degree of specificity and sensitivity for various diagnoses. No isolated imaging test can assure a correct diagnosis. Clinical information obtained by history taking and physical examination should form the basis for selecting an imaging procedure and interpreting its results.

C. Magnetic resonance imaging (MRI), myelography, or Computed Axial Tomography (CT) scanning following myelography may provide useful information for many spinal disorders. When a diagnostic procedure, in conjunction with clinical information, can provide sufficient information to establish an accurate diagnosis, the second diagnostic procedure will become a redundant procedure. At the same time, a subsequent diagnostic procedure can be a complementary diagnostic procedure if the first or preceding procedures, in conjunction with clinical information, cannot provide an accurate diagnosis. Usually, preference of a procedure over others depends upon availability, a patient's tolerance, and/or the treating practitioner's familiarity with the procedure.

1. Imaging studies are generally accepted, well-established and widely used diagnostic procedures. In the absence of myelopathy, or progressive neurological changes, or history of cancer, imaging usually is not appropriate until conservative therapy has been tried and failed. Six to eight weeks of treatment are usually an adequate period of time before an imaging procedure is in order, but the clinician should use judgment in this regard. When indicated, imaging studies can be utilized for further evaluation of the low back, based upon the mechanism of injury, symptoms, and patient history. Prudent choice of a single diagnostic procedure, a complementary combination of procedures, or a proper sequential order of complementary procedures will help ensure maximum diagnostic accuracy and minimize adverse effect to the patient. When the findings of the diagnostic imaging and testing procedures are not consistent with the clinical examination, the clinical findings should have preference. There is good evidence that in the asymptomatic population, disc bulges, annular tears, or high intensity zone areas, and disc height loss are prevalent 40–60 percent of the time depending on the condition, study, and age of the patient. Therefore, the existence of these anatomic findings should not be considered relevant without physiologic and clinical correlation in an individual patient. The studies below are listed in frequency of use, not importance:

a. Magnetic Resonance Imaging (MRI) is rarely indicated in patients with non-traumatic acute low back pain with no neuropathic signs or symptoms. It is generally the first follow-up imaging study in individuals who respond poorly to proper initial conservative care. MRI is useful in suspected nerve root compression, myelopathy, masses, infections, metastatic disease, disc herniation, annular tear, and cord contusion or severe incapacitating pain. MRI is contraindicated in patients with certain implants.

i. In general, the high field, conventional, MRI provides better resolution. A lower field scan may be indicated when a patient cannot fit into a high field scanner or who is too claustrophobic despite sedation. Inadequate resolution on the first scan may require a second MRI using a different technique. All questions in this regard should be discussed with the MRI center and/or radiologist.

ii. Specialized MRI Scans

(a). MRI with three-dimensional reconstruction. On rare occasions, MRI with three-dimensional reconstruction views may be used as a pre-surgical diagnostic procedure to obtain accurate information of characteristics, location, and spatial relationships among soft tissue and bony structures.

(b). Dynamic-kinetic MRI of the spine. Dynamic-kinetic MRI of the spine uses an MRI unit configured with a top-front open design which enables upright, weight-bearing patient positioning in a variety of postures not obtainable with the recumbent images derived from conventional, closed unit MRI systems. Imaging can be obtained in flexion, extension, and rotation of the spine, as well as in erect positioning. There is a theoretical advantage to imaging sequences obtained under more physiologic conditions than in the supine position. There is currently ongoing research to establish whether the theoretical advantages of positional and kinetic MRI result in improved

sensitivity and specificity in detecting spine pathology. Currently it remains investigational and is not recommended until the correlation with clinical syndromes and outcomes is firmly established.

b. Computed Axial Tomography (CT) provides excellent visualization of bone and is used to further evaluate bony masses and suspected fractures not clearly identified on radiographic evaluation. It may sometimes be done as a complement to MRI scanning to better delineate bony osteophyte formation in the neural foramen. Instrument-scatter reduction software provides better resolution when metallic artifact is of concern.

c. Myelography is the injection of radiopaque material into the spinal subarachnoid space, with x-rays then taken to define anatomy. It may be used as a diagnostic procedure to obtain accurate information of characteristics, location, and spatial relationships among soft tissue and bony structures. Myelography is an invasive procedure with complications including nausea, vomiting, headache, convulsion, arachnoiditis, cerebral-spinal fluid (CSF) leakage, allergic reactions, bleeding, and infection. Therefore, myelography should only be considered when CT and MRI are unavailable, for morbidly obese patients or those who have undergone multiple operations, and when other tests prove non-diagnostic. The use of small needles and a less toxic, water-soluble, nonionic contrast is recommended.

d. CT Myelogram provides more detailed information about relationships between neural elements and surrounding anatomy and is appropriate in patients with multiple prior operations or tumorous conditions.

e. Single Photon Emission Computerized Tomography (SPECT). A scanning technique which may be helpful to localize facet joint pathology and is useful in determining which patients are likely to have a response to facet injection. SPECT combines bone scans & CT Scans in looking for facet joint pathology.

f. Bone Scan (Radioisotope Bone Scanning) is generally accepted, well-established, and widely used. Bone scanning is more sensitive but less specific than MRI. 99mTechnetium diphosphonate uptake reflects osteoblastic activity and may be useful in diagnosing metastatic/primary bone tumors, stress fractures, osteomyelitis, and inflammatory lesions, but cannot distinguish between these entities.

g. Other Radioisotope Scanning: Indium and gallium scans are generally accepted, well-established, and widely used procedures usually to help diagnose lesions seen on other diagnostic imaging studies. 67Gallium citrate scans are used to localize tumor, infection, and abscesses. 111Indium-labeled leukocyte scanning is utilized for localizing infection or inflammation.

h. Dynamic [Digital] Fluoroscopy: Dynamic [Digital] Fluoroscopy of the lumbar spine measures the motion of intervertebral segments using a videofluoroscopy unit to capture images as the subject performs lumbar flexion and extension, storing the anatomic motion of the spine in a computer. Currently it is not recommended for use in the diagnosis of lumbar instability, since there is limited information on normal segmental motion for the age groups commonly presenting with low back pain, and diagnostic criteria for specific spinal conditions are not yet defined. No studies have yet demonstrated predictive value in terms of standard operative and non-operative therapeutic outcomes.

2. Other tests. The following diagnostic procedures in this subsection are listed in alphabetical order, not by importance:

a. Electrodiagnostic Testing

i. Electromyography (EMG), Nerve Conduction Studies (NCS) These are generally accepted, well-established and widely used diagnostic procedures. EMG and NCS, when performed and interpreted by a trained physician/electrophysiologist, may be useful for patients with suspected neural involvement whose symptoms are persistent or unresponsive to initial conservative treatments. They are used to differentiate peripheral neural deficits from radicular and spinal cord neural deficits and to rule out concomitant myopathy. However, F-Wave Latencies are not diagnostic for radiculopathy.

(a). In general, EMG and NCS are complementary to imaging procedures such as CT, MRI, and/or myelography or diagnostic injection procedures. Electrodiagnostic studies may provide useful, correlative neuropathophysiological information that would be otherwise unobtainable from the radiologic studies discussed above.

ii. Portable Automated Electrodiagnostic Device (also known as Surface EMG) is not a substitute for conventional diagnostic testing in clinical decision-making, and therefore, is not recommended.

iii. Somatosensory Evoked Potential (SSEP) is not recommended to identify radiculopathy. It may be used to evaluate myelopathy and other rare neurological disorders such as neurogenic bladder and sexual dysfunction.

iv. Current Perception Threshold (CPT) Evaluation may be useful as a screening tool, but its diagnostic efficacy in the evaluation of industrial low back pain has not been determined. Therefore, CPT is not recommended as a diagnostic tool.

v. Large Array Surface Electromyography measures low back muscle activity using a fixed array of 63 electrodes arranged in nine rows and seven columns between the seventh thoracic spinous process and the iliac crest. The array simultaneously collects myoelectric data from multifidus, iliocostalis, quadratus lumborum, and other lumbar muscles, which is analyzed for patterns of activity in these muscle groups. It is used in researching physiologic changes and adaptations to back pain, but is not recommended as a diagnostic procedure for individuals with back pain due to a lack of interpretive standards.

vi. Surface EMG in combination with Range of Motion and/or Functional Capacity Evaluation. This is designed to detect differences between persons with and without low back pain, measuring signals in lumbar flexion which show that painful paraspinal muscles fail to relax fully. It may show aspects of the pathophysiology of muscle activity which advance the scientific understanding of low back pain. The test also purports to determine the significance of disc pathology and the age of an injury. It has not been evaluated in a setting which tests a spectrum of patients commonly seen in clinical practice, using an interpretation which is tested against a diagnostic reference standard. Therefore, it is not suitable as a diagnostic test for

low back pain and its use for this purpose is not recommended.

b. Injections—Diagnostic

i. Description. Diagnostic spinal injections are generally accepted, well-established procedures. These injections may be useful for localizing the source of pain, and may have added therapeutic value when combined with injection of therapeutic medication(s). Each diagnostic injection has inherent risks, and risk versus benefit should always be evaluated when considering injection therapy.

ii. Indications. Since these procedures are invasive, less invasive or non-invasive procedures should be considered first. Selection of patients, choice of procedure, and localization of the level for injection should be determined by clinical information indicating strong suspicion for pathologic condition(s) and the source of pain symptoms. Because injections are invasive with an inherent risk, the number of diagnostic procedures should be limited in any individual patient to those most likely to be primary pain generators. Patients should not receive all of the diagnostic blocks listed merely in an attempt to identify 100 percent of the pain generators.

iii. The interpretation of the test results are primarily based on functional change, symptom report, and pain response (via a recognized pain scale), before and at an appropriate time period after the injection. The diagnostic significance of the test result should be evaluated in conjunction with clinical information and the results of other diagnostic procedures. Injections with local anesthetics of differing duration may be used to support a diagnosis. In some cases, injections at multiple levels may be required to accurately diagnose low back pain. (Refer to Injections—Therapeutic for information on specific injections.)

(a). It is obligatory that sufficient data be accumulated by the examiner performing this procedure such that the diagnostic value of the procedure be evident to other reviewers. This entails, at a minimum, documentation of patient response immediately following the procedure with details of any symptoms with a response and the degree of response. Additionally, a log must be recorded as part of the medical record which documents response, if any, on an hourly basis for, at a minimum, the expected duration of the local anesthetic phase of the procedure. Responses must be identified as to specific body part (e.g., low back, leg pain). The practitioner must identify the local anesthetic used and the expected duration of response for diagnostic purposes.

(b). Multiple injections provided at the same session without staging may seriously dilute the diagnostic value of these procedures. Practitioners must carefully weigh the diagnostic value of the procedure against the possible therapeutic value.

iv. Special Requirements for Diagnostic Injections. Since multi-planar fluoroscopy during procedures is required to document technique and needle placement, an experienced physician should perform the procedure. Permanent images are required to verify needle placement. The subspecialty disciplines of the physicians performing the injections may be varied, including, but not limited to: anesthesiology, radiology, surgery, neurology or physiatry. The practitioner should document hands-on training through workshops and/or completed fellowship training with interventional training. They must also be knowledgeable in radiation safety.

v. Complications. General complications of diagnostic injections may include transient neurapraxia, nerve injury, infection, headache, urinary retention, and vasovagal effects, as well as epidural hematoma, permanent neurologic damage, dural perforation, and CSF leakage, and spinal meningeal abscess. Permanent paresis, anaphylaxis, and arachnoiditis have been rarely reported with the use of epidural steroids.

vi. Contraindications. Absolute contraindications to diagnostic injections include: bacterial infection—systemic or localized to region of injection; bleeding diatheses; hematological conditions; and possible pregnancy.

(a). Relative contraindications to diagnostic injections may include: allergy to contrast, poorly controlled Diabetes Mellitus and hypertension. Drugs affecting coagulation may require restriction from use. Anti-platelet therapy and anti-coagulations should be addressed individually by a knowledgeable specialist. It is recommended to refer to the American Society of Regional Anesthesia for anticoagulation guidelines.

vii. Specific Diagnostic Injections. In general, relief should last for at least the duration of the local anesthetic used and should significantly relieve pain and result in functional improvement. Refer to "Injections – Therapeutic" for information on specific therapeutic injections.

(a). Medial Branch Blocks are generally accepted diagnostic injections, used to determine whether a patient is a candidate for radiofrequency medial branch neurotomy (also known as facet rhizotomy). ISIS suggests controlled blocks, using either placebo or anesthetics with varying lengths of activity (i.e., bupivacaine longer than lidocaine). To be a positive diagnostic block, the patient should report a reduction of pain of 50 percent or greater relief from baseline for the length of time appropriate for the local anesthetic used. In almost all cases, this will mean a reduction of pain to one or two on the Visual Analog Scale (VAS) 10-point scale correlated with functional improvement. The patient should also identify activities of daily living (which may include measurements of range of motion) that are impeded by their pain and can be observed to document functional improvement in the clinical setting. Ideally, these activities should be assessed throughout the observation period for function. The observer should not be the physician who performed the procedure. It is suggested that this be recorded on a form similar to ISIS recommendations or American Society of Interventional Pain Physicians (ASIPP)

(i). A separate comparative block on a different date may be performed to confirm the level of involvement. A comparative block uses anesthetics of varying lengths of activity. Medial Branch blocks are probably not helpful to determine the likelihood of success for spinal fusion.

[a]. Frequency and Maximum Duration: May be repeated once for comparative blocks. Limited to four levels

[b]. Transforaminal injections/Spinal Selective Nerve Block (SSNB) are generally accepted and

useful in identifying spinal pathology. When performed for diagnosis, small amounts of local anesthetic up to a total volume of 1.0 cc should be used to determine the level of nerve root irritation. A positive diagnostic block should result in a positive diagnostic functional benefit and a 50 percent reduction in nerve-root generated pain appropriate for the anesthetic used as measured by accepted pain scales (such as a VAS).

[i]. Time to produce effect: Less than 30 minutes for local anesthesia; corticosteroids up to 72 hours for most patients.

[ii]. Frequency and Maximum Duration: Once per suspected level. Limited to two levels

c. Zygapophyseal (Facet) Blocks

i. Facet blocks are generally accepted but should not be considered diagnostic blocks for the purposes of determining the need for a rhizotomy (radiofrequency medial branch neurotomy), nor should they be done with medial branch blocks.

ii. These blocks should not be considered a definitive diagnostic tool. They may be used diagnostically to direct functional rehabilitation programs. A positive diagnostic block should result in a positive diagnostic functional benefit and a 50 percent reduction in pain appropriate for the anesthetic used as measured by accepted pain scales (such as a VAS). They then may be repeated per the therapeutic guidelines when they are accompanied by a functional rehabilitation program. (Refer to Therapeutic Spinal Injections).

(a). Time to produce effect: Less than 30 minutes for local anesthesia; corticosteroids up to 72 hours for most patients;

(b). Frequency and maximum Duration: Once per suspected level, limited to two levels.

d. Sacroiliac Joint Injection

i. Description. A generally accepted Injection of local anesthetic in an intra-articular fashion into the sacroiliac joint under fluoroscopic guidance. Long-term therapeutic effect has not yet been established.

ii. Indications. Primarily diagnostic to rule out sacroiliac joint dysfunction versus other pain generators. Intra-articular injection can be of value in diagnosing the pain generator. There should be documented relief from previously painful maneuvers (e.g., Patrick's test) and at least 50 percent pain relief on post-injection physical exam (as measured by accepted pain scales such as a VAS) correlated with functional improvement. Sacroiliac joint blocks should facilitate functionally directed rehabilitation programs.

(a). Time to produce effect: Up to 30 minutes for local anesthetic;

(b). Frequency and Maximum Duration: 1;

e. Personality /Psychological /Psychiatric /Psychosocial Evaluation

i. These are generally accepted and well-established diagnostic procedures with selective use in the upper extremity population, but have more widespread use in subacute and chronic upper extremity populations. Diagnostic testing procedures may be useful for patients with symptoms of depression, delayed recovery, chronic pain, recurrent painful conditions, disability problems, and for preoperative evaluation. Psychological/psychosocial and measures have been shown to have predictive value for postoperative response, and therefore should be strongly considered for use pre-operatively when the surgeon has concerns about the relationship between symptoms and findings, or when the surgeon is aware of indications of psychological complication or risk factors for psychological complication (e.g. childhood psychological trauma). Psychological testing should provide differentiation between pre-existing conditions versus injury caused psychological conditions, including depression and posttraumatic stress disorder. Psychological testing should incorporate measures that have been shown, empirically, to identify comorbidities or risk factors that are linked to poor outcome or delayed recovery.

ii. Formal psychological or psychosocial evaluation should be performed on patients not making expected progress within 6 to 12 weeks following injury and whose subjective symptoms do not correlate with objective signs and test results. In addition to the customary initial exam, the evaluation of the injured worker should specifically address the following areas:

(a). employment history;

(b). interpersonal relationships-both social and work;

(c). patient activities;

(d). current perception of the medical system;

(e). current perception/attitudes toward employer/job;

(f). results of current treatment;

(g). risk factors and psychological comorbidities that may influence;

(h). outcome and that may require treatment:

(i). childhood history, including history of childhood psychological trauma, abuse and family history of disability;

(ii). personality/ psychological/ psychosocial evaluations consist of two components, clinical interview and psychological testing. Results should help clinicians with a better understanding of the patient in a number of ways. Thus the evaluation result will determine the need for further psychosocial interventions; and in those cases, Diagnostic and Statistical Manual of Mental Disorders (DSM) diagnosis should be determined and documented. The evaluation should also include examination of both psychological comorbidities and psychological risk factors that are empirically associated with poor outcome and/or delayed recovery. An individual with a Ph.D., Psy.D, or psychiatric M.D./D.O. credentials should perform initial evaluations, which are generally completed within one to two hours. A professional fluent in the primary language of the patient is preferred. When such a provider is not available, services of a professional language interpreter should be provided.

[a]. Frequency: one-time visit for the clinical interview. If psychometric testing is indicated as a part of the initial evaluation, time for such testing should not exceed an additional two hours of professional time.

f. Provocation Discography

i. Description. Discography is an accepted, but rarely indicated, invasive diagnostic procedure to identify or refute a discogenic source of pain for patients who are surgical candidates. Discography should only be performed

by physicians who are experienced and have been proctored in the technique. Discograms have a significant false positive rate. It is essential that all indications, pre-conditions, special considerations, procedures, reporting requirements, and results are carefully and specifically followed. Results should be interpreted judiciously.

ii. Indications. Discography may be indicated when a patient has a history of functionally limiting, unremitting low back pain of greater than four months duration, with or without leg pain, which has been unresponsive to all conservative interventions. A patient who does not desire operative therapeutic intervention is not a candidate for an invasive non-therapeutic intervention, such as provocation discography.

(a). Discography may prove useful for the evaluation of the pre-surgical spine, such as pseudarthrosis, discogenic pain at levels above or below a prior spinal fusion, annular tear, or internal disc disruption.

(b). Discography may show disc degeneration and annular disruption in the absence of low back pain. Discography may also elicit concordant pain in patients with mild and functionally inconsequential back pain. Because patients with mild back pain should not be considered for invasive treatment, discography should not be performed on these patients. In symptomatic patients with annular tears on discography, the side of the tear does not necessarily correlate with the side on which the symptoms occur. The presence of an annular tear does not necessarily identify the tear as the pain generator.

(c). Discography is not useful in previously operated discs, but may have a limited place in the work-up of pseudarthrosis. Discography may prove useful in evaluating the number of lumbar spine levels that might require fusion. CT-Discography provides further detailed information about morphological abnormalities of the disc and possible lateral disc herniations.

iii. Pre-conditions for provocation discography include all of the following.

(a). A patient with functionally limiting, unremitting back and/or leg pain of greater than four months duration in whom conservative treatment has been unsuccessful and in whom the specific diagnosis of the pain generator has not been made apparent on the basis of other noninvasive imaging studies (e.g., MRI, CT, plain films, etc.). It is recommended that discography be reserved for use in patients with equivocal MRI findings, especially at levels adjacent to clearly pathological levels. Discography may be more sensitive than MRI or CT in detecting radial annular tears. However, radial tears must always be correlated with clinical presentation.

(b). Psychosocial Evaluation has been completed. There is some evidence that false positives and complaints of long-term pain arising from the procedure itself occur more frequently in patients with somatoform disorders. Therefore, discograms should not be performed on patients with somatoform disorders.

(c). Patients who are considered surgical candidates (e.g., symptoms are of sufficient magnitude and the patient has been informed of the possible surgical options that may be available based upon the results of discography). Discography should never be the sole indication for surgery.

(d). Informed consent regarding the risks and potential diagnostic benefits of discography has been obtained.

iv. Complications—include, but are not limited to, discitis, nerve damage, chemical meningitis, pain exacerbation, and anaphylaxis therefore, prior to consideration of discography, the patient should undergo other diagnostic modalities in an effort to define the etiology of the patient's complaint including psychological evaluation, myelography, CT and MRI.

v. Contraindications—include:

(a) active infection of any type or continuing antibiotic treatment for infection; and/or

(b) bleeding diathesis or pharmaceutical anticoagulation with warfarin, etc.; and/or

(c) significant spinal stenosis at the level being studied as visualized by MRI, myelography or CT scan; and/or

(d) presence of clinical myelopathy; and/or

(e) effacement of the cord, thecal sac or circumferential absence of epidural fat; and

(f) known allergic reactions.

vi. Special Considerations

(a). Discography should not be performed by the physician expected to perform the therapeutic procedure. The procedure should be carried out by an experienced individual who has received specialized training in the technique of provocation discography.

(b). Discography should be performed in a blinded format that avoids leading the patient with anticipated responses. The procedure should always include one or more disc levels thought to be normal or non-painful in order to serve as an internal control. The patient should not know what level is being injected in order to avoid spurious results. Abnormal disc levels may be repeated to confirm concordance.

(c). Sterile technique must be utilized.

(d). Judicious use of light sedation during the procedure is acceptable, represents the most common practice nationally at the current time, and is recommended by most experts in the field. The patient must be awake and able to accurately report pain levels during the provocation portion of the procedure.

(e). The discography should be performed using a manometer to record pressure. Pressure should not exceed 50 pounds per square inch (psi) above opening pressure.

(f). Intradiscal injection of local anesthetic may be carried out after the provocation portion of the examination and the patient's response.

(g). It is recommended that a post-discogram CT be considered as it frequently provides additional useful information about disc morphology or other pathology.

vii. Reporting of Discography. In addition to a narrative report, the discography report should contain a standardized classification of (a) disc morphology (b) the pain response, and (c) the pressure at which pain is produced. All results should be clearly separated in the report from the narrative portion. Asymptomatic annular tears are common and the concordant pain response is an essential finding for a positive discogram.

(a). When discography is performed to identify the source of a patient's low-back pain, both a concordant

pain response and morphological abnormalities must be present at the pathological level prior to initiating any treatment directed at that level. The patient must be awake during the provocation phase of the procedure; therefore, sedative medication must be carefully titrated.

(b). Caution should be used when interpreting results from discography. Several studies indicate that a false positive discogram for pain is likely above a pressure reading of 50 psi above opening pressure. The false positive rate appears to drop to approximately 25 percent using a pressure of 20 psi above opening pressure in a population with low back pain.

(i). Reporting disc morphology as visualized by the post-injection CT scan (when available) should follow the Modified Dallas Discogram Scale where:

[a]. Grade 0 = Normal Nucleus

[b]. Grade 1 = Annular tear confined to inner one-third of annulus fibrosis.

[c]. Grade 2 = Annular tear extending to the middle third of the annulus fibrosis.

[d]. Grade 3 = Annular tear extending to the outer one-third of the annulus fibrosis.

[e]. Grade 4 = A grade 3 tear plus dissection within the outer annulus to involve more than 30 degrees of the disc circumference.

[f]. Grade 5 = Full thickness tear with extra-annular leakage of contrast, either focal or diffuse.

(ii). Reporting of pain response should be consistent with the operational criteria of the International Spine Intervention Society (ISIS) Guidelines or American Society of Interventional Pain Physicians (ASIPP) Guidelines. The report must include the level of concordance for back pain and /or leg pain using a 10-point VAS, or similar quantitative assessment. It should be noted that change in the VAS scale before and after provocation is more important than the number reported.

[a]. Unequivocal Discogenic Pain

[i]. stimulation of the target disc reproduces concordant pain

[ii]. the pain should be registered at least 7 on a 10-point VAS.

[iii]. the pain is reproduced at a pressure of less than 15 psi above opening pressure; and

[iv]. stimulation of two adjacent discs does not produce pain at all

[b]. Definite Discogenic Pain

[i]. stimulation of the target disc reproduces concordant pain

[ii]. the pain should be registered as at least 7 on a 10-point VAS.

[iii]. the pain is reproduced at a pressure of less than 15 psi above opening pressure; and

[iv]. stimulation of at least one adjacent disc does not produce pain at all

[c]. Highly Probable Discogenic Pain

[i]. stimulation of the target disc reproduces concordant pain

[ii]. that pain should be registered as at least 7 on a 10-point VAS.

[iii]. that the pain is reproduced at a pressure of less than 50 psi above opening pressure; and

[iv]. stimulation of two adjacent discs does not produce pain at all

[d]. Probable Discogenic Pain

[i]. stimulation of the target disc reproduces concordant pain;

[ii]. that pain should be registered as at least 7 on a 10-point VAS;

[iii]. the pain is reproduced at a pressure of less than 50 psi above opening pressure; and

[iv]. stimulation of one adjacent disc does not produce pain at all, and stimulation of another adjacent disc at greater than 50 psi, produces pain, but the pain is not concordant.

[e]. Multiple combinations of factors are possible. However, if the patient does not qualify for at least a 'Probable Discogenic Pain' level, then the discogram should be considered negative. The VAS score prior to the discogram should be taken into account when interpreting the VAS score reported by the patient during the discogram.

[i]. Time Parameters for Provocation Discography are as follows:

aa. Frequency: One time only

bb. Maximum: Repeat Discography is rarely indicated

g. Thermography is an accepted and established procedure, but has no use as a diagnostic test for low back pain. It may be used to diagnose regional pain disorders and in these cases, refer to the OWCA's Complex Regional Pain Syndrome/Reflex Sympathetic Dystrophy Medical Treatment Guidelines.

3. Special tests are generally well-accepted tests and are performed as part of a skilled assessment of the patients' capacity to return to work, his/her strength capacities, and physical work demand classifications and tolerance. The procedures in this subsection are listed in alphabetical order, not by importance.

a. Computer-Enhanced Evaluations: may include isotonic, isometric, isokinetic and/or isoinertial measurement of movement, range of motion, endurance, or strength. Values obtained can include degrees of motion, torque forces, pressures, or resistance. Indications include determining validity of effort, effectiveness of treatment and demonstrated motivation. These evaluations should not be used alone to determine return to work restrictions.

i. Frequency—one time for evaluation. Can monitor improvements in strength every three to four weeks up to a total of six evaluations.

b. Functional Capacity Evaluation (FCE) is a comprehensive or modified evaluation of the various aspects of function as they relate to the worker's ability to return to work. Areas such as endurance, lifting (dynamic and static), postural tolerance, specific range of motion, coordination and strength, worker habits, employability as well as psychosocial, cognitive, and sensory perceptual aspects of competitive employment may be evaluated. Components of this evaluation may include: musculoskeletal screen; cardiovascular profile/aerobic capacity; coordination;

lift/carrying analysis; job-specific activity tolerance; maximum voluntary effort; pain assessment/psychological screening; and non-material and material handling activities.

i. When an FCE is being used to determine return to a specific jobsite, the provider is responsible for fully understanding the job duties. A jobsite evaluation is frequently necessary. FCEs cannot be used in isolation to determine work restrictions. The authorized treating physician must interpret the FCE in light of the individual patient's presentation and medical and personal perceptions. FCEs should not be used as the sole criteria to diagnose malingering.

ii. Full FCEs are sometimes not necessary. If Partial FCEs are performed, it is recognized that all parts of the FCE that are not performed are considered normal. In many cases, a work tolerance screening will identify the ability to perform the necessary job tasks.

(a). Frequency can be used initially to determine baseline status. Additional evaluations can be performed to monitor and assess progress and aid in determining the endpoint for treatment.

c. Job site Evaluation: is a comprehensive analysis of the physical, mental, and sensory components of a specific job. These components may include, but are not limited to: postural tolerance (static and dynamic); aerobic requirements; range of motion; torque/force; lifting/carrying; cognitive demands; social interactions; visual perceptual; sensation; coordination; environmental requirements repetitiveness; and essential job functions. Job descriptions provided by the employer are helpful but should not be used as a substitute for direct observation.

i. A jobsite evaluation may include observation and instruction of how work is done, what material changes (desk, chair) should be made, and determination of readiness to return to work.

ii. Requests for a jobsite evaluation should describe the expected goals for the evaluation. Goals may include, but are not limited to the following:

(a). to determine if there are potential contributing factors to the person's condition and/or for the physician to assess causality;

(b). to make recommendations for, and to assess the potential for ergonomic changes;

(c). to provide a detailed description of the physical and cognitive job requirements;

(d). to assist the patient in their return to work by educating them on how they may be able to do their job more safely in a bio-mechanically appropriate manner;

(e). to give detailed work/activity restrictions.

(i). Frequency—one time with additional visits as needed for follow-up per jobsite.

d. Vocational Assessment. The vocational assessment should provide valuable guidance in the determination of future rehabilitation program goals. It should clarify rehabilitation goals, which optimize both patient motivation and utilization of rehabilitation resources. If prognosis for return to former occupation is determined to be poor, except in the most extenuating circumstances, vocational assessment should be implemented within 3 to 12 months post-injury. Declaration of MMI should not be delayed solely due to lack of attainment of a vocational assessment.

i. Frequency—one time with additional visits as needed for follow-up

e. Work Tolerance Screening is a determination of an individual's tolerance for performing a specific job as based on a job activity or task and may be used when a full Functional Capacity Evaluation is not indicated. It may include a test or procedure to specifically identify and quantify work-relevant cardiovascular, physical fitness and postural tolerance. It may also address ergonomic issues affecting the patient's return-to-work potential.

i. Frequency—one time for initial screen. May monitor improvements in strength every three to four weeks up to a total of six visits.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1658 (June 2011).

§2021. Therapeutic Procedures—Non-Operative

A. Before initiation of any therapeutic procedure, the authorized treating provider, employer, and insurer must consider these important issues in the care of the injured worker.

B. First, patients undergoing therapeutic procedure(s) should be released or returned to modified or restricted duty during their rehabilitation at the earliest appropriate time. Refer to "Return-to-Work" in this section for detailed information.

C. Second, cessation and/or review of treatment modalities should be undertaken when no further significant subjective or objective improvement in the patient's condition is noted. If patients are not responding within the recommended duration periods, alternative treatment interventions, further diagnostic studies or consultations should be pursued.

D. Third, providers should provide and document education to the patient. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of facilitating self-management of symptoms.

E. Lastly, formal psychological or psychosocial evaluation should be performed on patients not making expected progress within 6 to 12 weeks following injury and whose subjective symptoms do not correlate with objective signs and tests.

F. Home therapy is an important component of therapy and may include active and passive therapeutic procedures, as well as, other modalities to assist in alleviating pain, swelling, and abnormal muscle tone.

G. Non-operative treatment procedures for low back pain can be divided into two groups: conservative care and rehabilitation. Conservative care is treatment applied to a problem in which spontaneous improvement is expected in 90 percent of the cases within three months. It is usually provided during the tissue-healing phase and lasts no more than six months, and often considerably less. Rehabilitation is treatment applied to a more chronic and complex problem in a patient with de-conditioning and disability. It is provided during the period after tissue healing to obtain maximal medical recovery. Treatment modalities may be utilized sequentially or concomitantly depending on chronicity and complexity of the problem, and treatment

plans should always be based on a diagnosis utilizing appropriate diagnostic procedures.

H. The following procedures are listed in alphabetical order.

1. Acupuncture is an accepted and widely used procedure for the relief of pain and inflammation, and there is some scientific evidence to support its use. The exact mode of action is only partially understood. Western medicine studies suggest that acupuncture stimulates the nervous system at the level of the brain, promotes deep relaxation, and affects the release of neurotransmitters. Acupuncture is commonly used as an alternative or in addition to traditional Western pharmaceuticals. While it is commonly used when pain medication is reduced or not tolerated, it may be used as an adjunct to physical rehabilitation and/or surgical intervention to hasten the return of functional activity. Acupuncture should be performed by licensed practitioners.

a. Acupuncture: is the insertion and removal of filiform needles to stimulate acupoints (acupuncture points). Needles may be inserted, manipulated, and retained for a period of time. Acupuncture can be used to reduce pain, reduce inflammation, increase blood flow, increase range of motion, decrease the side effect of medication-induced nausea, promote relaxation in an anxious patient, and reduce muscle spasm.

i. Indications include joint pain, joint stiffness, soft tissue pain and inflammation, paresthesia, post-surgical pain relief, muscle spasm, and scar tissue pain.

b. Acupuncture with Electrical Stimulation: is the use of electrical current (micro-amperage or milli-amperage) on the needles at the acupuncture site. It is used to increase effectiveness of the needles by continuous stimulation of the acupoint. Physiological effects (depending on location and settings) can include endorphin release for pain relief, reduction of inflammation, increased blood circulation, analgesia through interruption of pain stimulus, and muscle relaxation.

i. It is indicated to treat chronic pain conditions, radiating pain along a nerve pathway, muscle spasm, inflammation, scar tissue pain, and pain located in multiple sites.

c. Total Time Frames For Acupuncture and Acupuncture with Electrical Stimulation: Time frames are not meant to be applied to each of the above sections separately. The time frames are to be applied to all acupuncture treatments regardless of the type or combination of therapies being provided.

i. time to produce effect: three to six treatments;
ii. frequency: one to three times per week;
iii. optimum duration: one to two months;
iv. maximum duration: 14 treatments.

(a). Any of the above acupuncture treatments may extend longer if objective functional gains can be documented or when symptomatic benefits facilitate progression in the patient's treatment program. Treatment beyond 14 treatments must be documented with respect to need and ability to facilitate positive symptomatic or functional gains. Such care should be re-evaluated and documented with each series of treatments.

(b). Other Acupuncture Modalities. Acupuncture treatment is based on individual patient needs and therefore treatment may include a combination of procedures to enhance treatment effect. Other procedures may include the use of heat, soft tissue manipulation/massage, and exercise. Refer to Active Therapy (Therapeutic Exercise) and Passive Therapy sections (Massage and Superficial Heat and Cold Therapy) for a description of these adjunctive acupuncture modalities and time frames.

2. Biofeedback is a form of behavioral medicine that helps patients learn self-awareness and self-regulation skills for the purpose of gaining greater control of their physiology, such as muscle activity, brain waves, and measures of autonomic nervous system activity. Electronic instrumentation is used to monitor the targeted physiology and then displayed or fed back to the patient visually, auditorially, or tactilely, with coaching by a biofeedback specialist. Biofeedback is provided by clinicians certified in biofeedback and/or who have documented specialized education, advanced training, or direct or supervised experience qualifying them to provide the specialized treatment needed (e.g., surface EMG, EEG, or other).

a. Treatment is individualized to the patient's work-related diagnosis and needs. Home practice of skills is required for mastery and may be facilitated by the use of home training tapes. The ultimate goal of biofeedback treatment is to normalize physiology to the pre-injury status to the extent possible, and involves transfer of learned skills to the workplace and daily life. Candidates for biofeedback therapy or training must be motivated to learn and practice biofeedback and self-regulation techniques.

b. Indications for biofeedback include individuals who are suffering from musculoskeletal injury in which muscle dysfunction or other physiological indicators of excessive or prolonged stress response affects and/or delays recovery. Other applications include training to improve self-management of emotional stress/pain responses such as anxiety, depression, anger, sleep disturbance, and other central and autonomic nervous system imbalances. Biofeedback is often used in conjunction with other treatment modalities.

i. time to produce effect: three to four sessions;
ii. frequency: one to two times per week;
iii. optimum duration: five to six sessions;
iv. maximum duration: 10 to 12 sessions. Treatment beyond 12 sessions must be documented with respect to need, expectation, and ability to facilitate positive functional gains.

3. Injections—Therapeutic

a. Therapeutic Spinal Injections. Description—Therapeutic spinal injections may be used after initial conservative treatments, such as physical and occupational therapy, medication, manual therapy, exercise, acupuncture, etc., have been undertaken. Therapeutic injections should be used only after imaging studies and diagnostic injections have established pathology. Injections are invasive procedures that can cause serious complications; thus clinical indications and contraindications should be closely adhered to. The purpose of spinal

injections is to facilitate active therapy by providing short-term relief through reduction of pain and inflammation. All patients should continue appropriate exercise with functionally directed rehabilitation. Active treatment, which patients should have had prior to injections, will frequently require a repeat of the sessions previously ordered (Refer to Active Therapy). Injections, by themselves, are not likely to provide long-term relief. Rather, active rehabilitation with modified work achieves long-term relief by increasing active ROM, strength, and stability. Subjective reports of pain response (via a recognized pain scale) and function should be considered and given relative weight when the pain has anatomic and physiologic correlation. Anatomic correlation must be based on objective findings.

i. Special Considerations. For all injections (excluding trigger point), multi-planar fluoroscopic guidance during procedures is required to document technique and needle placement, and should be performed by a physician experienced in the procedure. Permanent images are required to verify needle replacement. The subspecialty disciplines of the physicians performing injections may be varied, including, but not limited to: anesthesiology, radiology, neurology, surgery, or physiatry. The practitioner should document hands-on training through workshops of the type offered by organizations such as the International Spine Intervention Society (ISIS) and/or completed fellowship training in pain medicine with interventional training. They must also be knowledgeable in radiation safety.

ii. Complications. General complications of spinal injections may include transient neurapraxia, local pain, nerve injury, infection, headache, urinary retention, and vasovagal effects. Epidural hematoma, permanent neurologic damage, dural perforation and CSF leakage; and/or spinal meningeal abscess may also occur. Permanent paresis, anaphylaxis, and arachnoiditis have been rarely reported with the use of epidural steroids. With steroid injections, there may be a dose-dependent suppression of the hypothalamic-pituitary-adrenal axis lasting between one and three months.

iii. Contraindications. Absolute contraindications to therapeutic injections include: bacterial infection–systemic or localized to region of injection; bleeding diatheses; hematological conditions, and possible pregnancy.

(a). Relative contraindications to diagnostic injections may include: allergy to contrast, poorly controlled Diabetes Mellitus, and hypertension. Drugs affecting coagulation may require restriction from use. Anti-platelet therapy and anti-coagulations should be addressed individually by a knowledgeable specialist. It is recommended to refer to Am Society of Regional Anesthesia for anticoagulation guidelines.

iv. Epidural Steroid Injection (ESI)

(a). Description. Epidural steroid injections are injections of corticosteroid into the epidural space. The purpose of ESI is to reduce pain and inflammation in the acute or sub-acute phases of injury, restoring range of motion and, thereby, facilitating progress in more active treatment programs. ESI uses three approaches: transforaminal/Spinal Selective Nerve Block (SNRB), interlaminar (midline), and caudal. The transforaminal/ Spinal Selective Nerve Root Block approach is the preferred method for unilateral, single-level pathology and for post-surgical patients. There is good evidence that the transforaminal/ Spinal Selective Nerve Root Block approach can deliver medication to the target tissue with few complications and can be used to identify the specific site of pathology. The interlaminar approach is the preferred approach for multi-level pathology or spinal stenosis. Caudal therapeutic injections may be used, but it is difficult to target the exact treatment area, due to diffuse distribution.

(b). Needle Placement. Multi-planar fluoroscopic imaging is required for all epidural steroid injections. Contrast epidurograms allow one to verify the flow of medication into the epidural space. Permanent images are required to verify needle replacement.

(c). Indications. There is some evidence that epidural steroid injections are effective for patients with radicular pain or radiculopathy (sensory or motor loss in a specific dermatome or myotome). Up to 80 percent of patients with radicular pain may have initial relief. However, only 25-57 percent are likely to have excellent long-term relief. Although there is no evidence regarding the effectiveness of ESI for non-radicular disc herniation, it is an accepted intervention. Only patients who have pain affected by activity and annular tears verified by appropriate imaging may have injections for axial pain.

(i). There is some evidence that ESI injections are not effective for spinal stenosis without radicular findings. Additionally, there is some evidence that patients who smoke or who have pain unaffected by rest or activity are less likely to have a successful outcome from ESIs.

[a]. Time to produce effect: Local anesthetic, less than 30 minutes; corticosteroid, 48 to 72 hours for 80 percent of patients and 72 hours to 2 weeks for 20 percent of patients.

[b]. Frequency: Interlaminar (midline) or caudal techniques should be limited to one level per session. Transforaminal epidural injections should be limited to two levels per session Whether injections are repeated depends upon the patient's response to the previous injection. Subsequent injections may occur after one to two weeks if patient response has been favorable. Injections can be repeated after a hiatus of six months if the patient has demonstrated functional gain and pain returns or worsens. Injections should provide a positive patient response. Positive patient response results are defined primarily as functional gains that can be objectively measured. Objective functional gains include, but are not limited to, positional tolerances, range of motion (ROM), strength, endurance, activities of daily living, cognition, psychological behavior, and efficiency/velocity measures that can be quantified. Subjective reports of pain response (via a recognized pain scale) and function should be considered and given relative weight when the pain has anatomic and physiologic correlation.

[c]. Optimum duration: Usually one to three injection(s) over a period of six months depending upon each patient's response and functional gain.

[d]. Maximum duration: Two sessions (consisting of up to three injections each) may be done in one year, as per the patient's response to pain and function. Patients should be reassessed after each injection for an 50

percent improvement in pain (as measured by accepted pain scales) and evidence of functional improvement.

v. Zygapophyseal (Facet) Injection

(a). Description—a generally accepted intra-articular or pericapsular injection of local anesthetic and corticosteroid. Medial branch nerve blocks are diagnostic only. There is conflicting evidence to support a long-term therapeutic effect using facet injections. There is no justification for a combined facet and medial branch block.

(b). Indications—patients with pain 1) suspected to be facet in origin based on exam findings and 2) affecting activity; OR, patients who have refused a rhizotomy; OR, patients who have facet findings with a thoracic component. In these patients, facet injections may be occasionally useful in facilitating a functionally-directed rehabilitation program and to aid in identifying pain generators. Patients with recurrent pain should be evaluated with more definitive diagnostic injections, such as medial nerve branch injections, to determine the need for a rhizotomy. Because facet injections are not likely to produce long-term benefit by themselves and are not the most accurate diagnostic tool, they should not be performed at more than two levels.

(i). Facet injections may be repeated if they result in increased documented functional benefit for at least four to six weeks and at least an 50 percent initial improvement in pain scales as measured by accepted pain scales (such as VAS).

[a]. Time to produce effect: Up to 30 minutes for local anesthetic; corticosteroid up to 72 hours.

[b]. Frequency: one injection per level with a diagnostic response. If the first injection does not provide a diagnostic response of temporary and sustained pain relief substantiated by accepted pain scales, (i.e., 50 percent pain reduction substantiated by tools such as VAS), and improvement in function, similar injections should not be repeated. At least four to six weeks of functional benefit should be obtained with each therapeutic injection.

[c]. Optimum duration: two to three injections for each applicable joint per year. Not to exceed two joint levels.

[d]. Maximum Duration: four per level per year. Prior authorization must be obtained for injections beyond two levels.

vi. Sacroiliac Joint Injection

(a). Description—a generally accepted injection of local anesthetic in an intra-articular fashion into the sacroiliac joint under radiographic guidance. May include the use of corticosteroids. Long-term therapeutic effect has not yet been established.

(b). Indications—primarily diagnostic to rule out sacroiliac joint dysfunction vs. other pain generators. Intra-articular injection can be of value in diagnosing the pain generator. There should be documented relief from previously painful maneuvers (e.g., Patrick's test) on post-injection physical exam. These injections may be repeated if they result in increased documented functional benefit for at least 6 weeks and at least a 50 percent initial improvement in pain scales as measured by accepted pain scales (such as VAS). Sacroiliac joint blocks should facilitate a functionally directed rehabilitation program.

(i). Time to produce effect: Approximately 30 minutes for local anesthetic; 48 to 72 hours for corticosteroid.

(ii). Frequency and optimum duration: two to three injections per year. If the first injection does not provide a diagnostic response of temporary and sustained pain relief substantiated by accepted pain scales, (i.e.,50 percent pain reduction substantiated by tools such as VAS), and improvement in function, similar injections should not be repeated. At least six weeks of functional benefit should be obtained with each therapeutic injection.

(iii). Maximum duration: four injections per year.

(iv). Intradiscal Steroid Therapy

[a]. Intradiscal Steroid Therapy consists of injection of a steroid preparation into the intervertebral disc under fluoroscopic guidance at the time of discography. There is good evidence that it is not effective in the treatment of suspected discogenic back pain and its use is not recommended.

[b]. Radio Frequency Medial Branch Neurotomy/Facet Rhizotomy:

[i]. Description—a procedure designed to denervate the facet joint by ablating the corresponding sensory medial branches. Continuous percutaneous radiofrequency is the method generally used.

aa. There is good evidence to support Radio Frequency Medial Branch Neurotomy in the cervical spine but benefits beyond one year are not yet established. Evidence in the lumbar spine is conflicting; however, the procedure is generally accepted. In one study, 60 percent of patients maintained at least 90 percent pain relief at 12 months. Radio-frequency Medial Branch Neurotomy is the procedure of choice over alcohol, phenol, or cryoablation. Precise positioning of the probe using fluoroscopic guidance is required since the maximum effective diameter of the device is a 5x8 millimeter oval. Permanent images should be recorded to verify placement of the device.

[ii]. Indications—those patients with proven, significant, facetogenic pain. A minority of low back patients would be expected to qualify for this procedure. This procedure is not recommended for patients with multiple pain generators or involvement of more than 3 levels of medial branch nerves.

b. Individuals should have met all of the following indications: Pain of well-documented facet origin, unresponsive to active and/or passive therapy; unresponsive to manual therapy and in which a psychosocial screening has been performed (e.g., pain diagram, Waddell's signs, thorough psychosocial history, screening questionnaire). It is generally recommended that this procedure not be performed until three months of active therapy and manual therapy have been completed. All patients should continue appropriate exercise with functionally directed rehabilitation. Active treatment, which patients will have had prior to the procedure, will frequently require a repeat of the sessions previously ordered (Refer to Active Therapy.)

c. All patients should have a successful response to a diagnostic medial nerve branch block and a separate comparative block. ISIS suggests controlled blocks using either placebo or anesthetics with varying lengths of activity (i.e., bupivacaine longer than lidocaine). To be a positive diagnostic block the patient should report a reduction of pain of 50 percent or greater from baseline for the length of time appropriate for the local anesthetic used. In almost all cases this will mean a reduction of pain to one or two on the VAS 10-point scale correlated with functional improvement. The patient should also identify activities of daily living (which may include measurements of range of motion) that are impeded by their pain and can be observed to document functional improvement in the clinical setting. Ideally, these activities should be assessed throughout the observation period for function. The observer should not be the physician who performed the procedure. It is suggested that this be recorded on a form similar to ISIS recommendations.

i. A separate comparative block on a different date may be performed to confirm the level of involvement. A comparative block uses anesthetics with varying lengths of activity.

ii. Complications—bleeding, infection, or neural injury. The clinician must be aware of the risk of developing a localized neuritis, or rarely, a deafferentation centralized pain syndrome as a complication of this and other neuroablative procedures.

iii. Post-Procedure Therapy—active therapy. Implementation of a gentle aerobic reconditioning program (e.g., walking) and back education within the first post-procedure week, barring complications. Instruction and participation in a long-term home-based program of ROM, core strengthening, postural or neuromuscular re-education, endurance, and stability exercises should be accomplished over a period of four to ten visits post-procedure.

iv. Requirements for Repeat Radiofrequency Medial Branch Neurotomy (or additional-level RF Neurotomies): In some cases pain may recur. Successful RF Neurotomy usually provides from six to eighteen months of relief.

(a). Before a repeat RF Neurotomy is done, a confirmatory medial branch injection should be performed if the patient's pain pattern presents differently than the initial evaluation. In occasional patients, additional levels of RF neurotomy may be necessary. The same indications and limitations apply.

d. Sacro-iliac (SI) Joint Radiofrequency Denervation is a denervation of the SI joint. This procedure has limited evidence to support efficacy for its use and may be considered for therapeutic purposes.

e. Trigger Point Injections and Dry Needling Treatment

i. Description. Trigger point injections are a generally accepted treatment. Trigger point treatment can consist of dry needling or injection of local anesthetic, with or without corticosteroid, into highly localized, extremely sensitive bands of skeletal muscle fibers that produce local and referred pain when activated. Medication is injected in a four-quadrant manner in the area of maximum tenderness. Injection efficacy can be enhanced if injections are immediately followed by myofascial therapeutic interventions, such as vapo-coolant spray and stretch, ischemic pressure massage (myotherapy), specific soft tissue mobilization and physical modalities. There is conflicting evidence regarding the benefit of trigger point injections. A truly blinded study comparing dry needle treatment of trigger points is not feasible. There is no evidence that injection of medications improves the results of trigger-point injections. Needling alone may account for some of the therapeutic response.

(a). There is no indication for conscious sedation for patients receiving trigger point injections. The patient must be alert to help identify the site of the injection.

(b). Indications. Trigger point injections may be used to relieve myofascial pain and facilitate active therapy and stretching of the affected areas. They are to be used as an adjunctive treatment in combination with other treatment modalities such as functional restoration programs. Trigger point injections should be utilized primarily for the purpose of facilitating functional progress. Patients should continue in an aggressive aerobic and stretching therapeutic exercise program as tolerated throughout the time period they are undergoing intensive myofascial interventions. Myofascial pain is often associated with other underlying structural problems and any abnormalities need to be ruled out prior to injection.

(i). Trigger point injections are indicated in those patients where well circumscribed trigger points have been consistently observed, demonstrating a local twitch response, characteristic radiation of pain pattern and local autonomic reaction, such as persistent hyperemia following palpation. Generally, these injections are not necessary unless consistently observed trigger points are not responding to specific, noninvasive, myofascial interventions within approximately a six-week time frame. However, trigger point injections may be occasionally effective when utilized in the patient with immediate, acute onset of low back pain.

(c). Complications. Potential but rare complications of trigger point injections include infection, pneumothorax, anaphylaxis, penetration of viscera, neurapraxia, and neuropathy. If corticosteroids are injected in addition to local anesthetic, there is a risk of local myopathy developing. Severe pain on injection suggests the possibility of an intraneural injection, and the needle should be immediately repositioned.

(i). time to produce effect: Local anesthetic 30 minutes; 24 to 48 hours for no anesthesia;

(ii). frequency: Weekly. Suggest no more than 4 injection sites per session per week to avoid significant post-injection soreness;

(iii). optimum duration: four Weeks;

(iv). maximum duration: eight weeks. Occasional patients may require two to four repetitions of trigger point injection series over a one to two year period.

(v). Prolotherapy also known as sclerotherapy consists of a series of injections of hypertonic dextrose, with or without glycerine and phenol, into the ligamentous structures of the low back. Its proponents claim that the inflammatory response to the injections will recruit cytokine growth factors involved in the proliferation of connective tissue, stabilizing the ligaments of the low back when these structures have been damaged by mechanical insults.

[a]. There are conflicting studies concerning the effectiveness of Prolotherapy in the low back. Lasting functional improvement has not been shown. The injections are invasive, may be painful to the patient, and are not generally accepted or widely used. Therefore, the use of Prolotherapy for low back pain is not recommended.

f. Epiduroscopy and Epidural Lysis of Adhesions: is an investigational treatment of low back pain. It involves the introduction of a fiberoptic endoscope into the epidural space via the sacral hiatus. With cephalad advancement of the endoscope under direct visualization, the epidural space is irrigated with saline. Adhesiolysis may be done mechanically with a fiberoptic endoscope. The saline irrigation is performed with or without epiduroscopy and is intended to distend the epidural space in order to obtain an adequate visual field. It is designed to produce lysis of adhesions, which are conjectured to produce symptoms due to traction on painful nerve roots. Saline irrigation is associated with risks of elevated pressures which may impede blood flow and venous return, possibly causing ischemia of the cauda equina and retinal hemorrhage.

i. Other complications associated with instrumented lysis include catheter shearing, need for catheter surgical removal, infection (including meningitis), hematoma, and possible severe hemodynamic instability during application. Although epidural adhesions have been postulated to cause chronic low back pain, studies have failed to find a significant correlation between the level of fibrosis and pain or difficulty functioning. Studies of epidural lysis demonstrate no transient pain relief from the procedure. Given the low likelihood of a positive response, the additional costs and time requirement, and the possible complications from the procedure, epidural injection, or mechanical lysis, is not recommended.

(a). Epiduroscopy-directed steroid injections are also not recommended as there is no evidence to support an advantage for using an epiduroscope with steroid injections.

4. Medications use in the treatment of low back injuries is appropriate for controlling acute and chronic pain and inflammation. Use of medications will vary widely due to the spectrum of injuries from simple strains to post-surgical healing. All drugs should be used according to patient needs. A thorough medication history, including use of alternative and over the counter medications, should be performed at the time of the initial visit and updated periodically. Treatment for pain control is initially accomplished with acetaminophen and/or NSAIDs. The patient should be educated regarding the interaction with prescription and over-the-counter medications as well as the contents of over-the-counter herbal products. The following are listed in alphabetical order:

a. Acetaminophen: is an effective analgesic with antipyretic but not anti-inflammatory activity. Acetaminophen is generally well tolerated, causes little or no gastrointestinal irritation, and is not associated with ulcer formation. Acetaminophen has been associated with liver toxicity in overdose situations or in chronic alcohol use. Patients may not realize that many over-the-counter preparations may contain acetaminophen. The total daily dose of acetaminophen is recommended not to exceed 2250 mg per 24-hour period, from all sources, including narcotic-acetaminophen combination preparations.

i. Optimum duration: 7 to 10 days.

ii. Maximum duration: Chronic use as indicated on a case-by-case basis. Use of this substance long-term for 3 days per week or greater may be associated with rebound pain upon cessation.

b. Muscle Relaxants: are appropriate for muscle spasm with pain. There is strong evidence that muscle relaxants are more effective than placebo for providing short-term pain relief in acute low back pain. When prescribing these agents, physicians must seriously consider side effects of drowsiness or dizziness and the fact that benzodiazepines may be habit-forming.

i. optimum duration: one week;

ii. maximum duration: two weeks (or longer if used only at night).

c. Narcotics: should be primarily reserved for the treatment of severe low back pain. In mild to moderate cases of low back pain, narcotic medication should be used cautiously on a case-by-case basis. Adverse effects include respiratory depression, the development of physical and psychological dependence, and impaired alertness.

i. Narcotic medications should be prescribed with strict time, quantity, and duration guidelines, and with definitive cessation parameters. Pain is subjective in nature and should be evaluated using a scale to rate effectiveness of the narcotic prescribed. Any use beyond the maximum should be documented and justified based on the diagnosis and/or invasive procedures.

(a). optimum duration: three to seven days.

(b). maximum duration: two weeks. Use beyond two weeks is acceptable in appropriate cases. Refer to Chronic Pain Guidelines which gives a detailed discussion regarding medication use in chronic pain management.

(c). Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) are useful for pain and inflammation. In mild cases, they may be the only drugs required for analgesia. There are several classes of NSAIDs, and the response of the individual injured worker to a specific medication is unpredictable. For this reason, a range of NSAIDs may be tried in each case with the most effective preparation being continued. Patients should be closely monitored for adverse reactions. The US Food and Drug Administration advise that many NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. Naproxen sodium does not appear to be associated with increased risk of vascular events. Administration of proton pump inhibitors, Histamine 2 Blockers or prostaglandin analog misoprostol along with these NSAIDs may reduce the risk of duodenal and gastric ulceration but do not impact possible cardiovascular complications. Due to the cross-reactivity between aspirin and NSAIDs, NSAIDs should not be used in aspirin-sensitive patients, and should be used with caution in all asthma patients. NSAIDs are associated with abnormal renal function, including renal failure, as well as, abnormal liver function. Certain NSAIDs may have interactions with various other medications. Individuals may have adverse events not listed above. Intervals for metabolic screening are dependent upon the patient's age, general health status and should be within parameters listed for each specific medication. Complete Blood Count (CBC), and liver and

renal function should be monitored at least every six months in patients on chronic NSAIDs and initially when indicated.

(i). Non-Selective Nonsteroidal Anti-Inflammatory Drugs

[a]. Includes NSAIDs and acetylsalicylic acid (aspirin). Serious GI toxicity, such as bleeding, perforation, and ulceration can occur at any time, with or without warning symptoms in patients treated with traditional NSAIDs. Physicians should inform patients about the signs and/or symptoms of serious gastrointestinal toxicity and what steps to take if they occur. Anaphylactoid reactions may occur in patients taking NSAIDs. NSAIDs may interfere with platelet function. Fluid retention and edema have been observed in some patients taking NSAIDs.

[i]. optimal duration: one week;

[ii]. maximum duration: one year. Use of these substances long-term (three days per week or greater) is associated with rebound pain upon cessation.

[ii]. Selective Cyclo-oxygenase-2 (COX-2) Inhibitors

[b]. COX-2 inhibitors are more recent NSAIDs and differ in adverse side effect profiles from the traditional NSAIDs. The major advantages of selective COX-2 inhibitors over traditional NSAIDs are that they have less gastrointestinal toxicity and no platelet effects. COX-2 inhibitors can worsen renal function in patients with renal insufficiency, thus renal function may need monitoring.

[c]. COX-2 inhibitors should not be first-line for low risk patients who will be using an NSAID short term but are indicated in select patients for whom traditional NSAIDs are not tolerated. Serious upper GI adverse events can occur even in asymptomatic patients. Patients at high risk for GI bleed include those who use alcohol, smoke, are older than 65, take corticosteroids or anti-coagulants, or have a longer duration of therapy. Celecoxib is contraindicated in sulfonamide allergic patients.

[i]. optimal duration: 7 to 10 days

[ii]. maximum duration: Chronic use is appropriate in individual cases. Use of these substances long-term (three days per week or greater) is associated with rebound pain upon cessation.

d. Oral Steroids: have limited use but are accepted in cases requiring potent anti-inflammatory drug effect. There is no evidence supporting oral steroids for patients with low back pain with or without radiculopathy and are not recommended.

e. Intravenous Steroids: The risks of permanent neurological damage from acute spinal cord compression generally outweigh the risks of pharmacologic side effects of steroids in an emergent situation.

f. Psychotropic/Anti-anxiety/Hypnotic Agents: may be useful for treatment of mild and chronic pain, dysesthesias, sleep disorders, and depression. Antidepressant medications, such as tricyclics and, Selective Serotonin reuptake inhibitors (SSRIs) and norepinephrine reuptake inhibitors (SSNRIs) are useful for affective disorder and chronic pain management. Tricyclic antidepressant agents, in low dose, are useful for chronic pain but have more frequent side effects. Anti-anxiety medications should generally be limited to short-term use. Combinations of the above agents may be useful. As a general rule, providers (i.e., physician or medical psychologist) should access the patient's prior history of substance abuse or depression prior to prescribing any of these agents. Due to the habit-forming potential of the benzodiazepines and other drugs found in this class, they are not routinely recommended. Refer to the Chronic Pain Guidelines which give a detailed discussion regarding medication use in chronic pain management.

i. optimum duration: one to six months;

ii. maximum duration: 6 to 12 months, with monitoring.

g. Tramadol is useful in relief of low back pain and has been shown to provide pain relief equivalent to that of commonly prescribed NSAIDs. Although Tramadol may cause impaired alertness, it is generally well tolerated, does not cause gastrointestinal ulceration, or exacerbate hypertension or congestive heart failure. Tramadol should be used cautiously in patients who have a history of seizures or who are taking medication that may lower the seizure threshold, such as monoamine oxidase (MAO) inhibitors, SSRIs, and tricyclic antidepressants. This medication has physically addictive properties and withdrawal may follow abrupt discontinuation and is not recommended for those with prior opioid addiction.

i. optimum duration: three to seven days;

ii. maximum duration: two weeks. Use beyond two weeks is acceptable in appropriate cases.

5. Occupational rehabilitation programs

a. Non-Interdisciplinary. These generally accepted programs are work-related, outcome-focused, individualized treatment programs. Objectives of the program include, but are not limited to, improvement of cardiopulmonary and neuromusculoskeletal functions (strength, endurance, movement, flexibility, stability, and motor control functions), patient education, and symptom relief. The goal is for patients to gain full or optimal function and return to work. The service may include the time-limited use of passive modalities with progression to active treatment and/or simulated/real work.

i. Work Conditioning

(a). These programs are usually initiated once reconditioning has been completed but may be offered at any time throughout the recovery phase. Work conditioning should be initiated when imminent return of a patient to modified or full duty is not an option, but the prognosis for returning the patient to work at completion of the program is at least fair to good.

(i). length of visit: one to two hours per day;

(ii). frequency: two to five visits per week;

(iii). optimum duration: two to four weeks

(iv). maximum duration: six weeks. Participation in a program beyond six weeks must be documented with respect to need and the ability to facilitate positive symptomatic or functional gains.

ii. Work Simulation

(a). Work simulation is a program where an individual completes specific work-related tasks for a particular job and return to work. Use of this program is appropriate when modified duty can only be partially accommodated in the work place, when modified duty in the work place is unavailable, or when the patient requires more structured supervision. The need for work place simulation

should be based upon the results of a Functional Capacity Evaluation and/or Jobsite Analysis.

(i). length of visit: two to six hours per day;

(ii). frequency: two to five visits per week;

(iii). optimum duration: two to four weeks;

(iv). Maximum duration: six weeks. Participation in a program beyond six weeks must be documented with respect to need and the ability to facilitate positive symptomatic or functional gains.

(b). Interdisciplinary: programs are well-established treatment for patients with sub-acute and functionally impairing low back pain. They are characterized by a variety of disciplines that participate in the assessment, planning, and/or implementation of an injured worker's program with the goal for patients to gain full or optimal function and return to work. There should be close interaction and integration among the disciplines to ensure that all members of the team interact to achieve team goals. Programs should include cognitive-behavioral therapy as there is good evidence for its effectiveness in patients with chronic low back pain. These programs are for patients with greater levels of disability, dysfunction, de-conditioning and psychological involvement. For patients with chronic pain, refer to the OWCA's Chronic Pain Disorder Medical Treatment Guidelines.

(i). Work Hardening

[a]. Work Hardening is an interdisciplinary program addressing a patient's employability and return to work. It includes a progressive increase in the number of hours per day that a patient completes work simulation tasks until the patient can tolerate a full workday. This is accomplished by addressing the medical, psychological, behavioral, physical, functional, and vocational components of employability and return-to-work.

[b]. This can include a highly structured program involving a team approach or can involve any of the components thereof. The interdisciplinary team should, at a minimum, be comprised of a qualified medical director who is board certified with documented training in occupational rehabilitation; team physicians having experience in occupational rehabilitation; occupational therapist; physical therapist; case manager; and psychologist. As appropriate, the team may also include: chiropractor, RN, vocational specialist or Certified Biofeedback Therapist.

[i]. length of visit: Up to 8 hours/day;

[ii]. frequency: two to five visits per week;

[iii]. optimum duration: two to four weeks;

[iv]. maximum duration: six weeks. Participation in a program beyond six weeks must be documented with respect to need and the ability to facilitate positive symptomatic or functional gains.

(ii). Spinal Cord Programs

[a]. Spinal Cord Systems of Care provide coordinated, case-managed, and integrated service for people with spinal cord dysfunction, whether due to trauma or disease. The system includes an inpatient component in an organization licensed as a hospital and an outpatient component. Each component endorses the active participation and choice of the persons served throughout the entire program. The Spinal Cord System of Care also provides or formally links with key components of care that address the lifelong needs of the persons served.

[b]. This can include a highly structured program involving a team approach or can involve any of the components thereof. The interdisciplinary team should, at a minimum, be comprised of a qualified medical director who is board certified and trained in rehabilitation, a case manager, occupational therapy, physical therapy, psychologist, rehabilitation RN and MD, and therapeutic recreation specialist. As appropriate, the team may also include: rehabilitation counselor, respiratory therapist, social worker, or speech-language pathologist.

[c]. Timeframe durations for any spinal cord program should be determined based upon the extent of the patient's injury and at the discretion of the rehabilitation physician in charge.

6. Orthotics

a. Foot Orthoses and Inserts are accepted interventions for spinal disorders that are due to aggravated mechanical abnormalities, such as leg length discrepancy, scoliosis, or lower extremity misalignment. Shoe insoles or inserts may be effective for patients with acute low back problems who stand for prolonged periods of time.

b. Lumbar Support Devices include backrests for chairs and car seats. Lumbar supports may provide symptomatic relief of pain and movement reduction in cases of chronic low back problems.

c. Lumbar Corsets and Back Belts. There is insufficient evidence to support their use. They are an accepted treatment with limited application. The injured worker should be advised of the potential harm from using a lumbar support for a period of time greater than that which is prescribed. Harmful effects include de-conditioning of the trunk musculature, skin irritation, and general discomfort.

d. Lumbosacral Bracing. Rigid bracing devices are well accepted and commonly used for post-fusion, scoliosis, and vertebral fractures.

7. Patient Education. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of prolonging the beneficial effects of treatment, as well as facilitating self-management of symptoms and injury prevention. The patient should be encouraged to take an active role in the establishment of functional outcome goals. They should be educated on their specific injury, assessment findings, and plan of treatment. Instruction on proper body mechanics and posture, positions to avoid, self-care for exacerbation of symptoms, and home exercise should also be addressed:

a. time to produce effect: Varies with individual patient;

b. frequency: Should occur at every visit.

8. Personality/psychological/psychiatric/psychosocial intervention Psychosocial treatment is generally accepted, widely used, and well-established Intervention. This group of therapeutic and diagnostic modalities includes, but is not limited to, individual counseling, group therapy, stress management, psychosocial crises intervention, hypnosis, and meditation. Any evaluation or diagnostic workup should clarify and distinguish between pre-existing versus aggravated versus purely causative psychological conditions.

Psychosocial intervention is recommended as an important component in the total management program that should be implemented as soon as the problem is identified. There is some evidence that early cognitive-behavioral treatment reduces health care use in comparison to written information alone. This can be used alone, or in conjunction with other treatment modalities. Providers treating patients with chronic pain should refer to the OWCA's Chronic Pain Disorder Medical Treatment Guidelines:

a. time to produce effect: two to four weeks;

b. frequency: one to three times weekly for the first four weeks (excluding hospitalization, if required), decreasing to one to two times per week for the second month. Thereafter, two to four times monthly;

c. optimum duration: six weeks to three months;

d. maximum duration: 3 to 12 months. Counseling is not intended to delay but to enhance functional recovery. For select patients, longer supervised treatment may be required and if further counseling beyond three months is indicated, extensive documentation addressing which pertinent issues are pre-existing versus aggravated versus causative, as well as projecting a realistic functional prognosis, should be provided by the authorized treating provider every four to six weeks during treatment.

9. Restriction of Activities. Continuation of normal daily activities is the recommendation for acute and chronic low back pain without neurologic symptoms. There is good evidence against the use of bed rest in cases without neurologic symptoms. Bed rest may lead to de-conditioning and impair rehabilitation. Complete work cessation should be avoided, if possible, since it often further aggravates the pain presentation. Modified return-to-work is almost always more efficacious and rarely contraindicated in the vast majority of injured workers with low back pain.

10. Return-to-Work. Early return-to-work should be a prime goal in treating occupational injuries given the poor return-to-work prognosis for an injured worker who has been out of work for more than six months. It is imperative that the patient be educated regarding the benefits of return-to-work, work restrictions, and follow-up if problems arise. When attempting to return a patient to work after a specific injury, clear objective restrictions of activity level should be made. An accurate job description with detailed physical duty restrictions is often necessary to assist the physician in making return-to-work recommendations. This may require a jobsite evaluation.

a. Employers should be prepared to offer transitional work. This may consist of temporary work in a less demanding position, return to the regular job with restrictions, or gradual return to the regular job. Company policies which encourage return-to-work with positive communication are most likely to have decreased worker disability.

b. Return-to-work is defined as any work or duty that the patient is able to perform safely. It may not be the patient's regular work. Due to the large spectrum of injuries of varying severity and varying physical demands in the work place, it is not possible to make specific return-to-work guidelines for each injury. Therefore, the OWCA recommends the following:

c. Establishment of a Return-To-Work Status: Ascertaining a return-to-work status is part of medical care, should be included in the treatment and rehabilitation plan, and addressed at every visit. A description of daily activity limitations is part of any treatment plan and should be the basis for restriction of work activities. In most non-surgical cases, the patient should be able to return-to-work in some capacity or in an alternate position consistent with medical treatment within several days unless there are extenuating circumstances. Injuries requiring more than two weeks off work should be thoroughly documented.

d. Establishment of Activity Level Restrictions. Communication is essential between the patient, employer, and provider to determine appropriate restrictions and return-to-work dates. It is the responsibility of the physician to provide clear concise restrictions, and it is the employer's responsibility to determine if temporary duties can be provided within the restrictions. For low back pain injuries, the following should be addressed when describing the patient's activity level:

i. Lifting limits with the maximum amount of weight to be lifted. This may vary depending on the frequency of the lifting and/or the object height level. Pushing, pulling, as well as bending and twisting at the waist should be considered as well~~.~~;

ii. Lower body postures such as squatting, kneeling, crawling, stooping, or climbing should include duration and frequency~~.~~;

iii. Ambulatory level for distance, frequency, and terrain should be specified~~.~~;

iv. Duration and frequency of sitting, standing, and walking should be delineated. Balance issues should also be considered in these determinations~~.~~;

v. Use of adaptive devices or equipment for proper office ergonomics to enhance capacities can be included.

e. Compliance with Activity Restrictions: In some cases, compliance with restriction of activity levels may require a complete jobsite evaluation, a functional capacity evaluation (FCE) or other special testing. Refer to the "Special Tests" section of this guideline.

11. Therapy—active. The following active therapies are widely used and accepted methods of care for a variety of work-related injuries. They are based on the philosophy that therapeutic exercise and/or activity are beneficial for restoring flexibility, strength, endurance, function, range of motion, and can alleviate discomfort. Active therapy requires an internal effort by the individual to complete a specific exercise or task. This form of therapy requires supervision from a therapist or medical provider such as verbal, visual, and/or tactile instruction(s). At times, the provider may help stabilize the patient or guide the movement pattern but the energy required to complete the task is predominately executed by the patient.

a. Patients should be instructed to continue active therapies at home as an extension of the treatment process in order to maintain improvement levels. Follow-up visits to reinforce and monitor progress and proper technique are recommended. Home exercise can include exercise with or without mechanical assistance or resistance and functional activities with assistive devices.

12. The following active therapies are listed in alphabetical order:

a. Activities of Daily Living (ADL) are well-established interventions which involve instruction, active-assisted training, and/or adaptation of activities or equipment to improve a person's capacity in normal daily activities such as self-care, work re-integration training, homemaking, and driving.

i. time to produce effect: four to five treatments;

ii. frequency: three to five times per week;

iii. optimum duration: four to six weeks;

iv. maximum duration: six weeks.

b. Aquatic Therapy is a well-accepted treatment which consists of the therapeutic use of aquatic immersion for therapeutic exercise to promote strengthening, core stabilization, endurance, range of motion, flexibility, body mechanics, and pain management. Aquatic therapy includes the implementation of active therapeutic procedures in a swimming or therapeutic pool. The water provides a buoyancy force that lessens the amount of force gravity applies to the body. The decreased gravity effect allows the patient to have a mechanical advantage and more likely have a successful trial of therapeutic exercise. The therapy may be indicated for individuals who:

i. cannot tolerate active land-based or full-weight bearing therapeutic procedures;

ii. require increased support in the presence of proprioceptive deficit;

iii. are at risk of compression fracture due to decreased bone density;

iv. have symptoms that are exacerbated in a dry environment;

v. would have a higher probability of meeting active therapeutic goals than in a dry environment.

(a). The pool should be large enough to allow full extremity range of motion and fully erect posture. Aquatic vests, belts and other devices can be used to provide stability, balance, buoyancy, and resistance.

(i). time to produce effect: four to five treatments;

(ii). frequency: three to five times per week;

(iii). optimum duration: four to six weeks;

(iv). maximum duration: eight weeks;

(b). A self-directed program is recommended after the supervised aquatics program has been established, or, alternatively a transition to a self-directed dry environment exercise program.

(c). Functional Activities: are well-established interventions which involve the use of therapeutic activity to enhance mobility, body mechanics, employability, coordination, balance, and sensory motor integration.

(i). time to produce effect: four to five treatments;

(ii). frequency: three to five times per week;

(iii). optimum duration: four to six weeks;

(iv). maximum duration: six weeks.

(d). Functional Electrical Stimulation: is an accepted treatment in which the application of electrical current to elicit involuntary or assisted contractions of atrophied and/or impaired muscles. It may be indicated for muscle atrophy due to radiculopathy.

(i). time to produce effect: two to six treatments;

(ii). frequency: three times per week;

(iii). optimum duration: eight weeks;

(iv). maximum duration: eight weeks. If beneficial, provide with home unit.

(e). Neuromuscular Re-education is a generally accepted treatment. It is the skilled application of exercise with manual, mechanical, or electrical facilitation to enhance strength; movement patterns; neuromuscular response; proprioception, kinesthetic sense, coordination; education of movement, balance, and posture. Indications include the need to promote neuromuscular responses through carefully timed proprioceptive stimuli, to elicit and improve motor activity in patterns similar to normal neurologically developed sequences, and improve neuromotor response with independent control.

(i). time to produce effect: two to six treatments;

(ii). frequency: three times per week;

(iii). optimum duration: four to eight weeks;

(iv). maximum duration: eight weeks.

(f). Spinal Stabilization is a generally well-accepted treatment. The goal of this therapeutic program is to strengthen the spine in its neural and anatomic position. The stabilization is dynamic which allows whole body movements while maintaining a stabilized spine. It is the ability to move and function normally through postures and activities without creating undue vertebral stress.

(i). time to produce effect: four to eight treatments;

(ii). frequency: three to five times per week;

(iii). optimum duration: four to eight weeks;

(iv). maximum duration: eight weeks.

(g). Therapeutic Exercise is a generally well-accepted treatment. Therapeutic exercise, with or without mechanical assistance or resistance, may include isoinertial, isotonic, isometric and isokinetic types of exercises. Indications include the need for cardiovascular fitness, reduced edema, improved muscle strength, improved connective tissue strength and integrity, increased bone density, promotion of circulation to enhance soft tissue healing, improvement of muscle recruitment, improved proprioception, and coordination, increased range of motion. Therapeutic exercises are used to promote normal movement patterns, and can also include complementary/alternative exercise movement therapy (with oversight of a physician or appropriate healthcare professional).

(i). There is some evidence to support the effectiveness of yoga therapy in alleviating symptoms and decreasing medication use in uncomplicated low back pain.

[a]. time to produce effect: two to six treatments;

[b]. frequency: three to five times per week;

[c]. optimum duration: four to eight weeks;

[d]. maximum duration: eight weeks.

13. Therapy—passive. Most of the following passive therapies and modalities are generally accepted methods of

care for a variety of work-related injuries. Passive therapy includes those treatment modalities that do not require energy expenditure on the part of the patient. They are principally effective during the early phases of treatment and are directed at controlling symptoms such as pain, inflammation and swelling and to improve the rate of healing soft tissue injuries. They should be used adjunctively with active therapies such as postural stabilization and exercise programs to help control swelling, pain, and inflammation during the active rehabilitation process. Please refer to General Guideline Principles, Active Interventions. Passive therapies may be used intermittently as a therapist deems appropriate or regularly if there are specific goals with objectively measured functional improvements during treatment.

a. On occasion, specific diagnoses and post-surgical conditions may warrant durations of treatment beyond those listed as "maximum." factors such as exacerbation of symptoms, re-injury, interrupted continuity of care, and comorbidities may also extend durations of care. Specific goals with objectively measured functional improvement during treatment must be cited to justify extended durations of care. It is recommended that, if no functional gain is observed after the number of treatments under "time to produce effect" have been completed, alternative treatment interventions, further diagnostic studies, or further consultations should be pursued.

i. The following passive therapies are listed in alphabetical order:

(a). Electrical Stimulation (Unattended): is an accepted treatment. Once applied, unattended electrical stimulation requires minimal on-site supervision by the physical therapist, occupational therapist, or other provider. Indications include pain, inflammation, muscle spasm, atrophy, decreased circulation, and the need for osteogenic stimulation. A home unit should be purchased if treatment is effective and frequent use is recommended.

(i). time to produce effect: two to four treatments;

(ii). frequency: Varies, depending upon indication, between two to three times/day to one time/week. Home unit should be purchased if treatment is effective and frequent use is recommended;

(iii). optimum duration: four treatments for clinic use;

(iv). maximum duration: eight treatments for clinic use.

(b). Iontophoresis is an accepted treatment which consists of the transfer of medication, including, but not limited to, steroidal anti-inflammatories and anesthetics, through the use of electrical stimulation. Indications include pain (Lidocaine), inflammation (hydrocortisone, salicylate), edema (mecholyl, hyaluronidase, salicylate), ischemia (magnesium, mecholyl, iodine), muscle spasm (magnesium, calcium), calcific deposits (acetate), scars, and keloids (sodium chloride, iodine, acetate). There is no proven benefit for this therapy in the low back.

(i). time to produce effect: one to four treatments;

(ii). frequency: three times per week with at least 48 hours between treatments;

(iii). optimum duration: four to six weeks;

(iv). maximum duration: six weeks.

(c). Manipulation is generally accepted, well-established and widely used therapeutic intervention for low back pain. Manipulative Treatment (not therapy) is defined as the therapeutic application of manually guided forces by an operator to improve physiologic function and/or support homeostasis that has been altered by the injury or occupational disease, and has associated clinical significance.

(i). High velocity, low amplitude (HVLA) technique, chiropractic manipulation, osteopathic manipulation, muscle energy techniques, counter strain, and non-force techniques are all types of manipulative treatment. This may be applied by osteopathic physicians (D.O.), chiropractors (D.C.), properly trained physical therapists (P.T.), properly trained occupational therapists (O.T.), or properly trained medical physicians. Under these different types of manipulation exist many subsets of different techniques that can be described as direct- a forceful engagement of a restrictive/pathologic barrier; indirect- a gentle/non-forceful disengagement of a restrictive/pathologic barrier; the patient actively assists in the treatment; and the patient relaxing, allowing the practitioner to move the body tissues. When the proper diagnosis is made and coupled with the appropriate technique, manipulation has no contraindications and can be applied to all tissues of the body. Pre-treatment assessment should be performed as part of each manipulative treatment visit to ensure that the correct diagnosis and correct treatment is employed.

(ii). High velocity, low amplitude (HVLA) manipulation is performed by taking a joint to its end range of motion and moving the articulation into the zone of accessory joint movement, well within the limits of anatomical integrity. There is good scientific evidence to suggest that HVLA manipulation can be helpful for patients with acute low back pain problems without radiculopathy when used within the first four to six weeks of symptoms. Although the evidence for sub-acute and chronic low back pain and low back pain with radiculopathy is less convincing, it is a generally accepted and well-established intervention for these conditions. Indications for manipulation include joint pain, decreased joint motion, and joint adhesions. Contraindications to HVLA manipulation include joint instability, fractures, severe osteoporosis, infection, metastatic cancer, active inflammatory arthritides, aortic aneurysm, and signs of progressive neurologic deficits.

[a]. time to produce effect for all types of manipulative treatment: one to six treatments;

[b]. frequency: Up to three times per week for the first four weeks as indicated by the severity of involvement and the desired effect, then up to two treatments per week for the next four weeks. For further treatments, twice per week or less to maintain function;

[c]. optimum duration: 8 to 12 weeks;

[d]. maximum duration: three months. Extended durations of care beyond what is considered "maximum" may be necessary in cases of re-injury, interrupted continuity of care, exacerbation of symptoms, and in those patients with comorbidities. Refer to the Chronic Pain Guidelines for care beyond three months.

(d). Manipulation under General Anesthesia (MUA): refers to manual manipulation of the lumbar spine in combination with the use of a general anesthetic or conscious sedation. It is intended to improve the success of manipulation when pain, muscle spasm, guarding, and fibrosis appear to be limiting its application in patients otherwise suitable for their use. There have been no high quality studies to justify its benefits given the risks of general anesthetic and conscious sedation. It is not recommended.

(e). Manipulation under Joint Anesthesia (MUJA): refers to manipulation of the lumbar spine in combination with a fluoroscopically guided injection of anesthetic with or without corticosteroid agents into the facet joint at the level being manipulated. There are no controlled clinical trials to support its use. It is not recommended.

(f). Massage—Manual or Mechanical. Massage is manipulation of soft tissue with broad ranging relaxation and circulatory benefits. This may include stimulation of acupuncture points and acupuncture channels (acupressure), application of suction cups and techniques that include pressing, lifting, rubbing, pinching of soft tissues by, or with, the practitioner's hands. Indications include edema (peripheral or hard and non-pliable edema), muscle spasm, adhesions, the need to improve peripheral circulation and range of motion, or to increase muscle relaxation and flexibility prior to exercise.

(i). In sub-acute low back pain populations there is good evidence that massage can increase function when combined with exercise and patient education. Some studies have demonstrated a decrease in provider visits and pain medication use with combined therapy. One study indicated improved results with acupressure massage. It is recommended that all massage be performed by trained, experienced therapists and be accompanied by an active exercise program and patient education. In contrast to the sub-acute population, massage is a generally accepted treatment for the acute low back pain population, although no studies have demonstrated its efficacy for this set of patients.

[a]. time to produce effect: Immediate;

[b]. frequency: one to two times per week;

[c]. optimum duration: six weeks;

[d]. maximum duration: 2 months.

(g). Mobilization (Joint) is a generally well-accepted treatment. Mobilization is passive movement involving oscillatory motions to the vertebral segment(s). The passive mobility is performed in a graded manner (I, II, III, IV, or V), which depicts the speed and depth of joint motion during the maneuver. For further discussion on Level V joint mobilization please see section on HVLA manipulation [Refer to Clause 12.c.ii.]. It may include skilled manual joint tissue stretching. Indications include the need to improve joint play, segmental alignment, improve intracapsular arthrokinematics, or reduce pain associated with tissue impingement. Mobilization should be accompanied by active therapy. For Level V mobilization contraindications include joint instability, fractures, severe osteoporosis, infection, metastatic cancer, active inflammatory arthritides, aortic aneurysm, and signs of progressive neurologic deficits.

(i). time to produce effect: six to nine treatments;

(ii). frequency: Up to three times per week;

(iii). optimum duration: four to six weeks;

(iv). maximum duration: six weeks.

(h). Mobilization (Soft Tissue)~~:~~ is a generally well-accepted treatment. Mobilization of soft tissue is the skilled application of muscle energy, strain/counter strain, myofascial release, manual trigger point release, and manual therapy techniques designed to improve or normalize movement patterns through the reduction of soft tissue pain and restrictions. These can be interactive with the patient participating or can be with the patient relaxing and letting the practitioner move the body tissues. Indications include muscle spasm around a joint, trigger points, adhesions, and neural compression. Mobilization should be accompanied by active therapy.

(i). time to produce effect: four to nine treatments

(ii). frequency: Up to three times per week

(iii). optimum duration: four to six weeks

(iv). maximum duration: six weeks

(i). Short-Wave Diathermy is an accepted treatment which involves the use of equipment that exposes soft tissue to a magnetic or electrical field. Indications include enhanced collagen extensibility before stretching, reduced muscle guarding, reduced inflammatory response, and enhanced re-absorption of hemorrhage/hematoma or edema.

(i). time to produce effect: two to four treatments;

(ii). frequency: two to three times per week up to three weeks;

(iii). optimum duration: three to five weeks;

(iv). maximum duration: five weeks.

(j). Superficial Heat and Cold Therapy (excluding Infrared Therapy) is a generally accepted treatment. Superficial heat and cold are thermal agents applied in various manners that lower or raise the body tissue temperature for the reduction of pain, inflammation, and/or effusion resulting from injury or induced by exercise. Includes application of heat just above the surface of the skin at acupuncture points. Indications include acute pain, edema and hemorrhage, need to increase pain threshold, reduce muscle spasm, and promote stretching/flexibility. Cold and heat packs can be used at home as an extension of therapy in the clinic setting.

(i). time to produce effect: Immediate;

(ii). frequency: two to five times per week;

(iii). optimum duration: three weeks as primary or intermittently as an adjunct to other therapeutic procedures up to two months;

(iv). maximum duration: 2 months.

(k). Traction—Manual is an accepted treatment and an integral part of manual manipulation or joint mobilization. Indications include decreased joint space, muscle spasm around joints, and the need for increased synovial nutrition and response. Manual traction is contraindicated in patients with tumor, infection, fracture, or fracture dislocation.

(i). time to produce effect: one to three sessions;

(ii). frequency: two to three times per week;

(iii). optimum duration: 30 days;

(iv). maximum duration: one month.

(l). Traction—Mechanical. There is no evidence that mechanical traction is useful for low back pain patients without radicular symptoms. Therefore, it is not recommended in this population. It may be trialed in patients with radicular findings, and if successful, should be shifted to home traction. Traction modalities are contraindicated in patients with tumor, infections, fracture, or fracture dislocation. Non-oscillating inversion traction methods are contraindicated in patients with glaucoma or hypertension. A home lumbar traction unit can be purchased if therapy proves effective.

(i). Time to produce effect: one to three sessions up to 30 minutes. If response is negative after three treatments, discontinue this modality.

(ii). Frequency: two to three times per week. A home lumbar traction unit can be purchased if therapy proves effective.

(iii). Optimum duration: four weeks

(iv). Maximum duration: four weeks

(m). Transcutaneous Electrical Nerve Stimulation (TENS). is a generally accepted treatment. TENS should include at least one instructional session for proper application and use. Indications include muscle spasm, atrophy, and decreased circulation and pain control. Minimal TENS unit parameters should include pulse rate, pulse width and amplitude modulation. Consistent, measurable functional improvement must be documented prior to the purchase of a home unit.

(i). time to produce effect: Immediate;

(ii). frequency: Variable;

(iii). optimum duration: three sessions;

(iv). maximum duration: three sessions. If beneficial, provide with home unit or purchase if effective.

(n). Ultrasound (Including Phonophoresis) is an accepted treatment. Ultrasound uses sonic generators to deliver acoustic energy for therapeutic thermal and/or non-thermal soft tissue effects. Indications include scar tissue, adhesions, collagen fiber and muscle spasm, and the need to extend muscle tissue or accelerate the soft tissue healing. Ultrasound with electrical stimulation is concurrent delivery of electrical energy that involves dispersive electrode placement. Indications include muscle spasm, scar tissue, pain modulation, and muscle facilitation.

(i). Phonophoresis is the transfer of medication to the target tissue to control inflammation and pain through the use of sonic generators. These topical medications include, but are not limited to, steroidal anti-inflammatory and anesthetics.

[a]. time to produce effect: 6 to 15 treatments;

[b]. frequency: three times per week;

[c]. optimum duration: four to eight weeks;

[d]. maximum duration: eight weeks.

(o). Vertebral Axial Decompression (VAX-D)/DRX, 9000 Motorized traction devices which purport to produce non-surgical disc decompression by creating negative intradiscal pressure in the disc space include devices with the trade names of VAX-D and DRX 9000. There are no good studies to support their use. They are not recommended.

(p). Whirlpool/Hubbard Tank is a generally accepted treatment in which conductive exposure to water at varied temperatures that best elicits the desired effect. It generally includes massage by water propelled by a turbine or Jacuzzi jet system and has the same thermal effects as hot packs, if water temperature exceeds tissue temperature. It has the same thermal effects as cold application, if comparable temperature water is used. Indications include the need for analgesia, relaxing muscle spasm, reducing joint stiffness, and facilitating and preparing for exercise.

(i). time to produce effect: two to four treatments

(ii). frequency: three to five times per week

(iii). optimum duration: three weeks as primary, or intermittently as an adjunct to other therapeutic procedures up to two months;

(iv). maximum duration: two months.

14. Vocational rehabilitation is a generally accepted intervention. Initiation of vocational rehabilitation requires adequate evaluation of patients for quantification highest functional level, motivation, and achievement of maximum medical improvement. Vocational rehabilitation may be as simple as returning to the original job or as complicated as being retrained for a new occupation.

a. It may also be beneficial for full vocational rehabilitation to be started before MMI if it is evident that the injured worker will be unable to return to his/her previous occupation. A positive goal and direction may aid the patient in decreasing stress and depression and promote optimum rehabilitation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1664 (June 2011).

§2023. Therapeutic Procedures—Operative

A. All operative interventions must be based upon positive correlation of clinical findings, clinical course, and diagnostic tests. A comprehensive assimilation of these factors must lead to a specific diagnosis with positive identification of pathologic condition(s). It is imperative to rule out non-physiologic modifiers of pain presentation or non-operative conditions mimicking radiculopathy or instability (e.g., peripheral neuropathy, piriformis syndrome, myofascial pain, scleratogenous or sympathetically mediated pain syndromes, sacroiliac dysfunction, psychological conditions, etc.) prior to consideration of elective surgical intervention.

B. Operative treatment is indicated when the natural history of surgically treated lesions is better than the natural history for non-operatively treated lesions. All patients being considered for surgical intervention should first undergo a comprehensive neuro-musculoskeletal examination to identify mechanical pain generators that may respond to non-surgical techniques or may be refractory to surgical intervention.

C. While sufficient time allowances for non-operative treatment are required to determine the natural cause and response to non-operative treatment of low back pain disorders, timely decision making for operative intervention

is critical to avoid de-conditioning and increased disability (exclusive of "emergent" or urgent pathology such as cauda equina syndrome or associated rapidly progressive neurologic loss).

1. In general, if the program of non-operative treatment fails, operative treatment is indicated when:

a. Improvement of the symptoms has plateaued and the residual symptoms of pain and functional disability are unacceptable at the end of 6 to 12 weeks of active treatment, or at the end of longer duration of non-operative programs for debilitated patients with complex problems; and/or

b. Frequent recurrences of symptoms cause serious functional limitations even if a non-operative active treatment program provides satisfactory relief of symptoms, and restoration of function on each recurrence.

c. Mere passage of time with poorly guided treatment is not considered an active treatment program.

D. Surgical workup and implementation for simple decompression of patients with herniated nucleus pulposus and sciatica should occur within 6 to 12 weeks after injury at the latest, within the above stated contingencies. For patients with true, refractory mechanical low back pain in whom fusion is being considered, it is recommended that a decisive commitment to surgical or non-surgical interventions occur within 5 months following injury, at the latest.

E. Spinal decompression surgeries and fusion have re-operation rates of approximately 10 percent or more over the following five years. Re-operation is indicated only when the functional outcome following the re-operation is expected to be better, within a reasonable degree of certainty, than the outcome of other non-invasive or less invasive treatment procedures. “Functional outcomes” refer to the patient’s ability to improve functional tolerances such as sitting, standing, walking, strength, endurance, and/or vocational status. While timely surgical decision-making is critical to avoid de-conditioning and increased disability, a time limited trial of reconditioning should be tried prior to re-operation. Re-operation has a high rate of complications and failure and may lead to disproportionately increased disability.

F. Every post-operative patient should be involved in an active treatment program. (Refer to Therapeutic Procedures-Non-Operative. Interdisciplinary interventions should be strongly considered post-operatively in any patient not making functional progress within expected time frames. (Refer to Interdisciplinary Programs) Return to work restrictions should be specific according to the recommendations in Return to Work. Most non-fusion surgical patients can return to a limited level of duty between 3 to 6 weeks. Full activity is generally achieved between 6 weeks to 6 months depending on the procedure and healing of the individual.

1. Discectomy

a. Description: To enter into and partially remove the disc.

b. Complications: Appropriate medical disclosures should be provided to the patient as deemed necessary by the physician.

c. Surgical Indications: To include all of the following: Primary radicular symptoms, radiculopathy on exam, correlating imaging study, and failure of non-surgical care. There is good evidence that surgery provides initial improvement of radicular symptoms with respect to chronic low back pain. There is conflicting evidence that the long-term outcome differs from that of the natural history of healing.

d. Operative Treatment: Partial discectomy and root decompression.

e. Post-Operative Therapy: A formal physical therapy program should be implemented post-operatively. Active treatment, which patients should have had prior to surgery, will frequently require a repeat of the sessions previously ordered.

2. Percutaneous discectomy

a. Description. Percutaneous discectomy is an invasive operative procedure to accomplish partial removal of the disc through a needle which allows aspiration of a portion of the disc trocar under imaging control.

b. Complications. Appropriate medical disclosures should be provided to the patient as deemed necessary by the treating physician.

c. Surgical Indications. Percutaneous discectomy is indicated only in cases of suspected septic discitis in order to obtain diagnostic tissue. The procedure is not recommended for contained disc herniations or bulges with associated radiculopathy due to lack of evidence to support long-term improvement.

d. Operative Treatment. Partial discectomy.

3. Laminotomy/laminectomy/foramenotomy/ facetectomy

a. Description. These procedures provide access to produce neural decompression by partial or total removal of various parts of vertebral bone.

b. Complications. Appropriate medical disclosures should be provided to the patient as deemed necessary by the treating physician.

c. Surgical Indications include all of the following: Primary radicular symptoms, radiculopathy and radiculitis on exam, correlating imaging study, and failure of non-surgical care.

d. Operative Treatment. Laminotomy,and/or partial discectomy & root decompression.

e. Post-Operative Therapy: A formal physical therapy program should be implemented post-operatively. Active treatment, which patients should have had prior to surgery, will frequently require a repeat of the sessions previously ordered. The implementation of a gentle aerobic reconditioning program (e.g., walking) and back education within the first post-operative week is appropriate in uncomplicated post-surgical cases. Some patients may benefit from several occupational therapy visits to improve performance of ADLs. Participation in an active therapy program which includes restoration of ROM, core stabilization, strengthening, and endurance is recommended to be initiated 3-6 weeks post-operatively. The goals of the therapy program should include instruction in a long-term home based exercise program. (Refer to Active Therapy.)

4. Spinal fusion

a. Description. Use of bone grafts, sometimes combined with metal devices, to produce a rigid connection between two or more adjacent vertebrae.

b. Complications. Appropriate medical disclosures should be provided to the patient as deemed necessary by the treating physician.

c. Surgical Indications. A timely decision-making process is recommended when considering patients for possible fusion. For chronic low back problems, fusion should not be considered within the first five months of symptoms, except for fracture or dislocation.

i. Although there is a statistical correlation between successful radiographic fusion and a good functional outcome, the relationship is not strong in the first two years. However, a recent observational study appears to indicate clinical deterioration in patients with unsuccessful radiographic fusion at an average of seven years post-operatively. There is good evidence that instrumented fusion, compared to non-instrumented fusion, produces a slightly better radiographically-confirmed bony union, with small to moderate functional advantages. Studies of surgical procedures report higher rates of complications with instrumented fusion.

ii. There is good evidence that intensive exercise for approximately 25 hours per week for four weeks combined with cognitive interventions emphasizing the benefits of maintaining usual activity, produces functional results similar to those of posterolateral fusion after one year. There is some evidence that lumbar fusion produces better symptomatic and functional results in patients with chronic non-radicular pain when several months of conservative treatment have not produced a satisfactory outcome. Fusions associated with decompression are more likely to reduce leg pain.

iii. Recombinant Human Bone Morphogenetic Protein (rhBMP-2) is a member of a family of cytokines capable of inducing bone formation. It is produced from genetically modified cell lines using molecular cloning techniques. At the time of this guideline writing, rhBMP-2 is FDA approved for use in anterior lumbar interbody fusion (ALIF) and is used with a carrier such as a collagen sponge or other matrix, and a cage. There is some evidence that anterior interbody cage fusion using rhBMP-2 results in shorter operative time compared with the use of iliac crest bone autograft. Minor pain at the iliac crest donor site may persist for 24 months or longer in approximately 30 percent of patients who undergo an autograft procedure. RhBMP-2 avoids the need for harvesting iliac crest donor bone and can therefore, avoid this complication of persistent pain. There is a potential for patients to develop sensitizing or blocking antibodies to rhBMP-2 or to the absorbable collagen sponge. The long-term effects are unknown. The rhBMP-2 used with the interbody fusion device is contraindicated for patients with a known hypersensitivity to Recombinant Human Bone Morphogenetic Protein -2, bovine type 1 collagen, or to other components of the formulation. Use of rhBMP-2 outside the anterior cage may carry a risk of swelling and ectopic bone formation which can encroach on neurovascular structures. At the time of this guideline writing, it is still investigational. Information concerning safe and effective dosing and application are being submitted to the FDA. All other applications are considered off-label and not FDA approved. There is insufficient information to form a recommendation with instrumentation other than the cage specifically designed for anterior procedures. If the FDA approves its use for other operative approaches, prior authorization is required. The patient must meet all indications on the device manufacturer's list and have no contraindications. The formation of exuberant or ectopic bone growth at the upper levels (L2-L4) may have a deleterious impact on certain neurovascular structures, such as the aorta and sympathetic nerve chain. There are also reports of osteoclastic activity with the use of rhBMP-2.

d. Indications for spinal fusion may include:

i. Neural arch defect—Spondylolytic spondylolisthesis, congenital unilateral neural arch hypoplasia.

ii. Segmental Instability—Excessive motion, as in degenerative spondylolisthesis, surgically induced segmental instability.

iii. Primary Mechanical Back Pain/Functional Spinal Unit Failure—Multiple pain generators objectively involving two or more of the following:

(a). internal disc disruption (poor success rate if more than one disc involved);

(b). painful motion segment, as in annular tears;

(c). disc resorption;

(d) facet syndrome; and/or

(e). ligamentous tear.

iv. Revision surgery for failed previous operation(s) if significant functional gains are anticipated.

v. Infection, tumor, or deformity of the lumbosacral spine that cause intractable pain, neurological deficit, and/or functional disability.

e. Pre-operative Surgical Indications: Required pre-operative clinical surgical indications for spinal fusion include all of the following:

i. All pain generators are adequately defined and treated; and

ii. All physical medicine and manual therapy interventions are completed; and

iii. X-ray, MRI, or CT/Discography demonstrate disc pathology or spinal instability; and

iv. Spine pathology is limited to two levels; and

v. Psychosocial evaluation with confounding issues addressed.

vi. For any potential fusion surgery, it is recommended that the injured worker refrain from smoking for at least six weeks prior to surgery and during the period of fusion healing. Because smokers have a higher risk of non-union and higher post-operative costs, it is recommended that insurers cover a smoking cessation program peri-operatively.

f. Operative Therapy: Operative procedures may include:

(a). Intertransverse Fusion;

(b). Anterior Fusion (with or without rhBMP-2) – generally used for component of discogenic pain where there is no significant radicular component requiring decompression;

(c). Posterior Interbody Fusion – generally used for component of discogenic pain where posterior decompression for radicular symptoms also performed; or

(d). Anterior/posterior (360°) Fusion – most commonly seen in unstable or potentially unstable situations or non-union of a previous fusion.

g. Post-operative Therapy: A formal physical therapy program should be implemented post-operatively. Active treatment, which patients should have had prior to surgery, will frequently require a repeat of the sessions

previously ordered. The implementation of a gentle aerobic reconditioning program (e.g., walking), and back education within the first post-operative week is appropriate in uncomplicated post-surgical cases. Some patients may benefit from several occupational therapy visits to improve performance of ADLs. Participation in an active therapy program which includes core stabilization, strengthening, and endurance is recommended to be initiated once the fusion is solid and without complication. The goals of the therapy program should include instruction in a long-term home based exercise program. (Refer to Active Therapy).

h. Return-to-Work. Barring complications, patients responding favorably to spinal fusion may be able to return to sedentary-to-light work within 6 to 12 weeks post-operatively, light-to-medium work within six to nine months post-operatively and medium-to-medium/heavy work within 6 to 12 months post-operatively. Patients requiring fusion whose previous occupation involved heavy-to-very-heavy labor should be considered for vocational assessment as soon as reasonable restrictions can be predicted. The practitioner should release the patient with specific physical restrictions and should obtain a clear job description from the employer, if necessary. Once an injured worker is off work greater than six months, the functional prognosis with or without fusion becomes guarded for that individual.

5. Sacroiliac joint fusion

a. Description. Use of bone grafts, sometimes combined with metal devices, to produce a rigid connection between two or more adjacent vertebrae providing symptomatic instability as a part of major pelvic ring disruption.

b. Complications. Instrumentation failure, bone graft donor site pain, in-hospital mortality, deep infection, superficial infection, and graft extrusion.

c. Surgical Indications. Sacroiliac (SI) joint fusion may be indicated for stabilization of a traumatic severe disruption of the pelvic ring. This procedure has limited use in minor trauma and would be considered only on an individual case-by-case basis. In patients with typical mechanical low back pain, this procedure is considered to be investigational. Until the efficacy of this procedure for mechanical low back pain is determined by an independent valid prospective outcome study, this procedure is not recommended for mechanical low back pain.

6. Implantable spinal cord stimulators are reserved for those low back pain patients with pain of greater than six months duration who have not responded to the standard non-operative or operative interventions previously discussed within this document. Refer to OWCA's Chronic Pain Disorder Medical Treatment Guidelines.

7. Laser discectomy involves the delivery of laser energy into the center of the nucleus pulposus using a fluoroscopically guided laser fiber under local anesthesia. The energy denatures protein in the nucleus, causing a structural change which is intended to reduce intradiscal pressure. Its effectiveness has not been shown. Laser discectomy is not recommended.

8. Artificial lumbar disc replacement

a. Description. This involves the insertion of a prosthetic device into an intervertebral space from which a degenerated disc has been removed, sparing only the peripheral annulus. The endplates are positioned under intraoperative fluoroscopic guidance for optimal placement in the sagittal and frontal planes. The prosthetic device is designed to distribute the mechanical load of the vertebrae in a physiologic manner and maintain range of motion.

i. General selection criteria for lumbar disc replacement includes symptomatic one-level degenerative disc disease. The patient must also meet fusion surgery criteria, and if the patient is not a candidate for fusion, a disc replacement procedure should not be considered. Additionally, the patient should be able to comply with pre- and post-surgery protocol.

ii. The theoretical advantage of total disc arthroplasty is that it preserves range of motion and physiologic loading of the disc. This could be an advantage for adults who are physically active. Studies do not demonstrate a long-term advantage of measured function or pain over comparison groups undergoing fusion. The longevity of this prosthetic device has not yet been determined. Significant technical training and experience is required to perform this procedure successfully. Surgeons must be well-versed in anterior spinal techniques and should have attended appropriate training courses, or have undergone training during a fellowship. Mentoring and proctoring of procedures is highly recommended. Reasonable pre-operative evaluation may include an angiogram to identify great vessel location. The angiogram may be either with contrast or with magnetic resonance imaging. An assistant surgeon with anterior access experience is required.

b. Complications:

i. nerve and vascular injury;

ii. dural tears;

iii. sexual dysfunction (retrograde ejaculation);

iv. mal-positioning of the prosthesis;

v. suboptimal positioning of the prosthetic may compromise the long-term clinical result;

vi. Complex Regional Pain Syndrome (CRPS);

vii. complications from Abdominal Surgery, (e.g., hernia or adhesions);

viii. re-operation due to complications;

ix. appropriate medical disclosures should be provided to the patient as deemed necessary by the treating physician.

c. Surgical Indications

i. Symptomatic one-level degenerative disc disease established by objective testing (CT or MRI scan followed by positive provocation discogram)

ii. symptoms unrelieved after six months of active non-surgical treatment;

iii. all pain generators are adequately defined and treated'

iv. all physical medicine and manual therapy interventions are completed;

v. spine pathology limited to one level;

vi. psychosocial evaluation with confounding issues addressed;

d. Contraindications

i. significant spinal deformity/scoliosis;

ii. facet joint arthrosis;

iii. spinal instability;

iv. deficient posterior elements;

v. infection;

vi. any contraindications to an anterior abdominal approach (including multiple prior abdominal procedures);

vii. evidence of nerve root compression, depending on the device used;

viii. previous compression or burst fracture ;

ix. multiple-level degenerative disc disease (DDD);

x. spondylolysis;

xi. spondylolisthesis greater than 3 mm;

xii. osteoporosis or any metabolic bone disease;

xiii. chronic steroid use or use of other medication known to interfere with bone or soft tissue healing;

xiv. autoimmune disorder;

xv. allergy to device components/materials;

xvi. depending on the device selected, pregnancy or desire to become pregnant;

xvii. morbid obesity (e.g., body/mass index [BMI] of greater than 40, over 100 pounds overweight);

xviii. active malignancy;

e. Post-operative Therapy. Bracing may be appropriate. A formal physical therapy program should be implemented post-operatively. Active treatment, which patients should have had prior to surgery, will frequently require a repeat of the sessions previously ordered. The implementation of a gentle aerobic reconditioning program (e.g., walking) and back education within the first post-operative week is appropriate in uncomplicated post-surgical cases. Some patients may benefit from several occupational therapy visits to improve performance of ADLs. Participation in an active therapy program which includes restoration of ROM, core stabilization, strengthening, and endurance is recommended to be initiated at the discretion of the surgeon. Lifting and bending are usually limited for several months at least. Sedentary duty may be able to begin within six weeks in uncomplicated cases. The goals of the therapy program should include instruction in a long-term home based exercise program. (Refer to Active Therapy.)

8. Kyphoplasty

a. Description. A surgical procedure for the treatment of symptomatic thoracic or lumbar vertebral compression fractures, most commonly due to osteoporosis or other metabolic bone disease, and occasionally with post-traumatic compression fractures and minor burst fractures that do not significantly compromise the posterior cortex of the vertebral body. Pain relief can be expected in approximately 90 percent of patients. Vertebral height correction is inconsistent, with approximately 35 percent to 40 percent of procedures failing to restore height or kyphotic angle.

b. Complications: Cement leakage occurs in approximately nine percent of kyphoplasties and may cause complications. New vertebral compression fracture may occur following kyphoplasty, but their occurrence does not appear to exceed that of osteoporotic patients who did not receive treatment.

c. Operative Treatment: Kyphoplasty involves the percutaneous insertion of a trocar and inflatable balloon or expanding polymer into the vertebral body, which re-expands the body, elevating the endplates and reducing the compression deformity. Polymethylmethacrylate (PMMA) bone cement is injected under low pressure into the cavity created by the balloon inflation. In contrast to vertebroplasty, which introduces PMMA cement under high pressure, the space created by balloon inflation allows a higher viscosity PMMA to be injected under lower pressure, which may reduce the risks associated with extravertebral extravasation of the material. There may be an advantage to performing the procedure within one month of the fracture, since the elevation of the endplates may be more readily achieved than when the procedure is delayed.

d. Surgical Indications. Kyphoplasty is an accepted treatment for the following indications:

i. compression fracture ;

ii. vertebral height loss between 20 percent and 85 percent;

iii. vertebral height restoration. Kyphoplasty is more likely to increase vertebral height if performed within 30 days of fracture occurrence.

e. Contraindications

i. the presence of neurologic compromise related to fracture;

ii. high-velocity fractures with a significant burst component;

iii. significant posterior vertebral body wall fracture;

iv. severe vertebral collapse (vertebra plana);

v. infection, and

vi. coagulopathy .

9. Vertebroplasty

a. Description Vertebroplasty is a procedure for the treatment of painful thoracic and lumbar vertebral compression fractures caused by osteoporosis or other metabolic bone disease. Polymethylmethacrylate (PMMA) bone cement is injected with high pressure into the vertebral body via an 11- to 13-gauge needle, with the goal of stabilizing the spine and relieving pain. The procedure does not correct spinal deformity. Pain relief can be expected in approximately 90 percent of patients. Vertebral height correction is inconsistent, with approximately 35 percent to 40 percent of procedures failing to restore height or kyphotic angle.

b. Complications

i. Because the bone cement is of low viscosity, its injection under pressure frequently results in extravertebral extravasation of the material, with rare serious complications such as pulmonary embolism. Cement leakage alone occurs in approximately 40 percent of vertebroplasties.

ii. New vertebral compression fractures may occur following vertebroplasty, but their occurrence does not appear to exceed that of osteoporotic patients who did not receive treatment.

c. Indications:

i. compression fracture of preferably less than 30 days;

ii. vertebral height loss between 20 percent and 85 percent;

iii. intact posterior wall;

d. Contraindications:

i. the presence of neurologic compromise related to the fracture;

ii. high velocity fractures with a significant burst component;

iii. posterior vertebral body wall fracture;

iv. severe vertebral collapse (vertebra plana); and

v. infection; and,

vi. coagulopathy

10. Percutaneous radiofrequency disc decompression is an investigational procedure which introduces a 17 gauge cannula under local anesthesia and fluoroscopic guidance into the nucleus pulposus of the contained herniated disc, using radiofrequency energy to dissolve and remove disc material. Pressure inside the disc is lowered as a result. There have been no randomized clinical trials of this procedure at this time. Percutaneous radiofrequency disc decompression is not recommended.

11. Nucleus pulposus replacement involves the introduction of a prosthetic implant into the intervertebral disc, replacing the nucleus while preserving the annulus fibrosus. It is limited to investigational use in the United States at this time. It is not recommended.

12. Epiduroscopy and Epidural Lysis of Adhesions (Refer to Injections-Therapeutic).

13. Intraoperative Monitoring is a common intraoperative electrodiagnostic technique that may include somatosensory evoked potentials (SSEP), motor evoked potentials (MEP), or pedicle screw monitoring. The monitoring procedure may be used at the discretion of the physician.The use of intraoperative monitoring can be anticipated to become more common as percutaneous spinal procedures gain greater acceptance.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1676 (June 2011).

§2024. LWC-WC 1009. Disputed Claim for Medical Treatment

Mail to:
OWCA—Medical Services
ATTN: Medical Director
P.O. Box 94040
Baton Rouge, LA 70804

1. Social Security No.__-__-__
2. Date of Injury/Illness __-__-__
3. Parts of Body Injury_____
4. Date of Birth __-__-__
5. Date of This Request __-__-__
6. Claim Number _____

DISPUTED CLAIM FOR MEDICAL TREATMENT

NOTE: THIS REQUEST WILL NOT BE HONORED UNLESS THE INSURER HAS ISSUED A DENIAL FOR THE MEDICAL SERVICES IN DISPUTE AS PER R.S. 23:1203.1 J.

GENERAL INFORMATION
Claimant files this dispute with the Office of Workers' Compensation – Medical Services Director. This office must be notified immediately in writing of changes in address. An employee may be represented by an attorney, but it is not required.

7. This request is submitted by
___ Employee ___ Employer __ Insurer ___ Health Care Provider ___ Other ___

A. Copies of all relevant medical records must be included with this request.

B. A copy of the denial letter issued by the insurance carrier must be attached to this request.

EMPLOYEE
8. Name _____
Street or Box _____
City _____
State _____ Zip _____
Phone (____) _____

EMPLOYEE'S ATTORNEY
9. Name _____
Street or Box _____
City _____
State _____
Phone (____) _____
Fax (____) _____

EMPLOYER
10. Name _____
Street or Box _____
City _____
State _____ Zip _____
Phone (____) _____
Fax (____) _____

INSURER/ADMINISTRATOR
(circle one)
11. Name _____
Street or Box _____
City _____
State _____
Phone (____) _____
Fax (____) _____

EMPLOYER/INSURER'S ATTORNEY
12. Name _____
Street or Box _____
City _____
State _____ Zip _____
Phone (____) _____
Fax (____) _____

TREATING/REQUESTING PHYSICIAN
13. Name _____
Street or Box _____
City _____
State _____
Phone (____) _____
Fax (____) _____

LWC-WC 1009
11/2010

14. PLEASE PROVIDE A SUMMARY OF THE DETAILS REGARDING THE ISSUE AT DISPUTE:
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

You may attach a letter or petition with additional information with this disputed claim.
The information given above is true and correct to the best of my knowledge and belief.

_____ _____
SIGNATURE OF REQUESTING PARTY DATE

LWC-WC 1009
11/2010

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1681 (June 2011).

Chapter 21. Pain Medical Treatment Guidelines

Subchapter A. Chronic Pain Disorder Medical Treatment Guidelines

§2101. Introduction

A. This document has been prepared by the Louisiana Workforce Commission, Office of Workers' Compensation (OWCA) and should be interpreted within the context of guidelines for physicians/providers treating individuals qualifying under Louisiana Workers' Compensation Act as injured workers with chronic pain. The guidelines are enforceable under the Louisiana Workers Compensation Act. All medical care, services, and treatment owed by the employer to the employee in accordance with the Louisiana Workers' Compensation Act shall mean care, services, and treatment in accordance with these guidelines. Medical care, services, and treatment that varies from these guidelines shall also be due by the employer when it is demonstrated to the medical director of the office by a preponderance of the scientific medical evidence, that a variance from these guidelines is reasonably required to cure or relieve the

injured worker from the effects of the injury or occupational disease given the circumstances. Therefore, these guidelines are not relevant as evidence of a provider's legal standard of professional care. To properly utilize this document, the reader should not skip nor overlook any sections.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1681 (June 2011).

§2103. General Guideline Principles

A. The principles summarized in this section are key to the intended implementation of all Office of Workers' Compensation guidelines and critical to the reader's application of the guidelines in this document.

1. Application of Guidelines. The OWCA provides procedures to implement medical treatment guidelines and to foster communication to resolve disputes among the provider, payer, and patient through the Office of Workers Compensation.

2. Education. Education of the patient and family, as well as the employer, insurer, policy makers and the community should be the primary emphasis in the treatment of chronic pain. Currently, practitioners often think of education last, after medications, manual therapy, and surgery. Practitioners must develop and implement an effective strategy and skills to educate patients, employers, insurance systems, policy makers, and the community as a whole. An education-based paradigm should always start with inexpensive communication providing reassuring information to the patient. More in-depth education currently exists within a treatment regime employing functional restorative and innovative programs of prevention and rehabilitation. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of facilitating self-management of symptoms and prevention.

3. Treatment Parameter Duration. Time frames for specific interventions commence once treatments have been initiated, not on the date of injury. Obviously, duration will be impacted by patient compliance, as well as availability of services. Clinical judgment may substantiate the need to accelerate or decelerate the time frames discussed in this document. Such deviation shall be in accordance with La. R.S. 23:1203.1.

4. Active Interventions. Emphasizing patient responsibility, such as therapeutic exercise and/or functional treatment, are generally emphasized over passive modalities, especially as treatment progresses. Generally, passive interventions are viewed as a means to facilitate progress in an active rehabilitation program with concomitant attainment of objective functional gains.

5. Active Therapeutic Exercise Program. Exercise program goals should incorporate patient strength, endurance, flexibility, coordination, and education. This includes functional application in vocational or community settings.

6. Positive Patient Response. Positive results are defined primarily as functional gains that can be objectively measured. Standard measurement tools, including outcome measures, should be used.

a. Objective functional gains include, but are not limited to, positional tolerances, range-of-motion (ROM), strength, and endurance, activities of daily living, cognition, psychological behavior, and efficiency/velocity measures that can be quantified. Subjective reports of pain and function should be considered and given relative weight when the pain has anatomic and physiologic correlation. Anatomic correlation must be based on objective findings.

7. Re-evaluation treatment every three to four weeks. If a given treatment or modality is not producing positive results within three to four weeks, the treatment should be either modified or discontinued. Reconsideration of diagnosis should also occur in the event of poor response to a seemingly rational intervention.

8. Surgical Interventions. Surgery should be contemplated within the context of expected functional outcome and not purely for the purpose of pain relief. The concept of "cure" with respect to surgical treatment by itself is generally a misnomer. All operative interventions must be based upon positive correlation of clinical findings, clinical course, and diagnostic tests. A comprehensive assimilation of these factors must lead to a specific diagnosis with positive identification of pathologic conditions.

9. Six-Month Time Frame. The prognosis drops precipitously for returning an injured worker to work once he/she has been temporarily totally disabled for more than six months. The emphasis within these guidelines is to move patients along a continuum of care and return-to-work within a six-month time frame, whenever possible. It is important to note that time frames may not be pertinent to injuries that do not involve work-time loss or are not occupationally related.

10. Return-to-Work. Return to Work is therapeutic, assuming the work is not likely to aggravate the basic problem or increase long-term pain. The practitioner must provide specific written physical limitations and the patient should never be released to "sedentary" or "light duty." The following physical limitations should be considered and modified as recommended: lifting, pushing, pulling, crouching, walking, using stairs, bending at the waist, awkward and/or sustained postures, tolerance for sitting or standing, hot and cold environments, data entry and other repetitive motion tasks, sustained grip, tool usage and vibration factors. Even if there is residual chronic pain, return-to-work is not necessarily contraindicated. The practitioner should understand all of the physical demands of the patient’s job position before returning the patient to full duty and should request clarification of the patient’s job duties. Clarification should be obtained from the employer or, if necessary, including, but not limited to, an occupational health nurse, occupational therapist, vocational rehabilitation specialist, or an industrial hygienist.

11. Delayed Recovery. Strongly consider a psychological evaluation, if not previously provided, as well as initiating interdisciplinary rehabilitation treatment and vocational goal setting, for those patients who are failing to make expected progress 6 to 12 weeks after an injury. The OWCA recognizes that 3 to 10 percent of all industrially injured patients will not recover within the timelines outlined in this document despite optimal care. Such individuals may require treatments beyond the limits discussed within this document, but such treatment will require clear documentation by the authorized treating practitioner focusing on objective functional gains afforded by further treatment and impact upon prognosis.

12. Guideline Recommendations and Inclusion of Medical Evidence. Guidelines are recommendations based on available evidence and/or consensus recommendations. When possible, guideline recommendations will note the level of evidence supporting the treatment recommendation. When interpreting medical evidence statements in the guideline, the following apply:

a. *Consensus*—the opinion of experienced professionals based on general medical principles. Consensus recommendations are designated in the guideline as "generally well accepted," "generally accepted," "acceptable/accepted," or "well-established."

b. *Some*—the recommendation considered at least one adequate scientific study, which reported that a treatment was effective.

c. *Good*—the recommendation considered the availability of multiple adequate scientific studies or at least one relevant high-quality scientific study, which reported that a treatment was effective.

d. *Strong*—the recommendation considered the availability of multiple relevant and high quality scientific studies, which arrived at similar conclusions about the effectiveness of a treatment.

B. All recommendations in the guideline are considered to represent reasonable care in appropriately selected cases, regardless of the level of evidence or consensus statement attached to it. Those procedures considered inappropriate, unreasonable, or unnecessary are designated in the guideline as "not recommended."

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1682 (June 2011).

§2105. Introduction to Chronic Pain

A. The International Association for the Study of Pain (IASP) defines pain as "an unpleasant sensory and emotional experience with actual or potential tissue damage." Pain is a complex experience embracing physical, mental, social, and behavioral processes that often compromises the quality of life of many individuals. Pain is an unpleasant subjective perception usually in the context of tissue damage.

B. Pain is subjective and cannot be measured or indicated objectively. Pain evokes negative emotional reactions such as fear, anxiety, anger, and depression. People usually regard pain as an indicator of physical harm, despite the fact that pain can exist without tissue damage and tissue damage can exist without pain. Many people report pain in the absence of tissue damage or any likely pathophysiologic cause. There is no way to distinguish their experience from that due to actual tissue damage. If they regard their experience as pain and they report it the same way as pain caused by tissue damage, it should be accepted as pain.

C. Pain can generally be classified as:

1. Nociceptive which includes pain from visceral origins or damage to other tissues. Myofascial pain is a nociceptive type of pain characterized by myofascial trigger points limited to a specific muscle or muscles.

2. Neuropathic including that originating from brain, peripheral nerves or both;

3. Psychogenic that originates in mood, characterological, social, or psychophysiological processes.

D. Recent advances in the neurosciences reveal additional mechanisms involved in chronic pain. In the past, pain was seen as a sensation arising from the stimulation of pain receptors by damaged tissue, initiating a sequence of nerve signals ending in the brain and there recognized as pain. A consequence of this model was that ongoing pain following resolution of tissue damage was seen as less physiological and more psychological than acute pain with identifiable tissue injury. Current research indicates that chronic pain involves additional mechanisms that cause: neural remodeling at the level of the spinal cord and higher levels of the central nervous system; changes in membrane responsiveness and connectivity leading to activation of larger pain pathways; and recruitment of distinct neurotransmitters.

E. Changes in gene function and expression may occur, with lasting functional consequences. These physiologic functional changes cause chronic pain to be experienced in body regions beyond the original injury and to be exacerbated by little or no stimulation. The chronic pain experience clearly represents both psychologic and complex physiologic mechanisms, many of which are just beginning to be understood.

F. Chronic Pain is defined as "pain that persists for at least 30 days beyond the usual course of an acute disease or a reasonable time for an injury to heal or that is associated with a chronic pathological process that causes continuous pain (e.g., reflex sympathetic dystrophy)." The very definition of chronic pain describes a delay or outright failure to relieve pain associated with some specific illness or accident. Delayed recovery should prompt a clinical review of the case and a psychological evaluation by the health care provider. Referral to a recognized pain specialist for further evaluation is recommended. Consideration may be given to new diagnostic testing or a change in treatment plan.

G. Use of the term "chronic pain syndrome" has been used and defined in a variety of ways that generally indicate a belief on the part of the health care provider that the patient's pain is inappropriate or out of proportion to existing problems or illness. Use of the term "chronic pain syndrome" should be discontinued because the term ceases to have meaning due to the many different physical and psychosocial issues associated with it. Instead, practitioners should use the nationally accepted terminology indicated in the definition section and/or the psychiatric diagnosis of "Pain Disorder" and the subtypes according to established standards of the American Psychiatric Association (APA).

H. The IASP offers taxonomy of pain, which underscores the wide variety of pathological conditions associated with chronic pain. This classification system may not address the psychological and psychosocial issues that occur in the perception of pain, suffering, and disability and may require referral to psychiatric or psychological clinicians. These issues should be documented with preference to the diagnostic categories of the Diagnostic and Statistical Manual of Mental Disorders (DSM), published by the American Psychiatric Association including the subcategories of pain disorder and any other applicable diagnostic categories (i.e., depressive, anxiety, and adjustment disorders).

I. Chronic pain is a phenomenon not specifically relegated to anatomical or physiologic parameters. The prevailing biomedical model (which focuses on identified disease pathology as the sole cause of pain) cannot capture all of the important variables in pain behavior. While diagnostic labels may pinpoint contributory physical and/or psychological factors and lead to specific treatment interventions that are helpful, a large number of patients defy precise taxonomic classification. Furthermore, such diagnostic labeling often overlooks important social contributions to the chronic pain experience. Failure to address these operational parameters of the chronic pain experience may lead to incomplete or faulty treatment plans. The term "pain disorder" is perhaps the most useful term in the medical literature today, in that it captures the multi-factorial nature of the chronic pain experience.

J. It is recognized that some health care practitioners, by virtue of their experience, additional training, and/or accreditation by pain specialty organizations, have much greater expertise in the area of chronic pain evaluation and treatment than others. Referrals for the treatment of chronic pain should be to such recognized specialists. Chronic pain treatment plans should be monitored and coordinated by pain medicine physicians with such specialty training, in conjunction with other health care specialists.

K. Most acute and some chronic pain problems are adequately addressed in other OWCA treatment guidelines, and are generally beyond the scope of these guidelines. However, because chronic pain is more often than not multi-factorial, involving more than one pathophysiologic or mental disorder, some overlap with other guidelines is inevitable. These guidelines are meant to apply to any patient who fits the operational definition of chronic pain discussed at the beginning of this section.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1683 (June 2011).

§2107. Definitions

A. Aftersensation refers to the abnormal persistence of a sensory perception, provoked by a stimulus even though the stimulus has ceased.

B. Allodynia is pain due to a non-noxious stimulus that does not normally provoke pain.

1. Mechanical Allodynia—refers to the abnormal perception of pain from usually non-painful mechanical stimulation.

2. Static Mechanical Allodynia—refers to pain obtained by applying a single stimulus such as light pressure to a defined area.

3. Dynamic Mechanical Allodynia—obtained by moving the stimulus such as a brush or cotton tip across the abnormal hypersensitive area.

4. Thermal Allodynia—refers to the abnormal sensation of pain from usually non-painful thermal stimulation such as cold or warmth.

C. Analgesia. Absence of pain in response to stimulation that would normally be painful.

D. Biopsychosocial. A term that reflects the multiple facets of any clinical situation; namely, the biological, psychological, and social situation of the patient.

E. Central Pain. Pain initiated or caused by a primary lesion or dysfunction in the central nervous system.

F. Central Sensitization. The experience of pain evoked by the excitation of non-nociceptive neurons or of nerve fibers that normally relay non-painful sensations to the spinal cord. This results when non-nociceptive afferent neurons act on a sensitized central nervous system (CNS).

G. Dysesthesia. An abnormal sensation described by the patient as unpleasant. As with paresthesia, dysesthesia may be spontaneous or evoked by maneuvers on physical examination.

H. Hyperalgesia. Refers to an exaggerated pain response from a usually painful stimulation.

I. Hyperesthesia (positive sensory phenomena. Includes allodynia, hyperalgesia, and hyperpathia. Elicited by light touch, pin prick, cold, warm, vibration, joint position sensation or two-point discrimination, which is perceived as increased or more.

J. Hyperpathia. Refers to an abnormally painful and exaggerated reaction to stimulus, especially to a repetitive stimulus.

K. Hypoalgesia. Diminished pain perception in response to a normally painful stimulus.

L. Hypoesthesia (negative sensory phenomena). Refers to a stimulus such as light touch, pin prick, cold, point position sensation, two-point discrimination, or sensory neglect which is perceived as decreased.

M. Malingering. Intentional feigning of illness or disability in order to escape work or gain compensation.

N. Myofascial Pain. A regional pain characterized by tender points in taut bands of muscle that produce pain in a characteristic reference zone.

O. Myofascial Trigger Point. A physical sign in a muscle which includes, exquisite tenderness in a taut muscle band; and referred pain elicited by mechanical stimulation of the trigger point. The following findings may be associated with myofascial trigger points: Local twitch or contraction of the taut band when the trigger point is mechanically stimulated; Reproduction of the patient's spontaneous pain pattern when the trigger point is mechanically stimulated; Weakness without muscle atrophy; and restricted range of motion of the affected muscle; and Autonomic dysfunction associated with the trigger point such as changes in skin or limb temperature.

P. Neuralgia. Pain in the distribution of a nerve or nerves.

Q. Neuritis. Inflammation of a nerve or nerves.

R. Neurogenic Pain. Pain initiated or caused by a primary lesion, dysfunction, or transitory perturbation in the peripheral or central nervous system.

S. Neuropathic Pain. Pain due to an injured or dysfunctional central or peripheral nervous system.

T. Neuropathy. A disturbance of function or pathological change in a nerve: in one nerve, mononeuropathy; in several nerves, mononeuropathy multiplex; if diffuse and bilateral, polyneuropathy.

U. Nociceptor. A receptor preferentially sensitive to a noxious stimulus or to a stimulus which would become noxious if prolonged.

V. Pain Behavior. The non-verbal actions (such as grimacing, groaning, limping, using visible pain relieving or support devices and requisition of pain medications, among

others) that are outward manifestations of pain, and through which a person may communicate that pain is being experienced.

W. Pain Threshold. The smallest stimulus perceived by a subject as painful.

X. Paresthesia. An abnormal sensation that is not described as pain. It can be either a spontaneous sensation (such as pins and needles) or a sensation evoked from non-painful or painful stimulation, such as light touch, thermal, or pinprick stimulus on physical examination.

Y. Peripheral neurogenic pain. Pain initiated or caused by a primary lesion or dysfunction or transitory perturbation in the peripheral nervous system.

Z. Peripheral neuropathic pain. Pain initiated or caused by a primary lesion or dysfunction in the peripheral nervous system.

AA. Summation. Refers to abnormally painful sensation to a repeated stimulus although the actual stimulus remains constant. The patient describes the pain as growing and growing as the same intensity stimulus continues.

BB. Sympathetically Maintained Pain (smp). A pain that is maintained by sympathetic efferent innervations or by circulating catecholamines.

CC. Tender Points. Tenderness on palpation at a tendon insertion, muscle belly or over bone. Palpation should be done with the thumb or forefinger, applying pressure approximately equal to a force of four kilograms (blanching of the entire nail bed).

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1684 (June 2011).

§2109. Initial Evaluation and Diagnostic Procedures

A. The OWCA recommends the following diagnostic procedures be considered, at least initially, the responsibility of the workers' compensation carrier to ensure that an accurate diagnosis and treatment plan can be established. Standard procedures that should be utilized when initially diagnosing a work-related chronic pain complaint are listed below.

1. History and Physical Examination (Hx and PE).

a. Medical History. As in other fields of medicine, a thorough patient history is an important part of the evaluation of chronic pain. In taking such a history, factors influencing a patient's current status can be made clear and taken into account when planning diagnostic evaluation and treatment. One efficient manner in which to obtain historical information is by using a questionnaire. The questionnaire may be sent to the patient prior to the initial visit or administered at the time of the office visit. The following items are considered essential history:

i general information—general items requested are name, sex, age, birth date, etc;

ii. level of education—the level of patient's education may influence response to treatment;

iii. work history/occupation—to include both impact of injury on job duties and impact on ability to perform job duties, work history, job description, mechanical requirements of the job, duration of employment, and job satisfaction;

iv. current employment status;

v. marital status;

vi. family environment—Is the patient living in a nuclear family or with friends? Is there or were there, any family members with chronic illness or pain problems? Responses to such questions reveal the nature of the support system or the possibility of conditioning toward chronicity;

vii. ethnic origin—Ethnicity of the patient, including any existing language barriers, may influence the patient's perception of and response to pain. There is evidence that providers may under-treat patients of certain ethnic backgrounds due to underestimation of their pain;

viii. belief system—The patient may refuse various treatments or may have an altered perception of his pain due to his particular beliefs;

ix. activities of daily living—Pain has a multidimensional effect on the patient that is reflected in changes in usual daily vocational, social, recreational, and sexual activities;

x. past and present psychological problems;

xi. history of abuse—physical, emotional, sexual;

xii. history of disability in the family;

xiii. sleep disturbances

b. Pain History. Characterization of the patient's pain and of the patient's response to pain is one of the key elements in treatment.

i. site of pain—localization and distribution of the pain help determine the type of pain the patient has (i.e., central versus peripheral);

ii. pain drawing/Visual Analog Scale (VAS);

iii. duration;

iv. place of onset;

v.. pain characteristics—time of pain occurrence as well as intensity, quality and radiation give clues to the diagnosis and potential treatment;

vi.. response of pain to activity;

vii. associated symptoms—Does the patient have numbness or paresthesia, dysesthesia, weakness, bowel or bladder dysfunction, decreased temperature, increased sweating, cyanosis or edema? Is there local tenderness, allodynia, hyperesthesia, or hyperalgesia?

c. Medical Management History.

i. prior treatment—What has been tried and which treatments have helped?;

ii. prior surgery—If the patient has had prior surgery specifically for the pain, he/she is less likely to have a positive outcome;

iii. medications—History of and current use of medications, including over the counter and herbal/dietary supplements to determine drug usage (or abuse) interactions and efficacy of treatment;

iv. review of systems check list—Determine if there is any interplay between the pain complaint and other medical conditions;

v. psychosocial functioning—Determine if the following are present: current symptoms of depression or anxiety; evidence of stressors in the workplace or at home, and past history of psychological problems. It is recommended that patients diagnosed with Chronic Pain be referred for a psychosocial evaluation;

vi. diagnostic tests—All previous radiological and laboratory investigations should be reviewed;

vii. pre-existing conditions—Treatment of these conditions is appropriate when the pre-existing condition affects recovery from chronic pain.

d. Substance use/abuse

i. alcohol use;

ii. smoking history;

iii. history of drug use and abuse;

iv. caffeine or caffeine-containing beverages;

e. Other factors affecting treatment outcome

i. compensation/disability/litigation;

ii. treatment expectations—what does the patient expect from treatment: complete relief of pain or reduction to a more tolerable level?

f. Physical Examination

i. Neurologic Evaluation—Cranial nerves, muscle tone and strength, atrophy, upper motor neuron signs, motor evaluation reflexes, and provocative neurological maneuvers.

ii. Sensory Evaluation—A detailed sensory examination is crucial in evaluating a patient with chronic pain complaints. Quantitative sensory testing, such as Semmes-Weinstein, may be useful tools in determining sensory abnormalities. The examination should determine if the following sensory signs are present:

(a). Hyperalgesia;

(b). Hyperpathia;

(c). Paresthesia;

(d). Dysesthesia;

(e). Mechanical Allodynia—static versus dynamic;

(f). Thermal Allodynia;

(g). Hypoesthesia;

(h). Hyperesthesia;

(i). Summation.

iii. Musculoskeletal Evaluation—range of motion, segmental mobility, musculoskeletal provocative maneuvers, palpation, observation, and functional activities. All joints, muscles, ligaments, and tendons should be examined for swelling, laxity, and tenderness. A portion of the musculoskeletal evaluation is the myofascial examination. The myofascial examination includes palpating soft tissues for evidence of tightness and trigger points;

iv. evaluation of nonphysiologic findings

(a). Waddell's nonorganic findings including,superficial or nonorganic tenderness; pseudo maneuvers; discrepant straight leg raise; nonanatomic sensory and/or motor examination; and overreaction: collapsing, tremor, pain behavior, muscle tension.

(b). Variabilities on formal exam including variable sensory exam, inconsistent tenderness, and/or swelling secondary to extrinsic sources.

(c). Inconsistencies between formal exam and observed abilities of range of motion, motor strength, gait and cognitive/emotional state.

(d). Observation of consistencies between pain behavior, affect and verbal pain rating, and affect and physical re-examination.

2. Personality /Psychosocial/ Psychiatric/ Psychological Evaluation

a. These are generally accepted and well-established diagnostic procedures with selective use in the upper extremity population, but have more widespread use in subacute and chronic upper extremity populations. Diagnostic testing procedures may be useful for patients with symptoms of depression, delayed recovery, chronic pain, recurrent painful conditions, disability problems, and for preoperative evaluation. Psychological/ psychiatric/psychosocial and measures have been shown to have predictive value for postoperative response, and therefore should be strongly considered for use pre-operatively when the surgeon has concerns about the relationship between symptoms and findings, or when the surgeon is aware of indications of psychological complication or risk factors for psychological complication (e.g. childhood psychological trauma). Psychological testing should provide differentiation between pre-existing conditions versus injury caused psychological conditions, including depression and posttraumatic stress disorder. Psychological testing should incorporate measures that have been shown, empirically, to identify comorbidities or risk factors that are linked to poor outcome or delayed recovery. Formal psychological or psychosocial evaluation should be performed on patients not making expected progress within 6 to 12 weeks following injury and whose subjective symptoms do not correlate with objective signs and test results. In addition to the customary initial exam, the evaluation of the injured worker should specifically address the following areas:

i. employment history;

ii. interpersonal relationships-both social and work;

iii. patient activities;

iv. current perception of the medical system;

v. current perception/attitudes toward employer/job;

vi. results of current treatment;

vii. risk factors and psychological comorbidities that may influence outcome and that may require treatment;

viii. childhood history, including history of childhood psychological trauma, abuse and family history of disability.

b. Personality/psychological/psychiatric/psychosocial evaluations consist of two components, clinical interview and psychological testing. Results should help clinicians with a better understanding of the patient in a number of ways. Thus the evaluation result will determine the need for further psychosocial interventions; and in those cases, Diagnostic and Statistical Manual of Mental Disorders (DSM) diagnosis should be determined and documented. The evaluation should also include examination of both psychological comorbidities and psychological risk factors that are empirically associated with poor outcome and/or delayed recovery. An individual with a Ph.D., Psy.D, or psychiatric M.D./D.O. credentials should perform initial evaluations, which are generally completed within one to two hours. A professional fluent in the primary language of the patient is preferred. When such a provider is not available, services of a professional language interpreter should be provided.

i. Frequency: one-time visit for the clinical interview. If psychometric testing is indicated as a part of the initial evaluation, time for such testing should not exceed an additional two hours of professional time.

(a). Clinical Evaluation: All chronic pain patients should have a clinical evaluation that addresses the following areas:

(i). History of Injury—The history of the injury should be reported in the patient's words or using similar terminology. Caution must be exercised when using translators.

[a]. nature of injury;

[b]. psychosocial circumstances of the injury;

[c]. current symptomatic complaints;

[d]. extent of medical corroboration;

[e]. treatment received and results;

[f]. compliance with treatment;

[g]. coping strategies used, including perceived locus of control;

[h]. perception of medical system and employer;

[i]. history of response to prescription medications.

(ii). Health History

[a]. nature of injury;

[b]. medical history;

[c]. psychiatric history;

[d]. history of alcohol or substance abuse;

[e]. activities of daily living;

[f]. mental status exam;

[g]. previous injuries, including disability, impairment, and compensation

(iii). Psychosocial History

[a]. childhood history, including abuse;

[b]. educational history;

[c]. family history, including disability;

[d]. marital history and other significant adulthood activities and events;

[e]. legal history, including criminal and civil litigation;

[f]. employment and military history;

[g]. signs of pre-injury psychological dysfunction;

[h]. current interpersonal relations, support, living situation;

[i]. financial history.

(iv). Psychological test results, if performed

(v). Danger to self or others.

(vi). Current psychiatric diagnosis consistent with the standards of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders.

(vii). Pre-existing psychiatric conditions. Treatment of these conditions is appropriate when the pre-existing condition affects recovery from chronic pain.

(viii). Causality (to address medically probable cause and effect, distinguishing pre-existing psychological symptoms, traits and vulnerabilities from current symptoms).

(ix). Treatment recommendations with respect to specific goals, frequency, timeframes, and expected outcomes.

(b). Tests of Psychological Functioning: Psychometric Testing is a valuable component of a consultation to assist the physician in making a more effective treatment plan. Psychometric testing is useful in the assessment of mental conditions, pain conditions, cognitive functioning, treatment planning, vocational planning, and evaluation of treatment effectiveness. There is no general agreement as to which standardized psychometric tests should be specifically recommended for psychological evaluations of chronic pain conditions. It is appropriate for the mental health provider to use their discretion and administer selective psychometric tests within their expertise and within standards of care in the community. Some of these tests are available in Spanish and other languages, and many are written at a sixth grade reading level. Examples of frequently used psychometric tests performed include, but not limited to, the following.

(i). Comprehensive Inventories for Medical Patients

[a]. Battery for Health Improvement, 2nd Edition (BHI-2). What it measures – Depression, anxiety and hostility; violent and suicidal ideation; borderline, dependency, chronic maladjustment, substance abuse, conflicts with work, family and physician, pain preoccupation, somatization, perception of functioning and others. Benefits – When used as a part of a comprehensive evaluation, can contribute substantially to the understanding of psychosocial factors underlying pain reports, perceived disability, somatic preoccupation, and help to design interventions. Serial administrations can track changes in a broad range of variables during the course of treatment, and assess outcome.

[b]. Millon Behavioral Medical Diagnostic (MBMD). What it Measures – Updated version of the Millon Behavioral Health Inventory (MBHI). Provides information on Coping Styles (introversive, inhibited, dejected, cooperative, sociable, etc), Health Habits (smoking, drinking, eating, etc.), Psychiatric Indications (anxiety, depression, etc), stress moderators (Illness Apprehension vs. Illness Tolerance, etc), treatment prognostics (Interventional Fragility vs. Interventional Resilience, Medication Abuse vs. Medication Competence, etc) and other factors. Benefits – When used as a part of a comprehensive evaluation, can contribute substantially to the understanding of psychosocial factors affecting medical patients. Understanding risk factors and patient personality type can help to optimize treatment protocols for a particular patient.

[c]. Pain Assessment Battery (PAB). What it measures—collection of four separate measures that are administered together. Emphasis on the assessment of pain, coping strategies, degree and frequency of distress, health-related behaviors, coping success, beliefs about pain, quality of pain experience, stress symptoms analysis, and others. Benefits—When used as a part of a comprehensive evaluation, can contribute substantially to the understanding of patient stress, pain reports and pain coping strategies, and help to design interventions. Serial administrations can track changes in measured variables during the course of treatment, and assess outcome.

ii. Comprehensive Psychological Inventories. These tests are designed for detecting various psychiatric syndromes, but in general are more prone to false positive findings when administered to medical patients.

(a). Millon Clinical Multiaxial Inventory, 3rd Edition (MCMI-III). What it measures—has scales based on

DSM diagnostic criteria for affective, personality, and psychotic disorders and somatization. Benefits—when used as a part of a part of a comprehensive evaluation, can screen for a broad range of DSM diagnoses.

(b). Minnesota Multiphasic Personality Inventory, 2nd Edition (MMPI-2). What it measures—original scale constructs, such as hysteria and psychesthenia are archaic but continue to be useful. Newer content scales include depression, anxiety, health concerns, bizarre mentation, social discomfort, low self-esteem, and almost 100 others. Benefits – When used as a part of a comprehensive evaluation, measure a number of factors that have been associated with poor treatment outcome.

(c). Personality Assessment Inventory (PAI). What it measures—a good measure of general psychopathology. Measures depression, anxiety, somatic complaints, stress, alcohol and drug use reports, mania, paranoia, schizophrenia, borderline, antisocial, and suicidal ideation and more than 30 others. Benefits – When used as a part of a comprehensive evaluation, can contribute substantially to the identification of a wide variety of risk factors that could potentially affect the medical patient.

iii. Brief Multidimensional Screens for Medical Patients. Treating providers, to assess a variety of psychological and medical conditions, including depression, pain, disability and others, may use brief instruments. These instruments may also be employed as repeated measures to track progress in treatment, or as one test in a more comprehensive evaluation. Brief instruments are valuable in that the test may be administered in the office setting and hand scored by the physician. Results of these tests should help providers distinguish which patients should be referred for a specific type of comprehensive evaluation.

(a). Brief Battery for Health Improvement, 2nd Edition (BBHI-2). What it measures – Depression, anxiety, somatization, pain, function, and defensiveness. Benefits – Can identify patients needing treatment for depression and anxiety, and identify patients prone to somatization, pain magnification and self-perception of disability. Can compare the level of factors above to other pain patients and community members. Serial administrations can track changes in measured variables during the course of treatment, and assess outcome.

(b). Multidimensional Pain Inventory (MPI). What it measures—interference, support, pain severity, life-control, affective distress, response of significant other to pain, and self-perception of disability at home and work, and in social and other activities of daily living. Benefits – Can identify patients with high levels of disability perceptions, affective distress, or those prone to pain magnification. Serial administrations can track changes in measured variables during the course of treatment, and assess outcome.

(c). Pain Patient Profile (P3). What it measures – Assesses depression, anxiety, and somatization. Benefits – Can identify patients needing treatment for depression and anxiety, as well as identify patients prone to somatization. Can compare the level of depression, anxiety and somatization to other pain patients and community members. Serial administrations can track changes in measured variables during the course of treatment, and assess outcome.

(d). SF-36®. What it measures—a survey of general health well-being and functional states. Benefits—assesses a broad spectrum of patient disability reports. Serial administrations could be used to track patient perceived functional changes during the course of treatment, and assess outcome.

(e). Sickness Impact Profile (SIP). What it measures—perceived disability in the areas of sleep, eating, home management, recreation, mobility, body care, social interaction, emotional behavior, and communication. Benefits—assesses a broad spectrum of patient disability reports. Serial administrations could be used to track patient perceived functional changes during the course of treatment, and assess outcome.

(f). McGill Pain Questionnaire (MPQ). What it measures—cognitive, emotional and sensory aspects of pain. Benefits—can identify patients prone to pain magnification. Repeated administrations can track progress in treatment for pain.

(g). McGill Pain Questionnaire—Short Form (MPQ-SF). What it measures—emotional and sensory aspects of pain. Benefits—can identify patients prone to pain magnification. Repeated administrations can track progress in treatment for pain.

(h). Oswestry Disability Questionnaire. What it measures—disability secondary to low back pain. Benefits—can measure patients' self-perceptions of disability. Serial administrations could be used to track changes in self-perceptions of functional ability during the course of treatment, and assess outcome.

(i). Visual Analog Scales (VAS). What it measures—graphical measure of patient's pain report. Benefits—quantifies the patients' pain report. Serial administrations could be used to track changes in pain reports during the course of treatment and assess outcome.

iv. Brief Multidimensional Screens for Psychiatric Patients. These tests are designed for detecting various psychiatric syndromes, but in general are more prone to false positive findings when administered to medical patients.

(a). Brief Symptom Inventory. What it measures: Somatization, obsessive-compulsive, depression, anxiety, phobic anxiety, hostility, paranoia, psychoticism, and interpersonal sensitivity. Benefits: Can identify patients needing treatment for depression and anxiety, as well as identify patients prone to somatization. Can compare the level of depression, anxiety, and somatization to community members. Serial administrations could be used to track changes in measured variables during the course of treatment, and assess outcome.

(b). Brief Symptom Inventory—18 (BSI-18). What it Measures: Depression, anxiety, somatization. Benefits: Can identify patients needing treatment for depression and anxiety, as well as identify patients prone to somatization. Can compare the level of depression, anxiety, and somatization to community members. Serial administrations could be used to track patient perceived functional changes during the course of treatment, and assess outcome.

(c). Symptom Check List 90 (SCL 90). What it measures: Somatization, obsessive-compulsive, depression, anxiety, phobic anxiety, hostility, paranoia, psychoticism,

and interpersonal sensitivity. Benefits: Can identify patients needing treatment for depression and anxiety, as well as identify patients prone to somatization. Can compare the level of depression, anxiety and somatization to community members. Serial administrations could be used to track changes in measured variables during the course of treatment, and assess outcome.

v. Brief Specialized Psychiatric Screening Measures

(a). Beck Depression Inventory (BDI). What it measures: Depression. Benefits: Can identify patients needing referral for further assessment and treatment for depression and anxiety, as well as identify patients prone to somatization. Repeated administrations can track progress in treatment for depression, anxiety, and somatic preoccupation.

(b). Post Traumatic Stress Diagnostic Scale (PDS). What it Measures: Post Traumatic Stress Disorder (PTSD). Benefits: Helps confirm suspected PTSD diagnosis. Repeated administrations can track treatment progress of PTSD patients.

(c). Center of Epidemiologic Studies—Depression Questionnaire. What it measures: Depression. Benefits: Brief self-administered screening test. Requires professional evaluation to verify diagnosis.

(d). Brief Patient Health Questionnaire from PRIME - MD. What it measures: Depression, panic disorder. Benefits: Brief self-administered screening test. Requires professional evaluation to verify diagnosis.

(e). Zung Questionnaire. What it measures: Depression. Benefits: Brief self-administered screening test. Requires professional evaluation to verify diagnosis.

(f) Diagnostic Studies. Imaging of the spine and/or extremities is a generally accepted, well-established, and widely used diagnostic procedure when specific indications, based on history and physical examination, are present. Physicians should refer to individual OWCA guidelines for specific information about specific testing procedures.

(g). Radiographic Imaging, MRI, CT, bone scan, radiography, SPECT and other special imaging studies may provide useful information for many musculoskeletal disorders causing chronic pain. Single Photon Emission Computerized Tomography (SPECT): A scanning technique which may be helpful to localize facet joint pathology and is useful in determining which patients are likely to have a response to facet injection. SPECT combines bone scans & CT Scans in looking for facet joint pathology.

(h). Electrodiagnostic studies may be useful in the evaluation of patients with suspected myopathic or neuropathic disease and may include Nerve Conduction Studies (NCS), Standard Needle Electromyography, or Somatosensory Evoked Potential (SSEP). The evaluation of electrical studies is difficult and should be relegated to specialists who are well trained in the use of this diagnostic procedure.

(i). Special Testing Procedures may be considered when attempting to confirm the current diagnosis or reveal alternative diagnosis. In doing so, other special tests may be performed at the discretion of the physician.

(j). Testing for complex regional pain syndrome (CRPS-I) or sympathetically maintained pain (SMP) is described in the Complex Regional Pain Syndrome/Reflex Sympathetic Dystrophy Medical Treatment Guidelines.

4. Laboratory testing is generally accepted well-established and widely used procedures and can provide useful diagnostic and monitoring information. They may be used when there is suspicion of systemic illness, infection, neoplasia, or underlying rheumatologic disorder, connective tissue disorder, or based on history and/or physical examination. Tests include, but are not limited to:

a. Complete Blood Count (CBC) with differential can detect infection, blood dyscrasias, and medication side effects;

b. Erythrocyte sedimentation rate, rheumatoid factor, antinuclear antigen (ANA), human leukocyte antigen (HLA), and C-reactive protein can be used to detect evidence of a rheumatologic, infection, or connective tissue disorder;

c. Thyroid, glucose and other tests to detect endocrine disorders;

d. Serum calcium, phosphorous, uric acid, alkaline phosphatase, and acid phosphatase can detect metabolic bone disease;

e. Urinalysis to detect bacteria (usually with culture and sensitivity), calcium, phosphorus, hydroxyproline, or hematuria;

f. Liver and kidney function may be performed for baseline testing and monitoring of medications; and,

g. Toxicology Screen and/or Blood Alcohol Level if suspected drug or alcohol abuse.

5. Injections-Diagnostic

a. Spinal Diagnostic Injections:

i. Description—generally accepted, well-established procedures. These injections may be useful for localizing the source of pain, and may have added therapeutic value when combined with injection of therapeutic medication(s). Each diagnostic injection has inherent risks, and risk versus benefit should always be evaluated when considering injection therapy. Since these procedures are invasive, less invasive or non-invasive procedures should be considered first. Selection of patients, choice of procedure, and localization of the level for injection should be determined by clinical information indicating strong suspicion for pathologic condition(s) and the source of pain symptoms.

(a). Because injections are invasive with an inherent risk, the number of diagnostic procedures should be limited in any individual patient to those most likely to be primary pain generators. Patients should not receive all of the diagnostic blocks listed merely in an attempt to identify 100 percent of the pain generators. The interpretation of the test results are primarily based on functional change, symptom report, and pain response (via a recognized pain scale before and at an appropriate time after the injection). The diagnostic significance of the test result should be evaluated in conjunction with clinical information and the results of other diagnostic procedures. Injections with local anesthetics of differing duration may be used to support a diagnosis. In some cases, injections at multiple levels may be required to accurately diagnose cervical conditions. Refer to Injections—therapeutic for information on specific injections. It is obligatory that sufficient data be accumulated by the examiner performing this procedure such that the

diagnostic value of the procedure is evident to other reviewers. This entails, at a minimum, documentation of patient response immediately following the procedure with details of any symptoms with a response and the degree of response. Additionally, a log must be recorded as part of the medical record which documents response, if any, on an hourly basis for, at a minimum, the expected duration of the local anesthetic phase of the procedure. Responses must be identified as to specific body part (e.g., low back, neck, leg, or arm pain). The practitioner must identify the local anesthetic used and the expected duration of response for diagnostic purposes. Multiple injections provided at the same session without staging may seriously dilute the diagnostic value of these procedures. Practitioners must carefully weigh the diagnostic value of the procedure against the possible therapeutic value.

ii. Special Requirements for Diagnostic Injections. Since multi-planar, fluoroscopy during procedures is required to document technique and needle placement, an experienced physician should perform the procedure. Permanent images are required to verify needle placement for all spinal procedures. The subspecialty disciplines of the physicians performing injections may be varied, including, but not limited to: anesthesiology, radiology, surgery, or physiatry. The practitioner who performs spinal injections for low back pain should document hands-on training through workshops of the type offered by organizations such as the International Spine Intervention Society (ISIS) and/or completed fellowship training with interventional training. The practitioner who performs spinal injections for cervical pain should have completed fellowship training in pain medicine with interventional training, or its equivalent. Practitioners performing spinal injections for low back and cervical pain must also be knowledgeable in radiation safety.

iii. Complications. General complications of diagnostic injections may include transient neurapraxia, nerve injury, infection, headache, vasovagal effects, as well as epidural hematoma, permanent neurologic damage, dural perforation and CSF leakage, and spinal meningeal abscess. Severe complications of cervical injections are remote but can include spinal cord damage, quadriplegia, and/or death. Injections at a C2-C3 level frequently cause temporary neuritis with ataxia.

iv. Contraindications. Absolute contraindications to diagnostic injections include: bacterial infection, systemic or localized to region of injection, bleeding diatheses, hematological conditions, and possible pregnancy. Relative contraindications of diagnostic injections may include, allergy to contrast or shellfish, poorly controlled Diabetes Mellitus or and hypertension. Drugs affecting coagulation may require restriction from use. Anti-platelet therapy and anti-coagulations should be addressed individually by a knowledgeable specialist. It is recommended to refer to Am Society of Regional Anesthesia for anticoagulation guidelines.

v. Specific Diagnostic Injections. In general, relief should last for at least the duration of the local anesthetic used and should significantly relieve pain and result in functional improvement. Refer to Therapeutic Injections for information on other specific therapeutic injections. The following injections are used primarily for diagnosis:

(a). Medial Branch Blocks. Medial Branch Blocks are primarily diagnostic injections, used to determine whether a patient is a candidate for radiofrequency medial branch neurotomy (also known as facet rhizotomy). ISIS suggests controlled blocks—using either placebo or anesthetics with varying lengths of activity (i.e., bupivacaine longer than lidocaine). To be a positive diagnostic block, the patient should report a reduction of pain of 50 percent or greater relief from baseline for the length of time appropriate for the local anesthetic used. In almost all cases, this will mean a reduction of pain to 1 or 2 on the visual analog scale (VAS) 10-point scale correlated with functional improvement. The patient should also identify activities of daily living (which may include measurements of range of motion) that are impeded by their pain and can be observed to document functional improvement in the clinical setting. Ideally, these activities should be assessed throughout the observation period for function. The observer should not be the physician who performed the procedure. It is suggested that this be recorded on a form similar to ISIS recommendations. A separate comparative block on a different date should be performed to confirm the level of involvement. A comparative block uses anesthetics of varying lengths of activity. Medial Branch blocks are probably not helpful to determine the likelihood of success for spinal fusion.

(i). Frequency and Maximum Duration: May be repeated once for comparative blocks. Limited to four levels.

(b). Transforaminal Injections/ Selective Nerve Root Blocks are useful in identifying spinal pathology. When performed for diagnosis, small amounts of local anesthetic up to a total volume of 1.0 cc should be used to determine the level of nerve root irritation. A positive diagnostic block should result in a positive diagnostic functional benefit and an 50 percent reduction in nerve-root generated pain appropriate for the anesthetic used as measured by accepted pain scales (such as a VAS).

(i). Time to produce effect: Less than 30 minutes for local anesthesia; corticosteroids up to 72 hours for most patients.

(ii). Frequency and Maximum Duration: Once per suspected level. Limited to two levels.

(c). Zygapophyseal (facet) blocks: Facet blocks are generally accepted but should not be considered diagnostic blocks for the purposes of determining the need for a rhizotomy (radiofrequency medial branch neurotomy), nor should they be done with medial branch blocks. These blocks should not be considered a definitive diagnostic tool. They may be used diagnostically to direct functional rehabilitation programs. A positive diagnostic block should result in a positive diagnostic functional benefit and an 50 percent reduction in pain appropriate for the anesthetic used as measured by accepted pain scales (such as a Visual Analog Scale). They then may be repeated per the therapeutic guidelines when they are accompanied by a functional rehabilitation program. (Refer to Therapeutic Spinal Injections).

(i). Time to produce effect: Less than 30 minutes for local anesthesia; corticosteroids up to 72 hours for most patients

(ii). Frequency and Maximum Duration: Once per suspected level, limited to two levels

(d). Atlanto-Axial and Atlanto-Occipital Injections: are generally accepted for diagnosis and treatment but do not lend themselves to denervation techniques owing to variable neuroanatomy. Injection of this articulation is complicated by the proximity of the vertebral artery, which may be tortuous at the level of the C1 joint. Inadvertent injection of the vertebral artery may cause respiratory arrest, seizure, stroke, or permanent neurological sequelae. Only practitioners skilled in these injections should perform them.

(i). Frequency and Maximum Duration: Once per side

(e). Sacroiliac Joint Injection

(i). Description—a generally accepted injection of local anesthetic in an intra-articular fashion into the sacroiliac joint under fluoroscopic guidance. Long-term therapeutic effect has not yet been established.

(ii). Indications—Primarily diagnostic to rule out sacroiliac joint dysfunction versus other pain generators. Intra-articular injection can be of value in diagnosing the pain generator. There should be documented relief from previously painful maneuvers (e.g., Patrick's test) and at least 50 percent pain relief on post-injection physical exam (as measured by accepted pain scales such as VAS) correlated with functional improvement. Sacroiliac joint blocks should facilitate functionally directed rehabilitation programs.

(iii). Time to produce effect: Up to 30 minutes for local anesthetic

(iv). Frequency and Maximum Duration: 1

b. Other Diagnostic Injections: These injections are frequently employed in assessing the type of pain a patient may be having. They also aid in ascertaining possible mechanisms and origins of the pain as well as the site of the pain source. Some diagnostic injections have therapeutic properties that may be used to both diagnose and treat chronic pain. In those cases, refer to Non-Operative Treatment – Therapeutic Injections for specific information regarding these injections.

i. Description—generally accepted, well-established procedures. These injections may be useful for localizing the source of pain, and may have added therapeutic value when combined with injection of therapeutic medication(s). Each diagnostic injection has inherent risks, and risk versus benefit should always be evaluated when considering injection therapy. Since these procedures are invasive, less invasive or non-invasive procedures should be considered first. Selection of patients, choice of procedure, and localization of the level for injection should be determined by clinical information indicating strong suspicion for pathologic condition(s) and the source of pain symptoms.

ii. The interpretation of the test result is primarily based upon pain response; the diagnostic significance of the test result should be evaluated in conjunction with clinical information and the results of other diagnostic procedures. Injections with local anesthetics of differing duration are required to confirm a diagnosis. In some cases, injections at multiple levels may be required to accurately diagnose pain. Refer to Therapeutic Injections for information on specific injections.

iii. Special Requirements for Diagnostic Injections—Since fluoroscopic, arthrographic and/or CT guidance during procedures is required to document technique and needle placement, an experienced physician should perform the procedure. The subspecialty disciplines of the physicians may be varied, including, but not limited to: anesthesiology, radiology, surgery, or physiatry. The practitioner should have experience in ongoing injection training workshops provided by organizations such as the International Spine Injection Society (ISIS) and be knowledgeable in radiation safety. In addition, practitioners should obtain fluoroscopy training and radiation safety credentialing from their Departments of Radiology, as applicable.

iv. Complications—general complications of diagnostic injections may include transient neurapraxia, nerve injury, infection, headache, vasovagal effects, as well as epidural hematoma, permanent neurologic damage, dural perforation and CSF leakage, and spinal meningeal abscess. Severe complications of cervical injections are remote but can include spinal cord damage, quadriplegia, and/or death.

v. Contraindications—absolute contraindications of diagnostic injections include: bacterial infection—systemic or localized to region of injection; bleeding diatheses; hematological conditions; and possible pregnancy. Relative contraindications of diagnostic injections may include, allergy to contrast or shellfish, poorly controlled Diabetes Mellitus or hypertension, and aspirin/NSAIDs/antiplatelet therapy (drug may be held for three days or more, depending on the medication, prior to injection).

vi. Specific Diagnostic Injections — In general, relief should last for at least the duration of the local anesthetic used and give significant relief of pain. Refer to Therapeutic Injections for information on other specific therapeutic injections. The following injections are used primarily for diagnosis.

(a). Sympathetic Injections: are diagnostic injections that may be used in suspected cases of CRPS-I. Refer to the Complex Regional Pain Syndrome/Reflex Sympathetic Dystrophy Medical Treatment Guidelines for specific information regarding the use of these injections.

(b). Peripheral Nerve Blocks: are diagnostic injections that may be used in for specific nerve injury or entrapment syndromes. Refer to Injections – Therapeutic for detailed information about their use.

6. Special tests are generally well-accepted tests and are performed as part of a skilled assessment of the patients' capacity to return to work, his/her strength capacities, and/or physical work demand classifications and tolerance.

a. Computer-enhanced evaluations: Computer-enhanced evaluations may include isotonic, isometric, isokinetic and/or isoinertial measurement of movement, range of motion, endurance, or strength. Values obtained can include degrees of motion, torque forces, pressures, or resistance. Indications include determining validity of effort, effectiveness of treatment and demonstrated motivation.

These evaluations should not be used alone to determine return to work restrictions.

i. Frequency: One time for evaluation. Can monitor improvements in strength every three to four weeks up to a total of six evaluations.

b. Functional Capacity Evaluation (FCE): is a comprehensive or modified evaluation of the various aspects of function as they relate to the worker's ability to return-to-work. This test may also be known as Physical Capacity Evaluation, Functional Capacity Assessment, and Work Capacity Evaluation. Areas such as endurance, lifting (dynamic and static), postural tolerance, specific range of motion, coordination and strength, worker habits, employability and financial status, as well as psychosocial aspects of competitive employment may be evaluated. Components of this evaluation may include: musculoskeletal screen; cardiovascular profile/aerobic capacity; coordination; lift/carrying analysis; job-specific activity tolerance; maximum voluntary effort; pain assessment/psychological screening; non-material and material handling activities; and (i) validity of effort and reproducibility. Standardized national guidelines (such as National Institute for Occupational Safety and Health (NIOSH)) should be used as the basis for FCE recommendations.

i. Frequency: Can be used initially to determine baseline status. Additional evaluations can be performed to monitor and assess progress and aid in determining the endpoint for treatment.

c. Job Site Evaluation: is a comprehensive analysis of the physical, mental, and sensory components of a specific job. The goal of the Job Site evaluation is to identify any job modification needed to ensure the safety of the employee upon return to work. These components may include, but are not limited to postural tolerance (static and dynamic); aerobic requirements; range of motion; torque/force; lifting/carrying; cognitive demands; social interactions; visual perceptual; environmental requirements of a job; repetitiveness; and essential functions of a job; and ergonomic set up. Job descriptions provided by the employer are helpful but should not be used as a substitute for direct observation.

i. Frequency: One time with additional visits as needed for follow-up per Job Site.

d. Vocational Assessment. The vocational assessment should provide valuable guidance in the determination of future rehabilitation program goals. It should clarify rehabilitation goals, which optimize both patient motivation and utilization of rehabilitation resources. If prognosis for return to former occupation is determined to be poor, except in the most extenuating circumstances, vocational assessment should be implemented within 3 to 12 months post-injury. Declaration of Maximum Medical Improvement should not be delayed solely due to lack of attainment of a vocational assessment.

i. Frequency: One time with additional visits as needed for follow-up

e. Work Tolerance Screening: is a determination of an individual's tolerance for performing a specific job based on a job activity or task. It may include a test or procedure to specifically identify and quantify work-relevant cardiovascular, physical fitness and postural tolerance. It may also address ergonomic issues affecting the patient's return-to-work potential. May be used when a full FCE is not indicated.

i. Frequency: One time for evaluation. May monitor improvements in strength every three to four weeks up to a total of 6 evaluations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1685 (June 2011).

§2111. Therapeutic Procedures—Non–Operative

A. Non-operative therapeutic rehabilitation is applied to patients with chronic and complex problems of de-conditioning and functional disability. Treatment modalities may be utilized sequentially or concomitantly depending on chronicity and complexity of the problem, and treatment plans should always be based on a diagnosis utilizing appropriate diagnostic procedures.

B. Before initiation of any therapeutic procedure, the authorized treating physician, employer, and insurer must consider these important issues in the care of the injured worker:

1. Patients undergoing therapeutic procedure(s) should be released or returned to modified or restricted duty during their rehabilitation at the earliest appropriate time. Refer to Return-to-Work in this section for detailed information.

2. Reassessment of the patient's status in terms of functional improvement should be documented after each treatment. If patients are not responding within the recommended time periods, alternative treatment interventions, further diagnostic studies or consultations should be pursued. Continued treatment should be monitored using objective measures such as:

a. return-to-work or maintaining work status;

b. fewer restrictions at work or performing activities of daily living;

c. decrease in usage of medications;

d. measurable functional gains, such as increased range of motion or documented increase in strength;

3. Clinicians should provide and document education to the patient. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of facilitating self-management of symptoms.

4. Psychological or psychosocial screening should be performed on all chronic pain patients.

C. The following procedures are listed in alphabetical order.

1. Acupuncture is an accepted and widely used procedure for the relief of pain and inflammation and there is some scientific evidence to support its use. Credentialed practitioners must perform acupuncture evaluations, with experience in evaluation and treatment of chronic pain patients. The exact mode of action is only partially understood. Western medicine studies suggest that acupuncture stimulates the nervous system at the level of the brain, promotes deep relaxation, and affects the release of neurotransmitters. Acupuncture is commonly used as an alternative or in addition to traditional Western pharmaceuticals. It is commonly used when pain medication is reduced or not tolerated. It may be used as an adjunct to

physical rehabilitation, surgical intervention, and/or as part of multidisciplinary treatment to hasten the return of functional activity. Acupuncture should be performed by licensed practitioners.

a. Acupuncture is the insertion and removal of filiform needles to stimulate acupoints (acupuncture points). Needles may be inserted, manipulated, and retained for a period of time. Acupuncture can be used to reduce pain, reduce inflammation, increase blood flow, increase range of motion, decrease the side effect of medication-induced nausea, promote relaxation in an anxious patient, and reduce muscle spasm. Indications include joint pain, joint stiffness, soft tissue pain and inflammation, paresthesia, post-surgical pain relief, muscle spasm, and scar tissue pain.

i. Time to produce effect: three to six treatments
ii. Frequency: one to three times per week
iii. Optimum duration: one to two months
iv. Maximum duration: 14 treatments

b. Acupuncture with Electrical Stimulation: is the use of electrical current (micro- amperage or milli-amperage) on the needles at the acupuncture site. It is used to increase effectiveness of the needles by continuous stimulation of the acupoint. Physiological effects (depending on location and settings) can include endorphin release for pain relief, reduction of inflammation, increased blood circulation, analgesia through interruption of pain stimulus, and muscle relaxation. It is indicated to treat chronic pain conditions, radiating pain along a nerve pathway, muscle spasm, inflammation, scar tissue pain, and pain located in multiple sites.

i. Time to produce effect: three to six treatments;
ii. Frequency: 1 to 3 times per week;
iii. Optimum duration: 1 to 2 months;
iv. Maximum duration: 14 treatments.

c. Other Acupuncture Modalities: Acupuncture treatment is based on individual patient needs and therefore treatment may include a combination of procedures to enhance treatment effect. Other procedures may include the use of heat, soft tissue manipulation/massage, and exercise. Refer to Active Therapy (Therapeutic Exercise) and Passive Therapy sections (Massage and Superficial Heat and Cold Therapy) for a description of these adjunctive acupuncture modalities.

i. Time to produce effect: three to six treatments;
ii. Frequency: one to three times per week;
iii. Optimum duration: one to two months;
iv. Maximum duration: 14 treatments.

(a). Any of the above acupuncture treatments may extend longer if objective functional gains can be documented or when symptomatic benefits facilitate progression in the patient's treatment program. Treatment beyond 14 treatments must be documented with respect to need and ability to facilitate positive symptomatic or functional gains. Such care should be re-evaluated and documented with each series of treatments.

2. Biofeedback is a generally well-accepted form of behavioral medicine that helps patients learn self-awareness and self-regulation skills for the purpose of gaining greater control of their physiology. Stress-related psychophysiological reactions may arise as a reaction to organic pain and in some cases may cause pain. Electronic instrumentation is used to monitor the targeted physiology and then displayed or fed back to the patient visually, auditorially, or tactilely with coaching by a biofeedback specialist.

a. Indications for biofeedback include individuals who are suffering from musculoskeletal injury where muscle dysfunction or other physiological indicators of excessive or prolonged stress response affects and/or delays recovery. Other applications include training to improve self-management of pain, anxiety, panic, anger or emotional distress, narcotic withdrawal, insomnia/ sleep disturbance, and other central and autonomic nervous system imbalances. Biofeedback is often utilized for relaxation training. Mental health professionals may also utilize it as a component of psychotherapy, where biofeedback and other behavioral techniques are integrated with psychotherapeutic interventions. Biofeedback is often used in conjunction with physical therapy or medical treatment.

b. Recognized types of biofeedback include the following:

i. Electromyogram (EMG): Used for self-management of pain and stress reactions involving muscle tension.

ii. Skin Temperature: Used for self-management of pain and stress reactions, especially vascular headaches.

iii. Respiration Feedback (RFB): Used for self-management of pain and stress reactions via breathing control.

iv. Respiratory Sinus Arrhythmia (RSA): Used for self-management of pain and stress reactions via synchronous control of heart rate and respiration. Respiratory sinus arrhythmia is a benign phenomena which consists of a small rise in heart rate during inhalation, and a corresponding decrease during exhalation. This phenomenon has been observed in meditators and athletes, and is thought to be a psychophysiological indicator of health.

v. Heart Rate Variability (HRV): Used for self-management of stress via managing cardiac reactivity.

vi. Electrodermal Response (EDR,): Used for self-management of stress involving palmar sweating or galvanic skin response.

vii. Electroencephalograph (EEG, QEEG): Used for self-management of various psychological states by controlling brainwaves.

c. The goal in biofeedback treatment is normalizing the physiology to the pre-injury status to the extent possible and involves transfer of learned skills to the workplace and daily life. Candidates for biofeedback therapy or training must be motivated to learn and practice biofeedback and self-regulation techniques. In the course of biofeedback treatment, patient stressors are discussed and self-management strategies are devised. If the patient has not been previously evaluated, a psychological evaluation should be performed prior to beginning biofeedback treatment for chronic pain. The psychological evaluation may reveal cognitive difficulties, belief system conflicts, somatic delusions, secondary gain issues, hypochondriasis, and possible biases in patient self-reports, which can affect biofeedback. Home practice of skills is often helpful for mastery and may be facilitated by the use of home training tapes.

d. Psychologists or psychiatrists, who provide psychophysiological therapy which integrates biofeedback

with psychotherapy, should be either Biofeedback Certification Institute of America (BCIA) certified or practicing within the scope of their training. All other providers of Biofeedback for chronic pain patients must be BCIA certified and shall have their biofeedback treatment plan approved by the authorized treating psychologist or psychiatrist. Biofeedback treatment must be done in conjunction with the patient's psychosocial intervention. Biofeedback may also be provided by unlicensed health care providers, who follow a set treatment and educational protocol. Such treatment may utilize standardized material or relaxation tapes.

i. Time to produce effect: three to four sessions;

ii. Frequency: one to two times per week;

iii. Optimum duration: six to eight sessions;

iv. Maximum duration: 10 to 12 sessions. Treatment beyond 12 sessions must be documented with respect to need, expectation, and ability to facilitate positive symptomatic or functional gains.

3. Disturbances of sleep are common in chronic pain. Although primary insomnia may accompany pain as an independent co-morbid condition, it more commonly occurs secondary to the pain condition itself. Exacerbations of pain often are accompanied by exacerbations of insomnia; the reverse can also occur. Sleep laboratory studies have shown disturbances of sleep architecture in pain patients. Loss of deep slow-wave sleep and increase in light sleep occur and sleep efficiency, the proportion of time in bed spent asleep, is decreased. These changes are associated with patient reports of non-restorative sleep.

a. Many chronic pain patients develop behavioral habits that exacerbate and maintain sleep disturbances. Excessive time in bed, irregular sleep routine, napping, low activity, and worrying in bed are all maladaptive responses that can arise in the absence of any psychopathology. There is some evidence that behavioral modification, such as patient education and group or individual counseling, can be effective in reversing the effects of insomnia. Behavioral modifications are easily implemented and can include:

i. maintaining a regular sleep schedule, retiring and rising at approximately the same time on weekdays and weekends;

ii. avoiding daytime napping;

iii. avoiding caffeinated beverages after lunchtime;

iv. making the bedroom quiet and comfortable, eliminating disruptive lights, sounds, television sets, and keeping a bedroom temperature of about 65°F;

v. avoiding alcohol or nicotine within two hours of bedtime;

vi. avoiding large meals within two hours of bedtime;

vii. exercising vigorously during the day, but not within two hours of bedtime, since this may raise core temperature and activate the nervous system;

viii. associating the bed with sleep and sexual activity only, using other parts of the home for television, reading and talking on the telephone;

ix. leaving the bedroom when unable to sleep for more than 20 minutes, retuning to the bedroom when ready to sleep again.

b. These modifications should be undertaken before sleeping medication is prescribed for long term use.

4. Injections—Therapeutic

a. When considering the use of injections in chronic pain management, the treating physician must carefully consider the inherent risks and benefits. First, it is understood that these injections are seldom meant to be "curative" and when used for therapeutic purposes they are employed in conjunction with other treatment modalities for maximum benefit.

b. Second, education of the patient should include the proposed goals of the injections, expected gains, risks or complications, and alternative treatment.

c. Lastly, reassessment of the patient's status in terms of functional improvement should be documented after each injection and/or series of injections. Any continued use of injections should be monitored using objective measures such as:

i. return-to-work or maintaining work status;

ii. fewer restrictions at work or performing activities of daily living;

iii. decrease in usage of medications;

iv. measurable functional gains, such as increased range of motion for documented increase in strength.

d. Visual analog scales (VAS) provide important subjective data but cannot be used to measure function.

e. The physician must be aware of the possible placebo effect as well as the long-term effects of injections related to the patient's physical and mental status. Strict adherence to contraindications, both absolute and relative, may prevent potential complications. Subjecting the patient to potential risks, i.e., needle trauma, infection, nerve injury, or systemic effects of local anesthetics and corticosteroids, must be considered before the patient consents to such procedures.

i. Spinal Therapeutic Injections

(a). General Description. The following injections are considered to be reasonable treatment for patients with chronic pain. Other injections not listed may be beneficial. Therapeutic spinal injections may be used after initial conservative treatments, such as physical and occupational therapy, medication, manual therapy, exercise, acupuncture, etc., have been undertaken. Therapeutic injections should be used only after imaging studies and diagnostic injections have established pathology. Injections are invasive procedures that can cause serious complications; thus clinical indications and contraindications should be closely adhered to. The purpose of spinal injections is to facilitate active therapy by providing short-term relief through reduction of pain and inflammation. All patients should continue appropriate exercise with functionally directed rehabilitation. Active treatment, which patients should have had prior to injections, will frequently require a repeat of the sessions previously ordered (Refer to Active Therapy). Injections, by themselves, are not likely to provide long-term relief. Rather, active rehabilitation with modified work achieves long-term relief by increasing active ROM, strength, and stability. If the first injection does not provide a diagnostic response with temporary and sustained pain relief substantiated by accepted pain scales, (i.e., 50 percent pain reduction), and improvement in function, similar injections should not be repeated. Cervical injections are invasive procedures that can cause catastrophic

complications. Refer to the Cervical Spine Injury guideline for more specific contraindications.

(b). Special Considerations. For all spinal injections (excluding trigger point, botox and occipital or peripheral nerve blocks) multi-planar fluoroscopy, during procedures is required to document technique and needle placement, and should be performed by a physician experienced in the procedure. Permanent images are required to verify needle placement. The subspecialty disciplines of the physicians may be varied, including, but not limited to: anesthesiology, radiology, surgery, or physiatry. The practitioner who performs injections for low back pain should document hands on training through workshops of the type offered by organizations such as the International Spine Intervention Society (ISIS) and/or completed fellowship training with interventional training. The practitioner who performs injections for cervical pain should have completed fellowship training in pain medicine with interventional training, or its equivalent. Practitioners who perform spinal injections must also be knowledgeable of radiation safety.

(c). Complications. General complications of these spinal injections may include transient neurapraxia, local pain, nerve injury, infection, headache, urinary retention and vasovagal effects; epidural hematoma, permanent neurologic damage, dural perforation and cerebral spinal fluid (CSF) leakage, and/or spinal meningeal abscess may also occur; Permanent paresis, anaphylaxis and arachnoiditis have been rarely reported with the use of epidural steroids. With steroid injections, there may be a dose-dependent suppression of the hypothalamic-pituitary adrenal axis lasting between one and three months. For cervical injections, severe complications are remote but can include spinal cord damage, quadriplegia, and/or death.

(d). Contraindications. Absolute contraindications of therapeutic injections include: bacterial infection – systemic or localized to region of injection; bleeding diatheses; hematological conditions, and possible pregnancy. Relative contraindications may include allergy to contrast or shellfish; poorly controlled Diabetes Mellitus or hypertension. Drugs affecting coagulation may require restriction from use. Anti-platelet therapy and anti-coagulations should be addressed individually by a knowledgeable specialist. It is recommended to refer to the American Society of Regional Anesthesia for anticoagulation guidelines.

(e). Epidural Steroid Spinal Injections

(i). Description—Epidural steroid injections (ESI) deliver corticosteroid into the epidural space. The purpose of ESI is to reduce pain and inflammation, restoring range of motion and thereby facilitating progress in more active treatment programs. ESI uses three approaches: transforaminal, translaminar (midline), and caudal.

(ii). For ESI in the low back, the transforaminal approach is the preferred method for unilateral, single-level pathology and for post-surgical patients. Also for the low back, there is good evidence that the transforaminal approach can deliver medication to the target tissue with few complications and can be used to identify the specific site of pathology. The interlaminar approach is the preferred approach for multi-level pathology or spinal stenosis in the lumbar spine. Caudal therapeutic injections may be used, but it is difficult to target the exact treatment area, due to diffuse distribution.

(iii). Needle Placement—Multi-planar fluoroscipic imaging is required for all transforaminal epidural steroid injections. Contrast epidurograms allow one to verify the flow of medication into the epidural space. Permanent images are required to verify needle placement.

(iv). Indications—There is some evidence that epidural steroid injections are effective for patients with radicular pain or radiculopathy (sensory or motor loss in a specific dermatome or myotome). Although there is no evidence regarding the effectiveness of ESI for non-radicular pain, it is a generally accepted intervention. Only patients who have pain affected by activity and annular tears verified by appropriate imaging may have injections for axial pain.

(v). There is some evidence that ESI injections in the low back are not effective for spinal stenosis without radicular findings. Additionally, there is some evidence in studies of the lumbar spine that patients who smoke or who have pain unaffected by rest or activity are less likely to have a successful outcome from ESIs.

[a]. Time to produce effect: Local anesthetic, less than 30 minutes; corticosteroid, 48 to 72 hours for 80 percent of patients and 72 hours to 2 weeks for 20 percent of patients.

[i]. Frequency: One or more divided levels can be injected in one session. Whether injections are repeated depends upon the patient's response to the previous injection. Subsequent injections may occur after 1 to 2 weeks if there is a positive patient response. Positive patient response results are defined primarily as functional gains that can be objectively measured. Objective functional gains include, but are not limited to, positional tolerances, range of motion (ROM), strength, endurance, activities of daily living, cognition, psychological behavior, and efficiency/velocity measures that can be quantified. Subjective reports of pain response (via a recognized pain scale) and function should be considered and given relative weight when the pain has anatomic and physiologic correlation. Anatomic correlation must be based on objective findings.

[b]. Injections can be repeated after a hiatus of six months if the patient has demonstrated functional gain and pain returns or worsens. If the first injection does not provide a diagnostic response of temporary and sustained pain relief (at least two to six weeks) substantiated by accepted pain scales (i.e., 50 percent pain reduction as measured by tools such as VAS) and improvement in function, similar injections should not be repeated.

[c]. Optimum: Usually one up to three injection(s) over a period of six months, depending upon each patient's response and functional gain.

[d]. Maximum: Two sessions (consisting of up to three injections each) may be done in one year based upon the patient's response to pain and function. Patients should be reassessed after each injection session for a 50 percent improvement in pain (as measured by accepted pain scales) and evidence of functional improvement.

(f). Zygapophyseal (Facet) Injection

(i). Description – A generally accepted intra-articular or pericapsular injection of local anesthetic and corticosteroid. Medial branch nerve blocks may be diagnostic only. There is conflicting evidence to support a long-term therapeutic effect using facet injections. There is no justification for a combined facet and medial branch block.

(ii). Indications – Patients with pain, suspected to be facet in origin based on exam findings; and affecting activity; or patients who have refused a rhizotomy; or patients who have facet findings with a thoracic component. In these patients, facet injections may be occasionally useful in facilitating a functionally-directed rehabilitation program and to aid in identifying pain generators. Patients with recurrent pain should be evaluated with more definitive diagnostic injections, such as medial nerve branch injections, to determine the need for a rhizotomy. Because facet injections are not likely to produce long-term benefit by themselves and are not the most accurate diagnostic tool, they should not be performed at more than two levels.

(iii). Facet injections may be repeated if they result in increased documented functional benefit for at least four to six weeks and at least an 50 percent initial improvement in pain as measured by accepted pain scales (such as VAS).

[a]. Time to produce effect: Up to 30 minutes for local anesthetic; corticosteroid up to 72 hours.

[b]. Frequency: one injection per level with a diagnostic response. If the first injection does not provide a diagnostic response of temporary and sustained pain relief substantiated by accepted pain scales, (i.e., 50 percent pain reduction substantiated by tools such as VAS), and improvement in function, similar injections should not be repeated. At least four to six weeks of functional benefit should be obtained with each therapeutic injection.

[c]. Optimum duration: two to three injections for each applicable joint per year. Not to exceed two joint levels.

[d]. Maximum Duration: four per level per year. Prior authorization must be obtained for injections beyond two levels.

(g). Sacroiliac Joint Injection

(i). Description – A generally accepted injection of local anesthetic in an intra-articular fashion into the sacroiliac joint under radiographic guidance. May include the use of corticosteroids. Long-term therapeutic effect has not yet been established.

(ii). Indications – Primarily diagnostic to rule out sacroiliac joint dysfunction vs. other pain generators. Intra-articular injection can be of value in diagnosing the pain generator. There should be documented relief from previously painful maneuvers (e.g., Patrick's test) on post-injection physical exam. These injections may be repeated if they result in increased documented functional benefit for at least 6 weeks and at least an 50 percent initial improvement in pain scales as measured by accepted pain scales (such as VAS). Sacroiliac joint blocks should facilitate a functionally directed rehabilitation program.

[a]. Time to produce effect: Approximately 30 minutes for local anesthetic; 48 to 72 hours for corticosteroid.

[b]. Frequency and Optimum Duration: two injections per year. If the first injection does not provide a diagnostic response of temporary and sustained pain relief substantiated by accepted pain scales, (i.e., 80 percent pain reduction substantiated by tools such as VAS), and improvement in function, similar injections should not be repeated. At least six weeks of functional benefit should be obtained with each therapeutic injection.

[c]. Maximum Duration: three injections per year.

ii. Trigger Point Injections

(a). Description – Trigger point injection consists of dry needling or injection of local anesthetic with or without corticosteroid into highly localized, extremely sensitive bands of skeletal muscle fibers that produce local and referred pain when activated. Medication is injected in the area of maximum tenderness. Injection efficacy can be enhanced if injections are immediately followed by myofascial therapeutic interventions, such as vapo-coolant spray and stretch, ischemic pressure massage (myotherapy), specific soft tissue mobilization and physical modalities. The effectiveness of trigger point injection is uncertain, in part due to the difficulty of demonstrating advantages of active medication over injection of saline. Needling alone may be responsible for some of the therapeutic response.

(b). Indications – Trigger point injections may be used to relieve myofascial pain and facilitate active therapy and stretching of the affected areas. They are to be used as an adjunctive treatment in combination with other active treatment modalities. Trigger point injections should be utilized primarily for the purpose of facilitating functional progress. Patients should continue in an aggressive aerobic and stretching therapeutic exercise program as tolerated throughout the time period they are undergoing intensive myofascial interventions. Trigger point injections are indicated in those patients where well-circumscribed trigger points have been consistently observed, demonstrating a local twitch response characteristic radiation of pain pattern and local autonomic reaction, such as persistent hyperemia following palpation. Generally, these injections are not necessary unless consistently observed trigger points are not responding to specific, noninvasive, myofascial interventions within approximately a four-week timeframe.

(c). Complications – Potential but rare complications of trigger point injections include infection, pneumothorax, anaphylaxis, penetration of viscera, neurapraxia and neuropathy. If corticosteroids are injected in addition to local anesthetic, there is a risk of local myopathy developing. Severe pain on injection suggests the possibility of an intraneural injection, and the needle should be immediately repositioned.

(i). Time to produce effect: Local anesthetic 30 minutes; 24 to 48 hours for no anesthesia.

(ii). Frequency: Weekly. Suggest no more than four injection sites per session per week to avoid significant post-injection soreness.

(iii). Optimum duration: four sessions.

(iv). Maximum duration: eight weeks. Some patients may require two to four repetitions of trigger point injection series over a one to two year period.

(v). Botulinum Toxin (Botox) Injection:

[a]. Description – Used to temporarily weaken or paralyze muscles. May reduce muscle pain in conditions associated with spasticity, dystonia, or other types of painful muscle spasm. Neutralizing antibodies develop in at least four percent of patients treated with botulinum toxin type A, rendering it ineffective. Several antigenic types of botulinum toxin have been described. Botulinum toxin type B, first approved by the Food and Drug Administration (FDA) in 2001, is similar pharmacologically to botulinum toxin type A, and there is good evidence of its efficacy in improving function in cervical dystonia (torticollis). It appears to be effective in patients who have become resistant to the type A toxin. The immune responses to botulinum toxins type A and B are not cross-reactive, allowing type B toxin to be used when type A action is blocked by antibody. Experimental work with healthy human volunteers suggests that muscle paralysis from type B toxin is not as complete or as long lasting as that resulting from type A. The duration of treatment effect of botulinum toxin type B for cervical dystonia has been estimated to be 12 to 16 weeks. EMG needle guidance may permit more precise delivery of botulinum toxin to the target area.

[b]. Indications – To improve range of motion and reduce painful muscle spasm. May be useful in musculoskeletal conditions associated with muscle spasm or headaches. There should be evidence of limited range of motion prior to the injection. May be useful in central neurologic conditions that produce spasticity or dystonia (e.g., brain injury, spinal cord injury, or stroke).

[c]. Complications – Over-weakening of injected muscles, allergic reaction to medications. Rare systemic effects include flu-like syndrome, weakening of distant muscle. There is an increased risk of systemic effects in patients with motor neuropathy or disorders of the neuromuscular junction.

[i]. Time to produce effect: 24 to 72 hours post injection with peak effect by four to six weeks.

[ii]. Frequency: No less than three months between re-administration.

[iii]. Optimum duration: three to four months.

[iv]. Maximum duration: Currently unknown. Repeat injections should be based upon functional improvement and therefore used sparingly in order to avoid development of antibodies that might render future injections ineffective.

5. Interdisciplinary rehabilitation programs: are the gold standard of treatment for individuals with chronic pain who have not responded to less intensive modes of treatment. In addition, there are current studies to support the use of pain programs. There is strong evidence that interdisciplinary programs improve function in chronic pain and moderate evidence that these programs decrease pain in these patients.

a. These programs should assess the impact of pain and suffering on the patient's medical, physical, psychological, social, and/or vocational functioning. In general, interdisciplinary programs deal with irreversible, painful musculoskeletal, neurological, and other chronic painful disorders and psychological issues, including drug dependence, high levels of stress and anxiety, failed surgery and pre-existing or latent psychopathology. The number of professions involved in the team in a chronic pain program may vary due to the complexity of the needs of the person served. The OWCA recommends consideration of referral to an interdisciplinary program within 6 months post-injury in patients with delayed recovery unless surgical interventions or other medical complications intervene.

b. Chronic pain patients need to be treated within a continuum of treatment intensity. Chronic pain programs are available with services provided by a coordinated interdisciplinary team within the same facility (formal) or as coordinated by the authorized treating physician (informal). Formal programs are able to provide coordinated, high intensity level of services and are recommended for most chronic pain patients who have received multiple therapies during acute management. Informal programs offer a lesser intensity of service and may be considered for patients who are currently employed, those who cannot attend all day programs, those with language barriers, or those living in areas not offering formal programs. Before treatment has been initiated, the patient, physician, and insurer should agree on treatment approach, methods, and goals. Generally the type of program needed will depend on the degree of impact the pain has had on the patient's medical, physical, psychological, social and/or vocational functioning.

c. When referring a patient for formal interdisciplinary pain rehabilitation or Work Hardening programs, the OWCA recommends the programs be Commission on Accreditation of Rehabilitation Facilities (CARF) eligible and/or certified. CARF eligibility or certification ensures that programs meet specific care standards of design and efficacy.

d. Inpatient Pain Rehabilitation Programs are rarely needed but may be necessary for patients with any of the following conditions: High risk for medical instability; Moderate to severe impairment of physical/functional status; Moderate to severe pain behaviors; Moderate impairment of cognitive and/or emotional status; Dependence on medications from which he or she needs to be withdrawn; and The need for 24-hour supervised nursing.

e. Interdisciplinary pain programs, whether formal or informal, should be comprised of the following dimensions.

i. Communication. To ensure positive functional outcomes, communication between the patient, insurer and all professionals involved must be coordinated and consistent. Any exchange of information must be provided to all professionals, including the patient. Care decisions would be communicated to all.

ii. Documentation. Through documentation by all professionals involved and/or discussions with the patient, it should be clear that functional goals are being actively pursued and measured on a regular basis to determine their achievement or need for modification.

iii. Treatment Modalities. Use of modalities may be necessary early in the process to facilitate compliance with and tolerance to therapeutic exercise, physical conditioning, and increasing functional activities. Active treatments should be emphasized over passive treatments. Active treatments should encourage self-coping skills and management of pain, which can be continued independently at home or at work. Treatments that can foster a sense of dependency by the patient on the caregiver should be

avoided. Treatment length should be decided based upon observed functional improvement. For a complete list of Active and Passive Therapies, refer to those subparagraphs in this guideline. All treatment timeframes may be extended based upon the patient's positive functional improvement.

iv. Therapeutic Exercise Programs. There is strong evidence that these programs, including aerobic conditioning and strengthening, are superior to treatment programs that do not include exercise. There is no sufficient evidence to support the recommendation of any particular exercise regimen over any other exercise regimen. A therapeutic exercise program should be initiated at the start of any treatment rehabilitation. Such programs should emphasize education, independence, and the importance of an on-going exercise regime.

v. Return-to-work: The authorized treating physician should continually evaluate the patient for their potential to return to work. When return-to-work is an option, it may be appropriate to implement a Work Hardening Program (as described in this section). For patients currently employed, efforts should be aimed at keeping them employed. For more specific information regarding return-to-work, refer to the Return-to-work section in this guideline.

vi. Patient Education: Patients with pain need to re-establish a healthy balance in lifestyle. All providers should educate patients on how to overcome barriers to resuming daily activity, including pain management, decreased energy levels, financial constraints, decreased physical ability, and change in family dynamics.

vii. Psychosocial Evaluation and Treatment: Psychosocial evaluation should be initiated, if not previously done. Providers of care should have a thorough understanding of the patient's personality profile; especially if dependency issues are involved. Psychosocial treatment may enhance the patient's ability to participate in pain treatment rehabilitation, manage stress, and increase their problem-solving and self-management skills.

viii. Vocational Assistance: Vocational assistance can define future employment opportunities or assist patients in obtaining future employment. Refer to Return-to-work section for detailed information.

f. Interdisciplinary programs are characterized by a variety of disciplines that participate in the assessment, planning, and/or implementation of the treatment program. These programs are for patients with greater levels of perceived disability, dysfunction, de-conditioning and psychological involvement. The following programs are listed in order of decreasing intensity.

i. Formal Rehabilitation Programs:

(a). Interdisciplinary Pain Rehabilitation: An Interdisciplinary Pain Rehabilitation Program provides outcomes-focused, coordinated, goal-oriented interdisciplinary team services to measure and improve the functioning of persons with pain and encourage their appropriate use of health care system and services. The program can benefit persons who have limitations that interfere with their physical, psychological, social, and/or vocational functioning. The program shares information about the scope of the services and the outcomes achieved with patients, authorized providers, and insurers.

(b). The interdisciplinary team maintains consistent integration and communication to ensure that all interdisciplinary team members are aware of the plan of care for the patient, are exchanging information, and implement the plan of care. The team members make interdisciplinary team decisions with the patient and then ensure that decisions are communicated to the entire care team.

(c). The medical director of the pain program should be board certified in his or her specialty area, have at least two years full-time experience in an interdisciplinary pain rehabilitation program, and ideally be board certified in pain management. Individuals who assist in the accomplishment of functional, physical, psychological, social and vocational goal must include, at the least, a medical director, pain physician(s), psychologist, Biofeedback Therapist, Occupational Therapist, Physical Therapist, and Registered Nurse. Other disciplines on the team may include, but are not limited to, case manager, exercise physiologist, psychiatrist, and/or nutritionist.

(i). Time to produce effect: three to four weeks;

(ii). Frequency: No less than five hours/day, five days/week;

(iii). Optimum duration: three to four weeks five times a week, followed by six to nine weeks of follow-up one to three times a week;

(iv). Maximum duration: four months, including follow-up. Periodic review and monitoring thereafter on an as needed basis, is founded upon the documented maintenance of functional gains.

(d). Work Hardening is an interdisciplinary program addressing a patient's employability and return-to-work. It includes a progressive increase in the number of hours per day that a patient completes work simulation tasks until the patient can tolerate a full workday. A full workday is case specific and is defined by the previous employment of the patient. This is accomplished by addressing the medical, psychological, behavioral, physical, functional, and vocational components of employability and return-to-work.

(e). The interdisciplinary team should, at a minimum, be comprised of a qualified medical director who is board certified with documented training in occupational rehabilitation, team physicians having experience in occupational rehabilitation, occupational therapy, physical therapy, case manager, and psychologist. As appropriate, the team may also include: chiropractor, RN, or vocational specialist.

(i). Time to produce effect: two weeks;

(ii). Frequency: two to five visits per week, up to eight hours/day;

(iii). Optimum duration: two to four weeks;

(iv). Maximum duration: six weeks. Participation in a program beyond six weeks must be documented with respect to need and the ability to facilitate positive symptomatic or functional gains.

ii. Informal Rehabilitation Program: A Coordinated Interdisciplinary Pain Rehabilitation Program is one in which the authorized treating physician coordinates all aspects of care. This type of program is similar to the formal programs in that it is goal oriented and provides interdisciplinary rehabilitation services to manage the needs

of the patient in the following areas, functional; medical; physical; psychological; social; and vocational.

(a). This program is different from a formal program in that it involves lesser frequency and intensity of services/treatment. Informal rehabilitation is geared toward those patients who do not need the intensity of service offered in a formal program or who cannot attend an all-day program due to employment, daycare, language or other barriers.

(b). Patients should be referred to professionals experienced in outpatient treatment of chronic pain. The OWCA recommends the authorized treating physician consult with physicians experienced in the treatment of chronic pain to develop the plan of care.

(i). Time to produce effect: three to eight weeks

(ii). Frequency: two to six hours per day, two to five days each week.

(iii). Optimum duration: 6 to 12 weeks, including follow-up.

(iv). Maximum duration: four months, including follow-up. Periodic review and monitoring thereafter on an as needed basis, is founded upon the documented maintenance of functional gains.

6. Medications. There is no single formula for pharmacological treatment of patients with chronic nonmalignant pain. A thorough medication history, including use of alternative and over the counter medications, should be performed at the time of the initial visit and updated periodically. Appropriate application of pharmacological agents depends on the patient's age, past history (including history of substance abuse), drug allergies and the nature of all medical problems. It is incumbent upon the physician to thoroughly understand pharmacological principles when dealing with the different drug families and their respective side effects, bioavailability profiles, and primary reason for each medication's usage.

a. Control of chronic non-malignant pain is expected to involve the use of medication. Strategies for pharmacological control of pain cannot be precisely specified in advance. Rather, drug treatment requires close monitoring of the patient's response to therapy, flexibility on the part of the prescriber and a willingness to change treatment when circumstances change. Many of the drugs discussed in the medication section were licensed for indications other than analgesia, but are effective in the control of many types of chronic pain. Consensus regarding the use of opioids has generally been reached in the field of cancer pain, where nociceptive mechanisms are generally identifiable, expected survival may be short, and symptomatic relief is emphasized more than functional outcomes. In injured workers, by contrast, central and neuropathic mechanisms frequently overshadow nociceptive processes, expected survival is relatively long, and return to a high level of function is a major goal of treatment. Approaches to pain, which were developed in the context of malignant pain, therefore may not be transferable to chronic non-malignant pain.

b. All medications should be given an appropriate trial in order to test for therapeutic effect. Trials of medication requiring specific therapeutic drug levels may take several months to achieve, depending upon the half-life of the drug. It is recommended that patients with chronic nonmalignant pain be maintained on drugs that have the least serious side effects. For example, patients need to be tried or continued on acetaminophen and/or antidepressant medications whenever feasible as part of their overall treatment for chronic pain. It is recommended that use of opioid analgesic and sedative hypnotic medications in chronic pain patients be used in a very limited manner, with total elimination desirable whenever clinically feasible.

c. The preceding principles do no apply to chronic headache patients. These patients should be referred to a physician specializing in the diagnosis and treatment of headache and facial pain.

d. For the clinician to interpret the following material, it should be noted that drug profiles listed are not complete; dosing of drugs will depend upon the specific drug, especially for off-label use; and not all drugs within each class are listed, and other drugs within the class may be appropriate. Clinicians should refer to informational texts or consult a pharmacist before prescribing unfamiliar medications or when there is a concern for drug interactions.

e. The following drug classes are listed in alphabetical order, not in order of suggested use.

i.. Alpha-Acting Agents: Noradrenergic pain-modulating systems are present in the central nervous system, and the Alpha-2 adrenergic receptor may be involved in the functioning of these pathways. Alpha-2 agonists may act by stimulating receptors in the substantia gelatinosa of the dorsal horn of the spinal cord, inhibiting the transmission of nociceptive signals. Spasticity may be reduced by presynaptic inhibition of motor neurons. Given limited experience with their use, they cannot be considered first-line analgesics, but a trial of their use may be warranted in many cases of refractory pain.

(a). Clonidine (Catapres)

(i). Description – Central Alpha 2 agonist.

(ii). Indications – Sympathetically mediated pain, treatment of withdrawal from opioids.

(iii). Major Contraindications – Severe coronary insufficiency, renal impairment.

(iv). Dosing and Time to Therapeutic Effect – Increase dosage weekly to therapeutic effect.

(v). Major Side Effects – Sedation, orthostatic hypotension, sexual dysfunction, thrombocytopenia, weight gain, agitation, rebound hypertension with cessation.

(vi). Drug Interactions – Beta adrenergics, tricyclic antidepressants.

(vii). Recommended Laboratory Monitoring – Renal function.

(b). Tizanidine (Zanaflex)

(i). Description – Alpha 2 adrenergic agonist.

(ii). Indications – Spasticity, musculoskeletal disorders.

(iii). Major Contraindications – Hepatic disease.

(iv). Dosing and Time to Therapeutic Effect – As needed (PRN) or titrate to effective dose.

(v). Major Side Effects – Hypotension, sedation, hepatotoxicity, hallucinations and psychosis, dry mouth.

(vi). Drug Interactions – Alcohol, oral contraceptives, and acetaminophen. Use with caution with other alpha agonists.

(vii). Recommended Laboratory Monitoring – Hepatic and renal function.

ii. Anticonvulsants: Although the mechanism of action of anticonvulsant drugs in neuropathic pain states remains to be fully defined, they appear to act as nonselective sodium channel blocking agents. A large variety of sodium channels are present in nervous tissue, and some of these are important mediators of nociception, as they are found primarily in unmyelinated fibers and their density increases following nerve injury. While the pharmacodynamic effects of the various anticonvulsant drugs are similar, the pharmacokinetic effects differ significantly. Carbamazepine has important effects as an inducer of hepatic enzymes and may influence the metabolism of other drugs enough to present problems in patients taking more than one drug. Gabapentin and oxcarbazepine, by contrast, are relatively non-significant enzyme inducers, creating fewer drug interactions. Because anticonvulsant drugs may have more problematic side-effect profiles, their use should usually be deferred until antidepressant drugs have failed to relieve pain.

(a). Gabapentin (Neurontin)

(i). Description – Structurally related to gamma-aminobutyric acid (GABA) but does not interact with GABA receptors.

(ii). Indications – Neuropathic pain.

(iii). Relative Contraindications – Renal insufficiency.

(iv). Dosing and Time to Therapeutic Effect – Dosage may be increased over several days.

(v). Major Side Effects – Confusion, sedation.

(vi). Drug Interactions – Oral contraceptives, cimetidine, antacids.

(vii). Recommended Laboratory Monitoring – Renal function.

(b). Oxcarbazepine (Trileptal)

(i). Description – The mechanism of action resembles that of carbamazepine, but has an advantage in being a less potent inducer of hepatic enzymes. Controlled trials of its effectiveness in chronic pain are lacking.

(ii). Indications – Neuropathic pain.

(iii). Major Contraindications – Hypersensitivity to carbamazepine.

(iv). Dosing and Time to Therapeutic Effect – Dosage may be increased weekly.

(v). Major Side Effects – Sedation, visual disturbances.

(vi). Drug Interactions – Oral contraceptives, valproic acid, carbamazepine.

(vii). Recommended Laboratory Monitoring – Drug levels, renal and hepatic function.

(c). Carbamazepine (Tegretol)

(i). Description – Anticonvulsant structurally related to tricyclic antidepressants.

(ii). Indications – Trigeminal neuralgia and other neuropathic pain.

(iii). Major Contraindications – Bone marrow depression, hypersensitivity to tricyclic antidepressants.

(iv). Dosing and Time to Therapeutic Effect – Dosage levels typically exceed those utilized for seizure prophylaxis. Titrate to desired effect.

(v). Major Side Effects – Aplastic anemia, agranulocytosis, nausea, diplopia, pulmonary sensitivity, inappropriate antidiuretic hormone, dysphoria, disequilibrium.

(vi). Drug Interactions – Many interactions have been reported including, but not limited to, macrolide antibiotics, valproic acid, SSRI's, propoxyphene, doxycycline, bupropion, anticoagulants, and acetaminophen.

(vii). Recommended Laboratory Monitoring – Drug levels, renal and hepatic function, complete blood count.

iii. Antidepressants: are classified into a number of categories based on their chemical structure and their effects on neurotransmitter systems. Their effects on depression are attributed to their actions on disposition of norepinephrine and serotonin at the level of the synapse; although these synaptic actions are immediate, the symptomatic response in depression is delayed by several weeks. When used for chronic pain, the effects may in part arise from treatment of underlying depression, but may also involve additional neuromodulatory effects on endogenous opioid systems, raising pain thresholds at the level of the spinal cord.

(a). Pain responses may occur at lower drug doses with shorter times to symptomatic response than are observed when the same compounds are used in the treatment of mood disorders. Neuropathic pain, diabetic neuropathy, post-herpetic neuralgia, and cancer-related pain may respond to antidepressant doses low enough to avoid adverse effects that often complicate the treatment of depression.

(i). Tricyclics (e.g., amitriptyline [Elavil], nortriptyline [Pamelor, Aventyl], doxepin [Sinequan, Adapin])

[a]. Description – Serotonergics, typically tricyclic antidepressants (TCAs), are utilized for their serotonergic properties as increasing CNS serotonergic tone can help decrease pain perception in non-antidepressant dosages. Amitriptyline is known for its ability to repair Stage 4 sleep architecture, a frequent problem found in chronic pain patients and to treat depression, frequently associated with chronic pain.

[b]. Indications – Chronic musculoskeletal and/or neuropathic pain, insomnia. Second line drug treatment for depression.

[c]. Major Contraindications – Cardiac disease or dysrhythmia, glaucoma, prostatic hypertrophy, seizures, suicide risk.

[d]. Dosing and Time to Therapeutic Effect – Varies by specific tricyclic. Low dosages are commonly used for chronic pain and/or insomnia.

[e]. Major Side Effects – Anticholinergic side effects including, but not limited to, dry mouth, sedation, orthostatic hypotension, cardiac arrhythmia, weight gain.

[f]. Drug Interactions – Tramadol (may cause seizures), Clonidine, cimetidine, sympathomimetics, valproic acid, warfarin, carbamazepine, bupropion, anticholinergics, quinolones.

[g]. Recommended Laboratory Monitoring – Renal and hepatic function. EKG for those on high dosages or with cardiac risk.

iv. Serotonin and norepinephrine reuptakes

(a). Description – SSRIs are characterized by the predominance of inhibition of serotonin reuptake at the pre-synaptic nerve terminal.

(b). Indications – Depression, chronic pain with depression and/or anxiety. Less effective than tricyclic antidepressants for neuropathic pain.

(c). Major Contraindications – Allergy to SSRIs.

(d). Time to Produce Therapeutic Effect – three to four weeks.

(e). Major Side Effects – Insomnia, gastrointestinal (GI) distress, sexual dysfunction.

(f). Drug Interactions – Multiple drug interactions have been reported, including non-sedating antihistamine. May be used in combination with TCAs but therapeutic TCA levels (as used for depression) are known to increase when used in combination with SSRIs and may persist for at lease five weeks after discontinuance. Tramadol should not be used with SSRIs due to potential for seizures.

(g). Recommended Laboratory Monitoring – Renal and hepatic function.

v. Atypical Antidepressants/Other Agents

(a). Description – Venlafaxine, (Effexor), nefazadone (Serzone), trazodone (Deseryl), and mirtazapine (Remeron) share adjuvant analgesic effects with tricyclic antidepressants. They differ in their side effect and drug interaction profiles.

(b). Indications – Venlafaxine is approved for generalized anxiety disorder, bupropion for smoking cessation.

(c). Major Contraindications – Seizures, eating disorders.

(d). Major Side Effects – Depends on the drug, but commonly include GI distress, drowsiness, sexual dysfunction less than other classes except trazadone, which may cause priapism. Hypertension (venlafaxine).

(e). Drug Interactions – Drug specific. Prolongation of cardiac output (QT) interval with rare arrhythmias associated with nefazadone and non-sedating antihistamines.

(f). Recommended Laboratory Monitoring – Drug specific.

vi. Hypnotics and Sedatives: Sedative and hypnotic drugs decrease activity, induce drowsiness, and moderate agitation. Many drugs produce these effects incidental to their usual intended effects, similar to the side effects of many antihistamines and antidepressants. Due to the habit-forming potential of the benzodiazepines and other drugs found in this class, they are not routinely recommended but may be useful in some patients with chronic pain.

(a). Most insomnia in chronic pain patients should be managed primarily through behavioral interventions with medications as secondary measures (refer to Disturbances of Sleep).

(i). Zaleplon (Sonata)

[a]. Description – A nonbenzodiazepine hypnotic.

[b]. Indications – Insomnia.

[c]. Dosing and Time to Therapeutic Effect – Time of onset is 30 to 60 minutes. Due to rapid elimination, may be taken as little as four hours before awakening.

[d]. Major Side Effects – Dizziness, dose-related amnesia.

[e]. Drug Interactions – Increases sedative effect of other central nervous system (CNS) depressant drugs. Use low dose if on cimetidine.

[f]. Recommended Laboratory Monitoring—Hepatic function.

(ii). Zolpidem (Ambien)

[a]. Description – A nonbenzodiazepine hypnotic, which does not appear to cause rebound insomnia. It has little respiratory depression and insignificant anxiolytic or muscle relaxant activity.

[b]. Indications – Short-term use for insomnia

[c]. Time to Therapeutic Effect – Onset of action is 30 to 60 minutes

[d]. Major Side Effects – Dizziness, dose-related amnesia.

[e]. Drug Interactions – Increases sedative effect of other CNS depressant drugs.

[f]. Recommended Laboratory Monitoring – Hepatic function.

vii. Skeletal Muscle Relaxants

(a). Skeletal Muscle Relaxants are most useful for acute musculoskeletal injury or exacerbation of injury. Chronic use of benzodiazepines is discouraged due to their habit-forming potential and due to seizure risk following abrupt withdrawal.

(i). Cyclobenzaprine (Flexeril)

[a]. Description – Structurally related to tricyclics.

[b]. Indications – Chronic pain associated with muscle spasm.

[c]. Major Contraindications – Cardiac dysrhythmias.

[d]. Dosing and Time to Therapeutic Effect – Variable, onset of action is one hour.

[e]. Major Side Effects – Sedation, anticholinergic, blurred vision.

[f]. Drug Interactions – Consider interactions similar to tricyclic antidepressants as listed under antidepressant class.

[g]. Recommended Laboratory Monitoring – Hepatic and renal function.

(ii). Carisoprodol (Soma)

[a]. Description – Mode of action may be central; meprobamate is an active metabolite.

[b]. Indications – Chronic pain associated with muscle spasm.

[c]. Major Contraindications – Sensitivity to meprobamate, renal or hepatic disease.

[d]. Major Side Effects – Sedation, withdrawal symptoms, abuse potential.

[e]. Recommended Laboratory Monitoring – Renal and hepatic function.

(iii). Metazalone (Skelaxin)

[a]. Description – Central acting muscle relaxant.

[b]. Indications – Muscle spasm.

[c]. Major Contraindications – Hepatic disease, pregnancy, and disposition to drug induced hemolytic anemia.

[d]. Dosing and Time to Therapeutic Effect – Onset of action 1 hour.

[e]. Recommended Laboratory Monitoring – Hepatic function.

viii. Opioids

(a). Opioids are the most powerful analgesics. Their use in acute pain and moderate to severe cancer pain is well accepted. Their use in chronic nonmalignant pain, however, is fraught with controversy and lack of scientific research.

(b). Opioids include some of the oldest and most effective drugs used in the control of severe pain. The discovery of opioid receptors and their endogenous peptide ligands has led to an understanding of effects at the binding sites of these naturally occurring substances. Most of their analgesic effects have been attributed to their modification of activity in pain pathways within the central nervous system; however, it has become evident that they also are active in the peripheral nervous system. Activation of receptors on the peripheral terminals of primary afferent nerves can mediate antinociceptive effects, including inhibition of neuronal excitability and release of inflammatory peptides. Some of their undesirable effects on inhibiting gastrointestinal motility are peripherally mediated by receptors in the bowel wall.

(c). The central nervous system actions of these drugs account for much of their analgesic effect and for many of their other actions, such as respiratory depression, drowsiness, mental clouding, reward effects, and habit formation. With respect to the latter, it is crucial to distinguish between three distinct phenomena: tolerance, dependence, and addiction.

(i). Tolerance refers to a state of adaptation in which exposure to a drug over time causes higher doses of that drug to be required in order to produce the same physiologic effect.

(ii). Dependence refers to a set of disturbances in body homeostasis that leads to withdrawal symptoms, which can be produced with abrupt discontinuation, rapid reduction, decreasing blood levels, and/or by administration of an antagonist.

(iii). Addiction is a primary, chronic, neurobiologic disease, with genetic, psychological, and environmental factors influencing its development and manifestations. It is a behavioral pattern of drug craving and seeking which leads to a preoccupation with drug procurement and use.

(d). Tolerance and dependence are physiological phenomena, are expected with the continued administration of opioids, and should not deter physicians from their appropriate use. Before increasing the narcotic dose due to a presumption of physiologic tolerance, the physician should review other possible causes for the decline in analgesic effect. Consideration should be given to possible new psychologic stressors or an increase in the activity of the nociceptive pathways.

(e). The use of opioids is well accepted in treating cancer pain, where nociceptive mechanisms are generally present due to ongoing tissue destruction, expected survival may be short, and symptomatic relief is emphasized more than functional outcomes. In chronic non-malignant pain, by contrast, tissue destruction has generally ceased, meaning that central and neuropathic mechanisms frequently overshadow nociceptive processes. Expected survival in chronic pain is relatively long and return to a high level of function is a major goal of treatment. Therefore, approaches to pain developed in the context of malignant pain may not be transferable to chronic non-malignant pain. Opioids are generally not the best choice of medication for controlling neuropathic pain. Tricylics and anticonvulsants should be tried first.

(f). In most cases, analgesic treatment should begin with acetaminophen, aspirin, and NSAIDs. While maximum efficacy is modest, they may reduce pain sufficiently to permit adequate function. When these drugs do not satisfactorily reduce pain, opioids for moderate to moderately severe pain may be added to (not substituted for) the less efficacious drugs.

(g). Consultation or referral to a pain specialist should be considered when the pain persists but the underlying tissue pathology is minimal or absent and correlation between the original injury and the severity of impairment is not clear. Consider consultation if suffering and pain behaviors are present and the patient continues to request medication, or when standard treatment measures have not been successful or are not indicated.

(i). General Indications – There must be a clear understanding that opioids are to be used for a limited term in the first instance (see trial indications below), that their use is contingent upon certain obligations or goals being met by the patient, e.g., return-to-work, and the patient understands that there may be drug screening to ensure compliance.

(ii). Therapeutic Trial Indications – A therapeutic trial of opioids should not be employed unless the patient has begun or completed a full rehabilitation program. Once this criterion has been met, opioids would be indicated when a patient meets the following:

[a]. The failure of pain management alternatives, including active therapies, cognitive behavioral therapy, pain self-management techniques, and other appropriate medical techniques.

[b]. Physical and psychosocial assessment, performed by two specialists including the authorized treating physician and a specialist with expertise in chronic pain.

[c]. Informed, written, witnessed consent by the patient.

[d]. In addition, there should be documentation of sustained improvement of pain control and/or functional status, including return-to-work, with use of opioids. Frequent follow-up at least every two to four weeks may be necessary to titrate dosage and assess clinical efficacy.

(iii). On-Going, Long-Term Management – Actions should include:

[a]. Prescriptions from a single practitioner,

[b]. Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects,

[c]. Ongoing effort to gain improvement of social and physical function as a result of pain relief,

[d]. Contract detailing reasons for termination of supply, with appropriate tapering of dose,

[e]. Use of random drug screening as deemed appropriate by the prescribing physician,

[f]. Use of more than two opioids: a long acting opioid for maintenance of pain relief and a short acting opioid for limited rescue use when pain exceeds the routine level. If more than two opioids are prescribed for long-term use, a second opinion from specialist who is Board Certified in Neurology, Physical Medicine and Rehabilitation, or Anesthesiology with recognized training and/or certification in pharmacological pain management is strongly recommended.

[g]. Use of acetaminophen-containing medications in patients with liver disease should be limited; and

[h]. Continuing review of overall situation with regard to nonopioid means of pain control.

[i]. Inpatient treatment in complex cases. Refer to Interdisciplinary Rehabilitation Programs for detailed information on in-patient criteria.

(iv). Relative Contraindications – Extreme caution should be used in prescribing controlled substances for workers with one or more "relative contraindications":

[a]. History of alcohol or other substance abuse, or a history of chronic, high-dose benzodiazepine use;

[b]. off work for more than six months;

[c]. severe personality disorder

(v). General Contraindications

[a]. active alcohol or other substance abuse;

[b]. untreated mood or psychotic disorders (e.g., depression);

[c]. decreased physical or mental function with continued opioid use;.

[d]. addictive behaviors. Warning signs include:

[i]. preoccupation with drugs;

[ii]. refusal to participate in medication taper;

[iii]. reporting that nothing but a specific opioid works;

[iv]. strong preference for short-acting over long-acting opioids;

{v}. use of multiple prescribers and pharmacies;

[vi]. use of street drugs or other patients drugs;

[vii]. not taking medications as prescribed;

[viii]. loss of medications more than once; and/or

[ix]. criminal behaviors to obtain drugs, i.e., forged prescriptions.

(vi). Dosing and Time to Therapeutic Effect – Oral route is the preferred route of analgesic administration because it is the most convenient and cost-effective method of administration. When patients cannot take medications orally, rectal and transdermal routes should be considered because they are also relatively noninvasive.

(vii). Major Side Effects – There is great individual variation in susceptibility to opioid-induced side effects and clinicians should monitor for these potential side effects. Common initial side effects include nausea, vomiting, drowsiness, unsteadiness, and confusion. Occasional side effects include dry mouth, sweating, pruritus, hallucinations, and myoclonus. Rare side effects include respiratory depression and psychological dependence. Constipation and nausea/vomiting are common problems associated with long-term opioid administration and should be anticipated, treated prophylactically, and monitored constantly.

(viii). Drug Interactions – Patients receiving opioid agonists should not be given a mixed agonist-antagonist (pentazocine [Talwin], butorphanol [Stadol]) because doing so may precipitate a withdrawal syndrome and increase pain.

(ix). Recommended Laboratory Monitoring – Primary laboratory monitoring is recommended for acetaminophen/aspirin/NSAIDs combinations (renal and liver function, blood dyscrasias). May perform urine and/or blood drug screen if suspect use of other narcotics or lack of compliance with full medication regimen.

(x). Patient Physician Contracts – All patients on chronic opioids should have an informed, written, witnessed consent. The contract should discuss side effects of opioids, results of use in pregnancy, inability to refill lost or missing medication, withdrawal symptoms, requirement for drug testing, and necessity of tapering.

(xi). Potentiating Agents – Some medications appear to potentiate the analgesic effects of opioids. Dextromethorphan is available as a nonopioid non-prescription antitussive agent in numerous cough and cold remedies. It antagonizes N-methyl-D-aspartate receptors involved in central sensitization of pain pathways. It may exert some morphine sparing effects in patients taking morphine, but its activity as an analgesic in neuropathic pain is likely to be weak. It is well tolerated in most patients. Because the patient profiles that might predict response to dextromethorphan are undefined, its use in chronic pain must be empirically tried on an individual basis. Diphenhydramine and hydroxyzine (Atarax, Vistaril) are antihistamines, which act at H1 receptors to alleviate allergic symptoms and produce somnolence. Diphenhydramine is a component of some non-prescription sleeping preparations. Their use in potentiating the effects of analgesic drugs is not clearly defined, but it may be used empirically for this purpose.

ix. Nonsteroidal Anti-Inflammatory Drugs

(a). Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) are useful for pain and inflammation. In mild cases, they may be the only drugs required for analgesia. There are several classes of NSAIDs and the response of the individual injured worker to a specific medication is

unpredictable. For this reason a range of NSAIDs may be tried in each case with the most effective preparation being continued. Patients should be closely monitored for adverse reactions. The US Food and Drug Administration advises all NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. Naproxen sodium does not appear to be associated with increased risk of vascular events. Administration of proton pump inhibitors, histamine 2 blockers, or prostaglandin analog misoprostol along with these NSAIDs may reduce the risk of duodenal and gastric ulceration but do not impact possible cardiovascular complications. Due to the cross-reactivity between aspirin and NSAIDs, NSAIDs should not be used in aspirin-sensitive patients, and should be used with caution in all asthma patients. NSAIDs are associated with abnormal renal function, including renal failure, as well as, abnormal liver function. Certain NSAIDs may have interactions with various other medications. Individuals may have adverse events not listed above. Intervals for metabolic screening are dependent upon the patient's age, general health status and should be within parameters listed for each specific medication. Complete blood count (CBC), liver and renal function should be monitored at least every six months in patients on chronic NSAIDs and initially when indicated.

(i). Non-selective Nonsteroidal Anti-Inflammatory Drugs

[a]. Includes NSAIDs and acetylsalicylic acid (aspirin). Serious GI toxicity, such as bleeding, perforation, and ulceration can occur at any time, with or without warning symptoms in patients treated with traditional NSAIDs. Physicians should inform patients about the signs and/or symptoms of serious gastrointestinal toxicity and what steps to take if they occur. Anaphylactoid reactions may occur in patients taking NSAIDs. NSAIDs may interfere with platelet function. Fluid retention and edema have been observed in some patients taking NSAIDs.

[i]. Optimal duration: one week

[ii]. Maximum duration: one year. Use of these substances long-term (three days per week or greater) is associated with rebound pain upon cessation.

(ii). Selective Cyclo-oxygenase-2 (COX-2) Inhibitors

[a]. COX-2 inhibitors are more recent NSAIDs and differ in adverse side effect profiles from the traditional NSAIDs. The major advantages of selective COX-2 inhibitors over traditional NSAIDs are that they have less gastrointestinal toxicity and no platelet effects. COX-2 inhibitors can worsen renal function in patients with renal insufficiency; thus, renal function may need monitoring.

[b]. COX-2 inhibitors should not be first-line for low risk patients who will be using an NSAID short term but are indicated in select patients for whom traditional NSAIDs are not tolerated. Serious upper GI adverse events can occur even in asymptomatic patients. Patients at high risk for GI bleed include those who use alcohol, smoke, are older than 65, take corticosteroids or anti-coagulants, or have a longer duration of therapy. Celecoxib is contraindicated in sulfonamide allergic patients.

[i]. Optimal duration: 7 to 10 days

[ii]. Maximum duration: Chronic use is appropriate in individual cases. Use of these substances long-term (three days per week or greater) is associated with rebound pain upon cessation.

x. Topical Drug Delivery:

(a). Description – Topical medications may be an alternative treatment for localized musculoskeletal disorders and is an acceptable form of treatment in selected patients although there is no scientific evidence to support its use in chronic pain.

(b). Indications – Generalized musculoskeletal or joint pain. Patient selection must be rigorous to select those patients with the highest probability of compliance.

(c). Dosing and Time to Therapeutic Effect – It is necessary that all topical agents be used with strict instructions for application as well as maximum number of applications per day to obtain the desired benefit and avoid potential toxicity.

(d). Side Effects – Localized skin reactions may occur, depending on drug.

xi. Herbal/Dietary Supplements: Botanical preparations have been used for centuries to remedy human illnesses, but only recently have been subjected to systematic study. Many medications currently manufactured by pharmaceutical firms are derivatives of compounds originally isolated from plants.

(a). Clinical trials of folk remedies have been few in number, and often flawed by methodological problems. The lack of reliable data on the clinical and biological effects of herbal remedies often leads to inappropriate use. Patients commonly use non-standard remedies without discussing them with their physicians; when pharmacological interactions exist between herbs and prescription drugs, adverse effects may follow. Quality control varies between manufacturers, and because herbs are classified as dietary supplements, they are exempt from regulations governing standardization of ingredients. Physicians should ask all patients about their use of herbal medications and dietary supplements.

(i). Description – The following herbs may be appropriate for patients who prefer herbs as an alterative to prescription analgesics or NSAIDs:

[a]. White Willow Bark – There is some evidence of the effectiveness of Salix (willow) bark extract in chronic low back pain. A principal ingredient is salicin, with salicylic acid as the principal metabolite. In doses of 240 mg of salicin daily, willow bark extract is more effective than placebo in alleviating pain and improving scores of physical impairment. This dose is approximately equivalent to 50 mg of acetylsalicylate, which cannot alone account for its analgesic effect. It is well tolerated, with gastrointestinal complaints occurring no more frequently than with placebo. In patients at risk for GI problems from NSAID drugs, willow bark may be an appropriate option.

[b]. Devil's Claw Root – Extract of Hapagophytum procumbens, with the common name of devil's claw root, have been used in parts of Europe for conditions of the musculoskeletal system, including osteoarthritis and low back pain. There is some evidence that it may relieve back pain more effectively than placebo, but functional improvement has not yet been shown. The doses used in clinical trials have consisted of 50 to 100 mg of harpagoside daily. Mild gastrointestinal upset has been reported at higher doses.

[c]. Phytodolor – A standardized extract of Populus tremula (aspen), Fraxinus excelsior (European ash), and Solidago virgaurea (goldenrod), Phytodolor may have anti-inflammatory properties through inhibition of cyclooxygenase pathways. In doses of up to 180 drops per day in 3 divided doses, it has shown superiority to placebo in osteoarthritis and epicondylitis when pain and grip strength were evaluated. Adverse effects were not reported to exceed those of placebo.

[d]. St. John's Wort – An herbal extract of the flowering plant Hypericum perforatum commonly used in the treatment of mild to moderate depression, St. John's Wort has been tested for effectiveness in neuropathic pain. There is some evidence that it lacks effectiveness on pain in polyneuropathy. The OWCA does not recommend its use as an alternative analgesic in chronic pain conditions. There is also some evidence that it is no more effective than placebo in the treatment of major depression. It should not be considered an antidepressant agent in patients requiring medical treatment of depression.

(ii). Specific Drug Interactions – Current regulations prohibit herb manufacturers from claiming that their products treat or prevent disease, but allow them to make claims about the product's effect on body function. Because herbal products are biologically active, they may interact with prescription drugs and with one another. Much of what is known concerning drug interactions is based on case reports or case series, which commonly lack crucial documentation of concomitant medication use or positive identification of herbs involved.

[a]. Physicians should be aware that patients on warfarin should have international normalized ratio (INR) measured a week after starting to take any herbal preparation.

[b]. Ginkgo, ginseng, and garlic are commonly used for reasons unrelated to relief of pain; they interfere with platelet function, and patients who take them should have bleeding times monitored.

[c].St. John's Wort should not be combined with an SSRI, since a serotonin syndrome may result. St. John's Wort induces the CYP3A4 hepatic enzyme, lowering levels of drugs metabolized by this system; these drugs include anticonvulsants, oral contraceptives, antiretroviral, and calcium channel blockers.

[d]. Kava, often used to alleviate anxiety, may potentiate benzodiazepine anxiolytics and produce excess sedation.

[e]. Herbal preparation usage during the perioperative period should be discouraged.

xii. Other Agents:

(a). Tramadol (Ultram)

(i). Description – An opioid partial agonist that is generally well tolerated, does not cause GI ulceration, or exacerbate hypertension or congestive heart failure.

(ii). Indications – Mild to moderate pain relief. This drug has been shown to provide pain relief equivalent to that of commonly prescribed NSAIDs.

(iii). Contraindications – Use cautiously in patients who have a history of seizures or who are taking medication that may lower the seizure threshold, such as MAO inhibitors, SSRIs, and TCAs. Not recommended in those with prior opioid addiction.

(iv). Side Effects – May cause impaired alertness or nausea. This medication has physically addictive properties and withdrawal may follow abrupt discontinuation.

(v). Drug Interactions – Narcotics, sedating medications.

(vi). Recommended Laboratory Monitoring – Renal and hepatic function.

(b). Baclofen (Lioresal)

(i). Description – May be effective due to stimulation of Gamma Aminobutyric Acid (GABA) receptors.

(ii). Indications – Pain from muscle rigidity.

(iii). Side Effects – Development of ovarian cysts, exacerbation of psychotic disorders, may precipitate seizures in epileptics, dry mouth, sexual dysfunction.

(iv). Recommended Laboratory Monitoring – Renal function.

(c). Mexilitene (Mexitil)

(i). Description – An antiarrhythmic drug, which, like some anticonvulsive agents, may act on ion channels in neuronal tissue and reduce its pathological activity to a more stable level. Low concentrations may suffice to abolish impulses in damaged nerves, and mexilitene has been used successfully to treat neuropathic pain.

(ii). Indications – Neuropathic pain.

(iii). Major Contraindications – Heart disease (may depress ventricular function).

(iv). Dosing and Time to Therapeutic Effect – Titrate to therapeutic effect.

(v). Major Side Effects – Tremor, light-headedness, coordination difficulties, and nausea are common dose-related adverse effects that may be reduced by taking with food.

(vi). Drug Interactions – Lidocaine.

(vii). Recommended Laboratory Monitoring – Hepatic function, CBC. Plasma levels may also be necessary.

7. Orthotics/prosthetics/equipment

a. Devices and adaptive equipment may be necessary in order to reduce impairment and disability, to facilitate medical recovery, to avoid re-aggravation of the injury, and to maintain maximum medical improvement. Indications would be to provide relief of the industrial injury or prevent further injury and include the need to control neurological and orthopedic injuries for reduced stress during functional activities. In addition, they may be used to modify tasks through instruction in the use of a device or physical modification of a device. Equipment needs may need to be reassessed periodically. Return-to-work for more detailed information.

b. Equipment may include high and low technology assistive devices, computer interface or seating, crutch or walker training, and self-care aids. It should improve safety and reduce risk of re-injury. Standard equipment to alleviate the effects of the injury on the performance of activities of daily living may vary from simple to complex adaptive devices to enhance independence and safety. Certain equipment related to cognitive impairments may also be required.

c. Ergonomic modifications may be necessary to facilitate medical recovery, to avoid re-aggravation of the injury, and to maintain maximum medical improvement. Ergonomic evaluations with subsequent recommendations may assist with the patients return-to-work. (Refer to Job Site Evaluation for further information.)

d. For chronic pain disorders, equipment such as foot orthoses or lumbar support devices may be helpful. The injured worker should be educated as to the potential harm from using a lumbar support for a period of time greater than which is prescribed. Harmful effects include de-conditioning of the trunk musculature, skin irritation, and general discomfort. Use of cervical collars is not recommended for chronic cervical myofascial pain. Special cervical orthosis and/or equipment may have a role in the rehabilitation of a cervical injury such as those injuries to a cervical nerve root resulting in upper extremity weakness or a spinal cord injury with some degree of paraparesis or tetraparesis. Use of such devices would be in a structured rehabilitation setting as part of a comprehensive rehabilitation program.

e. Fabrication/modification of orthotics, including splints, would be used when there is need to normalize weight-bearing, facilitate better motion response, stabilize a joint with insufficient muscle or proprioceptive/reflex competencies, to protect subacute conditions as needed during movement, and correct biomechanical problems. Orthotic/prosthetic training is the skilled instruction (preferably by qualified providers) in the proper use of orthotic devices and/or prosthetic limbs.

f. For information regarding specific types of orthotics/prosthetics/equipment, refer to individual medical treatment guidelines.

8. Patient Education

a. Patients should be educated on their specific injury, assessment findings, and plan of treatment and encouraged to take an active role in establishing functional outcome goals. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of prolonging the beneficial effects of rehabilitation, as well as facilitating self-management of symptoms and prevention of secondary disability. There is good evidence that patient education in self-management of asthma, anticoagulation, and other diseases improves appropriate use of medications, increases patient satisfaction with care, and reduces unscheduled physician visits for dealing with complications of treatment.

b. Patient education is an interactive process that provides an environment where the patient not only acquires knowledge but also gains an understanding of the application of that knowledge. Therefore, patients should be able to describe and/or will need to be educated on:

i. the treatment plan;

ii. indications for and potential side effects of medications;

iii. their home exercise program;

iv. expected results of treatment;

v. tests to be performed, the reasons for them and their results;

vi. activity restrictions and return-to-work status;

vii. home management for exacerbations of pain;

viii. procedures for seeking care for exacerbations after office hours;

ix. home self-maintenance program;

x. patient responsibility to communicate with all medical providers and the employer; and

xi. patient responsibility to keep appointments.

c. Educational efforts should also target family and other support persons, the case manager, the insurer, and the employer as indicated to optimize the understanding of the patient and the outcome. Professional translators should be provided for non-English speaking patients to assure optimum communication. All education, teaching, and instruction given to the patient should be documented in the medical record.

d. Effects of education weaken over time. Continuing patient education sessions will be required to maximize the patient's function. The effectiveness of educational efforts can be enhanced through attention to the learning style and receptivity of the patient. Written educational materials may reinforce and prolong the impact of verbal educational efforts.

e. Overall, patient education should emphasize health and wellness, return-to-work and return to a productive life.

i. Time to produce effect: Varies with individual patient

ii. Frequency: At each visit

9. Personality/psychological/psychiatric/ psychosocial intervention

a. Psychosocial treatment is a generally accepted, well-established therapeutic and diagnostic procedure with selected use in acute pain problems, but with more widespread use in sub-acute and chronic pain populations. Psychosocial treatment is recommended as an important component in the total management of a patient with chronic pain and should be implemented as soon as the problem is identified. Once a diagnosis consistent with the standards of the American Psychiatric Association Diagnostic Statistical Manual of Mental Disorders has been determined, the patient should be evaluated for the potential need for psychiatric medications. Use of any medication to treat a diagnosed condition may be ordered by the authorized treating physician, psychiatrist or medical psychologist.

b. Visits for management of psychiatric medications are medical in nature and are not a component of psychosocial treatment. Therefore, separate visits for medication management may be necessary, depending upon the patient and medications selected.

c. The screening or diagnostic workup should have clarified and distinguished between pre-existing, aggravated, and/or purely causative psychological conditions. Therapeutic and diagnostic modalities include, but are not limited to, individual counseling, and group therapy. Treatment can occur within an individualized model, a multi-disciplinary model, or within a structured pain management program.

d. A psychologist with a PhD, PsyD, EdD credentials, Medical psychologists , or a Psychiatric MD/DO may perform psychosocial treatments. Other licensed mental health providers working in consultation with a PhD, PsyD, EdD, or Psychiatric MD/DO, and with experience in treating chronic pain disorders in injured workers may also perform treatment.

e. A status report must be provided to the authorized treating physician within two weeks of each visit to facilitate the patient's care. The report should provide documentation of progress towards functional recovery and discussion of the psychosocial issues affecting the patient's ability to participate in treatment. The report should also address pertinent issues such as pre-existing, aggravated, and/or causative, as well as project realistic functional prognosis.

i. Time to produce effect: two to four weeks

ii. Frequency: one to five times weekly for the first four weeks (excluding hospitalization, if required), decreasing to one to two times per week for the second month. Thereafter, two to four times monthly with the exception of exacerbations which may require increased frequency of visits. Not to include visits for medication management.

iii. Optimum duration: two to six months

iv. Maximum duration: 6 to 12 months, not to include visits for medication management. For select patients, longer supervised treatment may be required and, if further counseling beyond six months is indicated, functional progress must be documented.

10. Restriction of activities.

a. Continuation of normal daily activities is the recommendation for chronic pain patients since immobility will negatively affect rehabilitation. Prolonged immobility results in a wide range of deleterious effects, such as a reduction in aerobic capacity and conditioning, loss of muscle strength and flexibility, increased segmental stiffness, promotion of bone demineralization, impaired disc nutrition, and the facilitation of the illness role.

b. Immobility may range from bed rest to the continued use of othoses, such as cervical collars and lumbar support braces. While these interventions may have been ordered in the acute phase, the provider should be aware of their impact on the patient's ability to adequately comply with and successfully complete rehabilitation.

c. Patients should be educated to the detrimental effects of immobility versus the efficacious use of rest periods. Adequate rest allows the patient to comply with active treatment and benefit from the rehabilitation program. In addition complete work cessation should be avoided, if possible, since it often further aggravates the pain presentation and promotes disability. Modified return-to-work is almost always more efficacious and rarely contraindicated in the vast majority of injured workers with chronic pain.

11. Return-to-work

a. Return to work is one of the major components in chronic pain management. Return-to-work is a subject that should be addressed by each workers' compensation provider at the first meeting with the injured employee, and be updated at each additional visit. A return-to-work format should be part of a company's health plan, knowing that return-to-work can decrease anxiety, reduce the possibility of depression, and reconnect the worker with society.

b. Because a prolonged period of time off work will decrease the likelihood of return to work, the first weeks of treatment are crucial in preventing and/or reversing chronicity and disability mindset. In complex cases, experienced nurse case managers may be required to assist in return-to-work. Other services, including psychological evaluation and/or treatment and vocational assistance should be employed.

c. The following should be considered when attempting to return an injured worker with chronic pain to work.

i. Job History Interview: The authorized treating physician should perform a job history interview at the time of the initial evaluation and before any plan of treatment is established. Documentation should include the workers' job demands, stressors, duties of current job, and duties of job at the time of the initial injury. In addition, cognitive and social issues should be identified and treatment of these issues should be incorporated into the plan of care.

ii. Coordination of Care: Management of the case is a significant part of return-to-work and may be the responsibility of the authorized treating physician, occupational health nurse, risk manager, or others. Case management is a method of communication between the primary provider, referral providers, insurer, employer, and employee. Because case management may be coordinated by a variety of professionals, the case manager should be identified in the medical record.

iii. Communication: is essential between the patient, authorized treating physician, employer, and insurer. Employers should be contacted to verify employment status, job duties and demands, and policies regarding injured workers. In addition, availability of temporary and permanent restrictions, for what duration, as well as other placement options should be discussed and documented.

iv. Establishment of a Return-To-Work Status: Return-to-work for persons with chronic pain should be thought of as therapeutic, assuming that work is not likely to aggravate the basic problem or increase the discomfort. In most cases of chronic pain, the worker may not be currently working or even employed. The goal of return-to-work would be to implement a plan of care to return the worker to any level of employment with the current employer or to return them to any type of new employment.

v. Establishment of Activity Level Restrictions: A formal job description for the injured/ill employee who is employed is necessary to identify physical demands at work and assist in the creation of modified duty. A Job Site Evaluation may be utilized to identify tasks such as pushing, pulling, lifting, reaching above shoulder level, grasping, pinching, sitting, standing, posture, ambulatory distance and terrain, and if applicable, environment for temperature, air flow, noise and the number of hours that may be worked per day. Work restriction assigned by the authorized treating physician may be temporary or permanent. The case manager should continue to seek out modified work until restrictions become less cumbersome or as the worker's condition improves or deteriorates.

vi. Rehabilitation and Return-to-work: As part of rehabilitation, every attempt should be made to simulate work activities so that the authorized treating physician may promote adequate job performance. The use of ergonomic or adaptive equipment, therapeutic breaks, and interventional modalities at work may be necessary to maintain employment.

vii. Vocational Assistance: Formal vocational rehabilitation is a generally accepted intervention and can

assist disabled persons to return to viable employment. Assisting patients to identify vocational goals will facilitate medical recovery and aid in the maintenance of MMI by 1) increasing motivation towards treatment and 2) alleviating the patient's emotional distress. Chronic pain patients will benefit most if vocational assistance is provided during the interdisciplinary rehabilitation phase of treatment. To assess the patient's vocational capacity, a vocational assessment may be utilized to identify rehabilitation program goals, as well as optimize both patient motivation and utilization of rehabilitation resources.

d. Recommendations to Employers and Employees of Small Businesses – Employees of small businesses who are diagnosed with chronic pain may not be able to perform any jobs for which openings exist. Temporary employees may fill those slots while the employee functionally improves. Some small businesses hire other workers and if the injured employee returns to the job, the supervisor/owner may have an extra employee. To avoid this, it is suggested that case managers be accessed through their insurer or third party insurers. Case managers may assist with resolution of these problems, as well as assist in finding modified job tasks, or find jobs with reduced hours, etc., depending upon company philosophy and employee needs.

e. Recommendations to Employers and Employees of Mid-Sized and Large Businesses – Employers are encouraged by the OWCA to identify modified work within the company that may be available to injured workers with chronic pain who are returning to work with temporary or permanent restrictions. To assist with temporary or permanent placement of the injured worker, it is suggested that a program be implemented that allows the case manager to access descriptions of all jobs within the organization.

12. Therapy—active.

a. The following active therapies have some evidence to support their use and are widely used and accepted methods of care for a variety of work-related injuries. Active therapy is based on the philosophy that therapeutic exercise and/or activity are beneficial for restoring flexibility, strength, endurance, function, range of motion, and can alleviate discomfort.

b. Active therapy requires an internal effort by the individual to complete a specific exercise or task. This form of therapy requires supervision from a therapist or medical provider such as verbal, visual, and/or tactile instruction(s). Active therapy is intended to promote independence and self-reliance in managing the physical pain as well as to improve the functional status in regard to the specific diagnosis and general conditioning and well-being. At times, a provider may help stabilize the patient or guide the movement pattern but the energy required to complete the task is predominately executed by the patient.

c. Patients should be instructed to continue active therapies at home as an extension of the treatment process in order to maintain improvement levels. Home exercise can include exercise with or without mechanical assistance or resistance and functional activities with assistive devices.

d. The following active therapies are listed in alphabetical order:

i. Activities of Daily Living (ADL): are instruction, active-assisted training, and/or adaptation of activities or equipment to improve a person's capacity in normal daily activities such as self-care, work re-integration training, homemaking, and driving.

(a). Time to produce effect: four to five treatments

(b). Frequency: three to five times per week

(c). Optimum duration: four to six weeks

(d). Maximum duration: six weeks

ii. Aquatic Therapy: is the implementation of active therapeutic procedures in a swimming or therapeutic pool. The water provides a buoyancy force that lessens the amount of force of gravity applied to the body, and the pool should be large enough to allow full extremity range of motion and full erect posture. The decreased gravity effect allows the patient to have a mechanical advantage and more likely have a successful trial of therapeutic exercise. Indications are for individuals who may not tolerate active land-based or full weight bearing therapeutic procedures or who require augmentation of other therapy. Aquatic vests, belts and other devices can be used to provide stability, balance, buoyancy, and resistance.

(a). Time to produce effect: four to five treatments

(b). Frequency: three to five times per week

(c). Optimum duration: four to six weeks

(d). Maximum duration: six weeks

iii. Functional Activities: are the use of therapeutic activity to enhance mobility, body mechanics, employability, coordination, and sensory motor integration.

(a). Time to produce effect: four to five treatments

(b). Frequency: three to five times per week

(c). Optimum duration: four to six weeks

(d). Maximum duration: six weeks

iv. Functional Electrical Stimulation: is the application of electrical current to elicit involuntary or assisted contractions of atrophied and/or impaired muscles. Indications include muscle atrophy, weakness, and sluggish muscle contraction secondary to pain, injury, neuromuscular dysfunction, peripheral nerve lesion, or radicular symptoms. This modality may be prescribed for use at home when patients have demonstrated knowledge of how to self-administer and are in an independent exercise program.

(a). Time to produce effect: two to six treatments

(b). Frequency: three times per week

(c). Optimum duration: eight weeks

(d). Maximum duration: eight weeks. If beneficial, provide with home unit.

v. Lumbar Stabilization: is a therapeutic program whose goal is to strengthen the spine in its neutral and anatomic position. The stabilization is dynamic which allows whole body movements while maintaining a stabilized spine. It is the ability to move and function normally through postures and activities without creating undue vertebral stress. Lumbar stabilization programs can be performed with or without increase in spinal axial loading, on land or in a pool. Indications include lumbar instability, lumbar mechanical pain, lumbar segmental hypermobility, spondylolisthesis, discogenic injury or pain, facet joint injury, or pain after lumbar surgery.

(a). Time to produce effect: four to eight treatments

(b). Frequency: three to five times per week

(c). Optimum duration: four to eight weeks

(d). Maximum duration: eight weeks.

vi. Neuromuscular Re-education: is the skilled application of exercise with manual, mechanical, or electrical facilitation to enhance strength, movement patterns, neuromuscular response, proprioception, kinesthetic sense, coordination, education of movement, balance and posture. Indications include the need to promote neuromuscular responses through carefully timed proprioceptive stimuli, to elicit and improve motor activity in patterns similar to normal neurologically developed sequences, and improve neuromotor response with independent control.

(a). Time to produce effect: two to six treatments

(b). Frequency: three times per week

(c). Optimum duration: four to eight weeks

(d). Maximum duration: eight weeks

vii. Therapeutic Exercise: with or without mechanical assistance or resistance, may include isoinertial, isotonic, isometric and isokinetic types of exercises. Indications include the need for cardiovascular fitness, reduced edema, improved muscle strength, improved connective tissue strength and integrity, increased bone density, promotion of circulation to enhance soft tissue healing, improvement of muscle recruitment, and increased range of motion are used to promote normal movement patterns. Can also include, alternative/complementary exercise movement therapy. Therapeutic exercise programs should be tissue specific to the injury and address general functional deficits as identified in the diagnosis and clinical assessment. Patients should be instructed in and receive a home exercise program that is progressed as their functional status improves. Upon discharge, the patient would be independent in the performance of the home exercise program and would have been educated in the importance of continuing such a program. Educational goals would be to maintain or further improve function and to minimize the risk for aggravation of symptoms in the future.

(a). Time to produce effect: two to six treatments

(b). Frequency: three to five times per week

(c). Optimum duration: four to eight weeks and concurrent with an active daily home exercise program.

(d). Maximum duration: 8 to 12 weeks of therapist oversight. Home exercise should continue indefinitely.

viii.. Work Conditioning: These programs are work-related, outcome-focused, individualized treatment programs. Objectives of the program includes, but are not limited to, improvement of cardiopulmonary and neuromusculoskeletal functions (strength, endurance, movement, flexibility, stability, and motor control functions), patient education, and symptom relief. The goal is for patients to gain full or optimal function and return to work. The service may include the time-limited use of modalities, both active and passive, in conjunction with therapeutic exercise, functional activities, general conditioning body mechanics and lifting techniques re-training. These programs are usually initiated once re-conditioning has been completed but may be offered at any time throughout the recovery phase. It should be initiated when imminent return of a patient to modified or full duty is not an option, but the prognosis for returning the patient to work at completion of the program is at least fair to good.

(a). Length of visit: one to two hours per day

(b). Frequency: two to five visits per week

(c). Optimum duration: two to four weeks

(d). Maximum duration: six weeks. Participation in a program beyond six weeks must be documented with respect to need and the ability to facilitate positive symptomatic or functional gains.

ix. Work Simulation: is a program where an individual completes specific work-related tasks for a particular job and return to work. Use of this program is appropriate when modified duty can only be partially accommodated in the work place, when modified duty in the work place is unavailable, or when the patient requires more structured supervision. The need for work place simulation should be based upon the results of a Functional Capacity Evaluation and/or Job Site Analysis.

(a). Length of visit: two to six hours per day

(b). Frequency: two to five visits per week. Optimum duration: two to four weeks

(c). Maximum duration six weeks. Participation in a program beyond six weeks must be documented with respect to need and the ability to facilitate positive symptomatic or functional gains.

13. Therapy - Passive.

a. Most of the following passive therapies and modalities are generally accepted methods of care for a variety of work-related injuries. Passive therapy includes those treatment modalities that do not require energy expenditure on the part of the patient. They are principally effective during the early phases of treatment and are directed at controlling symptoms such as pain, inflammation and swelling and to improve the rate of healing soft tissue injuries. They should be used adjunctively with active therapies to help control swelling, pain and inflammation during the rehabilitation process. They may be used intermittently as a therapist deems appropriate, or regularly if there are specific goals with objectively measured functional improvements during treatment.

b. Factors such as exacerbation of symptoms, re-injury, interrupted continuity of care and co-morbidities may extend durations of care. Having specific goals with objectively measured functional improvement during treatment can support extended durations of care. It is recommended that if after six to eight visits no treatment effect is observed, alternative treatment interventions, further diagnostic studies or further consultations should be pursued.

c. The following passive therapies are listed in alphabetical order.

i. Electrical Stimulation (Unattended): Electrical stimulation, once applied, requires minimal on-site supervision by the physical or nonphysical provider. Indications include pain, inflammation, muscle spasm, atrophy, decreased circulation, and the need for osteogenic stimulation.

(a). Time to produce effect: two to four treatments

(b). Frequency: Varies, depending upon indication, between two to three times per day to one time week.

(c). Optimum duration: one to three months

(d). Maximum duration: three months. Provide home unit if intended for frequent use.

ii. Infrared Therapy: is a radiant form of heat application. Indications include the need to elevate the pain threshold before exercise and to alleviate muscle spasm to promote increased movement.

(a). Time to produce effect: two to four treatments

(b). Frequency: three to five times per week

(c). Optimum duration: three weeks as primary, or intermittently as an adjunct to other therapeutic procedures up to two months

(d). Maximum duration: two months

iii. Iontophoresis: is the transfer of medication, including, but not limited to, steroidal anti-inflammatories and anesthetics, through the use of electrical stimulation. Indications include pain (Lidocaine), inflammation (hydrocortisone, salicylate), edema (mecholyl, hyaluronidase, salicylate), ischemia (magnesium, mecholyl, iodine), muscle spasm (magnesium, calcium), calcific deposits (acetate), scars and keloids (chlorine, iodine, acetate).

(a). Time to produce effect: two to six treatments

(b). Frequency: 3 times per week with at least 48 hours between treatments

(c). Optimum duration: four to six weeks

(d). Maximum duration: six weeks

iv. Manipulation: is a generally accepted, well-established and widely used therapeutic intervention for pain. Manipulation may include, but is not limited to, high velocity, low amplitude technique (adjustment, grade V mobilization, mobilization with impulse), chiropractic manipulation, osteopathic manipulation, muscle energy techniques, and non-force techniques. It is performed by taking a joint to its end range of motion and moving the articulation into the zone of accessory joint movement, well within the limits of anatomical integrity.

d. The purpose of manipulation in the treatment of chronic pain is to assess the structure and function of the patient and to identify areas of musculoskeletal dysfunction that may be causing, or contributing to, the patient's symptoms.

e. Evaluations for manipulation in the chronic pain patient should be comprehensive, taking into consideration the entire musculoskeletal system and identifying both local and remote factors in the generation of pain and dysfunction. The evaluation should be designed to isolate the presence of dysfunctional entities that will be responsive to manual medicine interventions. Results of the evaluation should assist in the differentiation of biomechanical dysfunction from anatomic pathology, as well as the clinical significance of both as possible pain generators. It is important to consider visceral causes of somatic pain and to rule out organic disease.

f. The physical evaluation involves a direct palpatory examination to assess asymmetries of form and function; alterations in range of motion, including hypermobility and hypomobility; tissue-texture abnormalities, particularly muscular, fascial, and ligamentous structures. Special attention should be given to the presence of restrictions within the expected range of motion (hypomobility) in vertebral segments and the muscular responses to these restrictions. Extremities should also be considered in the physical evaluation. The evaluation may include use of other assessment tools such as Surface EMG, postural analysis, radiographic imaging, and imaging studies.

g. Manipulation may be indicated in patients who have not had an evaluation for manual medicine, or have not progressed adequately in an exercise program. Manipulation should be considered when there is evidence of suspicion of scoliosis, apparent leg length inequality, pelvic imbalance, facet restriction, sacroiliac dysfunction, myofascial dysfunction, gait disturbances, or postural dysfunction.

h. Indications for manipulation include joint pain, decreased joint motion and joint adhesions. Contraindications may include joint instability, fractures, severe osteoporosis, infection, metastatic cancer, active inflammatory arthridites, aortic aneurysm, and signs of new or progressive neurologic deficits.

i. Response to treatment will depend on the appropriate application of procedures used for the clinical condition, the number of body regions involved, the chronicity of the condition, the age and general health of the patient, invasiveness of previous therapeutic interventions, and psychological factors. For chronic pain patients who have not had manipulation previously, providers should refer to the current medical treatment guidelines of the original injury for treatment and timeframe parameters. Daily treatment is usually not indicated unless they have not had any prior manipulation or they have had a recent exacerbation.

i. Time to produce effect: six to six treatments.

ii. Frequency: one to two times per week for the first two weeks as indicated by the severity of the condition. Treatment may continue at one treatment per week for the next six weeks.

iii. Optimum duration: eight weeks.

iv. Maximum duration: eight weeks. At week eight, patients should be reevaluated. Care beyond eight weeks may be indicated for certain chronic pain patients in whom manipulation is helpful in improving function, decreasing pain and improving quality of life. In these cases, treatment may be continued at 1 treatment every other week until the patient has reached MMI and maintenance treatments have been determined. Extended durations of care beyond what is considered "maximum" may be necessary in cases of re-injury, interrupted continuity of care, exacerbation of symptoms, and in those patients with comorbidities. Such care should be re-evaluated and documented on a monthly basis.

v. Massage—Manual or Mechanical. Massage is manipulation of soft tissue with broad ranging relaxation and circulatory benefits. This may include stimulation of acupuncture points and acupuncture channels (acupressure), application of suction cups and techniques that include pressing, lifting, rubbing, pinching of soft tissues by or with the practitioners hands. Indications include edema (peripheral or hard and non-pliable edema), muscle spasm, adhesions, the need to improve peripheral circulation and range of motion, or to increase muscle relaxation and flexibility prior to exercise.

(a). Time to produce effect: Immediate
(b). Frequency: one to two times per week
(c). Optimum duration: six weeks
(d). Maximum duration: two months

vi. Mobilization (Joint): is a generally well-accepted treatment consisting of passive movement involving oscillatory motions to the vertebral segment(s). The passive mobility is performed in a graded manner (I, II, III, IV, or V), which depicts the speed and depth of joint motion during the maneuver. For further discussion on Level V joint mobilization please see section on HVLA manipulation. It may include skilled manual joint tissue stretching. Indications include the need to improve joint play, segmental alignment, improve intracapsular arthrokinematics, or reduce pain associated with tissue impingement. Mobilization should be accompanied by active therapy. For Level V mobilization, contraindications include joint instability, fractures, severe osteoporosis, infection, metastatic cancer, active inflammatory arthritides, and signs of progressive neurologic deficits, myelopathy, vertebrobasilar insufficiency, or carotid artery disease. Relative contraindications include stenosis, spondylosis, and disc herniation.

(a). Time to Produce Effect: six to nine treatments
(b). Frequency: Up to three times per week
(c). Optimum Duration: four to six weeks
(d). Maximum Duration: six weeks

vii. Mobilization (Soft Tissue): is a generally well-accepted treatment. Mobilization of soft tissue is the skilled application of muscle energy, strain/counter strain, myofascial release, manual trigger point release, and other manual therapy techniques designed to improve or normalize movement patterns through the reduction of soft tissue pain and restrictions. These can be interactive with the patient participating or can be with the patient relaxing and letting the practitioner move the body tissues. Indications include muscle spasm around a joint, trigger points, adhesions, and neural compression. Mobilization should be accompanied by active therapy.

(a). Time to Produce Effect: four to nine treatments
(b). Frequency: Up to three times per week
(c). Optimum Duration: four to six weeks
(d). Maximum Duration: six weeks

viii. Superficial Heat and Cold Therapy: Superficial heat and cold are thermal agents applied in various manners that lowers or raises the body tissue temperature for the reduction of pain, inflammation, and/or effusion resulting from injury or induced by exercise. Includes application of heat just above the surface of the skin at acupuncture points. Indications include acute pain, edema and hemorrhage, need to increase pain threshold, reduce muscle spasm and promote stretching/flexibility. Cold and heat packs can be used at home as an extension of therapy in the clinic setting.

(a). Time to produce effect: Immediate
(b). Frequency: two to five times per week
(c). Optimum duration: three weeks as primary or intermittently as an adjunct to other therapeutic procedures up to two months
(d). Maximum duration: two months

ix. Traction Manual. Manual traction is an integral part of manual manipulation or joint mobilization. Indications include decreased joint space, muscle spasm around joints, and the need for increased synovial nutrition and response. Manual traction is contraindicated in patients with tumor, infection, fracture, or fracture dislocation.

(a). Time to produce effect: one to three sessions
(b). Frequency: two to three times per week
(c). Optimum duration: four weeks
(d). Maximum duration: one month

x. Traction—Mechanical: Mechanical traction is indicated for decreased joint space, muscle spasm around joints, and the need for increased synovial nutrition and response. Traction modalities are contraindicated in patients with tumor, infections, fracture, or fracture dislocation. Nonoscillating inversion traction methods are contraindicated in patients with glaucoma or hypertension.

(a). Time to produce effect: 1 to 3 sessions up to 30 minutes. If response is negative after 3 treatments, discontinue this modality.
(b). Frequency: two to three times per week
(c). Optimum duration: four weeks
(d). Maximum duration: one month

xi. Transcutaneous Electrical Nerve Stimulation (TENS): should include least one instructional session for proper application and use. Indications include muscle spasm, atrophy, and decreased circulation and pain control. Minimal TENS unit parameters should include pulse rate, pulse width and amplitude modulation.

(a). Time to produce effect: Immediate
(b). Frequency: Variable
(c). Optimum duration: three sessions. If beneficial, provide with home unit.
(d). Maximum duration: three sessions. Purchase if effective.

xii. Ultrasound: uses sonic generators to deliver acoustic energy for therapeutic thermal and/or nonthermal soft tissue effects. Indications include scar tissue, adhesions, collagen fiber and muscle spasm, and the need to extend muscle tissue or accelerate the soft tissue healing. Ultrasound with electrical stimulation is concurrent delivery of electrical energy that involves dispersive electrode placement. Indications include muscle spasm, scar tissue, pain modulation and muscle facilitation. Phonophoresis is the transfer of medication through the use of sonic generators to the target tissue to control inflammation and pain. These topical medications include, but are not limited to, steroidal anti-inflammatory and anesthetics.

(a). Time to produce effect: 6 to 15 treatments
(b). Frequency: three times per week
(c). Optimum duration: four to 8 weeks
(d). Maximum duration: two months

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1692 (June 2011).

§2113. Therapeutic procedures – Operative

A. When considering operative intervention in chronic pain management, the treating physician must carefully consider the inherent risk and benefit of the procedure. All operative intervention should be based on a positive

correlation with clinical findings, the clinical course, and diagnostic tests. A comprehensive assessment of these factors should have led to a specific diagnosis with positive identification of the pathologic condition.

1. Surgical procedures are seldom meant to be curative and would be employed in conjunction with other treatment modalities for maximum functional benefit. Functional benefit should be objectively measured and includes the following:

a. return-to-work or maintaining work status;

b. fewer restrictions at work or performing activities of daily living;.

c. decrease in usage of medications;

d. measurable functional gains, such as increased range of motion or documented increase in strength;

e. education of the patient should include the proposed goals of the surgery, expected gains, risks or complications, and alternative treatment

2. Neurostimulation

a. Description — Neurostimulation is the delivery of low-voltage electrical stimulation to the spinal cord or peripheral nerves to inhibit or block the sensation of pain. This is a generally accepted procedure that has limited use. May be most effective in patients with chronic, intractable limb pain who have not achieved relief with oral medications, rehabilitation therapy, or therapeutic nerve blocks, and in whom the pain has persisted for longer than six months. Particular technical expertise is required to perform this procedure and is available in some neurosurgical, rehabilitation, and anesthesiology training programs and fellowships. Physicians performing this procedure must be trained in neurostimulation implantation and participate in ongoing injection training workshops, such as those sponsored by the Internal Society for Injection Studies or as sponsored by implant manufacturers.

b. Complications — May include paraplegia, epidural hematoma, epidural hemorrhage, undesirable change in stimulation, seroma, CSF leakage, infection, erosion, allergic response, hardware malfunction or equipment migration, pain at implantation site, loss of pain relief, chest wall stimulation, and other surgical risks.

c. Surgical Indications — Failure of conservative therapy including active and/or passive therapy, medication management, or therapeutic injections. Preauthorization is required. Habituation to narcotic analgesics in the absence of a history of addictive behavior does not preclude the use of neurostimulation. Only patients who meet the following criteria should be considered candidates for neurostimulation:

i. A diagnosis of a specific physical condition known to be chronically painful has been made on the basis of objective findings; and

ii. All reasonable surgical and non-surgical treatment has been exhausted; and

iii. Pre-surgical psychiatric or psychological evaluation has been performed and has demonstrated motivation and long-term commitment without issues of secondary gain; and

iv. There is no evidence of addictive behavior. (Tolerance and dependence to narcotic analgesics are not addictive behaviors and do not preclude implantation.); and

v. The topography of pain and its underlying pathophysiology are amenable to stimulation coverage (the entire painful area has been covered); and

vi. A successful neurostimulation screening test of two-three days. A screening test is considered successful if the patient (a) experiences a 50 percent decrease in pain, which may be confirmed by visual analogue scale (VAS), and (b) demonstrates objective functional gains or decreased utilization of pain medications. Functional gains may be evaluated by an occupational therapist and/or physical therapist prior to and before discontinuation of the trial.

vii. For spinal cord stimulation, a temporary lead is implanted at the level of pain and attached to an external source to validate therapy effectiveness. (For peripheral nerve screening, a nerve block is performed to define the specific nerve branch but if multiple branches are involved, a screening test for spinal cord stimulation may be indicated.) Long-term functional improvement is anticipated when objective functional improvement has been observed during time of neurostimulation screen exam.

d. Contraindications — Unsuccessful neurostimulation test – either inability to obtain functional improvement or reduction of pain, those with cardiac pacemakers, patient unable to properly operate the system. It should not be used if future MRI is planned.

e. Operative Treatment – Implantation of stimulating leads connected by extensions to either an implanted neurostimulator or an implanted receiver powered by an external transmitter. The procedure may be performed either as an open or a percutaneous procedure, depending on the presence of epidural fibrosis and the anatomical placement required for optimal efficacy.

f. Post-Operative Considerations – MRI is contraindicated after placement of neurostimulators.

g. Post-Operative Therapy – Active and/or passive therapy should be employed to improve function. Implantable stimulators will require frequent monitoring such as adjustment of the unit and replacement of batteries.

3. Intrathecal drug delivery

a. Description - This mode of therapy delivers small doses of medications directly into the cerebrospinal fluid. Clinical studies are conflicting regarding long-term, effective pain relief in patients with non-malignant pain. As with other routes of drug administration, escalation of dose may be required. Typically, pump refills are needed every two to three months.

b. Complications - Intrathecal delivery is associated with significant complications, such as infection, catheter disconnects, CSF leak, arachnoiditis, pump failure, nerve injury, and paralysis.

c. General Indications – The OWCA does not routinely recommend the use of Intrathecal Drug Delivery systems in injured workers with chronic pain. It may be considered only in rare cases where all other commonly used methods to control pain have failed and must be based on preauthorization and the recommendation of at least one physician experienced in chronic pain management in consultation with the primary treating physician. Patients should only be selected for intrathecal drug delivery if they have opioid-responsive pain but cannot tolerate the effects of systemic administration. The patient must have good to excellent pain relief with a test dose using a temporary

catheter prior to pump implantation. The patient must be motivated for the procedure, and must understand the potential for complications and requirements of treatment maintenance.

d. Surgical Indications – Failure of conservative therapy including active and/or passive therapy, medication management, or therapeutic injections. Only patients who meet the following criteria should be considered candidates for intraspinal analgesic infusions:

i. A diagnosis of a specific physical condition known to be chronically painful has been made on the basis of objective findings; and

ii. All reasonable surgical and non-surgical treatment has been exhausted; and

iii. Pre-surgical psychiatric or psychological evaluation has been performed and has demonstrated motivation and long-term commitment without issues of secondary gain;

iv. There is no evidence of addictive behavior. (Tolerance and dependence to narcotic analgesics are not addictive behaviors and do not preclude implantation.); and

v. A successful trial of continuous infusion by a percutaneous spinal infusion pump for a minimum of 24 hours. A screening test is considered successful if the patient experiences a 50 percent decrease in pain, which may be confirmed by VAS, and demonstrates objective functional gains or decreased utilization of pain medications. Functional gains may be evaluated by an occupational therapist and/or physical therapist prior to and before discontinuation of the trial.

e. Contraindications – Infection, body size insufficient to support the size and weight of the implanted device. Patients with other implanted programmable devices should not be given these pumps, since interference between devices may cause unintended changes in infusion rates.

4. Neuroablation with rhizotomy as the Exception

a. Neuroablation or neuro-destructive procedures are not commonly used in the management of non-malignant pain. These techniques require specific expertise to perform, have erratic results, and high rates of complication. Therefore, the OWCA does not recommend the use of neuroablative procedures, excepting rhizotomy, for injured workers with chronic pain.

5. Facet Rhizotomy

a. Description – A procedure designed to denervate the facet joint by ablating the periarticular facet nerve branches. There is good evidence to support this procedure for the cervical spine and some evidence in lumbar spine but benefits beyond one year are not yet established. Therefore, the patient should be committed to active therapy during the first post-surgical year.

b. Complications – Bleeding, infection, neural injury. There is a risk of developing a deafferentation centralized pain syndrome as a complication of this and other neuroablative procedures.

c. Surgical Indications – Pain of well-documented facet origin, unresponsive to active and/or passive therapy, unresponsive to manual therapy, and in whom a psychosocial evaluation has been performed. This procedure is commonly used to provide a window of pain relief allowing for participation in active therapy. All patients must have a successful response to diagnostic medial nerve branch blocks. A successful response is considered to be a 50 percent or greater relief of pain for the length of time appropriate to the local anesthetic used (i.e., bupivacaine greater than lidocaine).

d. Contraindications – Failure to obtain 50 percent or greater relief of pain with diagnostic medial branch block as well as bacterial infection – systemic or localized to region of implantation, bleeding diatheses, hematological conditions, and possible pregnancy.

e. Operative Treatment – Percutaneous radio-frequency rhizotomy is the procedure of choice over alcohol, phenol, or cryoablation. Position of the probe using fluoroscopic guidance is recommended since the maximum effective radius of the device is two millimeters.

f. Post-Operative Therapy – Active and/or passive therapy, implementation of a gentle aerobic re-conditioning program (e.g., walking) and back education within the first post-procedure week, barring complications. Instruction and participation in a long-term home-based program of ROM, strengthening, endurance and stability exercises should be done one to two weeks post procedure.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1711 (June 2011).

§2115. Maintenance Management

A. Successful management of chronic pain conditions results in fewer relapses requiring intense medical care. Failure to address long-term management as part of the overall treatment program may lead to higher costs and greater dependence on the health care system. Management of CRPS and CPD continues after the patient has met the definition of maximum medical improvement (MMI). MMI is declared when a patient's condition has plateaued and the authorized treating physician believes no further medical intervention is likely to result in improved function. When the patient has reached MMI, a physician must describe in detail the maintenance treatment.

B. Maintenance care in CRPS and CPD requires a close working relationship between the carrier, the providers, and the patient. Providers and patients have an obligation to design a cost-effective, medically appropriate program that is predictable and allows the carrier to set aside appropriate reserves. Carriers and adjusters have an obligation to assure that medical providers can design medically appropriate programs. A designated primary physician for maintenance team management is recommended.

1. Maintenance care will be based on principles of patient self-management. When developing a maintenance plan of care, the patient, physician and insurer should attempt to meet the following goals:

a. maximal independence will be achieved through the use of home exercise programs or exercise programs requiring special facilities (e.g., pool, health club) and educational programs;

b. modalities will emphasize self-management and self-applied treatment;

c. management of pain or injury exacerbations will emphasize initiation of active therapy techniques and may occasionally require anesthetic injection blocks;

d. dependence on treatment provided by practitioners other than the authorized treating physician will be minimized;

e. periodic reassessment of the patient's condition will occur as appropriate;

f. patients will understand that failure to comply with the elements of the self-management program or therapeutic plan of care may affect consideration of other interventions.

2. Home exercise programs and exercise equipment. Most patients have the ability to participate in a home exercise program after completion of a supervised exercise rehabilitation program. Programs should incorporate an exercise prescription including the continuation of an age-adjusted and diagnosis-specific program for aerobic conditioning, flexibility, stabilization, and strength. Some patients may benefit from the purchase or rental of equipment to maintain a home exercise program. Determination for the need of home equipment should be based on medical necessity to maintain MMI, compliance with an independent exercise program, and reasonable cost. Before the purchase or long-term rental of equipment, the patient should be able to demonstrate the proper use and effectiveness of the equipment. Effectiveness of equipment should be evaluated on its ability to improve or maintain functional areas related to activities of daily living or work activity. Occasionally, compliance evaluations may be made through a four-week membership at a facility offering similar equipment. Home exercise programs are most effective when done three to five times a week.

3. Exercise programs requiring special facilities Some patients may have higher compliance with an independent exercise program at a health club versus participation in a home program. All exercise programs completed through a health club facility should focus on the same parameters of an age-adjusted and diagnosis-specific program for aerobic conditioning, flexibility, stabilization, and strength. Selection of health club facilities should be limited to those able to track attendance and utilization, and provide records available for physician and insurer review. Prior to purchasing a membership, a therapist and/or exercise specialist who has treated the patient may visit the facility with the patient to assure proper use of the equipment.

a. Frequency: two to three times per week.

b. Optimal duration: one to three months.

c. Maximum maintenance duration: three months. Continuation beyond three months should be based on functional benefit and patient compliance. Health club membership should not extend beyond three months if attendance drops below two times per week on a regular basis.

4. Patient Education Management. Educational classes, sessions, or programs may be necessary to reinforce self-management techniques. This may be performed as formal or informal programs, either group or individual.

a. Maintenance duration: two to six educational sessions during one 12-month period.

5. Psychological Management. An ideal maintenance program will emphasize management options implemented in the following order: individual self-management (pain control, relaxation and stress management, etc.); group counseling, individual counseling by a psychologist or psychiatrist; and in-patient treatment. Aggravation of the injury may require psychological treatment to restore the patient to baseline. In those cases, use treatments and timeframe parameters listed in the Biofeedback and Psychological Evaluation or Intervention sections.

a. Maintenance duration: 6 to 10 visits during one 12-month period.

6. Non-narcotic medication management. In some cases, self-management of pain and injury exacerbations can be handled with medications, such as those listed in the Medication section. Physicians must follow patients who are on any chronic medication or prescription regimen for efficacy and side effects. Laboratory or other testing may be appropriate to monitor medication effects on organ function.

a. Maintenance duration: Usually, four medication reviews within a 12-month period. Frequency depends on the medications prescribed. Laboratory and other monitoring as appropriate.

7. Narcotic Medication Management. As compared with other pain syndromes, there may be a role for chronic augmentation of the maintenance program with narcotic medications. In selected cases, scheduled medications may prove to be the most cost effective means of insuring the highest function and quality of life; however, inappropriate selection of these patients may result in a high degree of iatrogenic illness. A patient should have met the criteria in the opioids section of these guidelines before beginning maintenance narcotics. Laboratory or other testing may be appropriate to monitor medication effects on organ function. The following management is suggested for maintenance narcotics:

a. The medications should be clearly linked to improvement of function, not just pain control. All follow up visits should document the patient's ability to perform routine functions satisfactorily. Examples include the abilities to: perform work tasks, drive safely, pay bills or perform basic math operations, remain alert for 10 hours, or participate in normal family and social activities. If the patient is not maintaining reasonable levels of activity the patient should usually be tapered from the narcotic and tried on a different long acting opioid.

b. A low dose narcotic medication regimen should be defined, which may minimally increase or decrease over time. Dosages will need to be adjusted based on side effects of the medication and objective function of the patient. A patient may frequently be maintained on additional non-narcotic medications to control side effects, treat mood disorders, or control neuropathic pain; however, only one long-acting narcotic and one short acting narcotic for rescue use should be prescribed in most cases.

c. All patients on chronic narcotic medication dosages need to sign an appropriate narcotic contract with their physician for prescribing the narcotics.

d. The patient must understand that continuation of the medication is contingent on their cooperation with the maintenance program. Use of non-prescribed drugs may result in tapering of the medication. The clinician may order random drug testing when deemed appropriate to monitor medication compliance.

e. Patients on chronic narcotic medication dosages must receive them through one prescribing physician.

i. Maintenance duration: Up to 12 visits within a 12-month period to review the narcotic plan. Laboratory and other monitoring as appropriate.

8. Therapy Management. Some treatment may be helpful on a continued basis during maintenance care if the therapy maintains objective function and decreases medication use. Aggravation of the injury may require intensive treatment to get the patient back to baseline. In those cases, treatments and timeframe parameters listed in the Active and Passive Therapy sections apply.

a. Active Therapy, Acupuncture, and Manipulation maintenance duration: 10 visits in a 12-month period.

9. Injection Therapy

a. Sympathetic Blocks - These injections are considered appropriate if they maintain or increase function for a minimum of four to eight weeks. Maintenance blocks are usually combined with and enhanced by the appropriate neuropharmacological medication(s) and other care. It is anticipated that the frequency of the maintenance blocks may increase in the cold winter months or with stress.

i. Maintenance duration: Not to exceed 6 to 8 blocks in a 12-month period for a single extremity and to be separated by no less than four week intervals. Increased frequency may need to be considered for multiple extremity involvement or for acute recurrences of pain and symptoms. For treatment of acute exacerbations, consider two to six blocks with a short time interval between blocks.

b. Trigger Point Injections - These injections may occasionally be necessary to maintain function in those with myofascial problems.

i. Maintenance duration: Not more than 4 injections per session not to exceed 3 to 6 sessions per 12-month period.

c. Epidural and Selective Nerve Root Injections - Patients who have experienced functional benefits from these injections in the past may require injection for exacerbations of the condition.

i. Maintenance duration: 2 to 4 injections per 12-month period.

10. Purchase or Rental of Durable Medical Equipment. It is recognized that some patients may require ongoing use of self-directed modalities for the purpose of maintaining function and/or analgesic effect. Purchase or rental of modality based equipment should be done only if the assessment by the physician and/or therapist has determined the effectiveness, compliance, and improved or maintained function by its application. It is generally felt that large expense purchases such as spas, whirlpools, and special mattresses are not necessary to maintain function beyond the areas listed above.

a. Maintenance duration: Not to exceed 3 months for rental equipment. Purchase if effective.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1713 (June 2011).

§2116. LWC-WC 1009. Disputed Claim for Medical Treatment

Mail to:
OWCA—Medical Services
ATTN: Medical Director
P.O. Box 94040
Baton Rouge, LA 70804

1. Social Security No. __-__-__
2. Date of Injury/Illness __-__-__
3. Parts of Body Injury_____
4. Date of Birth __-__-__
5. Date of This Request __-__-__
6. Claim Number _____

DISPUTED CLAIM FOR MEDICAL TREATMENT

NOTE: THIS REQUEST WILL NOT BE HONORED UNLESS THE INSURER HAS ISSUED A DENIAL FOR THE MEDICAL SERVICES IN DISPUTE AS PER R.S. 23:1203.1 J.

GENERAL INFORMATION
Claimant files this dispute with the Office of Workers' Compensation – Medical Services Director. This office must be notified immediately in writing of changes in address. An employee may be represented by an attorney, but it is not required.

7. This request is submitted by
___ Employee ___ Employer __ Insurer ___ Health Care Provider ___ Other ___

A. Copies of all relevant medical records must be included with this request.

B. A copy of the denial letter issued by the insurance carrier must be attached to this request.

EMPLOYEE
8. Name _____
Street or Box _____
City _____
State _____ Zip _____
Phone (____) _____

EMPLOYEE'S ATTORNEY
9. Name _____
Street or Box _____
City _____
State _____
Phone (____) _____
Fax (____) _____

EMPLOYER
10. Name _____
Street or Box _____
City _____
State _____ Zip _____
Phone (____) _____
Fax (____) _____

INSURER/ADMINISTRATOR
(circle one)
11. Name _____
Street or Box _____
City _____
State _____
Phone (____) _____
Fax (____) _____

EMPLOYER/INSURER'S ATTORNEY
12. Name _____
Street or Box _____
City _____
State _____ Zip _____
Phone (____) _____
Fax (____) _____

TREATING/REQUESTING PHYSICIAN
13. Name _____
Street or Box _____
City _____
State _____
Phone (____) _____
Fax (____) _____

LWC-WC 1009
11/2010

14. PLEASE PROVIDE A SUMMARY OF THE DETAILS REGARDING THE ISSUE AT DISPUTE:
_____
_____
_____
_____
_____
_____
_____
_____

_____
_____
_____
_____
_____
_____

You may attach a letter or petition with additional information with this disputed claim.
The information given above is true and correct to the best of my knowledge and belief.

_____ _____
SIGNATURE OF REQUESTING PARTY DATE

LWC-WC 1009
11/2010

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1715 (June 2011).

Subchapter B. Complex Regional Pain Syndrome

§2117. Introduction

A. This document has been prepared by the Louisiana Workforce Commission, Office of Workers' Compensation and should be interpreted within the context of guidelines for physicians/providers treating individuals qualifying under Louisiana's Workers' Compensation Act as injured workers with cervical spine injuries. These guidelines are enforceable under the Louisiana Workers Compensation Act. All medical care, services, and treatment owed by the employer to the employee in accordance with the Louisiana Workers' Compensation Act shall mean care, services, and treatment in accordance with these guidelines. Medical Care, services, and treatment hat varies from these guidelines shall also be due by the employer when it is demonstrated to the medical director of the office by a preponderance of the scientific medical evidence, that a variance from these guidelines is reasonably required to cure or relieve the injured worker from the effects of the injury or occupational disease given the circumstances. Therefore, these guidelines are not relevant as evidence of a provider's legal standard of professional care. To properly utilize this document, the reader should not skip nor overlook any sections.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1716 (June 2011).

§2119. General Guideline Principles

A. The principles summarized in this section are key to the intended implementation of all Office of Workers' Compensation guidelines and critical to the reader's application of the guidelines in this document.

1. Application of Guidelines. The OWCA provides procedures to implement medical treatment guidelines and to foster communication to resolve disputes among the provider, payer, and patient through the Office of Worker's Compensation.

2. Education of the patient and family, as well as the employer, insurer, policy makers and the community should be the primary emphasis in the treatment of complex regional pain. Currently, practitioners often think of education last, after medications, manual therapy, and surgery. Practitioners must develop and implement an effective strategy and skills to educate patients, employers, insurance systems, policy makers, and the community as a whole. An education-based paradigm should always start with inexpensive communication providing reassuring information to the patient. More in-depth education currently exists within a treatment regime employing functional restorative and innovative programs of prevention and rehabilitation. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of facilitating self-management of symptoms and prevention.

3. Treatment parameter duration Time frames for specific interventions commence once treatments have been initiated, not on the date of injury. Obviously, duration will be impacted by patient compliance, as well as availability of services. Clinical judgment may substantiate the need to accelerate or decelerate the time frames discussed in this document. Such deviation shall be in accordance with La. R.S. 23:1203.1.

4. Active interventions emphasizing patient responsibility, such as therapeutic exercise and/or functional treatment, are generally emphasized over passive modalities, especially as treatment progresses. Generally, passive interventions are viewed as a means to facilitate progress in an active rehabilitation program with concomitant attainment of objective functional gains.

5. Active Therapeutic Exercise Program. Exercise program goals should incorporate patient strength, endurance, flexibility, coordination, and education. This includes functional application in vocational or community settings.

6. Positive Patient Response. Positive results are defined primarily as functional gains that can be objectively measured. Standard measurement tools, including outcome measures, should be used. Objective functional gains include, but are not limited to, positional tolerances, range-of-motion (ROM), strength, and endurance, activities of daily living, cognition, psychological behavior, and efficiency/velocity measures that can be quantified. Subjective reports of pain and function should be considered and given relative weight when the pain has anatomic and physiologic correlation. Anatomic correlation must be based on objective findings.

7. Re-Evaluation Treatment Every three to four Weeks. If a given treatment or modality is not producing positive results within three to four weeks, the treatment should be either modified or discontinued. Reconsideration of diagnosis should also occur in the event of poor response to a seemingly rational intervention.

8. Surgical Interventions. Surgery should be contemplated within the context of expected functional outcome and not purely for the purpose of pain relief. The concept of "cure" with respect to surgical treatment by itself is generally a misnomer. All operative interventions must be based upon positive correlation of clinical findings, clinical course, and diagnostic tests. A comprehensive assimilation of these factors must lead to a specific diagnosis with positive identification of pathologic conditions.

9. Six-Month Time Frame. The prognosis drops precipitously for returning an injured worker to work once he/she has been temporarily totally disabled for more than six months. The emphasis within these guidelines is to move patients along a continuum of care and return-to-work within

a six-month time frame, whenever possible. It is important to note that time frames may not be pertinent to injuries that do not involve work-time loss or are not occupationally related.

10. Return To Work. Return to work is therapeutic, assuming the work is not likely to aggravate the basic problem or increase long-term pain. The practitioner must provide specific written physical limitations and the patient should never be released to "sedentary" or "light duty." The following physical limitations should be considered and modified as recommended: lifting, pushing, pulling, crouching, walking, using stairs, bending at the waist, awkward and/or sustained postures, tolerance for sitting or standing, hot and cold environments, data entry and other repetitive motion tasks, sustained grip, tool usage and vibration factors. Even if there is residual chronic pain, return-to-work is not necessarily contraindicated.

a. The practitioner should understand all of the physical demands of the patient's job position before returning the patient to full duty and should request clarification of the patient's job duties. Clarification should be obtained from the employer or, if necessary, including, but not limited to, an occupational health nurse, occupational therapist, vocational rehabilitation specialist, or an industrial hygienist.

11. Delayed Recovery. Delayed recovery strongly considers a psychological evaluation, if not previously provided, as well as initiating interdisciplinary rehabilitation treatment and vocational goal setting, for those patients who are failing to make expected progress 6 to 12 weeks after an injury. The OWCA recognizes that 3 to 10 percent of all industrially injured patients will not recover within the timelines outlined in this document despite optimal care. Such individuals may require treatments beyond the limits discussed within this document, but such treatment will require clear documentation by the authorized treating practitioner focusing on objective functional gains afforded by further treatment and impact upon prognosis.

12. Guideline recommendations and inclusion of medical evidence. Guidelines are recommendations based on available evidence and/or consensus recommendations. When possible, guideline recommendations will note the level of evidence supporting the treatment recommendation. When interpreting medical evidence statements in the guideline, the following apply:

a. *Consensus* means the opinion of experienced professionals based on general medical principles. Consensus recommendations are designated in the guideline as "generally well accepted," "generally accepted," "acceptable/accepted," or "well-established."

b. *"Some"* means the recommendation considered at least one adequate scientific study, which reported that a treatment was effective.

c. *"Good"* means the recommendation considered the availability of multiple adequate scientific studies or at least one relevant high-quality scientific study, which reported that a treatment was effective.

d. *"Strong"* means the recommendation considered the availability of multiple relevant and high quality scientific studies, which arrived at similar conclusions about the effectiveness of a treatment.

B. All recommendations in the guideline are considered to represent reasonable care in appropriately selected cases, regardless of the level of evidence or consensus statement attached to it. Those procedures considered inappropriate, unreasonable, or unnecessary are designated in the guideline as "not recommended."

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1716 (June 2011).

§2121. Introduction to complex regional pain syndrome

A. Complex Regional Pain Syndrome (CRPS Types I and II) describes painful syndromes, which were formerly referred to as Reflex Sympathetic Dystrophy (RSD) and causalgia. CRPS conditions usually follow injury that appears regionally and have a distal predominance of abnormal findings, exceeding the expected clinical course of the inciting event in both magnitude and duration and often resulting in significant impairment of limb function.

B. CRPS-I (RSD) is a syndrome that usually develops after an initiating noxious event, is not limited to the distribution of a single peripheral nerve, and is apparently disproportionate to the inciting event. It is associated at some point with evidence of edema, changes in skin, blood flow, abnormal sudomotor activity in the region of the pain, allodynia or hyperalgesia. The site is usually in the distal aspect of an affected extremity or with a distal to proximal gradient. The peripheral nervous system and possibly the central nervous system are involved.

C. CRPS-II (Causalgia) is the presence of burning pain, allodynia, and hyperpathia usually in the hand or foot after partial injury to a nerve or one of its major branches. Pain is within the distribution of the damaged nerve but not generally confined to a single nerve.

D. Stages seen in CRPS-I are not absolute and in fact, may not all be observed in any single patient. In some patients, stages may be missed or the patient may remain for long periods of time in one stage.

E. Stage 1—Acute (Hyperemic)

1. Starts at the time of injury or even weeks later. Associated with spontaneous pain, aching, burning. Typically restricted to the distal extremity. Hyperpathia, allodynia, hypoesthesia or hyperesthesia may be present. Initially, hair and nail growth may be increased but later decrease. Skin may be warm or cold.

F. Stage 2—Dystrophic (Ischemic)

1. Spontaneous burning and/or aching pain, more pronounced hyperpathia and or allodynia. Signs of chronic sympathetic over activity include reduced blood flow; sudomotor changes; increased edema; cyanotic skin; muscle wasting; decreased hair and nail growth; and osteoporosis.

G. Stage 3—Atrophic

1. Signs and symptoms of this stage include pain may be less prominent; decreased hyperpathia and/or allodynia; reduction in blood flow; skin temperature and sweating may be increased or decreased; irreversible trophic changes in skin and integument; and pronounced muscle atrophy with contractures.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1717 (June 2011).

§2123. Definitions

A. *After Sensation*—refers to the abnormal persistence of a sensory perception, provoked by a stimulus even though the stimulus has ceased.

B. *Allodynia*—pain due to a non-noxious stimulus that does not normally provoke pain.

1. *Mechanical Allodynia*—refers to the abnormal perception of pain from usually non-painful mechanical stimulation.

2. *Static Mechanical Allodynia*—refers to pain obtained by applying a single stimulus such as light pressure to a defined area.

3. *Dynamic Mechanical Allodynia*—obtained by moving the stimulus such as a brush or cotton tip across the abnormal hypersensitive area.

4. *Thermal Allodynia*—refers to the abnormal sensation of pain from usually non-painful thermal stimulation such as cold or warmth.

C. *Central Pain*—pain initiated or caused by a primary lesion or dysfunction in the central nervous system (CNS).

D. *Central Sensitization*—the experience of pain evoked by the excitation of non-nociceptive neurons or of nerve fibers that normally relay non-painful sensations to the spinal cord. This result when non-nociceptive afferent neurons act on a sensitized CNS.

E. *Dystonia*—state of abnormal (hypo or hyper) tonicity in any of the tissues.

F. *Hyperalgesia*—refers to an exaggerated pain response from a usually painful stimulation.

G. *Hyperemia*—presence of increased blood in a part or organ.

H. *Hyperesthesia* (Positive Sensory Phenomenon)—includes allodynia, hyperalgesia, and hyperpathia. Elicited by light touch, pin-prick, cold, warm vibration, joint position sensation or two-point discrimination, which is perceived as increased or more.

I. *Hyperpathia*—refers to an abnormally painful and exaggerated reaction to stimulus, especially to a repetitive stimulus, in a patient who perceives the stimulus as less intense because of an increased threshold.

J. *Hypoesthesia* (also *hypesthesia*)—diminished sensitivity to stimulation.

K. *Pain Behavior*—the nonverbal actions (such as grimacing, groaning, limping, using visible pain relieving or support devices and requisition of pain medications, among others) that are outward manifestations of pain, and through which a person may communicate that pain is being experienced.

L. *Sudomotor Changes*—alteration in function of sweat glands; sweat output may increase or decrease due to changes in autonomic input to the gland.

M. *Sympathetically Maintained Pain* (SMP)—a pain that is maintained by sympathetic efferent innervations or by circulating catecholalmines.

N. *Trophic Changes*—tissue alterations due to interruption of nerve or blood supply; may include changes in hair growth and texture of skin.

O. *Vasomotor Changes*—alteration in regulation of dilation or constriction of blood vessels.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1718 (June 2011).

§2125. Initial Evaluation

A. All potential pain generators should be thoroughly investigated by complete neurological and musculoskeletal exam and diagnostic procedures. Because CRPS-I is commonly associated with other injuries, it is essential that all related diagnoses are defined and treated. These disturbances are typically restricted to one extremity, usually distally, but are variable in their expression.

1. History and physical examination (Hx& PE) The history and physical exam establish the basis for subsequent diagnostic and therapeutic procedures. When clinical evaluation findings do not complement the findings of other diagnostic procedures, clinical findings should have preference. Before the diagnosis of CRPS-I or CRPS-II is established, an experienced practitioner must perform a detailed neurological and musculoskeletal exam to exclude other potentially treatable pain generators or neurological lesions.

a. Medical History. As in other fields of medicine, a thorough patient history is an important part of the evaluation of pain. In taking such a history, factors influencing a patients' current status can be made clear and taken into account when planning diagnostic evaluation and treatment. History should ascertain the following elements:

i. Causality: How did this injury occur? Was the problem initiated by a work-related injury or exposure?

ii. Presenting symptoms:

(a). Severe, generally unremitting burning and/or aching pain, and/or allodynia;

(b). Swelling of the involved area;

(c). Changes in skin color;

(d). Asymmetry in nail and/or hair growth;

(e). Abnormal sweat patterns of the involved extremity;

(f). Dystonia; and/or

(g). Subjective temperature changes of the affected area.

b. Pain History. The patient's description of and response to pain is one of the key elements in treatment. Characterization of the patient's pain and of the patient's response to pain is one of the key elements in treatment.

i. Site of Pain. Localization and distribution of the pain help determine the type of pain the patient has (i.e., central versus peripheral).

ii. Pain Drawing/Visual Analog Scale (VAS)

iii. Duration

iv. Place of onset

v. Pain Characteristics. Time of pain occurrence as well as intensity, quality and radiation give clues to the diagnosis and potential treatment.

vi. Response of Pain to Activity

vii. Associated Symptoms. Does the patient have numbness or paresthesia, dysesthesia, weakness, bowel or bladder dysfunction, decreased temperature, increased sweating, cyanosis or edema? Is there local tenderness, allodynia, hyperesthesia or hyperalgesia?

c. Substance Use/Abuse:

i. alcohol use;

ii. smoking history;

iii. History of drug use and abuse.

iv. Caffeine or caffeine-containing beverages.

d. Other Factors Affecting Treatment Outcome:

i. Compensation/disability/litigation;

ii. Treatment Expectations. What does the patient expect from treatment: complete relief of pain or reduction to a more tolerable level?

e. Medical Management History. Refer to the Chronic Pain Disorder Medical Treatment Guideline's for detailed elements when performing a review of prior medical management. In addition, history may include:

i. Chronological review of medical records including previous medical evaluations and response to treatment interventions.

ii. History of diagnostic tests and results including but not limited to any response to sympathetic nerve blocks, results of general laboratory studies, EMG and nerve conduction studies, radiological examinations, including triple phase bone scan or thermography with autonomic stress testing.

iii. Medications, including prescription, over-the-counter and herbal/dietary supplements.

iv. Review of Systems check list. Determine if there is any interplay between the pain complaint and other medical conditions.

v. Psychosocial Functioning. Determine if the following are present: current symptoms of depression or anxiety, evidence of stressors in the workplace or at home, and past history of psychological problems. It is recommended that patients diagnosed with CRPS be referred for a psychosocial evaluation. All patients with CRPS have Chronic Pain, and are likely to suffer psychosocial consequences.

vi. Pre-existing Conditions. Treatment of these conditions is appropriate when the preexisting condition affects recovery from chronic pain.

f. Physical Examination. Should include examination techniques applicable to those portions of the body in which the patient is experiencing subjective symptomatology and should include:

i. Inspection. Changes in appearance of the involved area, to include trophic changes, changes in hair and nail growth, muscular atrophy, changes in skin turgor, swelling and color changes.

ii. Temperature Evaluation. Palpable temperature changes may not be detectable in early disease stages, and the examiner will generally only be able to appreciate significant temperature variations. Thermography, or other objective testing may be necessary to display temperature asymmetries.

iii. Motor Evaluation. Involuntary movements, dystonia or muscle weakness in the involved limb(s).

iv. Sensory Evaluation. A detailed sensory examination is crucial in evaluating a patient with chronic pain complaints. Presence of allodynia. Anatomic pattern of any associated sensory abnormalities to light touch, deep touch, pain and thermal stimulation. Quantitative sensory testing may be useful.

v. Musculoskeletal Evaluation. Presence of associated myofascial problems, such as contractures, ROM or trigger points.

vi. Evaluation of Nonphysiologic Findings. Determine the presence of the following: Variabilities on formal exam including variable sensory exam, inconsistent tenderness, and or swelling secondary to extrinsic sources; Inconsistencies between formal exam and observed abilities of range of motion, motor strength, gait and cognitive/emotional state; and/or, observation of consistencies between pain behavior, affect and verbal pain rating, and affect and physical re-examination.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1718 (June 2011).

§2127. Diagnostic Procedures

A. Diagnostic imaging is a generally accepted, well-established, and widely used diagnostic procedure when specific indications, based on history and physical examination, are present. Physicians should refer to individual OWCA guidelines for specific information about specific testing procedures.

1. Plain Film Radiography:

a. Description. A radiological finding in CRPS may be unilateral osteoporosis; however, osteoporosis may be absent in many cases. In CRPS-I, the osteoporosis may be rapid in progression. The disorder typically affects the distal part of an extremity such as a hand or foot, yet intermediate joints such as the knee or elbow may be involved.

b. Results. The radiological appearance of osteoporosis has been characterized as spotty or patchy. Although CRPS-I may exist in the absence of osteoporosis, the diagnosis of CRPS-I cannot be made solely on the basis of radiographic appearance or the osteoporosis alone.

2. Triple Phase Bone Scan:

a. Description. Radionucleotide imaging scintigraphy employing radio-pharmaceutical technetium coupled to a phosphate complex has been used to help facilitate the diagnosis of CRPS-1. It was hoped that a three-phase radionucleotide study would be selective in the face of demineralization of the bone as seen in CRPS-I. However there are many different types of conditions that can produce osteoporosis and a triple-phase bone scan does not distinguish between the causes of bone demineralization.

b. Results. Clinical information can be derived from each of the three phases of the bone scan following injection. In the early course of CRPS-I, there is an increased uptake seen during Phase 1. However, in the late course of the disease process, there can actually be a decreased uptake seen. In Phase 2, which reflects the soft tissue vascularity, an increased diffuse uptake may be appreciated during the early course of CRPS-I. During Phase 3, one will see a diffuse uptake of multiple bone involvement of the involved limb, reflecting the bone turnover secondary to osteoporosis. Negative bone scans may be found in up to 40 percent of patients clinically diagnosed with CRPS-I; however when positive it may help to confirm the diagnosis of CRPS-I.

B. Injections – diagnostic sympathetic

1. Description. Diagnostic sympathetic injections are generally accepted procedures to aid in the diagnosis of CRPS I and II and SMP. Sympathetic blocks lack specificity for CRPS I and II. Each diagnostic injection has inherent

risk and risk versus benefit should always be evaluated when considering injection therapy. Since these procedures are invasive, less invasive or non-invasive procedures should be considered first. Selection of patients, choice of procedure, and localization of the level for injection should be determined by clinical information.

2. Special Considerations. Injections with local anesthetics of differing duration are required to confirm a diagnosis. In some cases, injections at multiple levels may be required to accurately diagnose pain. Refer to "Injections – Therapeutic" for information on specific injections.

a. Since fluoroscopic and/or CT guidance during procedures is recommended to document technique and needle placement, an experienced physician should perform the procedure. The practitioner should have experience in ongoing injection training workshops provided by organizations such as the International Spinal Injection Society (ISIS) and be knowledgeable in radiation safety. In addition, practitioners should obtain fluoroscopy training and radiation safety credentialing from their Departments of Radiology, as applicable.

3. Complications. Complications may include transient neurapraxia, nerve injury, inadvertent spinal injection, infection, venous or arterial vertebral puncture, laryngeal paralysis, respiratory arrest, vasovagal effects, as well as permanent neurological damage.

4. Contraindications. Absolute contraindications of diagnostic injections include: bacterial infection – systemic or localized to region of injection, bleeding diatheses, hematological conditions, and possible pregnancy. Relative contraindications of diagnostic injections may include: aspirin/antiplatelet therapy (drug may be held for at least three days prior to injection).

5. Test Results. The interpretation of the test result is primarily based upon pain relief of 50 percent or greater. The diagnostic significance of the test result should be evaluated in conjunction with clinical information and further information can be obtained from functional reassessment performed by physical and/or occupational therapy or from results of other diagnostic procedures following a successful block.

a. Local anesthetics of different durations of action should be considered and could take the place of doing a "placebo" block (i.e. - procaine, lidocaine, marcaine). Pain relief should be at least 50 percent or greater for the duration of the local anesthetic. It should be noted that with CRPS-I it is not unusual for the relief to last longer than the duration of the local anesthetic. If a placebo block is done, the needle should not be placed down to the sympathetic chain nor should an injection of saline be done around the sympathetic chain. Contact with the sympathetic nerves by a needle or pressure on the chain by saline can cause a temporary sympathetic block and give a false positive placebo test. A "sham block" would be preferable to see if the patient is a placebo responder. Additionally, patients with definite CRPS-I can also be placebo responders. The fact that the patient responds positively to a placebo does not mean that he/she does not have CRPS-1. It merely means that the patient is a placebo responder. This increases the value of doing another confirmatory test.

i. Stellate Ganglion Block. For diagnosis and treatment of sympathetic pain involving the face, head, neck, and upper extremities secondary to CRPS-I and II. This block is commonly used for differential diagnosis and is the preferred treatment of CRPS-I pain involving the upper extremity.

(a). For diagnostic testing, use three blocks over a 3-14 day period. For a positive response, pain relief should be 50 greater or greater for the duration of the local anesthetic and pain relief should be associated with functional improvement.

ii. Lumbar Sympathetic Block. Useful for diagnosis and treatment of pain of the pelvis and lower extremity secondary to CRPS-I and II. This block is commonly used for differential diagnosis and is the preferred treatment of sympathetic pain involving the lower extremity. For diagnostic testing, use three blocks over a 3-14 day period. For a positive response, pain relief should be 50 percent or greater for the duration of the local anesthetic and pain relief should be associated with functional improvement.

iii. Phentolamine Infusion Test. An intravenous infusion of phentoalmine, an alpha 2 blocker, which results in generalized systemic sympatholysis. The infusion begins with intravenous saline for placebo control. For a positive response, pain relief should be 50 percent or greater and associated with functional improvement. This test aids in the diagnosis of Sympathetically Maintained Pain.

C. Thermography (infrared stress thermography)

1. Description. A generally accepted procedure with some evidence to support its limited use. Infrared thermography may be useful for patients with suspected CRPS-I and II, and SMP. Thermography can distinguish abnormal thermal asymmetry of 1.0 degree Celsius which is not distinguishable upon physical examination. It may also be useful in cases of suspected small caliber fiber neuropathy and to evaluate patient response to sympatholytic interventions.

2. Special Considerations. The practitioner who supervises and interprets the thermographic evaluation shall follow recognized protocols and be board certified by one of the examining boards of the American Academy of Medical Infrared Imaging, American Academy of Thermology, or American Chiropractic College of Thermology.

3. Medications with anticholinergic activity (tricyclics, cyclobenzaprine, antiemetics, antipsychotics) may interfere with autonomic testing. The pre-testing protocol which includes cessation of specific medications therapy must be followed for accurate test results. Results of autonomic testing may be affected by peripheral polyneuropathy, radiculopathy or peripheral nerve injury, peripheral vascular disease, generalized autonomic failure, or by Shy-Drager syndrome.

4. Thermographic Tests. Functional autonomic stress testing may include any of the following methods:

a. Cold Water Stress Test (Cold Pressor Test). Paroxysmal cooling is strongly suggestive of vasomotor instability.

b. Warm Water Stress Test. Paroxysmal warming is strongly suggestive of vasomotor instability.

D. Autonomic test battery

1. Description. Resting skin temperature (RST), resting sweat output (RSO), and quantitative sudomotor axon reflex test (QSART) are a recently developed test

battery with some evidence to support its limited use in the diagnosis of CRPS-I. Prior authorization is required.

2. Special Considerations. Medications with anticholinergic activity (tricyclics, cyclobenzaprine, antiemetics, antipsychotics) may interfere with autonomic testing. Results of autonomic testing may be affected by peripheral polyneuropathy, radiculopathy or peripheral nerve injury, peripheral vascular disease, generalized autonomic failure, or by Shy-Drager syndrome.

3. Test Battery. These tests measure asymmetries in physiologic manifestations of autonomic activity between an affected limb and an unaffected contralateral limb. Skin temperature reflects vasomotor activity and sweat output measures sudomotor activity. The results of the three test components must be combined and scored. The battery of tests must include a measurement of each component (RST, RSO, and QSART).

a. Infrared Resting Skin Temperature (RST) provides thermographic measurements between the affected and unaffected limb. Generally, a 1° Celsius difference is significant.

b. Resting Sweat Output (RSO) measures an increase or reduction of 50 percent between the affected and unaffected limb.

c. Quantitative Sudomotor Axon Reflex Test (QSART) measures the sweat output elicited by iontophoretic application of acetylcholine. An increase or reduction of 50 percent between the affected and unaffected limb is significant.

E. Other diagnostic tests not specific for crps. The following tests and procedures are not used to establish the diagnosis of CRPS but may provide additional information. The following are listed in alphabetical order.

1. Electrodiagnostic Procedures. Electromyography (EMG) and Nerve Conduction Studies (NCS) are generally accepted, well-established and widely used for localizing the source of the neurological symptoms and establishing the diagnosis of focal nerve entrapments, such as carpal tunnel syndrome or radiculopathy, which may contribute to or coexist with CRPS II (causalgia). Traditional electrodiagnosis includes nerve conduction studies, late responses, (F-Wave, H-reflex) and electromyographic assessment of muscles with needle electrode examination. As CRPS II occurs after partial injury to a nerve, the diagnosis of the initial nerve injury can be made by electrodiagnostic studies. The later development of sympathetically mediated symptomatology however, has no pathognomonic pattern of abnormality on EMG/NCS. When issues of diagnosis are in doubt, a referral or consultation with a physiatrist or neurologist trained in electrodiagnosis is appropriate.

2. Laboratory Tests are generally accepted well-established and widely used procedures and can provide useful diagnostic and monitoring information. They may be used when there is suspicion of systemic illness, infection, neoplasia, or underlying rheumatologic disorder, connective tissue disorder, or based on history and/or physical examination. Tests include, but are not limited to:

a. Complete Blood Count (CBC) with differential can detect infection, blood dyscrasias, and medication side effects.

b. Erythrocyte sedimentation rate, rheumatoid factor, antinuclear antigen (ANA), human leukocyte antigen (HLA), and C-reactive protein can be used to detect evidence of a rheumatologic, infection, or connective tissue disorder, serum protein electrophoresis.

c. Thyroid, glucose and other tests to detect endocrine disorders.

d. Serum calcium, phosphorous, uric acid, alkaline phosphatase, and acid phosphatase can detect metabolic bone disease.

e. urinalysis for calcium, phosphorus, hydroxyproline, or hematuria;

f. Liver and kidney function may be performed for baseline testing and monitoring of medications; and

g. Toxicology Screen and/or Blood Alcohol Level if suspected drug or alcohol abuse.

3. Peripheral Blood Flow (Laser Doppler or Xenon Clearance Techniques): This is currently being evaluated as a diagnostic procedure in CRPS-I and is not recommended by the OWCA at this time.

a. Personality/Psychosocial/Psychiatric/ Psychological Evaluation:

i. These are generally accepted and well-established diagnostic procedures with selective use in the upper extremity population, but have more widespread use in subacute and chronic upper extremity populations. Diagnostic testing procedures may be useful for patients with symptoms of depression, delayed recovery, chronic pain, recurrent painful conditions, disability problems, and for preoperative evaluation. Psychological/psychosocial and measures have been shown to have predictive value for postoperative response, and therefore should be strongly considered for use pre-operatively when the surgeon has concerns about the relationship between symptoms and findings, or when the surgeon is aware of indications of psychological complication or risk factors for psychological complication (e.g. childhood psychological trauma). Psychological testing should provide differentiation between pre-existing conditions versus injury caused psychological conditions, including depression and posttraumatic stress disorder. Psychological testing should incorporate measures that have been shown, empirically, to identify comorbidities or risk factors that are linked to poor outcome or delayed recovery.

ii Formal psychological or psychosocial evaluation should be performed on patients not making expected progress within 6 to 12 weeks following injury and whose subjective symptoms do not correlate with objective signs and test results. In addition to the customary initial exam, the evaluation of the injured worker should specifically address the following areas:

(a). employment history;

(b). interpersonal relationships-both social and work;

(c). patient activities;

(d). current perception of the medical system;

(e). current perception/attitudes toward employer/job

(f). results of current treatment

(g). Risk factors and psychological comorbidities that may influence outcome and that may require treatment.

(h). Childhood history, including history of childhood psychological trauma, abuse and family history of disability.

iii. Personality/psychological/psychosocial evaluations consist of two components, clinical interview and psychological testing. Results should help clinicians with a better understanding of the patient in a number of ways. Thus the evaluation result will determine the need for further psychosocial interventions; and in those cases, Diagnostic and Statistical Manual of Mental Disorders (DSM) diagnosis should be determined and documented. The evaluation should also include examination of both psychological comorbidities and psychological risk factors that are empirically associated with poor outcome and/or delayed recovery. An individual with a Ph.D., Psy.D, or psychiatric M.D./D.O. credentials should perform initial evaluations, which are generally completed within one to two hours. A professional fluent in the primary language of the patient is preferred. When such a provider is not available, services of a professional language interpreter should be provided.

iv. Frequency. One-time visit for the clinical interview. If psychometric testing is indicated as a part of the initial evaluation, time for such testing should not exceed an additional two hours of professional time.

(a). Tests of Psychological Functioning

(i). Psychometric testing is a valuable component of a consultation to assist the physician in making a more effective treatment plan. Psychometric testing is useful in the assessment of mental conditions, pain conditions, cognitive functioning, treatment planning, vocational planning and evaluation of treatment effectiveness. There is no general agreement as to which standardized psychometric tests should be specifically recommended for psychological evaluations of chronic pain conditions. It is appropriate for the mental health provider to use their discretion and administer selective psychometric tests within their expertise and within standards of care in the community. Some of these tests are available in Spanish and other languages, and many are written at a 6th grade reading level.

4. Special Tests. Tests are generally well-accepted tests and are performed as part of a skilled assessment of the patients' capacity to return to work, strength capacity, and or physical work demands classifications and tolerance. Tests include Computer-Enhanced Evaluations, Functional Capacity Evaluation (FCE), Jobsite Evaluation, Vocational Assessment, and Work Tolerance Screening. Refer to the Chronic Pain Medical Treatment Guidelines for detailed information and frequency of each special testing procedure.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1719 (June 2011).

§2129. Diagnosis of CRPS

A. Diagnostic Components of CRPS-I (RSD)

1. Subjective Complaints. Complaint of pain, usually burning or aching pain and out of proportion to identified pathology. May be sharp, or lancinating. Frequently is present without provocation or movement.

2. Physical Findings:

a. Swelling, generally unilateral and variable in presentation.

b. Vasomotor signs – Unilateral. Initial extremity warming early on, coldness of extremity as condition progresses. Discoloration of skin usually darker blue or purple, may be mottled, may be paler.

c. Sudomotor sign – Increased sweating of the involved extremity.

d. Trophic Changes – Coarse, thick hair, later may be sparse; nails brittle, ridged, may grow faster initially, later grow more slowly; skin is smooth, shiny; digits tapered (pencil pointing); joints stiff with decreased ROM; muscle wasting; motor disturbances; increased physiological tremor, dystonia.

3. Diagnostic Testing Procedures:

a. x-rays of both extremities;

b. triple phase bone scan;

c. sympathetic blocks;

d. infrared thermogram;

e. autonomic test battery.

B. Diagnostic Criteria for CRPS

1. CRPS-I (RSD):

a. Patient complains of pain, usually diffuse burning or aching;

b. Patient has physical findings on examination of at least vasomotor and/or sudomotor signs. Allodynia and/or trophic changes add strength to the diagnosis of CRPS-I; and

c. At least two diagnostic testing procedures are positive. Even the most sensitive tests can have false negatives. The patient can still have CRPS-I, if clinical signs are strongly present. In patients with continued signs and symptoms of CRPS-I, further diagnostic testing may be appropriate.

2. CRPS-II (causalgia):

a. Patient complains of pain;

b. Documentation of peripheral nerve injury with pain initially in the distribution of the injured nerve;

c. Patient has physical findings on examination of at least vasomotor and/or sudomotor signs. Allodynia and/or trophic changes add strength to the diagnosis of CRPS-II; and

d. At least two diagnostic testing procedures are positive. Even the most sensitive tests can have false negatives. The patient can still have CRPS-II, if clinical signs are strongly present. In patients with continued signs and symptoms of CRPS-II, further diagnostic testing may be appropriate.

3. Sympathetically Mediated Pain (SMP):

a. Patient complains of pain;

b. Usually does not have clinically detectable vasomotor or sudomotor signs; and

c. Has pain relief with sympathetic blocks.

4. Not CRPS:

a. Patient complains of pain;

b. May or may not have vasomotor or sudomotor signs;

c. No relief with sympathetic blocks; and

d. No more than one other diagnostic test procedure is positive.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1722 (June 2011).

§2131. Therapeutic Procedures – Non-Operative

A. Non-operative therapeutic rehabilitation is applied to patients with CRPS or SMP who experience chronic and complex problems of de-conditioning and functional disability. Treatment modalities may be utilized sequentially or concomitantly depending on chronicity and complexity of the problem, and treatment plans should always be based on a diagnosis utilizing appropriate diagnostic procedures.

B. Before initiation of any therapeutic procedure, the authorized treating physician, employer and insurer must consider these important issues in the care of the injured worker:

1. Patients undergoing therapeutic procedure(s) should be released or returned to modified or restricted duty during their rehabilitation at the earliest appropriate time. Refer to Return-to-Work for detailed information.

2. Reassessment of the patient's status in terms of functional improvement should be documented after each treatment. If patients are not responding within the recommended time periods, alternative treatment interventions, further diagnostic studies or consultations should be pursued. Continued treatment should be monitored using objective measures such as:

a. Return to work or maintaining work status.

b. Fewer restrictions at work or performing or limitations in activities of daily living (ADL).

c. Decrease in usage of medications.

d. Measurable functional gains, such as increased range of motion or documented increase in strength.

3. Clinicians should provide and document education to the patient. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of facilitating self-management of symptoms.

4. Psychological or psychosocial screening should be performed on all chronic pain patients.

C. The following procedures are listed in alphabetical order.

1. Acupuncture is an accepted and widely used procedure for the relief of pain and inflammation and there is some scientific evidence to support its use. Credentialed practitioners must perform acupuncture evaluations, with experience in evaluation and treatment of chronic pain patients. The exact mode of action is only partially understood. Western medicine studies suggest that acupuncture stimulates the nervous system at the level of the brain, promotes deep relaxation, and affects the release of neurotransmitters. Acupuncture is commonly used as an alternative or in addition to traditional Western pharmaceuticals. It is commonly used when pain medication is reduced or not tolerated. It may be used as an adjunct to physical rehabilitation, surgical intervention, and or as part of multidisciplinary treatment to hasten the return of functional activity. Acupuncture should be performed by licensed practitioners.

a. Refer to the Chronic Pain Medical Treatment guideline's for detailed information on acupuncture and timeframe parameters.

2. Biofeedback is a generally well-accepted form of behavioral medicine that helps patients learn self-awareness and self-regulation skills for the purpose of gaining greater control of their physiology. Biofeedback treatment is intended to assist patients in managing stress-related psychophysiological reactions that may arise as a reaction to organic pain, or which may cause pain. The biofeedback specialist may utilize a variety of interventions for teaching physiological self-management. Biological feedback may then be provided through mechanisms ranging from simple devices to electronic instrumentation, and displayed or fed back to the patient visually, auditorially, or tactilely. This enables the patient to identify and refine effective interventions.

a. The application of biofeedback to patients with CRPS is not well researched. However, based on CRPS symptomology, temperature or skin conductance feedback modalities may be of particular interest. Refer to the Chronic Pain Medical Treatment Guideline's for detailed information on biofeedback and time parameters.

3. Disturbances of sleep are common in chronic pain. Although primary insomnia may accompany pain as an independent comorbid condition, it more commonly occurs, secondary to the pain condition itself. Exacerbations of pain often are accompanied by exacerbations of insomnia; the reverse can also occur. Sleep laboratory studies have shown disturbances of sleep architecture in pain patients. Loss of deep slow-wave sleep and increase in light sleep occur and sleep efficiency, the proportion of time in bed spent asleep, is decreased. These changes are associated with patient reports of non-restorative sleep.

a. Many chronic pain patients develop behavioral habits that exacerbate and maintain sleep disturbances. Excessive time in bed, irregular sleep routine, napping, low activity and worrying in bed are all maladaptive responses that can arise in the absence of any psychopathology. There is some evidence that behavioral modification, such as patient education and group or individual counseling, can be effective in reversing the effects of insomnia. Behavioral modifications are easily implemented and can include:

i. Maintaining a regular sleep schedule, retiring and rising at approximately the same time on weekdays and weekends.

ii. Avoiding daytime napping.

iii. Avoiding caffeinated beverages after lunchtime

iv. Making the bedroom quiet and comfortable, eliminating disruptive lights, sounds television sets, and keeping a bedroom temperature of about 65°F.

v. Avoiding alcohol or nicotine within two hours of bedtime.

vi. Avoiding large meals within two hours of bedtime.

vii. Exercising vigorously during the day, but not within two hours of bedtime, since this may raise core temperature and activate the nervous system.

viii. Associating the bed with sleep and sexual activity only, using other parts of the home for television, reading and talking on the telephone.

ix. Leaving the bedroom when unable to sleep for more than 20 minutes, retuning to the bedroom when ready to sleep again.

b. These modifications should be undertaken before sleeping medication is prescribed.

4. Injections — therapeutic. When considering the use of injections in CRPS management, the treating physician must carefully consider the inherent risks and benefits. First, it is understood that these injections are seldom meant to be "curative" but may have diagnostic or prognostic qualities and when used for therapeutic purposes they are employed in conjunction with other treatment modalities for maximum benefit. Second, education of the patient should include the proposed goals of the injections, expected gains, risks or complications, and alternative treatment. Lastly, reassessment of the patient's status in terms of functional improvement should be documented after each injection and/or series of injections.

a. Any continued use of injections should be monitored using objective measures such as:

i. Return to work or maintaining work status.

ii. Fewer restrictions at work or when performing activities of daily living (ADL).

iii. Decrease in usage of medications.

iv. Measurable functional gains, such as increased range of motion or documented increase in strength.

(a). Visual analog scales (VAS) provide important subjective data but are not an appropriate measure of function.

(b). The physician must be aware of the possible placebo effect as well as the long-term effects of injections related to the patient's physical and mental status. Strict adherence to contraindications, both absolute and relative, may prevent potential complications. Subjecting the patient to potential risks, i.e., needle trauma, infection, nerve injury, or systemic effects of local anesthetics and corticosteroids, must be considered before the patient consents to such procedures.

b. Sympathetic Injections:

i. Description. Sympathetic injections are generally accepted, well-established procedures. They include stellate ganglion blocks, lumbar sympathetic, and intravenous regional (Bier) blocks. Regional blocks frequently use bretylium with additional agents (narcotics and or anti-inflammatory drugs). There is some evidence that bretylium reduces pain intensity. It is recommended that all patients receiving therapeutic blocks participate in an appropriate exercise program that may include a functionally directed rehabilitation program.

ii. Indications. Pain relief and functional improvement from previous diagnostic or therapeutic blocks.

iii. Special Considerations. Except for Bier blocks, fluoroscopic and/or CT guidance during procedures is recommended to document technique and needle placement; an experienced physician should perform the procedure. The practitioner should participate in ongoing injection training workshops provided by organizations such as the International Spinal Injection Society (ISIS) and be knowledgeable in radiation safety. In addition, practitioners should obtain fluoroscopy training and radiation safety credentialing from their Departments of Radiology, as applicable.

iv. Complications may include transient neurapraxia, nerve injury, inadvertent spinal injection, infection, venous or arterial vertebral puncture, laryngeal paralysis, respiratory arrest, vasovagal effects, as well as permanent neurologic damage.

v. Contraindications. Absolute contraindications of therapeutic injections include:

(a). bacterial infection – systemic or localized to region of injection,

(b). bleeding diatheses,

(c). hematological conditions, and

(d). possible pregnancy. Relative contraindications of therapeutic injections may include: aspirin/antiplatelet therapy (drug may be held for at least 3 days prior to injection).

vi. Treatment Parameters. To be effective as a treatment modality, the patient should be making measurable progress in their rehabilitation program and should be achieving an increasing or sustained duration of relief between blocks. If appropriate outcomes are not achieved, changes in treatment should be undertaken.

(a). Time to produce effect: one to three blocks

(b). Frequency: Variable, depending upon duration of pain relief and functional gains. During the first two weeks of treatment, blocks may be provided every three to five days, based on patient response. After the first two weeks, blocks may be given weekly with tapering for a maximum of seven injections over six weeks.

(c). Optimum duration: three months.

(d). Maximum duration: three to four months for initial treatment. For the use of blocks during maintenance care, refer to the Maintenance Care section for treatment parameters.

(e). Trigger Point Injections: May be appropriate when myofascial trigger points are present on examination. Refer to chronic pain guidelines for treatment parameters.

(f). Peripheral Nerve Blocks: May be appropriate when peripheral nerve pathology is identified. Refer to chronic pain guidelines for treatment parameters.

(g). Intravenous lidocaine: May be used as a prognostic indicator for the use of mexilitine. It is infrequently used as a therapeutic treatment.

5. Interdisciplinary rehabilitation programs are the gold standard of treatment for individuals with chronic pain who have not responded to less intensive modes of treatment. In addition, there are current studies to support the use of pain programs. There is strong evidence that interdisciplinary programs improve function in chronic pain and moderate evidence that these programs decrease pain in these patients.

a. These programs should assess the impact of pain and suffering on the patient's medical, physical, psychological, social, and/or vocational functioning. In general, interdisciplinary programs deal with irreversible, painful musculoskeletal, neurological, and other chronic painful disorders and psychological issues, including drug dependence, high levels of stress and anxiety, failed surgery and pre-existing or latent psychopathology. The number of professions involved in the team in a chronic pain program may vary due to the complexity of the needs of the person served. The OWCA recommends consideration of referral to an interdisciplinary program within 6 months post-injury in patients with delayed recovery unless surgical interventions or other medical complications intervene.

b. Chronic pain patients need to be treated within a continuum of treatment intensity. Chronic pain programs are available with services provided by a coordinated interdisciplinary team within the same facility (formal) or as coordinated by the authorized treating physician (informal). Formal programs are able to provide coordinated, high intensity level of services and are recommended for most chronic pain patients who have received multiple therapies during acute management. Informal programs offer a lesser intensity of service and may be considered for patients who are currently employed, those who cannot attend all day programs, those with language barriers, or those living in areas not offering formal programs. Before treatment has been initiated, the patient, physician, and insurer should agree on treatment approach, methods, and goals. Generally the type of program needed will depend on the degree of impact the pain has had on the patient's medical, physical, psychological, social and/or vocational functioning.

c. When referring a patient for formal interdisciplinary pain rehabilitation or Work Hardening programs, the OWCA recommends the programs be Commission on Accreditation of Rehabilitation Facilities (CARF) eligible and/or certified. CARF eligibility or certification ensures that programs meet specific care standards of design and efficacy.

d. Inpatient Pain Rehabilitation Programs are rarely needed but may be necessary for patients with any of the following conditions: High risk for medical instability; Moderate to severe impairment of physical/functional status; Moderate to severe pain behaviors; Moderate impairment of cognitive and/or emotional status; Dependence on medications from which he or she needs to be withdrawn; and the need for 24-hour supervised nursing.

e. Interdisciplinary pain programs, whether formal or informal, should be comprised of the following dimensions:

i. Communication. To ensure positive functional outcomes, communication between the patient, insurer and all professionals involved must be coordinated and consistent. Any exchange of information must be provided to all professionals, including the patient. Care decisions would be communicated to all.

ii. Documentation. Through documentation by all professionals involved and/or discussions with the patient, it should be clear that functional goals are being actively pursued and measured on a regular basis to determine their achievement or need for modification.

iii. Treatment Modalities. Use of modalities may be necessary early in the process to facilitate compliance with and tolerance to therapeutic exercise, physical conditioning, and increasing functional activities. Active treatments should be emphasized over passive treatments. Active treatments should encourage self-coping skills and management of pain, which can be continued independently at home or at work. Treatments that can foster a sense of dependency by the patient on the caregiver should be avoided. Treatment length should be decided based upon observed functional improvement. For a complete list of Active and Passive Therapies, refer to those Subparagrahps of this guideline. All treatment timeframes may be extended based upon the patient's positive functional improvement.

iv. Therapeutic Exercise Programs. There is strong evidence that these programs, including aerobic conditioning and strengthening, are superior to treatment programs that do not include exercise. There is no sufficient evidence to support the recommendation of any particular exercise regimen over any other exercise regimen. A therapeutic exercise program should be initiated at the start of any treatment rehabilitation. Such programs should emphasize education, independence, and the importance of an on-going exercise regime.

v. Return-to-work. The authorized treating physician should continually evaluate the patient for their potential to return to work. When return-to-work is an option, it may be appropriate to implement a Work Hardening Program (as described in this section). For patients currently employed, efforts should be aimed at keeping them employed. For more specific information regarding return-to-work, refer to the Return-to-work section in this guideline.

vi. Patient Education. Patients with pain need to re-establish a healthy balance in lifestyle. All providers should educate patients on how to overcome barriers to resuming daily activity, including pain management, decreased energy levels, financial constraints, decreased physical ability, and change in family dynamics.

vii. Psychosocial Evaluation and Treatment. Psychosocial evaluation should be initiated, if not previously done. Providers of care should have a thorough understanding of the patient's personality profile; especially if dependency issues are involved. Psychosocial treatment may enhance the patient's ability to participate in pain treatment rehabilitation, manage stress, and increase their problem-solving and self-management skills.

viii. Vocational Assistance. Vocational assistance can define future employment opportunities or assist patients in obtaining future employment. Refer to Return-to-work section for detailed information.

f. Interdisciplinary programs are characterized by a variety of disciplines that participate in the assessment, planning, and/or implementation of the treatment program. These programs are for patients with greater levels of perceived disability, dysfunction, de-conditioning and psychological involvement. The following programs are listed in order of decreasing intensity.

i. Formal Rehabilitation Programs:

(a). Interdisciplinary Pain Rehabilitation. An Interdisciplinary Pain Rehabilitation Program provides outcomes-focused, coordinated, goal-oriented interdisciplinary team services to measure and improve the functioning of persons with pain and encourage their appropriate use of health care system and services. The program can benefit persons who have limitations that interfere with their physical, psychological, social, and/or vocational functioning. The program shares information about the scope of the services and the outcomes achieved with patients, authorized providers, and insurers.

(b). The interdisciplinary team maintains consistent integration and communication to ensure that all interdisciplinary team members are aware of the plan of care for the patient, are exchanging information, and implement the plan of care. The team members make interdisciplinary

team decisions with the patient and then ensure that decisions are communicated to the entire care team.

(c). The medical director of the pain program should be board certified in his or her specialty area, have at least two years full-time experience in an interdisciplinary pain rehabilitation program, and ideally be board certified in pain management. Individuals who assist in the accomplishment of functional, physical, psychological, social and vocational goal must include, at the least, a medical director, pain physician(s), psychologist, Biofeedback Therapist, Occupational Therapist, Physical Therapist, and Registered Nurse. Other disciplines on the team may include, but are not limited to, case manager, exercise physiologist, psychiatrist, and/or nutritionist.

(i). Time to produce effect: three to four weeks

(ii). Frequency: No less than five hours/day, five days/week

(iii). Optimum duration: three to four weeks five times a week, followed by six to nine weeks of follow-up one to three times a week.

(iv). Maximum duration: Four months, including follow-up. Periodic review and monitoring thereafter on an as needed basis, is founded upon the documented maintenance of functional gains.

(d). Work Hardening is an interdisciplinary program addressing a patient's employability and return-to-work. It includes a progressive increase in the number of hours per day that a patient completes work simulation tasks until the patient can tolerate a full workday. A full workday is case specific and is defined by the previous employment of the patient. This is accomplished by addressing the medical, psychological, behavioral, physical, functional, and vocational components of employability and return-to-work.

(e). The interdisciplinary team should, at a minimum, be comprised of a qualified medical director who is board certified with documented training in occupational rehabilitation, team physicians having experience in occupational rehabilitation, occupational therapy, physical therapy, case manager, and psychologist. As appropriate, the team may also include: chiropractor, RN, or vocational specialist.

(i). Time to produce effect: two weeks

(ii). Frequency: two to five visits per week, up to eight hours/day.

(iii). Optimum duration: two to four weeks

(iv). Maximum duration: six weeks. Participation in a program beyond six weeks must be documented with respect to need and the ability to facilitate positive symptomatic or functional gains.

ii. Informal Rehabilitation Program: A Coordinated Interdisciplinary Pain Rehabilitation Program is one in which the authorized treating physician coordinates all aspects of care. This type of program is similar to the formal programs in that it is goal oriented and provides interdisciplinary rehabilitation services to manage the needs of the patient in the following areas: functional, medical, physical, psychological, social, and vocational.

(a). This program is different from a formal program in that it involves lesser frequency and intensity of services/treatment. Informal rehabilitation is geared toward those patients who do not need the intensity of service offered in a formal program or who cannot attend an all-day program due to employment, daycare, language or other barriers.

(b). Patients should be referred to professionals experienced in outpatient treatment of chronic pain. The OWCA recommends the authorized treating physician consult with physicians experienced in the treatment of chronic pain to develop the plan of care.

(i). Time to produce effect: three to eight weeks

(ii). Frequency: two to six hours per day, two to five days each week.

(iii). Optimum duration: 6 to 12 weeks, including follow-up.

(iv). Maximum duration: Four months, including follow-up. Periodic review and monitoring thereafter on an as needed basis, is founded upon the documented maintenance of functional gains.

6. Medications. There is no single formula for pharmacological treatment of patients with chronic nonmalignant pain. A thorough medication history, including use of alternative and over the counter medications, should be performed at the time of the initial visit and updated periodically. Appropriate application of pharmacological agents depends on the patient's age, past history (including history of substance abuse), drug allergies, and the nature of all medical problems. It is incumbent upon the physician to thoroughly understand pharmacological principles when dealing with the different drug families and their respective side effect, bioavailability profiles and primary reason for each medication's usage.

a. Control of chronic non-malignant pain is expected to involve the use of medication. Strategies for pharmacological control of pain cannot be precisely specified in advance. Rather, drug treatment requires close monitoring of the patient's response to therapy, flexibility on the part of the prescriber, and a willingness to change treatment when circumstances change. Many of the drugs discussed in the medication section were licensed for indications other than analgesia, but are effective in the control of many types of chronic pain.

b. All medications should be given an appropriate trial in order to test for therapeutic effect. Trials of medication requiring specific therapeutic drug levels may take several months to achieve, depending upon the half-life of the drug. It is recommended that patients with CRPS be maintained on drugs that have the least serious side effects. For example, patients need to be tried or continued on acetaminophen and or antidepressant medications whenever feasible as part of their overall treatment for chronic pain. It is recommended that use of opioid analgesic and sedative hypnotic medications in chronic pain patients be used in a very limited manner, with total elimination desirable whenever clinically feasible.

c. For the clinician to interpret the following material, it should be noted that: drug profiles listed are not complete; dosing of drugs will depend upon the specific drug, especially for off-label use; and not all drugs within each class are listed, and other drugs within the class may be appropriate. Clinicians should refer to informational texts or consult a pharmacist before prescribing unfamiliar

medications or when there is a concern regarding drug interactions.

d. The following drug classes are listed in alphabetical order, not in order of suggested use.

i. Anticonvulsants. Although the mechanism of action of anticonvulsant drugs in neuropathic pain states remains to be fully defined, they appear to act as nonselective sodium channel blocking agents. A large variety of sodium channels are present in nervous tissue, and some of these are important mediators of nociception, as they are found primarily in unmyelinated fibers and their density increases following nerve injury. While the pharmacodynamic effects of the various anticonvulsant drugs are similar, the pharmacokinetic effects differ significantly. Carbamazepine has important effects as an inducer of hepatic enzymes and may influence the metabolism of other drugs enough to present problems in patients taking more than one drug. Gabapentin and oxcarbazepine, by contrast, are relatively non-significant enzyme inducers, creating fewer drug interactions. Because anticonvulsant drugs may have more problematic side-effect profiles, their use should usually be deferred until antidepressant drugs have failed to relieve pain.

(a). Gabapentin (Neurontin)

(i). Description – Structurally related to gamma aminobutyric acid (GABA) but does not interact with GABA receptors.

(ii). Indications – Neuropathic pain.

(iii). Relative Contraindications – Renal insufficiency.

(iv). Dosing and Time to Therapeutic Effect – Dosage may be increased over several days.

(v). Major Side Effects – Confusion, sedation.

(vi). Drug Interactions – Oral contraceptives, cimetidine, antacids.

(vii). Recommended Laboratory Monitoring – Renal function.

ii. Antidepressants are classified into a number of categories based on their chemical structure and their effects on neurotransmitter systems. Their effects on depression are attributed to their actions on disposition of norepinephrine and serotonin at the level of the synapse; although these synaptic actions are immediate, the symptomatic response in depression is delayed by several weeks. When used for chronic pain, the effects may in part arise from treatment of underlying depression, but may also involve additional neuromodulatory effects on endogenous opioid systems, raising pain thresholds at the level of the spinal cord.

(a). Pain responses may occur at lower drug doses with shorter times to symptomatic response than are observed when the same compounds are used in the treatment of mood disorders. Neuropathic pain, diabetic neuropathy, post-herpetic neuralgia, and cancer-related pain may respond to antidepressant doses low enough to avoid adverse effects that often complicate the treatment of depression.

(i). Tricyclics (e.g., amitryptiline [Elavil], nortriptyline [Pamelor, Aventyl], doxepin [Sinequan, Adapin])

[a]. Description – Serotonergics, typically tricyclic antidepressants (TCAs), are utilized for their serotonergic properties as increasing CNS serotonergic tone can help decrease pain perception in non-antidepressant dosages. Amitriptyline is known for its ability to repair Stage 4 sleep architecture, a frequent problem found in chronic pain patients and to treat depression, frequently associated with chronic pain.

[b]. Indications – Chronic musculoskeletal and/or neuropathic pain, insomnia. Second line drug treatment for depression.

[c]. Major Contraindications – Cardiac disease or dysrhythmia, glaucoma, prostatic hypertrophy, seizures, suicide risk.

[d]. Dosing and Time to Therapeutic Effect – Varies by specific tricyclic. Low dosages are commonly used for chronic pain and/or insomnia.

[e]. Major Side Effects – Anticholinergic side effects including, but not limited to, dry mouth, sedation, orthostatic hypotension, cardiac arrhythmia, weight gain.

[f]. Drug Interactions – Tramadol (may cause seizures), Clonidine, cimetidine, sympathomimetics, valproic acid, warfarin, carbamazepine, bupropion, anticholinergics, quinolones.

[g]. Recommended Laboratory Monitoring – Renal and hepatic function. Electrocardiogram (EKG) for those on high dosages or with cardiac risk.

iii. Hypnotics and Sedatives: Sedative and hypnotic drugs decrease activity, induce drowsiness, and moderate agitation. Many drugs produce these effects incidental to their usual intended effects, similar to the side effects of many antihistamines and antidepressants. Due to the habit-forming potential of the benzodiazepines and other drugs found in this class, they are not routinely recommended but may be useful in some patients with chronic pain.

(a). Most insomnia in chronic pain patients should be managed primarily though behavioral interventions with medications as secondary measures (refer to Disturbances of Sleep).

(i). Zaleplon (Sonata)

[a]. Description – A nonbenzodiazepine hypnotic.

[b]. Indications – Insomnia.

[c]. Dosing and Time to Therapeutic Effect – Time of onset is 30 to 60 minutes. Due to rapid elimination, may be taken as little as 4 hours before awakening.

[d]. Major Side Effects – Dizziness, dose-related amnesia.

[e]. Drug Interactions – Increases sedative effect of other CNS depressant drugs. Use low dose if on cimetidine.

[f]. Recommended Laboratory Monitoring – Hepatic function.

(ii). Zolpidem (Ambien)

[a]. Description – A nonbenzodiazepine hypnotic, which does not appear to cause rebound insomnia. It has little respiratory depression and insignificant anxiolytic or muscle relaxant activity.

[b]. Indications – Short-term use for insomnia

[c]. Time to Produce Therapeutic Effect – Onset of action is 30 to 60 minutes

[d]. Major Side Effects – Dizziness, dose-related amnesia.

[e]. Drug Interactions – Increases sedative effect of other CNS depressant drugs.

[f]. Recommended Laboratory Monitoring – Hepatic function.

iv. Opioids are the most powerful analgesics. Their use in acute pain and moderate to severe cancer pain is well accepted. Their use in chronic nonmalignant pain, however, is fraught with controversy and lack of scientific research.

(a). Opioids include some of the oldest and most effective drugs used in the control of severe pain. The discovery of opioid receptors and their endogenous peptide ligands has led to an understanding of effects at the binding sites of these naturally occurring substances. Most of their analgesic effects have been attributed to their modification of activity in pain pathways within the central nervous system; however, it has become evident that they also are active in the peripheral nervous system. Activation of receptors on the peripheral terminals of primary afferent nerves can mediate antinociceptive effects, including inhibition of neuronal excitability and release of inflammatory peptides. Some of their undesirable effects on inhibiting gastrointestinal motility are peripherally mediated by receptors in the bowel wall.

(b). The central nervous system actions of these drugs account for much of their analgesic effect and for many of their other actions, such as respiratory depression, drowsiness, mental clouding, reward effects, and habit formation. With respect to the latter, it is crucial to distinguish between three distinct phenomena: tolerance, dependence, and addiction.

(c). Tolerance refers to a state of adaptation in which exposure to a drug over time causes higher doses of that drug to be required in order to produce the same physiologic effect.

(d). Dependence refers to a set of disturbances in body homeostasis that leads to withdrawal symptoms, which can be produced with abrupt discontinuation, rapid reduction, decreasing blood levels, and /or by administration of an antagonist.

(e). Addiction is a primary, chronic, neurobiologic disease, with genetic, psychological, and environmental factors influencing its development and manifestations. It is a behavioral pattern of drug craving and seeking which leads to a preoccupation with drug procurement and use.

(f). Tolerance and dependence are physiological phenomena, are expected with the continued administration of opioids, and should not deter physicians from their appropriate use.

(g). The use of opioids is well accepted in treating cancer pain, where nociceptive mechanisms are generally present due to ongoing tissue destruction, expected survival may be short, and symptomatic relief is emphasized more than functional outcomes. In chronic non-malignant pain, by contrast, tissue destruction has generally ceased, meaning that central and neuropathic mechanisms frequently overshadow nociceptive processes. Expected survival in chronic pain is relatively long and return to a high level of function is a major goal of treatment. Therefore, approaches to pain developed in the context of malignant pain may not be transferable to chronic non-malignant pain.

(h). In most cases, analgesic treatment should begin with acetaminophen, aspirin, and NSAIDs. While maximum efficacy is modest, they may reduce pain sufficiently to permit adequate function. When these drugs do not satisfactorily reduce pain, opioids for moderate to moderately severe pain may be added to (not substituted for) the less efficacious drugs.

(i). Consultation or referral to a pain specialist should be considered when the pain persists but the underlying tissue pathology is minimal or absent and correlation between the original injury and the severity of impairment is not clear. Consider consultation if suffering and pain behaviors are present and the patient continues to request medication, or when standard treatment measures have not been successful or are not indicated.

(i). General Indications – There must be a clear understanding that opioids are to be used for a limited term in the first instance (see trial indications below), that their use is contingent upon certain obligations or goals being met by the patient, e.g., return to work, and the patient understands that there may be drug screening to ensure compliance.

(ii). Therapeutic Trial Indications – A therapeutic trial of opioids should not be employed unless the patient has begun a rehabilitation program. Once this criterion has been met, opioids would be indicated when a patient meets the following:

[a]. The failure of pain management alternatives, including active therapies, cognitive behavioral therapy, pain self-management techniques, and other appropriate medical techniques.

[b]. Physical and psychosocial assessment, performed by two specialists with one being the authorized treating physician.

[c]. Informed, written, witnessed consent by the patient.

[i]. In addition, there should be documentation of sustained improvement of pain control and/or functional status, including return to work, with use of opioids. Frequent follow-up at least every two to four weeks may be necessary to titrate dosage and assess clinical efficacy.

(iii). On-Going, Long-Term Management – Actions should Include:

[a]. Prescriptions from a single practitioner.

[b]. Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects.

[c]. Ongoing effort to gain improvement of social and physical function as a result of pain relief.

[d]. Contract detailing reasons for termination of supply, with appropriate tapering of dose.

[e]. Use of random drug screening, as deemed appropriate by the prescribing physician.

[f]. Use of more than two opioids. A long acting opioid for maintenance of pain relief and a short acting opioid for limited rescue use when pain exceeds the

routine level. If more than two opioids are prescribed for long-term use a second opinion from specialist who is Board Certified in Neurology, Physical Medicine and Rehabilitation, or Anesthesiology with recognized training and/or certification in pharmacological pain management is strongly recommended.

[g].Use of acetaminophen-containing medications in patients with liver disease should be limited; and

[h]. Continuing review of overall situation with regard to nonopioid means of pain control.

[i]. Inpatient treatment in complex cases. Refer to Interdisciplinary Rehabilitation Programs for detailed information on in-patient criteria.

(iv). Relative Contraindications – Extreme caution should be used in prescribing controlled substances for workers with one or more "relative contraindications":

[a]. History of alcohol or other substance abuse, or a history of chronic, high-dose benzodiazepine use;

[b]. Off work for more than six months;

[c]. Severe personality disorder.

(v). General Contraindications –

[a]. Active alcohol or other substance abuse.

[b]. Untreated mood or psychotic disorders (e.g., depression).

[c]. Decreased physical or mental function with continued opioid use.

[d]. Addictive behaviors. Warning signs include:

[i]. Preoccupation with drugs;

[ii]. Refusal to participate in medication taper.

[iii]. Reporting that nothing but a specific opioid works;

[iv]. Strong preference for short-acting over long-acting opioids.

[v]. Use of multiple prescribers and pharmacies.

[vi]. Use of street drugs or other patients drugs.

[vii]. Not taking medications as prescribed.

[viii]. Loss of medications more than once; and/or

[ix]. Criminal behaviors to obtain drugs, i.e., forged prescriptions.

(vi). Dosing and Time to Therapeutic Effect. Oral route is the preferred route of analgesic administration because it is the most convenient and cost-effective method of administration. When patients cannot take medications orally, rectal and transdermal routes should be considered because they are also relatively noninvasive.

(vii). Major Side Effects. There is great individual variation in susceptibility to opioid-induced side effects and clinicians should monitor for these potential side effects. Common initial side effects include nausea, vomiting, drowsiness, unsteadiness, and confusion. Occasional side effects include dry mouth, sweating, pruritus, hallucinations, and myoclonus. Rare side effects include respiratory depression and psychological dependence. Constipation and nausea/vomiting are common problems associated with long-term opioid administration and should be anticipated, treated prophylactically, and monitored constantly.

(viii). Drug Interactions. Patients receiving opioid agonists should not be given a mixed agonist-antagonist (pentazocine [Talwin], butorphanol [Stadol]) because doing so may precipitate a withdrawal syndrome and increase pain.

(ix). Recommended Laboratory Monitoring. Primary laboratory monitoring is recommended for acetaminophen/aspirin/ibuprofen combinations (renal and liver function, blood dyscrasias). May perform urine and or blood drug screen if suspect use of other narcotics or lack of compliance with full medication regimen.

{x}. Patient Physician Contracts. All patients on chronic opioids should have an informed, written, witnessed consent. The contract should discuss side effects of opioids, results of use in pregnancy, inability to refill lost or missing medication, withdrawal symptoms, requirement for drug testing, and necessity of tapering.

(xi). Potentiating Agents. Some medications appear to potentiate the analgesic effects of opioids. Dextromethorphan is available as a nonopioid non-prescription antitussive agent in numerous cough and cold remedies. It antagonizes n-methyl-d-aspartate receptors involved in central sensitization of pain pathways. It may exert some morphine sparing effects in patients taking morphine, but its activity as an analgesic in neuropathic pain is likely to be weak. It is well tolerated in most patients. Because the patient profiles that might predict response to dextromethorphan are undefined, its use in chronic pain must be empirically tried on an individual basis. Diphenhydramine and hydroxyzine (atarax, vistaril) are antihistamines, which act at H 1 receptors to alleviate allergic symptoms and produce somnolence. Diphenhydramine is a component of some non-prescription sleeping preparations. Their use in potentiating the effects of analgesic drugs is not clearly defined, but it may be used empirically for this purpose.

v. Topical Drug Delivery:

(a). Description. Topical medications, such as ketamine and capsacin, may be an alternative treatment for neuropathic disorders and is an acceptable form of treatment in selected patients although there is no literature addressing its use in patients with CRPS.

(b). Indications. Pain. Patient selection must be rigorous to select those patients with the highest probability of compliance.

(c). Dosing and Time to Therapeutic Effect. It is necessary that all topical agents be used with strict instructions for application as well as maximum number of applications per day to obtain the desired benefit and avoid potential toxicity.

(d). Side Effects. Localized skin reactions may occur, depending on drug.

vi. Other Agents:

(a). Tramadol (Ultram)

(i). Description. An opioid partial agonist that is generally well tolerated, does not cause GI ulceration, or exacerbate hypertension or congestive heart failure.

(ii). Indications. Mild to moderate pain relief. This drug has been shown to provide pain relief equivalent to that of commonly prescribed NSAIDs.

(iii). Contraindications. Use cautiously in patients who have a history of seizures or who are taking medication that may lower the seizure threshold, such as monoamine oxidase (MAO) inhibitors, selective serotonin reuptake inhibitors (SSRIs), and tricyclic antidepressants (TCAs). Not recommended in those with prior opioid addiction.

(iv). Side Effects. May cause impaired alertness or nausea. This medication has physically addictive properties and withdrawal may follow abrupt discontinuation.

(v). Drug Interactions. Narcotics, sedating medications.

(vi). Recommended Laboratory Monitoring. Renal and hepatic function.

(b). Agents not listed which may be useful in the treatment of CRPS and SMP include propranolol, nifedipine, calcitonin, bisphosphonates and short-term oral steroids, during the acute phase of the disease. Although propranolol, nifedipine, oral steroids, and calcitonin are used in practice, at this time there is a lack of well-designed studies to support their effectiveness compared to placebo. In individual patients, they may be effective. There is some evidence to support the use of intravenous bisphosphonate drugs, currently licensed for use in malignant bone disease and Paget's disease, in CRPS patients with abnormal bone scans. Oral use of bisphosphonates has not been studied in CRPS.

7. Orthotics/prosthetics/equipment. Devices and adaptive equipment may be necessary in order to reduce impairment and disability, to facilitate medical recovery, to avoid re-aggravation of the injury, and to maintain maximum medical improvement. Refer to the Chronic Pain Medical Treatment Guidelines for detailed information on Orthotics/Prosthetics/Equipment.

8. Patient education. Patients should be educated on their specific injury, assessment findings, and plan of treatment and encouraged to take an active role in establishing functional outcome goals. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of prolonging the beneficial effects of rehabilitation, as well as facilitating self-management of symptoms and prevention of secondary disability. There is good evidence that patient education in self-management of asthma, anticoagulation, and other diseases improves appropriate use of medications, increases patient satisfaction with care, and reduces unscheduled physician visits for dealing with complications of treatment.

a. Patient education is an interactive process that provides an environment where the patient not only acquires knowledge but also gains an understanding of the application of that knowledge. Therefore, patients should be able to describe and/or will need to be educated on:

i. The treatment plan.

ii. Indications for and potential side effects of medications.

iii. Their home exercise program.

iv. Expected results of treatment.

v. Tests to be performed, the reasons for them and their results.

vi. Activity restrictions and return-to-work status.

vii. Home management for exacerbations of pain.

viii. Procedures for seeking care for exacerbations after office hours.

ix. Home self-maintenance program.

x. Patient responsibility to communicate with all medical providers and the employer; and

xi. Patient responsibility to keep appointments.

b. Educational efforts should also extend to family and other support persons, the case manager, the insurer and the employer as indicated to optimize the understanding of the patient and the outcome. Professional translators should be provided for non-English speaking patients to assure optimum communication. All education, teaching, and instruction given to the patient should be documented in the medical record.

c. Effects of education weaken over time; continuing patient education sessions will be required to maximize the patient's function. The effectiveness of educational efforts can be enhanced through attention to the learning style and receptivity of the patient. Written educational materials may reinforce and prolong the impact of verbal educational efforts. Overall, patient education should emphasize health and wellness, return to work and return to a productive life.

i. Time to produce effect: Varies with individual patient

ii. Frequency: At each visit

9. Personality/psychological/psychiatric/ psychosocial intervention. Psychosocial treatment is generally accepted, well-established therapeutic and diagnostic procedure with selected use in acute pain problems, but with more widespread use in sub-acute and chronic pain populations. Psychosocial treatment is recommended as an important component in the total management of a patient with chronic pain and should be implemented as soon as the problem is identified.

a. Once a diagnosis consistent with the standards of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders (DSM) has been determined, the patient should be evaluated for the potential need for psychiatric medications. Use of any medication to treat a diagnosed condition may be ordered by the authorized treating physician or by the consulting psychiatrist and/or medical psychologists. Visits for management of psychiatric medications are medical in nature and are not a component of psychosocial treatment. Therefore, separate visits for medication management may be necessary, depending upon the patient and medications selected.

b. The screening or diagnostic workup should have clarified and distinguished between preexisting, aggravated, and or purely causative psychological conditions. Therapeutic and diagnostic modalities include, but are not limited to, individual counseling, and group therapy. Treatment can occur within an individualized model, a multi-disciplinary model, or within a structured pain management program.

c. Refer to Chronic Pain guideline for detailed information on whom may perform the service and timeframe parameters.

10. Restriction of activities. Continuation of normal daily activities is the recommendation for chronic pain

patients since immobility will negatively affect rehabilitation. Prolonged immobility results in a wide range of deleterious effects, such as a reduction in aerobic capacity and conditioning, loss of muscle strength and flexibility, increased segmental stiffness, promotion of bone demineralization, impaired disc nutrition, and the facilitation of the illness role.

a. Patients should be educated to the detrimental effects of immobility versus the efficacious use of rest periods. Adequate rest allows the patient to comply with active treatment and benefit from the rehabilitation program. In addition, complete work cessation should be avoided, if possible, since it often further aggravates the pain presentation and promotes disability. Modified return to work is almost always more efficacious and rarely contraindicated in the vast majority of injured workers with chronic pain.

11. Return-to-work is one of the major components in chronic pain management. Return to work is a subject that should be addressed by each workers' compensation provider at the first meeting with the injured employee, and be updated at each additional visit. A return to work format should be part of a company's health plan, knowing that return to work can decrease anxiety, reduce the possibility of depression, and reconnect the worker with society.

a. Because a prolonged period of time off work will decrease the likelihood of return to work, the first weeks of treatment are crucial in preventing and/or reversing chronicity and disability mindset. In complex cases, experienced nurse case managers may be required to assist in return to work. Other services, including psychological evaluation and/or treatment and vocational assistance should be employed.

b. The following should be considered when attempting to return an injured worker with chronic pain to work.

i. Job History Interview. The authorized treating physician should perform a job history interview at the time of the initial evaluation and before any plan of treatment is established. Documentation should include the workers' job demands, stressors, duties of current job, and duties of job at the time of the initial injury. In addition, cognitive and social issues should be identified and treatment of these issues should be incorporated into the plan of care.

ii. Coordination of Care. Management of the case is a significant part of return to work and may be the responsibility of the authorized treating physician, occupational health nurse, risk manager, or others. Case management is a method of communication between the primary provider, referral providers, insurer, employer and employee. Because case management may be coordinated by a variety of professionals, the case manager should be identified in the medical record.

iii. Communication is essential between the patient, authorized treating physician, employer and insurer. Employers should be contacted to verify employment status, job duties and demands, and policies regarding injured workers. In addition, availability of temporary and permanent restrictions, for what duration, as well as other placement options should be discussed and documented.

iv. Establishment of a Return-To-Work Status. Return to work for persons with chronic pain should be thought of as therapeutic, assuming that work is not likely to aggravate the basic problem or increase the discomfort. In most cases of chronic pain, the worker may not be currently working or even employed. The goal of return to work would be to implement a plan of care to return the worker to any level of employment with the current employer or to return them to any type of new employment.

v. Establishment of Activity Level Restrictions. A formal job description for the injured/ill employee who is employed is necessary to identify physical demands at work and assist in the creation of modified duty. A jobsite evaluation may be utilized to identify tasks such as pushing, pulling, lifting, reaching above shoulder level, grasping, pinching, sitting, standing, posture, ambulatory distance and terrain, and if applicable, environment for temperature, air flow, noise and the number of hours that may be worked per day. Work restrictions assigned by the authorized treating physician may be temporary or permanent. The case manager should continue to seek out modified work until restrictions become less cumbersome or as the worker's condition improves or deteriorates.

vi. Rehabilitation and Return to Work. As part of rehabilitation, every attempt should be made to simulate work activities so that the authorized treating physician may promote adequate job performance. The use of ergonomic or adaptive equipment, therapeutic breaks, and interventional modalities at work may be necessary to maintain employment.

vii. Vocational Assistance. Formal vocational assistance is a generally accepted intervention and can assist disabled persons to return to viable employment. Assisting patients to identify vocational goals will facilitate medical recovery and aid in the maintenance of MMI by increasing motivation towards treatment and alleviating the patient's emotional distress. Chronic pain patients will benefit most if vocational assistance is provided during the interdisciplinary rehabilitation phase of treatment. To assess the patient's vocational capacity, a vocational assessment may be utilized to identify rehabilitation program goals, as well as optimize both patient motivation and utilization of rehabilitation resources.

(a). Employers and employees of small businesses who are diagnosed with chronic pain may not be able to perform any jobs for which openings exist. Temporary employees may fill those slots while the employee functionally improves. Some small businesses hire other workers and if the injured employee returns to the job, the supervisor/owner may have an extra employee. To avoid this, it is suggested that case managers be accessed through their insurer or third party insurers. Case managers may assist with resolution of these problems, as well as assist in finding modified job tasks, or find jobs with reduced hours, etc., depending upon company philosophy and employee needs.

(b). Employers and employees of mid-sized and large businesses are encouraged by the OWCA to identify modified work within the company that may be available to injured workers with chronic pain who are returning to work

with temporary or permanent restrictions. To assist with temporary or permanent placement of the injured worker, it is suggested that a program be implemented that allows the case manager to access descriptions of all jobs within the organization.

12. Therapy — active is based on the philosophy that therapeutic exercise and/or activity are beneficial for restoring flexibility, strength, endurance, function, range of motion, and can alleviate discomfort.

a. Active therapy requires an internal effort by the individual to complete a specific exercise or task. This form of therapy requires supervision from a therapist or medical provider such as verbal, visual and/or tactile instruction(s). Active therapy is intended to promote independence and self-reliance in managing the physical pain as well as to improve the functional status in regard to the specific diagnosis and general conditioning and well-being. At times, a provider may help stabilize the patient or guide the movement pattern but the energy required to complete the task is predominately executed by the patient.

b. Patients should be instructed to continue active therapies at home as an extension of the treatment process in order to maintain improvement levels. Home exercise can include exercise with or without mechanical assistance or resistance and functional activities with assistive devices.

c. Since CRPS and SMP patients frequently have additional myofascial pain generators, other active therapies not listed may be used in treatment. Refer to the Chronic Pain Medical Treatment Guideline for therapies and timeframe parameters not listed. The following active therapies are listed in alphabetical order:

i. Activities of Daily Living (ADL) Activities of daily living are instruction, active-assisted training, and/or adaptation of activities or equipment to improve a person's capacity in normal daily activities such as self-care, work re-integration training, homemaking and driving.

(a). Time to produce effect: four to five treatments

(b). Frequency: three to five times per week

(c). Optimum duration: four to six weeks

(d). Maximum duration: six weeks

ii. Aquatic Therapy is the implementation of active therapeutic procedures (individual or group) in a swimming or therapeutic pool heated to 88-92 degrees. The water provides a buoyancy force that lessens the amount of force gravity applies to the body, and the pool should be large enough to allow full extremity range of motion and full erect posture. The decreased gravity effect allows the patient to have a mechanical advantage increases the likelihood of successful therapeutic exercise. Multiple limb involvement, weight bearing problems, and vasomotor abnormalities are frequently treated with water exercise. Indications for individuals who may not tolerate active land-based or full weight bearing therapeutic procedures or who require augmentation or other therapy. Aquatic vests, belts and other devices can be used to provide stability, balance, buoyancy, and resistance.

(a). Time to produce effect: 5 to 10 sessions

(b). Frequency: one to three times per week

(c). Optimum duration: four to six weeks

(d). Maximum duration: Six weeks. Multiple limb involvement may require longer intervention.

iii. Gait Training. Indications include the need to promote normal gait pattern with assistive devices and/or to reduce risk of fall or loss of balance. This may include instruction in safety and proper use of assistive devices and gait instruction on uneven surfaces and steps (with or without railings).

(a). Time to produce effect: one to six sessions

(b). Frequency: one to three times per week

(c). Optimum duration: two weeks. Could be needed intermittently as changes in functional status occur.

(d). Maximum duration: one month.

iv. Neuromuscular Re-education is the skilled application of exercise with manual, mechanical, or electrical facilitation to enhance strength, movement patterns, neuromuscular response, proprioception, kinesthetic sense, coordination, education of movement, balance, and posture. Indications include the need to promote neuromuscular responses through carefully timed proprioceptive stimuli, to elicit and improve motor activity in patterns similar to normal neurologically developed sequences, and improve neuromotor response with independent control.

(a). Time to produce effect: six treatments

(b). Frequency: one to three times per week

(c). Optimum duration: four to eight weeks

(d). Maximum Duration: 8 to 12 weeks

v. Stress Loading is considered a reflex and sensory integration technique involving the application of a compressive load and a carry load. It is carried out in a consistent, progressive manner and integrated as part of a home program. Use of this technique may increase symptoms initially, but symptoms generally subside with program consistency.

(a). Time to produce effect: three weeks

(b). Frequency: two to three times per week.

(c). Optimum duration: Four to six weeks and concurrent with an active daily home exercise program.

(d). Maximum Duration: 6 to 10 weeks

vi. Therapeutic exercise with or without mechanical assistance or resistance, may include isoinertial, isotonic, isometric and isokinetic types of exercises. Stress loading exercises are recommended. Indications include the need for cardiovascular fitness, reduced edema, improved muscle strength, improved connective tissue strength and integrity, increased bone density, promotion of circulation to enhance soft tissue healing, improvement of muscle recruitment, increased range of motion and are used to promote normal movement patterns. This can also include, alternative/complementary exercise movement therapy. Therapeutic exercise programs should be tissue specific to the injury and address general functional deficits as identified in the diagnosis and clinical assessment. Patients should be instructed in and receive a home exercise program that progresses as their functional status improves. Upon discharge, the patient would be independent in the performance of the home exercise program and would have been educated in the importance of continuing such a program. Educational goals would be to maintain or further improve function and to minimize the risk for aggravation of symptoms in the future.

(a). Time to produce effect: three weeks

(b). Frequency: one to three times per week

(c). Optimum duration: Four to eight weeks and concurrent with an active daily home exercise program.

(d). Maximum Duration: 8 to 12 weeks of therapist oversight. Home exercise should continue indefinitely.

13. Therapy — passive. Most of the following passive therapies and modalities are generally accepted methods of care for a variety of work-related injuries. Passive therapy includes those treatment modalities that do not require energy expenditure on the part of the patient. They are principally effective during the early phases of treatment and are directed at controlling symptoms such as pain, inflammation and swelling and to improve the rate of healing soft tissue injuries. They should be used adjunctively with active therapies to help control swelling, pain and inflammation during the rehabilitation process. They may be used intermittently as a therapist deems appropriate, or regularly if there are specific goals with objectively measured functional improvements during treatment.

a. Factors such as exacerbation of symptoms, re-injury, interrupted continuity of care, and co-morbidities may extend durations of care. Having specific goals with objectively measured functional improvement during treatment can support extended durations of care. It is recommended that if after 6 to 8 visits no treatment effect is observed, alternative treatment interventions, further diagnostic studies or further consultations should be pursued.

b. Since CRPS and SMP patients frequently have additional myofascial pain generators, other passive therapies not listed may be used in treatment. Refer to the Chronic Pain Disorder Medical Treatment Guideline's for therapies and timeframe parameters not listed. The following passive therapies are listed in alphabetical order:

i. Continuous Passive Motion (CPM): is rarely indicated in CRPS but may occasionally be warranted if the patient shows signs of contracture despite active therapy.

(a). Time to produce effect: Four to six treatments

(b). Frequency: Varies, between two to three times per day and one time per week.

(c). Optimum duration: Four treatments

(d). Maximum duration: Six treatments. Provide home unit with improvement.

ii. Fluidotherapy. Used primarily for desensitization and to facilitate increased active range of motion. Thermal heat conduction and convection is advantageous for vasodilation, muscle relaxation, and preparation for stress and activity (exercise).

(a). Time to produce effect: Three treatments

(b). Frequency: Three times per week

(c). Optimum duration: Two months

(d). Maximum duration: Two months as a primary therapy or intermittently as an adjunct therapy to other procedures.

iii. Orthotics/Splinting. Static splinting is discouraged. Dynamic splinting may occasionally be useful in controlling proximal hypertonicity or for other concurrent pain generators.

(a). Time to produce effect: One week

(b). Frequency: varies depending upon application

(c). Optimum duration: One month

(d). Maximum duration: Two months

iv. Paraffin Bath. Indications include the need to enhance collagen extensibility before stretching, reduce muscle guarding, and to prepare for functional restoration activities.

(a). Time to produce effect: One to two treatments

(b). Frequency: One to three times per week as an adjunct treatment to other procedures. May use daily if available at home

(c). Optimum duration: Two weeks

(d). Maximum duration: Three to four weeks. If effective, purchase home unit.

v. Desensitization is accomplished through sensory integration techniques. Concurrent desensitization techniques are generally accepted as a treatment for CRPS. Home techniques using soft cloths of various textures, massage, and vibrators may be beneficial in reducing allodynia and similar sensory abnormalities.

(a). Time to produce effect: Six treatments

(b). Frequency: Three times per week and concurrent with home exercise program

(c). Optimum duration: Three weeks with reinforcement of home program

(d). Maximum duration: One month.

vi. Superficial Heat Therapy. Superficial heat is a thermal agent applied to raise the body tissue temperature. It is indicated before exercise to elevate the pain threshold, alleviate muscle spasm, and promote increased movement. Heat packs can be used at home as an extension of therapy in the clinic setting.

(a). Time to produce effect: Immediate

(b). Frequency: One to three times per week

(c). Optimum duration: Two weeks as primary or intermittently as an adjunct to other therapeutic procedures.

(d). Maximum duration: Two weeks. Home use as a primary modality may continue at the providers' discretion.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1723 (June 2011).

§2133. Therapeutic Procedures—Operative

A. When considering operative intervention in chronic pain management, the treating physician must carefully consider the inherent risk and benefit of the procedure. All operative intervention should be based on a positive correlation with clinical findings, the clinical course, and diagnostic tests. A comprehensive assessment of these factors should have led to a specific diagnosis with positive identification of the pathologic conditions(s).

B. Surgical procedures are seldom meant to be curative and would be employed in conjunction with other treatment modalities for maximum functional benefit. Functional benefit should be objectively measured and includes the following:

1. Return to work or maintaining work status.

2. Fewer restrictions at work or performing activities of daily living (ADL).

3. Decrease in usage of medications.

4. Measurable functional gains, such as increased range of motion or documented increase in strength.

C. Education of the patient should include the proposed goals of the surgery, expected gains, risks or complications, and alternative treatment.

1. Intrathecal drug delivery. This mode of therapy delivers small doses of medications directly into the cerebrospinal fluid. Refer to the Chronic Pain Medical Treatment Guideline's for detailed information and recommendations for its use in CRPS patients with chronic pain.

2. Neurostimulation is the delivery of low-voltage electrical stimulation to the spinal cord or peripheral nerves to inhibit or block the sensation of pain. Refer to the Chronic Pain Medical Treatment Guideline's for detailed information and recommendations for its use in CRPS patients with chronic pain.

3. Sympathectomy

a. Description. Destruction of part of the sympathetic nervous system, which is not generally accepted or widely used. Long-term success with this pain relief treatment is poor. This procedure requires prior authorization.

b. Indications. Single extremity CRPS-I or SMP; distal pain only (should not be done if the proximal extremity is involved). Local anesthetic Stellate Ganglion Block or Lumbar Sympathetic Block consistently gives 90 to 100 percent relief each time a technically good block is performed (with measured rise in temperature). The procedure may be considered for individuals who have limited duration of relief from blocks. Permanent neurological complications are common.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1733 (June 2011).

§2135. Maintenance Management

A. Successful management of chronic pain conditions results in fewer relapses requiring intense medical care. Failure to address long-term management as part of the overall treatment program may lead to higher costs and greater dependence on the health care system. Management of CRPS and SMP continues after the patient has met the definition of maximum medical improvement (MMI). MMI is declared when a patient's condition has plateaued and the authorized treating physician believes no further medical intervention is likely to result in improved function. When the patient has reached MMI, a physician must describe in detail the maintenance treatment.

B. Maintenance care in CRPS and SMP requires a close working relationship between the carrier, the providers, and the patient. Providers and patients have an obligation to design a cost effective, medically appropriate program that is predictable and allows the carrier to set aside appropriate reserves. Carriers and adjusters have an obligation to assure that medical providers can plan medically appropriate programs. A designated primary physician for maintenance team management is recommended.

C. Maintenance Care will be based on principles of patient self-management. When developing a maintenance plan of care, the patient, physician and insurer should attempt to meet the following goals:

1. Maximal independence will be achieved through the use of home exercise programs or exercise programs requiring special facilities (e.g., pool, health club) and educational programs;

2. Modalities will emphasize self management and self-applied treatment;

3. Management of pain or injury exacerbations will emphasize initiation of active therapy techniques and may occasionally require anesthetic injection blocks.

4. Dependence on treatment provided by practitioners other than the authorized treating physician will be minimized;

5. Periodic reassessment of the patient's condition will occur as appropriate.

6. Patients will understand that failure to comply with the elements of the self-management program or therapeutic plan of care may affect consideration of other interventions.

D. Specific Maintenance Interventions and Parameters

1. Home exercise programs and exercise equipment. Most patients have the ability to participate in a home exercise program after completion of a supervised exercise rehabilitation program. Programs should incorporate an exercise prescription including the continuation of an age-adjusted and diagnosis-specific program for aerobic conditioning, flexibility, stabilization, and strength. Some patients may benefit from the purchase or rental of equipment to maintain a home exercise program. Determination for the need of home equipment should be based on medical necessity to maintain MMI, compliance with an independent exercise program, and reasonable cost. Before the purchase or long-term rental of equipment, the patient should be able to demonstrate the proper use and effectiveness of the equipment. Effectiveness of equipment should be evaluated on its ability to improve or maintain functional areas related to activities of daily living or work activity. Occasionally, compliance evaluations may be made through a 4-week membership at a facility offering similar equipment. Home exercise programs are most effective when done three to five times a week.

2. Exercise programs requiring special facilities. Some patients may have higher compliance with an independent exercise program at a health club versus participation in a home program. All exercise programs completed through a health club facility should focus on the same parameters of an age-adjusted and diagnosis-specific program for aerobic conditioning, flexibility, stabilization, and strength. Selection of health club facilities should be limited to those able to track attendance and utilization, and provide records available for physician and insurer review. Prior to purchasing a membership, a therapist and or exercise specialist who has treated the patient may visit the facility with the patient to assure proper use of the equipment.

a. Frequency: two to three times per week.

b. Optimal Duration: one to three months.

c. Maximum Maintenance duration: Three months. Continuation beyond three months should be based on functional benefit and patient compliance. Health club membership should not extend beyond three months if attendance drops below two times per week on a regular basis.

3. Patient education management. Educational classes, sessions, or programs may be necessary to reinforce self-management techniques. This may be performed as formal or informal programs, either group or individual.

a. Maintenance duration: Two to six educational sessions during one 12-month period.

4. Psychological management. An ideal maintenance program will emphasize management options implemented in the following order: individual self-management (pain control, relaxation and stress management, etc.), group counseling, individual counseling by a psychologist or psychiatrist and in-patient treatment. Aggravation of the injury may require more intense psychological treatment to restore the patient to baseline. In those cases, use treatments and timeframe parameters listed in the Biofeedback and Psychological Evaluation or Intervention sections.

a. Maintenance duration: 6 to 10 visits during one 12-month period.

5. Non-narcotic medication management. In some cases, self-management of pain and injury exacerbations can be handled with medications, such as those listed in Medication Section. Physicians must follow patients who are on any chronic medication or prescription regimen for efficacy and side effects. Laboratory or other testing may be appropriate to monitor medication effects on organ function.

a. Maintenance duration: Usually, four medication reviews within a 12-month period. Frequency depends on the medications prescribed. Laboratory and other monitoring as appropriate.

6. Narcotic medication management. As compared with other pain syndromes, there may be a role for chronic augmentation of the maintenance program with narcotic medications. In selected cases, scheduled medications may prove to be the most cost effective means of insuring the highest function and quality of life; however, inappropriate selection of these patients may result in a high degree of iatrogenic illness. A patient should have met the criteria in opioids section of these guidelines before beginning maintenance narcotics. Laboratory or other testing may be appropriate to monitor medication effects on organ function. The following management is suggested for maintenance narcotics:

a. The medications should be clearly linked to improvement of function, not just pain control. All follow up visits should document the patient's ability to perform routine functions satisfactorily. Examples include the abilities to: perform work tasks, drive safely, pay bills or perform basic math operations, remain alert for 10 hours, or participate in normal family and social activities. If the patient is not maintaining reasonable levels of activity the patient should usually be tapered from the narcotic and tried on a different long-acting opioid.

b. A low dose narcotic medication regimen should be defined, which may minimally increase or decrease over time. Dosages will need to be adjusted based on side effects of the medication and objective function of the patient. A patient may frequently be maintained on additional non-narcotic medications to control side effects, treat mood disorders, or control neuropathic pain; however, only one long-acting narcotic and one short-acting narcotic for rescue use should be prescribed in most cases.

c. All patients on chronic narcotic medication dosages need to sign an appropriate narcotic contract with their physician for prescribing the narcotics.

d. The patient must understand that continuation of the medication is contingent on their cooperation with the maintenance program. Use of non-prescribed drugs may result in tapering of the medication. The clinician may order random drug testing when deemed appropriate to monitor medication compliance.

e. Patients on chronic narcotic medication dosages must receive them through one prescribing physician.

i. Maintenance duration: Up to 12 visits within a 12-month period to review the narcotic plan. Laboratory and other monitoring as appropriate.

7. Therapy management. Some treatment may be helpful on a continued basis during maintenance care if the therapy maintains objective function and decreases medication use. Aggravation of the injury may require intensive treatment to get the patient back to baseline. In those cases, treatments and timeframe parameters listed in Section H, 13 and 14, Active and Passive Therapy.

a. Active Therapy, Acupuncture, and Manipulation maintenance duration: 10 visits in a 12-month period.

8. Injection therapy

a. Sympathetic Blocks. These injections are considered appropriate if they maintain or increase function for a minimum of four to eight weeks. Maintenance blocks are usually combined with and enhanced by the appropriate neuropharmacological medication(s) and other care. It is anticipated that the frequency of the maintenance blocks may increase in the cold winter months or with stress.

i. Maintenance duration. Not to exceed six to eight blocks in a 12-month period for a single extremity and to be separated by no less than four-week intervals. Increased frequency may need to be considered for multiple extremity involvement or for acute recurrences of pain and symptoms. For treatment of acute exacerbations, consider 2 to 6 blocks with a short time interval between blocks.

b. Trigger Point Injections. These injections may occasionally be necessary to maintain function in those with myofascial problems.

i. Maintenance duration. Not more than four injections per session not to exceed three to six sessions per 12-month period.

9. Purchase or rental of durable medical equipment. It is recognized that some patients may require ongoing use of self-directed modalities for the purpose of maintaining function and or analgesic effect. Purchase or rental of modality based equipment should be done only if the assessment by the physician and or therapist has determined the effectiveness, compliance, and improved or maintained function by its application. It is generally felt that large expense purchases such as spas, whirlpools, and special mattresses are not necessary to maintain function beyond the areas listed above.

a. Maintenance duration: Not to exceed three months for rental equipment. Purchase if effective.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1734 (June 2011).

§2136. LWC-WC 1009. Disputed Claim for Medical Treatment

Mail to:
OWCA—Medical Services
ATTN: Medical Director
P.O. Box 94040
Baton Rouge, LA 70804

1. Social Security No.__-__-__
2. Date of Injury/Illness __-__-__
3. Parts of Body Injury_____
4. Date of Birth __-__-__
5. Date of This Request __-__-__
6. Claim Number _____

DISPUTED CLAIM FOR MEDICAL TREATMENT

NOTE: THIS REQUEST WILL NOT BE HONORED UNLESS THE INSURER HAS ISSUED A DENIAL FOR THE MEDICAL SERVICES IN DISPUTE AS PER R.S. 23:1203.1 J.

GENERAL INFORMATION
Claimant files this dispute with the Office of Workers' Compensation – Medical Services Director. This office must be notified immediately in writing of changes in address. An employee may be represented by an attorney, but it is not required.

7. This request is submitted by
___ Employee ___ Employer __ Insurer ___ Health Care Provider ___ Other ___

A. Copies of all relevant medical records must be included with this request.

B. A copy of the denial letter issued by the insurance carrier must be attached to this request.

EMPLOYEE
8. Name _____
Street or Box _____
City _____
State _____ Zip _____
Phone (____) _____

EMPLOYEE'S ATTORNEY
9. Name _____
Street or Box _____
City _____
State _____
Phone (____) _____
Fax (____) _____

EMPLOYER
10. Name _____
Street or Box _____
City _____
State _____ Zip _____
Phone (____) _____
Fax (____) _____

INSURER/ADMINISTRATOR
(circle one)
11. Name _____
Street or Box _____
City _____
State _____
Phone (____) _____
Fax (____) _____

EMPLOYER/INSURER'S ATTORNEY
12. Name _____
Street or Box _____
City _____
State _____ Zip _____
Phone (____) _____
Fax (____) _____

TREATING/REQUESTING PHYSICIAN
13. Name _____
Street or Box _____
City _____
State _____
Phone (____) _____
Fax (____) _____

LWC-WC 1009
11/2010

14. PLEASE PROVIDE A SUMMARY OF THE DETAILS REGARDING THE ISSUE AT DISPUTE:
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

You may attach a letter or petition with additional information with this disputed claim.
The information given above is true and correct to the best of my knowledge and belief.

_____ _____
SIGNATURE OF REQUESTING PARTY DATE

LWC-WC 1009
11/2010

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1736 (June 2011).

Chapter 22. Neurological and Neuromuscular Disorder Medical Treatment Guidelines

Subchapter A. Carpal Tunnel Syndrome (CTS) Medical Treatment Guidelines

§2201. Introduction

A. This document has been prepared by the Louisiana Workforce Commission, Office of Workers' Compensation and should be interpreted within the context of guidelines for physicians/providers treating individuals qualifying under Louisiana's Workers' Compensation Act as injured workers with CTS. These guidelines are enforceable under the Louisiana Workers Compensation Act. All medical care, services, and treatment owed by the employer to the employee in accordance with the Louisiana Workers' Compensation Act shall mean care, services, and treatment in accordance with these guidelines. Medical care, services, and treatment that varies from these guidelines shall also be due by the employer when it is evidence, that a variance from these guidelines is reasonably required to cure or relieve the injured worker from the effects of the injury or occupational disease given the circumstances. Therefore, these guidelines are not relevant as evidence of a provider's legal standard of professional care. To properly utilize this document, the reader should not skip nor overlook any sections.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1736 (June 2011).

§2203. General Guideline Principles

A. The principles summarized in this section are key to the intended implementation of all Office of Workers' Compensation guidelines and critical to the reader's application of the guidelines in this document.

1. Application of Guidelines. The OWCA provides procedures to implement medical treatment guidelines and to foster communication to resolve disputes among the provider, payer, and patient through the Office of Worker's Compensation.

2. Education. Education of the patient and family, as well as the employer, insurer, policy makers and the community should be the primary emphasis in the treatment of CTS. Currently, practitioners often think of education last, after medications, manual therapy, and surgery. Practitioners must develop and implement an effective strategy and skills to educate patients, employers, insurance systems, policy makers, and the community as a whole. An education-based paradigm should always start with inexpensive

communication providing reassuring information to the patient. More in-depth education currently exists within a treatment regime employing functional restorative and innovative programs of prevention and rehabilitation. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of facilitating self-management of symptoms and prevention.

3. Treatment Parameter Duration. Time frames for specific interventions commence once treatments have been initiated, not on the date of injury. Obviously, duration will be impacted by patient compliance, as well as availability of services. Clinical judgment may substantiate the need to accelerate or decelerate the time frames discussed in this document. Such deviation shall be in accordance with La. R.S. 23:1203.1.

4. Active Interventions. Emphasizing patient responsibility, such as therapeutic exercise and/or functional treatment, are generally emphasized over passive modalities, especially as treatment progresses. Generally, passive interventions are viewed as a means to facilitate progress in an active rehabilitation program with concomitant attainment of objective functional gains.

5. Active Therapeutic Exercise Program. Exercise program goals should incorporate patient strength, endurance, flexibility, coordination, and education. This includes functional application in vocational or community settings.

6. Positive Patient Response. Positive results are defined primarily as functional gains that can be objectively measured. Standard measurement tools, including outcome measures, should be used. Objective functional gains include, but are not limited to, positional tolerances, range-of-motion (ROM), strength, and endurance, activities of daily living, cognition, psychological behavior, and efficiency/velocity measures that can be quantified. Subjective reports of pain and function should be considered and given relative weight when the pain has anatomic and physiologic correlation. Anatomic correlation must be based on objective findings.

7. Re-Evaluation Treatment Every three to four Weeks. If a given treatment or modality is not producing positive results within three to four weeks, the treatment should be either modified or discontinued. Reconsideration of diagnosis should also occur in the event of poor response to a seemingly rational intervention.

8. Surgical Interventions. Surgery should be contemplated within the context of expected functional outcome and not purely for the purpose of pain relief. The concept of "cure" with respect to surgical treatment by itself is generally a misnomer. All operative interventions must be based upon positive correlation of clinical findings, clinical course, and diagnostic tests. A comprehensive assimilation of these factors must lead to a specific diagnosis with positive identification of pathologic conditions.

9. Six-Month Time Frame. The prognosis drops precipitously for returning an injured worker to work once he/she has been temporarily totally disabled for more than six months. The emphasis within these guidelines is to move patients along a continuum of care and return-to-work within a six-month time frame, whenever possible. It is important to note that time frames may not be pertinent to injuries that do not involve work-time loss or are not occupationally related.

10. Return To Work. Return to work is therapeutic, assuming the work is not likely to aggravate the basic problem or increase long-term pain. The practitioner must provide specific written physical limitations and the patient should never be released to "sedentary" or "light duty." The following physical limitations should be considered and modified as recommended: lifting, pushing, pulling, crouching, walking, using stairs, bending at the waist, awkward and/or sustained postures, tolerance for sitting or standing, hot and cold environments, data entry and other repetitive motion tasks, sustained grip, tool usage and vibration factors. Even if there is residual chronic pain, return-to-work is not necessarily contraindicated. The practitioner should understand all of the physical demands of the patient's job position before returning the patient to full duty and should request clarification of the patient's job duties. Clarification should be obtained from the employer or, if necessary, including, but not limited to, an occupational health nurse, occupational therapist, vocational rehabilitation specialist, or an industrial hygienist.

11. Delayed Recovery. Delayed recovery strongly considers a psychological evaluation, if not previously provided, as well as initiating interdisciplinary rehabilitation treatment and vocational goal setting, for those patients who are failing to make expected progress 6 to 12 weeks after an injury. The OWCA recognizes that 3 to 10 percent of all industrially injured patients will not recover within the timelines outlined in this document despite optimal care. Such individuals may require treatments beyond the limits discussed within this document, but such treatment will require clear documentation by the authorized treating practitioner focusing on objective functional gains afforded by further treatment and impact upon prognosis.

12. Guideline Recommendations and Inclusion of Medical Evidence. Guidelines are recommendations based on available evidence and/or consensus recommendations. When possible, guideline recommendations will note the level of evidence supporting the treatment recommendation. When interpreting medical evidence statements in the guideline, the following apply:

a. *"Consensus"* means the opinion of experienced professionals based on general medical principles. Consensus recommendations are designated in the guideline as "generally well accepted," "generally accepted," "acceptable/accepted," or "well-established."

b. *"Some"* means the recommendation considered at least one adequate scientific study, which reported that a treatment was effective.

c. *"Good"* means the recommendation considered the availability of multiple adequate scientific studies or at least one relevant high-quality scientific study, which reported that a treatment was effective.

d. *"Strong"* means the recommendation considered the availability of multiple relevant and high quality scientific studies, which arrived at similar conclusions about the effectiveness of a treatment.

e. All recommendations in the guideline are considered to represent reasonable care in appropriately selected cases, regardless of the level of evidence or consensus statement attached to it. Those procedures considered inappropriate, unreasonable, or unnecessary are designated in the guideline as "not recommended."

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1736 (June 2011).

§2205. Definitions

A. Carpal tunnel syndrome (CTS) is one of the most common mononeuropathies (a disorder involving only a single nerve). The median nerve is extremely vulnerable to compression and injury in the region of the wrist and palm. In this area, the nerve is bounded by the wrist bones and the transverse carpal ligament. The most common site of compression is at the proximal edge of the flexor retinaculum (an area near the crease of the wrist). There is often a myofascial component in the patient's presentation. This should be considered when proceeding with the diagnostic workup and therapeutic intervention.

B. Studies have repeatedly confirmed that the diagnosis cannot be made based on any single historical factor or physical examination finding. Electrodiagnostic tests may be negative in surgically confirmed cases. Conversely, electrodiagnostic testing may be positive in asymptomatic individuals. The diagnosis of CTS, therefore, remains a clinical diagnosis based on a preponderance of supportive findings.

C. Classic findings of CTS include subjective numbness or dysesthesias confined to the median nerve distribution, worsening of symptoms at night, and positive exam findings. When the diagnosis is in question, steroid injection into the carpal tunnel is a strongly supportive test if it is followed by significant relief of symptoms.

1. Please refer to other appropriate upper extremity guidelines as necessary.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1738 (June 2011).

§2207. Initial Diagnostic Procedures

A. Introduction. The two standard procedures that are to be utilized when initially evaluating a work-related carpal tunnel complaint are History Taking, and Physical Examination. History-taking and Physical Examination are generally accepted, well-established, and widely used procedures which establish the foundation/basis for and dictate all ensuing stages of diagnostic and therapeutic procedures. When findings of clinical evaluation and those of other diagnostic procedures do not complement each other, the objective clinical findings should have preference.

B. History

1. Description of symptoms should address at least the following.

a. numbness, tingling, and/or burning of the hand involving the distal median nerve distribution; however, distribution of the sensory symptoms may vary considerably between individuals. Although the classic median nerve distribution is to the palmar aspect of the thumb, the index finger, the middle finger and radial half of the ring finger, patients may report symptoms in any or all of the fingers. The Katz Hand diagram (see Fig. 1) may be useful in documenting the distribution of symptoms; the classic pattern of carpal tunnel affects at least two of the first three digits and does not involve dorsal and palmar aspects of the hand. A probable pattern involves the palmar but not dorsal aspect of the hand (excluding digits).

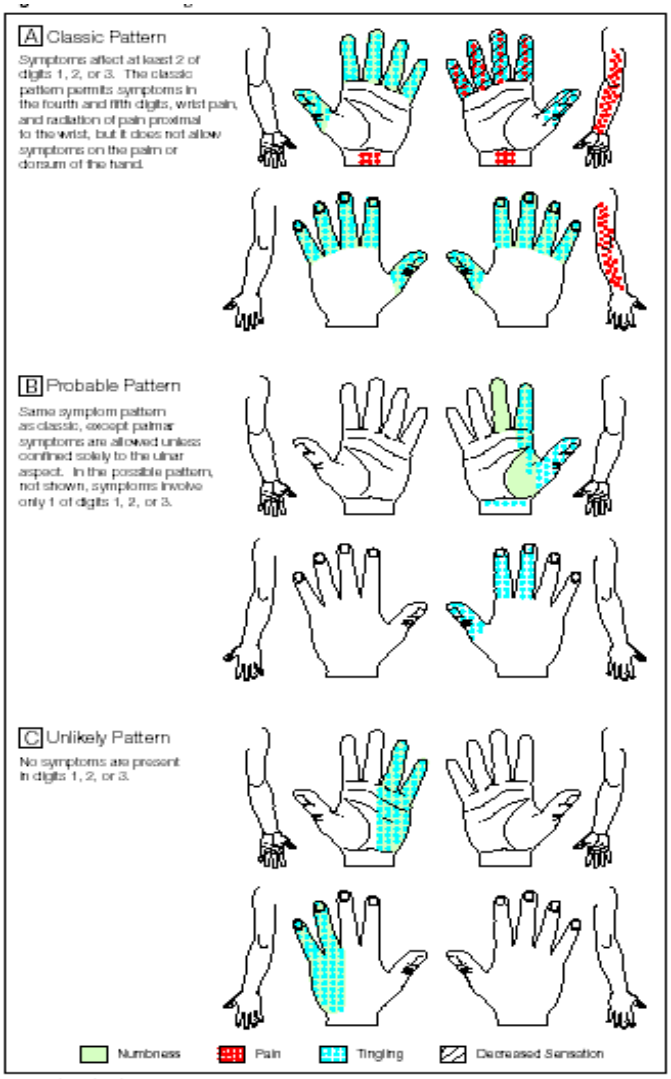
b. nocturnal symptoms frequently disrupt sleep and consist of paresthesias and/or pain in the hand and/or arm.

c. pain in the wrist occurs frequently and may even occur in the forearm, elbow or shoulder. While proximal pain is not uncommon, its presence warrants evaluation for other pathology in the cervical spine, shoulder and upper extremity.

d. the "flick sign," or shaking the symptomatic hand to relieve symptoms may be reported.

e. clumsiness of the hand or dropping objects is often reported, but may not be present early in the course.

Figure 1. Katz Hand Diagram



2. Identification of Occupational Risk Factors. Job title alone is not sufficient information. The clinician is responsible for documenting specific information regarding repetition, force and other risk factors, as listed in the table

entitled, 'Risk Factors Associated with CTS'- Table 2. A job site evaluation may be required.

3. Demographics. Age, hand dominance, gender, etc.

4. Past Medical History and Review of Systems. A study of CTS patients showed a 33 percent prevalence of related disease. Risk factors for CTS include female gender; obesity; Native American, Hispanic, or Black heritage, and certain medical conditions:

a. Pregnancy

b. Arthropathies including connective tissue disorders, rheumatoid arthritis, systemic lupus erythematosus, gout, osteoarthritis and spondyloarthropathy

c. Colles' fracture or other acute trauma

d. Amyloidosis

e. Hypothyroidism, especially in older females

f. Diabetes mellitus, including family history or gestational diabetes

g.. Acromegaly

h. Use of corticosteroids or estrogens

i. Vitamin B6 deficiency

5. Activities of Daily Living (ADLs): include such activities as self care and personal hygiene, communication, ambulation, attaining all normal living postures, travel, non-specialized hand activities, sexual function, sleep, and social and recreational activities. Specific movements in this category include pinching or grasping keys/pens/other small objects, grasping telephone receivers or cups or other similar-sized objects, and opening jars. The quality of these activities is judged by their independence, appropriateness, and effectiveness. Assess not simply the number of restricted activities but the overall degree of restriction or combination of restrictions.

6. Avocational Activities. Information must be obtained regarding sports, recreational, and other avocational activities that might contribute to or be impacted by CTD development. Activities such as hand-operated video games, crocheting/needlepoint, home computer operation, golf, racquet sports, bowling, and gardening are included in this category.

7. Social History. Exercise habits, alcohol consumption, and psychosocial factors.

C. Physical Examination . Please refer to Table 1 for respective sensitivities and specificities for findings used to diagnose CTS (a-f).

1. Sensory loss to pinprick, light touch, two-point discrimination or Semmes-Weinstein Monofilament tests in a median nerve distribution may occur.

2. Thenar atrophy may appear, but usually late in the course.

3. Weakness of the abductor pollicis brevis may be present.

4. Phalen's sign may be positive.

5. Tinel's sign over the carpal tunnel may be positive.

6. Closed Fist test – holding fist closed for 60 seconds reproduces median nerve paresthesia.

7. Evaluation of the contralateral wrist is recommended due to the frequency of bilateral involvement.

8. Evaluation of the proximal upper extremity and cervical spine for other disorders including cervical radiculopathy, thoracic outlet syndrome, other peripheral neuropathies, and other musculoskeletal disorders.

9. Signs of underlying medical disorders associated with CTS, e.g., diabetes mellitus, arthropathy, and hypothyroidism.

10. Myofascial findings requiring treatment may present in soft tissue areas near other CTD pathology, and should be documented. Refer to the Cumulative Trauma Disorder Medical Treatment Guidelines.

Table 1: Sensitivities and Specificities and Evidence Level for Physical Examination findings

Procedure	Sensitivity (%)	Specificity (%)	Evidence
1. Sensory testing			
Hypesthesia	15-51	85-93	Good
Katz Hand Diagram	62-89	73-88	Good
Two-point discrimination	22-33	81-100	Some
Semmes-Weinstein	52-91	59-80	Some
Vibration	20-61	71-81	None
2. Phalen's	51-88	32-86	Some
3. Tinel's	25-73	55-94	Some
4. Carpal tunnel compression	28-87	33-95	Some
5. Thenar atrophy	3-28	82-100	Good
Abductor pollicis brevis weakness	63-66	62-66	Good
6. Closed fist test	61	92	Some
7. Tourniquet test	16-65	36-87	None

D. Risk factors. A critical review of epidemiologic literature identified a number of physical exposures associated with CTS. For example, trauma and fractures of the hand and wrist may result in CTS. Other physical exposures considered risk factors include: repetition, force, vibration, pinching and gripping, and cold environment. When workers are exposed to several risk factors simultaneously, there is an increased likelihood of CTS. Not all risk factors have been extensively studied. Exposure to cold environment, for example, was not examined independently; however, there is good evidence that combined with other risk factors cold environment increases the likelihood of a CTS. Table 2 at the end of this section entitled, "Risk Factors Associated CTS," summarizes the results of currently available literature. No single epidemiologic study will fulfill all criteria for causality. The clinician must recognize that currently available epidemiologic data is based on population results, and that individual variability lies outside the scope of these studies. Many published studies are limited in design and methodology, and, thus, preclude conclusive results. Most studies' limitations tend to attenuate, rather than inflate, associations between workplace exposures and CTS. These guidelines are based on current epidemiologic knowledge. As with any scientific work, the guidelines are expected to change with advancing knowledge. The clinician should remain flexible and incorporate new information revealed in future studies.

Table 2: Risk Factors Associated with Carpal Tunnel Syndrome

Diagnosis: Carpal Tunnel Syndrome:	
Strong evidence	Combination of high exertional force (Varied from greater than 6 kg) and high repetition (work cycles less than 30 sec or greater than 50% of cycle time performing same task, length of shortest task less than 10 sec).

Good evidence	Repetition or force independently, use of vibration hand tools.
Some evidence	Wrist ulnar deviation and extension
Insufficient or conflicting evidence	Pinch/grip, keyboarding.

E. Laboratory tests are generally accepted, well-established, and widely used procedures. Patients should be carefully screened at the initial exam for signs or symptoms of diabetes, hypothyroidism, arthritis, and related inflammatory diseases. The presence of concurrent disease does not negate work-relatedness of any specific case. When a patient's history and physical examination suggest infection, metabolic or endocrinologic disorders, tumorous conditions, systemic musculoskeletal disorders (e.g., rheumatoid arthritis), or potential problems related to prescription of medication (e.g., renal disease and nonsteroidal anti-inflammatory medications), then laboratory tests, including, but not limited to, the following can provide useful diagnostic information:

1. Serum rheumatoid factor and Antinuclear Antigen (ANA) for rheumatoid work-up;
2. Thyroid Stimulating Hormone (TSH) for hypothyroidism;
3. Fasting glucose is recommended for obese men and women over 40 years of age, patients with a history of family diabetes, those from high-risk ethnic groups, and with a previous history of impaired glucose tolerance. A fasting blood glucose greater than 125mg/dl is diagnostic for diabetes. Urine dipstick positive for glucose is a specific but not sensitive screening test. Quantitative urine glucose is sensitive and specific in high-risk populations;
4. Serum protein electrophoresis;
5. Sedimentation rate, nonspecific, but elevated in infection, neoplastic conditions and rheumatoid arthritis;
6. Serum calcium, phosphorus, uric acid, alkaline and acid phosphatase for metabolic, endocrine and neoplastic conditions;
7. Complete Blood Count (CBC), liver and kidney function profiles for metabolic or endocrine disorders or for adverse effects of various medications;
8. Bacteriological (microorganism) work-up for wound, blood and tissue;
9. Serum B6 routine screening is not recommended due to the fact that vitamin B6 supplementation has not been proven to affect the course of carpal tunnel syndrome. However, it may be appropriate for patients on medications that interfere with the effects of vitamin B6, or for those with significant nutritional problems.

a. The OWCA recommends the above diagnostic procedures be considered, at least initially, the responsibility of the workers' compensation carrier to ensure that an accurate diagnosis and treatment plan can be established.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1738 (June 2011).

§2209. Follow-Up Diagnostic Testing Procedures

A. Electrodiagnostic (EDX) studies are well established and widely accepted for evaluation of patients suspected of having CTS. The results are highly sensitive and specific for the diagnosis. Studies may confirm the diagnosis or direct the examiner to alternative disorders. Studies require clinical correlation due to the occurrence of false positive and false negative results. Symptoms of CTS may occur with normal EDX studies, especially early in the clinical course. EDX findings in CTS reflect slowing of median motor and sensory conduction across the carpal tunnel region due to demyelination. Axonal loss, when present, is demonstrated by needle electromyography in median nerve-supplied thenar muscles. Findings include fibrillations, fasciculations, neurogenic recruitment and polyphasic units (reinnervation).

1. Needle electromyography of a sample of muscles innervated by the C5 to T1 spinal roots, including a thenar muscle innervated by the median nerve of the symptomatic limb, is frequently required.
2. The following EDX studies are not recommended to confirm a clinical diagnosis of CTS:

a. Low sensitivity and specificity compared to other EDX studies: multiple median F wave parameters, median motor nerve residual latency, and sympathetic skin response

b. Investigational studies: evaluation of the effect on median NCS of limb ischemia, dynamic hand exercises, and brief or sustained wrist positioning

3. To assure accurate testing, temperature should be maintained at 30-34C preferably recorded from the hand/digits. For temperature below 30C the hand should be warmed.
4. All studies must include normative values for their laboratories.
5. Positive Findings – Any of these nerve conduction study findings must be accompanied by median nerve symptoms to establish the diagnosis.

a. Slowing of median distal sensory and/or motor conduction through the carpal tunnel region

b. Electromyographic changes in the median thenar muscles in the absence of proximal abnormalities

c. Suggested guidelines for the upper limits of normal latencies:

i. Median distal motor latency (DML)-4.5msec/8cm

ii. Median distal sensory peak latency (DSL)-3.6msec/14cm

iii. Median intrapalmar peak latency (palm-wrist)-2.2msec/8cm

iv. Median-ulnar palmar sensory latency difference greater than 0.3msec

6. Because laboratories establish their own norms, a degree of variability from the suggested guideline values is acceptable.
7. In all cases, normative values are to be provided with the neurodiagnostic evaluation.
8. Suggested grading scheme by electrodiagnostic criteria for writing a consultation or report may be:

a. Mild CTS-prolonged (relative or absolute) median sensory or mixed action potential distal latency (orthodromic, antidromic, or palmar).

b. Moderate CTS-abnormal median sensory latencies as above, and prolongation (relative or absolute) of median motor distal latency.

c. Severe CTS-prolonged median motor and sensory distal latencies, with either absent or sensory or palmar potential, or low amplitude or absent thenar motor

action potential. Needle examination reveals evidence of acute and chronic denervation with axonal loss.

9. Frequency of Studies/Maximum Number of Studies:

a. Indications for Initial Testing

i. patients who do not improve symptomatically or functionally with conservative measures for carpal tunnel syndrome over a three to four week period;

ii. patients in whom the diagnosis is in question;

iii. patients for whom surgery is contemplated;

iv. to rule out other nerve entrapments or a radiculopathy.

b. repeated studies may be performed:

i. to determine disease progression. 8-12 weeks is most useful when the initial studies were normal and CTS is still suspected.

ii. for inadequate improvement with non-surgical treatment for 8-12 weeks ;

iii. for persistent or recurrent symptoms following carpal tunnel release, post-op three to six months, unless an earlier evaluation is required by the surgeon.

B. Imaging Studies

1. Radiographic Imaging. Not generally required for most CTS diagnoses. However, it may be necessary to rule out other pathology in the cervical spine, shoulder, elbow, wrist or hand. Wrist and elbow radiographs would detect degenerative joint disease, particularly scapholunate dissociation and thumb carpometacarpal abnormalities which occasionally occur with CTS.

2. Magnetic Resonance Imaging (MRI). Considered experimental and not recommended for diagnosis of Carpal Tunnel Syndrome. Trained neuroradiologists have not identified a single MRI parameter that is highly sensitive and specific. MRI is less accurate than standard electrodiagnostic testing, and its use as a diagnostic tool is not recommended.

3. Sonography. This tool has not been sufficiently studied to define its diagnostic performance relative to electrodiagnostic studies. It is not a widely applied test. Sonography may detect synovial thickening in CTS caused by rheumatoid arthritis. It may be useful if space-occupying lesions, such as, lipomas, hemangiomas, fibromas, and ganglion cysts, are suspected. Its routine use in CTS is not recommended.

C. Adjunctive testing. Clinical indications for the use of tests and measurements are predicated on the history and systems review findings, signs observed on physical examination, and information derived from other sources and records. They are not designed to be the definitive indicator of dysfunction.

1. Electromyography. is a generally accepted, well-established procedure. It is indicated when acute and/or chronic neurogenic changes in the thenar eminence are associated with the conduction abnormalities discussed above.

2. Electroneurometer is not recommended as a diagnostic tool because it requires patient participation, cannot distinguish between proximal and distal lesions, and does not have well-validated reference values.

3. Portable Automated Electrodiagnostic. Device measures distal median nerve motor latency and F-wave latency at the wrist and has been tested in one research setting. It performed well in this setting following extensive calibration of the device. Motor nerve latency compared favorably with conventional electrodiagnostic testing, but F-wave latency added little to diagnostic accuracy. It remains an investigational instrument whose performance in a primary care setting is as yet not established, and is not recommended as a substitute for conventional electrodiagnostic testing in clinical decision-making.

4. Quantitative Sensory Testing (QST) may be used as a screening tool in clinical settings pre- and post-operatively. Results of tests and measurements of sensory integrity are integrated with the history and systems review findings and the results of other tests and measures. QST has been divided into two types of testing:

a. Threshold tests measure topognosis, the ability to exactly localize a cutaneous sensation, and pallesthesia, the ability to sense mechanical using vibration discrimination testing (quickly adapting fibers); Semmes-Wienstein monofilament testing (slowly adapting fibers);

b. Density Tests also measure topognosis and pallesthesia using static two-point discrimination (slowly adapting fibers); moving two-point discrimination (quickly adapting fibers).

5. Pinch and Grip Strength Measurements are Not generally accepted as a diagnostic tool for CTS. Strength is defined as the muscle force exerted by a muscle or group of muscles to overcome a resistance under a specific set of circumstances. Pain, the perception of pain secondary to abnormal sensory feedback, and/or the presence of abnormal sensory feedback affecting the sensation of the power used in grip/pinch may cause a decrease in the force exerted and thereby not be a true indicator of strength. When all five handle settings of the dynamometer are used, a bell-shaped curve, reflecting maximum strength at the most comfortable handle setting, should be present. These measures provide a method for quantifying strength that can be used to follow a patient's progress and to assess response to therapy. In the absence of a bell-shaped curve, clinical reassessment is indicated.

6. Laboratory Tests. In one study of carpal tunnel patients seen by specialists, nine percent of patients were diagnosed with diabetes, seven percent with hypothyroidism, and 15 percent with chronic inflammatory disease including spondyloarthropathy, arthritis, and systemic lupus erythematosis. Up to two thirds of the patients were not aware of their concurrent disease. Estimates of the prevalence of hypothyroidism in the general population vary widely, but data collected from the Colorado Thyroid Disease Prevalence Study revealed subclinical hypothyroidism in 8.5 percent of participants not taking thyroid medication. The prevalence of chronic joint symptoms in the Behavioral Risk Factor Surveillance System (BRFSS) from the Centers for Disease Control (CDC) was 12.3 percent. If after two to three weeks, the patient is not improving the physician should strongly consider the following laboratory studies: thyroid function studies, rheumatoid screens, chemical panels, and others, if clinically indicated. Laboratory testing may be required periodically to monitor patients on chronic medications.

D. Special tests are generally well-accepted tests and are performed as part of a skilled assessment of the patients' capacity to return to work, his/her strength capacities, and physical work demand classifications and tolerance.

1. Personality/Psychological/Psychiatric/ Psychosocial Evaluations.

a. These are generally accepted and well-established diagnostic procedures with selective use in the upper extremity population, but have more widespread use in subacute and chronic upper extremity populations. Diagnostic testing procedures may be useful for patients with symptoms of depression, delayed recovery, chronic pain, recurrent painful conditions, disability problems, and for preoperative evaluation. Psychological/psychosocial and measures have been shown to have predictive value for postoperative response, and therefore should be strongly considered for use pre-operatively when the surgeon has concerns about the relationship between symptoms and findings, or when the surgeon is aware of indications of psychological complication or risk factors for psychological complication (e.g. childhood psychological trauma). Psychological testing should provide differentiation between pre-existing conditions versus injury caused psychological conditions, including depression and posttraumatic stress disorder. Psychological testing should incorporate measures that have been shown, empirically, to identify comorbidities or risk factors that are linked to poor outcome or delayed recovery;

b. Formal psychological or psychosocial evaluation should be performed on patients not making expected progress within 6 to 12 weeks following injury and whose subjective symptoms do not correlate with objective signs and test results. In addition to the customary initial exam, the evaluation of the injured worker should specifically address the following areas:

i. employment history;

ii. interpersonal relationships-both social and work;

iii. patient activities;

iv. current perception of the medical system;

v. current perception/attitudes toward employer/job;

vi. results of current treatment;

vii. risk factors and psychological comorbidities that may influence outcome and that may require treatment;

viii. childhood history, including history of childhood psychological trauma, abuse and family history of disability.

c. Personality/psychological/psychosocial evaluations consist of two components, clinical interview and psychological testing. Results should help clinicians with a better understanding of the patient in a number of ways. Thus the evaluation result will determine the need for further psychosocial interventions; and in those cases, Diagnostic and Statistical Manual of Mental Disorders (DSM) diagnosis should be determined and documented. The evaluation should also include examination of both psychological comorbidities and psychological risk factors that are empirically associated with poor outcome and/or delayed recovery. An individual with a Ph.D., Psy.D, or psychiatric M.D./D.O. credentials should perform initial evaluations, which are generally completed within one to two hours. A professional fluent in the primary language of he patient is preferred. When such a provider is not available, services of a professional language interpreter should be provided.

d. Frequency: one-time visit for the clinical interview. If psychometric testing is indicated as a part of the initial evaluation, time for such testing should not exceed an additional two hours of professional time.

i. Job site evaluation is a comprehensive analysis of the physical, mental and sensory components of a specific job. These components may include, but are not limited to: postural tolerance (static and dynamic); aerobic requirements; range of motion; torque/force; lifting/carrying; cognitive demands; social interactions; visual perceptual; environmental requirements of a job; repetitiveness; and essential functions of a job. Job descriptions provided by the employer are helpful but should not be used as a substitute for direct observation.

(a). Frequency: One time with additional visits as needed for follow-up per job site.

ii. Functional Capacity evaluation is a comprehensive or modified evaluation of the various aspects of function as they relate to the worker's ability to return to work. Areas such as endurance, lifting (dynamic and static), postural tolerance, specific range of motion, coordination and strength, worker habits, employability and financial status, as well as psychosocial aspects of competitive employment may be evaluated. Components of this evaluation may include: musculoskeletal screen; cardiovascular profile/aerobic capacity; coordination; lift/carrying analysis; job-specific activity tolerance; maximum voluntary effort; pain assessment/psychological screening; and non-material and material handling activities.

(a). Frequency: Can be used initially to determine baseline status. Additional evaluations can be performed to monitor and assess progress and aid in determining the endpoint for treatment.

iii. Vocational Assessment: The vocational assessment should provide valuable guidance in the determination of future rehabilitation program goals. It should clarify rehabilitation goals, which optimize both patient motivation and utilization of rehabilitation resources. If prognosis for return to former occupation is determined to be poor, except in the most extenuating circumstances, vocational assessment should be implemented within 3 to 12 months post-injury. Declaration of MMI should not be delayed solely due to lack of attainment of a vocational assessment.

(a). Frequency: One time with additional visits as needed for follow-up

iv. Work Tolerance Screening: is a determination of an individual's tolerance for performing a specific job as based on a job activity or task. It may include a test or procedure to specifically identify and quantify work-relevant cardiovascular, physical fitness and postural tolerance. It may also address ergonomic issues affecting the patient's return-to-work potential. May be used when a full FCE is not indicated.

a. Frequency: One time for evaluation. May monitor improvements in strength every three to four weeks up to a total of six evaluations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of WorkersCompensation Administration, LR 37:1740 (June 2011).

§2211. Therapeutic Procedures—Non-Operative

A. Before initiation of any therapeutic procedure, the authorized treating provider, employer, and insurer must consider these important issues in the care of the injured worker.

B. First, patients undergoing therapeutic procedure(s) should be released or returned to modified or restricted duty during their rehabilitation at the earliest appropriate time. Refer to "Return-to-Work" in this section for detailed information.

C. Second, cessation and/or review of treatment modalities should be undertaken when no further significant subjective or objective improvement in the patient's condition is noted. If patients are not responding within the recommended duration periods, alternative treatment interventions, further diagnostic studies or consultations should be pursued.

D. Third, providers should provide and document education to the patient. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of facilitating self-management of symptoms.

E. Lastly, formal psychological or psychosocial screening should be performed on patients not making expected progress within 6 to 12 weeks following injury and whose subjective symptoms do not correlate with objective signs and tests.

F. In cases where a patient is unable to attend an outpatient center, home therapy may be necessary. Home therapy may include active and passive therapeutic procedures as well as other modalities to assist in alleviating pain, swelling, and abnormal muscle tone. Home therapy is usually of short duration and continues until the patient is able to tolerate coming to an outpatient center.

G. Non-operative treatment procedures for CTS can be divided into two groups: conservative care and rehabilitation. Conservative care is treatment applied to a problem in which spontaneous improvement is expected in 90 percent of the cases within three months. It is usually provided during the tissue-healing phase and lasts no more than six months, and often considerably less. Rehabilitation is treatment applied to a more chronic and complex problem in a patient with de-conditioning and disability. It is provided during the period after tissue healing to obtain maximal medical recovery. Treatment modalities may be utilized sequentially or concomitantly depending on chronicity and complexity of the problem, and treatment plans should always be based on a diagnosis utilizing appropriate diagnostic procedures.

H. The following procedures are listed in alphabetical order.

1. Acupuncture is an accepted and widely used procedure for the relief of pain and inflammation and there is some scientific evidence to support its use. The exact mode of action is only partially understood. Western medicine studies suggest that acupuncture stimulates the nervous system at the level of the brain, promotes deep relaxation, and affects the release of neurotransmitters. Acupuncture is commonly used as an alternative or in addition to traditional Western pharmaceuticals. While it is commonly used when pain medication is reduced or not tolerated, it may be used as an adjunct to physical rehabilitation and/or surgical intervention to hasten the return of functional activity. Acupuncture should be performed by licensed practitioners.

a. Definition: Acupuncture is the insertion and removal of filiform needles to stimulate acupoints (acupuncture points). Needles may be inserted, manipulated, and retained for a period of time. Acupuncture can be used to reduce pain, reduce inflammation, increase blood flow, increase range of motion, decrease the side effect of medication-induced nausea, promote relaxation in an anxious patient, and reduce muscle spasm. Indications include joint pain, joint stiffness, soft tissue pain and inflammation, paresthesia, post-surgical pain relief, muscle spasm, and scar tissue pain.

i. Time to produce effect: three to six treatments
ii. Frequency: one to three times per week
iii. Optimum duration: one to two months
iv. Maximum duration: 14 treatments

b. Acupuncture with Electrical Stimulation is the use of electrical current (micro- amperage or milli-amperage) on the needles at the acupuncture site. It is used to increase effectiveness of the needles by continuous stimulation of the acupoint. Physiological effects (depending on location and settings) can include endorphin release for pain relief, reduction of inflammation, increased blood circulation, analgesia through interruption of pain stimulus, and muscle relaxation. It is indicated to treat chronic pain conditions, radiating pain along a nerve pathway, muscle spasm, inflammation, scar tissue pain, and pain located in multiple sites.

i. Time to produce effect: three to six treatments
ii. Frequency: one to three times per week
iii. Optimum duration: one to two months
iv. Maximum duration: 14 treatments

c. Other Acupuncture Modalities. Acupuncture treatment is based on individual patient needs and therefore treatment may include a combination of procedures to enhance treatment effect. Other procedures may include the use of heat, soft tissue manipulation/massage, and exercise. Refer to Active Therapy and Passive Therapy for a description of these adjunctive acupuncture modalities.

i. Time to produce effect: three to six treatments
ii. Frequency: one to three times per week
iii. Optimum duration: one to two months
iv. Maximum duration: 14 treatments

(a). Any of the above acupuncture treatments may extend longer if objective functional gains can be documented or when symptomatic benefits facilitate progression in the patient's treatment program. Treatment beyond 14 treatments must be documented with respect to need and ability to facilitate positive symptomatic or functional gains. Such care should be re-evaluated and documented with each series of treatments.

2. Biofeedback

a. A form of behavioral medicine that helps patients learn self-awareness and self-regulation skills for the purpose of gaining greater control of their physiology, such as muscle activity, brain waves, and measures of autonomic nervous system activity. Electronic instrumentation is used to monitor the targeted physiology and then displayed or fed back to the patient visually, auditorially or tactilely, with coaching by a biofeedback specialist. Biofeedback is

provided by clinicians certified in biofeedback and/or who have documented specialized education, advanced training, or direct or supervised experience qualifying them to provide the specialized treatment needed (e.g., surface EMG, EEG, or other).

b. Treatment is individualized to the patient's work-related diagnosis and needs. Home practice of skills is required for mastery and may be facilitated by the use of home training tapes. The ultimate goal in biofeedback treatment is normalizing the physiology to the pre-injury status to the extent possible and involves transfer of learned skills to the workplace and daily life. Candidates for biofeedback therapy or training must be motivated to learn and practice biofeedback and self-regulation techniques.

c. Indications for biofeedback include individuals who are suffering from musculoskeletal injury where muscle dysfunction or other physiological indicators of excessive or prolonged stress response affects and/or delays recovery. Other applications include training to improve self-management of emotional stress/pain responses such as anxiety, depression, anger, sleep disturbance, and other central and autonomic nervous system imbalances. Biofeedback is often utilized along with other treatment modalities.

i. Time to produce effect: three to four sessions

ii. Frequency: one to two times per week

iii. Optimum duration: five to six sessions

iv. Maximum duration: 10 to 12 sessions. Treatment beyond 12 sessions must be documented with respect to need, expectation, and ability to facilitate positive symptomatic or functional gains.

3. Injections-Therapeutic.

a. Steroids Injections. Beneficial effects of injections are well-established, but generally considered to be temporary. Recurrence of symptoms is frequent. It is not clear whether or not injections slow progression of electrodiagnostic changes. Therefore, although symptoms may be temporarily improved, nerve damage may be progressing. When motor changes are present, surgery is preferred over injections. Injections may be given for confirmation of Carpal Tunnel Syndrome Diagnosis.

i. Time to produce effect: two to five days

ii. Frequency: every six to eight weeks

iii. Optimum number: two injections

iv. Maximum number: three injections in 6 months

b. If following the first injection, symptomatic relief is followed by recurrent symptoms, the decision to perform a second injection must be weighed against alternative treatments such as surgery. Surgery may give more definitive relief of symptoms.

4. Job Site Alteration. Early evaluation and training of body mechanics and other ergonomic factors are essential for every injured worker and should be done by a qualified individual. In some cases, this requires a job site evaluation. Some evidence supports alteration of the job site in the early treatment of Carpal Tunnel Syndrome (CTS). There is no single factor or combination of factors that is proven to prevent or ameliorate CTS, but a combination of ergonomic and psychosocial factors is generally considered to be important. Physical factors that may be considered include use of force, repetition, awkward positions, upper extremity vibration, cold environment, and contact pressure on the carpal tunnel. Psychosocial factors to be considered include pacing, degree of control over job duties, perception of job stress, and supervisory support. The job analysis and modification should include input from the employee, employer, and ergonomist or other professional familiar with work place evaluation. The employee must be observed performing all job functions in order for the job site analysis to be valid. Periodic follow-up is recommended to evaluate effectiveness of the intervention and need for additional ergonomic changes.

a. Ergonomic changes should be made to modify the hazards identified. In addition workers should be counseled to vary tasks throughout the day whenever possible. Occupational Safety and Health Administration (OSHA) suggests that workers who perform repetitive tasks, including keyboarding, take 15-30 second breaks every 10 to 20 minutes, or 5-minute breaks every hour. Mini breaks should include stretching exercises.

b. Interventions should consider engineering controls, e.g., mechanizing the task, changing the tool used, or adjusting the work site, or administrative controls, e.g., adjusting the time an individual performs the task.

c. Seating Description. The following description may aid in evaluating seated work positions: The head should incline only slightly forward, and if a monitor is used, there should be 18-24 inches of viewing distance with no glare. Arms should rest naturally, with forearms parallel to the floor, elbows at the sides, and wrists straight or minimally extended. The back must be properly supported by a chair, which allows change in position and backrest adjustment. There must be good knee and legroom, with the feet resting comfortably on the floor or footrest. Tools should be within easy reach, and twisting or bending should be avoided.

d. Job Hazard Checklist. The following Table 3 is adopted from Washington State's job hazard checklist, and may be used as a generally accepted guide for identifying job duties which may pose ergonomic hazards. The fact that an ergonomic hazard exists at a specific job, or is suggested in the table, does not establish a causal relationship between the job and the individual with a musculoskeletal injury. However, when an individual has a work-related injury and ergonomic hazards exist that affect the injury, appropriate job modifications should be made. Proper correction of hazards may prevent future injuries to others, as well as aid in the recovery of the injured worker.

Table 3: Identifying Job Duties Which May Pose Ergonomic Hazards

Type of Job Duty	Hours per Day
Pinching an unsupported object(s) weighing 2 lbs or more per hand, or pinching with a force of 4 lbs or more per hand (comparable to pinching a half a ream of paper): Highly repetitive motion Palmar flexion greater than 30 degrees, dorsiflexion greater than 45 degrees, or radial deviation greater than 30 degrees ---------- No other risk factors	More than 3 hours total/day ---------- More than 4 hours total/day
Gripping an unsupported object(s) weighing 10 lbs or more/hand, or gripping with a force of 10 lbs or more/hand (comparable to clamping light duty	More than 3 hours total/day

Type of Job Duty	Hours per Day
automotive jumper cables onto a battery): *Handles should be rounded and soft, with at least 1-2.5" in diameter grips at least 5" long. Highly repetitive motion Palmar flexion greater than 30 degrees, dorsiflexion greater than 45 degrees, or radial deviation greater than 30 degrees ---------- No other risk factors	---------- More than 4 hours total/day
Repetitive Motion (using the same motion with little or no variation every few seconds), excluding keying activities: High, forceful exertions with the hands, with palmar flexion greater than 30 degrees, dorsiflexion greater than 45 degrees, or radial deviation greater than 30 degrees ---------- No other risk factors	More than 2 hours total/day ---------- More than 6 hours total/day
Intensive Keying: Palmar flexion greater than 30 degrees, dorsiflexion greater than 45 degrees, or radial deviation greater than 30 degrees ---------- No other risk factors	More than 4 hours total/day ---------- More than 7 hours total/day
Repeated Impact: Using the hand (heel/base of palm) as a hammer more than once/minute	More than 2 hours total/day
Vibration: Two determinants of the tolerability of segmental vibration of the hand are the frequency and the acceleration of the motion of the vibrating tool, with lower frequencies being more poorly tolerated at a given level of imposed acceleration, expressed below in multiples of the acceleration due to gravity (10m/sec/sec). Frequency range 8-15 Hz and acceleration 6 g Frequency range 80 Hz and acceleration 40 g Frequency range 250 Hz and acceleration 250 g ---------- Frequency range 8-15 Hz and acceleration 1.5 g Frequency range 80 Hz and acceleration 6 g Frequency range 250 Hz and acceleration 20 g	More than 30 minutes at a time ---------- More than 4 hours at a time

5. Medications including nonsteroidal anti-inflammatory medications (NSAIDS), oral steroids, diuretics, and pyridoxine (Vitamin B6) have not been shown to have significant long-term beneficial effect in treating Carpal Tunnel Syndrome. Although NSAIDS are not curative, they and other analgesics may provide symptomatic relief. All narcotics and habituating medications should be prescribed with strict time, quantity, and duration guidelines with a definite cessation parameter. Prescribing these drugs on an as needed basis (PRN) should almost always be avoided.

a. Vitamin B6: Randomized trials have demonstrated conflicting results. Higher doses may result in development of a toxic peripheral neuropathy. In the absence of definitive literature showing a beneficial effect, use of Vitamin B6 cannot be recommended.

b. Oral Steroids: have been shown to have short-term symptomatic benefit but no long-term functional benefit and are not recommended due to possible side effects.

6. Occupational Rehabilitation Programs

a. Non-Interdisciplinary. These programs are work-related, outcome-focused, individualized treatment programs. Objectives of the program include, but are not limited to, improvement of cardiopulmonary and neuromusculoskeletal functions (strength, endurance, movement, flexibility, stability, and motor control functions), patient education, and symptom relief. The goal is for patients to gain full or optimal function and return to work. The service may include the time-limited use of passive modalities with progression to achieve treatment and/or simulated/real work.

i. Work Conditioning. These programs are usually initiated once reconditioning has been completed but may be offered at any time throughout the recovery phase. It should be initiated when imminent return of a patient to modified or full duty is not an option, but the prognosis for returning the patient to work at completion of the program is at least fair to good.

(a). Length of visit: one to two hours per day

(b). Frequency: two to five visits per week

(c). Optimum duration: two to four weeks

(d). Maximum duration: six weeks. Participation in a program beyond six weeks must be documented with respect to need and the ability to facilitate positive symptomatic or functional gains.

ii. Work Simulation is a program where an individual completes specific work-related tasks for a particular job and return to work. Use of this program is appropriate when modified duty can only be partially accommodated in the work place, when modified duty in the work place is unavailable, or when the patient requires more structured supervision. The need for work place simulation should be based upon the results of a Functional Capacity Evaluation and or Job site Analysis.

(a). Length of visit: two to six hours per day

(b). Frequency: two to five visits per week

(c). Optimum duration: two to four weeks

(d). Maximum duration: six weeks. Participation in a program beyond six weeks must be documented with respect to need and the ability to facilitate positive symptomatic or functional gains.

b. Interdisciplinary programs are characterized by a variety of disciplines that participate in the assessment, planning, and/or implementation of an injured workers program with the goal for patients to gain full or optimal function and return to work. There should be close interaction and integration among the disciplines to ensure that all members of the team interact to achieve team goals. These programs are for patients with greater levels of perceived disability, dysfunction, de-conditioning and psychological involvement. For patients with chronic pain, refer to the Chronic Pain Disorder Medical Treatment Guideline.

i. Work Hardening is an interdisciplinary program addressing a patient's employability and return to work. It includes a progressive increase in the number of hours per day that a patient completes work simulation tasks until the patient can tolerate a full workday. This is accomplished by addressing the medical, psychological, behavioral, physical, functional, and vocational components of employability and return-to-work.

ii. This can include a highly structured program involving a team approach or can involve any of the components thereof. The interdisciplinary team should, at a minimum, be comprised of a qualified medical director who is board certified with documented training in occupational rehabilitation, team physicians having experience in

occupational rehabilitation, occupational therapy, physical therapy, case manager, and psychologist. As appropriate, the team may also include: chiropractor, RN, or vocational specialist.

(a). Length of visit: Up to eight hours/day

(b). Frequency: two to five visits per week

(c). Optimum duration: two to four weeks

(d). Maximum duration: six weeks. Participation in a program beyond six weeks must be documented with respect to need and the ability to facilitate positive symptomatic or functional gains.

7. Orthotics/Immobilization with Splinting is a generally accepted, well-established and widely used therapeutic procedure. There is some evidence that splinting leads to more improvement in symptoms and hand function than watchful waiting alone. Because of limited patient compliance with day and night splinting in published studies, evidence of effectiveness is limited to nocturnal splinting alone. Splints should be loose and soft enough to maintain comfort while supporting the wrist in a relatively neutral position. This can be accomplished using a soft or rigid splint with a metal or plastic support. Splint comfort is critical and may affect compliance. Although off-the-shelf splints are usually sufficient, custom thermoplastic splints may provide better fit for certain patients.

a. Splints may be effective when worn at night or during portions of the day, depending on activities. Most studies show that full time night splinting for a total of four to six weeks is the most effective protocol. Depending on job activities, intermittent daytime splinting can also be helpful. Splint use is rarely mandatory. Providers should be aware that over-usage is counterproductive, and should counsel patients to minimize daytime splint use in order avoid detrimental effects such as stiffness and dependency over time.

b. Splinting is generally effective for milder cases of CTS. Long-term benefit has not been established. An effect should be seen in two-sour weeks.

i. Time to produce effect: one-four weeks. If, after four weeks, the patient has partial improvement, continue to follow since neuropathy may worsen, even in the face of diminished symptoms.

ii. Frequency: Nightly. Daytime intermittent, depending on symptoms and activities

iii. Optimum duration: four to eight weeks

iv. Maximum duration: two to four months. If symptoms persist, consideration should be given to either repeating electrodiagnostic studies or to more aggressive treatment.

8. Patient Education

a. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of prolonging the beneficial effects of treatment, as well as facilitating self-management of symptoms and injury prevention. The patient should be encouraged to take an active role in the establishment of functional outcome goals. They should be educated on their specific injury, assessment findings, and plan of treatment. Instruction on proper body mechanics and posture, positions to avoid, self-care for exacerbation of symptoms, and home exercise should also be addressed.

i. Time to produce effect: Varies with individual patient

ii. Frequency: Should occur at every visit

9. Personality/Psychological/Psychiatric/ Psychosocial Intervention is generally accepted, widely used and well established. This group of therapeutic and diagnostic modalities includes, but is not limited to, individual counseling, group therapy, stress management, psychosocial crises intervention, hypnosis and meditation. Any screening or diagnostic workup should clarify and distinguish between preexisting versus aggravated versus purely causative psychological conditions. Psychosocial intervention is recommended as an important component in the total management program that should be implemented as soon as the problem is identified. This can be used alone or in conjunction with other treatment modalities. Providers treating patients with chronic pain should refer to the Chronic Pain Disorder Medical Treatment Guidelines.

a. Time to produce effect: two to four weeks

b. Frequency: one to three times weekly for the first 4 weeks (excluding hospitalization, if required), decreasing to one to two times per week for the second month. Thereafter, two to four times monthly.

c. Optimum duration: six weeks to three months

d. Maximum duration: 3 to 12 months. Counseling is not intended to delay but to enhance functional recovery. For select patients, longer supervised treatment may required and if further counseling beyond 3 months is indicated, documentation addressing which pertinent issues are pre-existing versus aggravated versus causative, as well as projecting a realistic functional prognosis, should be provided by the authorized treating provider every 4 to 6 weeks during treatment.

10. Restriction of Activities. Continuation of normal daily activities is the recommendation for acute and chronic pain without neurologic symptoms. There is good evidence against the use of bed rest in cases without neurologic symptoms. Bed rest may lead to de-conditioning and impair rehabilitation. Complete work cessation should be avoided, if possible, since it often further aggravates the pain presentation. Modified return-to-work is almost always more efficacious and rarely contraindicated in the vast majority of injured workers with Carpal Tunnel Syndrome

a. Medication use in the treatment of Carpal Tunnel Syndrome is appropriate for controlling acute and chronic pain and inflammation. Use of medications will vary widely due to the spectrum of injuries from simple strains to post-surgical healing. All drugs should be used according to patient needs. A thorough medication history, including use of alternative and over the counter medications, should be performed at the time of the initial visit and updated periodically.

11. Return to Work. Early return-to-work should be a prime goal in treating Carpal Tunnel Syndrome given the poor prognosis for the injured employee who is out of work for more than six months. The employee and employer should be educated in the benefits of early return-to-work. When attempting to return an employee with CTS to the workplace, clear, objective physical restrictions that apply to both work and non-work related activities should be

specified by the provider. Good communication between the provider, employee, and employer is essential. Return-to-work is any work or duty that the employee can safely perform, which may not be the worker's regular job activities. Due to the large variety of jobs and the spectrum of severity of CTS, it is not possible for the OWCA to make specific return-to-work guidelines, but the following general approach is recommended:

a. Establishment of Return-To-Work. Ascertainment of return-to-work status is part of the medical treatment and rehabilitation plan, and should be addressed at every visit. Limitations in ADLs should also be reviewed at every encounter, and help to provide the basis for work restrictions provided they are consistent with objective findings. The OWCA recognizes that employers vary in their ability to accommodate restricted duty, but encourages employers to be active participants and advocates for early return-to-work. In most cases, the patient can be returned to work in some capacity, either at a modified job or alternate position, immediately unless there are extenuating circumstances, which should be thoroughly documented and communicated to the employer. Return-to-work status should be periodically reevaluated, at intervals generally not to exceed three weeks, and should show steady progression towards full activities and full duty.

b. Establishment of Activity Level Restrictions: It is the responsibility of the physician/provider to provide both the employee and employer clear, concise, and specific restrictions that apply to both work and non-work related activities. The employer is responsible to determine whether modified duty can be provided within the medically determined restrictions. Refer to the "Job Site Alteration" section for specific activity and ergonomic factors to be considered when establishing work restrictions for an employee with CTS.

c. Compliance with Activity Level Restrictions: The employee's compliance with the activity level restrictions is an important part of the treatment plan and should be reviewed at each visit. In some cases, a job site analysis, a functional capacity evaluation, or other special testing may be required to facilitate return-to-work and document compliance. Refer to the "Job Site Alteration" and "Work Tolerance Screening" sections.

12. Therapy - Active.

a. Active therapies are based on the philosophy that therapeutic exercises and/or activities are beneficial for restoring flexibility, strength, endurance, function, range of motion, and alleviating discomfort. Active therapy requires an internal effort by the individual to complete a specific exercise or task, and thus assists in developing skills promoting independence to allow self-care to continue after discharge. This form of therapy requires supervision from a therapist or medical provider such as verbal, visual, and/or tactile instructions(s). At times a provider may help stabilize the patient or guide the movement pattern, but the energy required to complete the task is predominately executed by the patient.

b. Patients should be instructed to continue active therapies at home as an extension of the treatment process in order to maintain improvement levels. Home exercise can include exercise with or without mechanical assistance or resistance and functional activities with assistance devices.

c. Interventions are selected based on the complexity of the presenting dysfunction with ongoing examination, evaluation and modification of the plan of care as improvement or lack thereof occurs. Change and/or discontinuation of an intervention should occur if there is attainment of expected goals/outcome, lack of progress, lack of tolerance and/or lack of motivation. Passive interventions/ modalities may only be used as adjuncts to the active program.

i. Nerve Gliding exercises consist of a series of flexion and extension movements of the hand and wrist that produce tension and longitudinal movement along the length of the median and other nerves of the upper extremity. These exercises are based on the principle that the tissues of the peripheral nervous system are designed for movement, and that tension and glide (excursion) of nerves may have an effect on neurophysiology through alterations in vascular and axoplasmic flow. Biomechanical principles have been more thoroughly studied than clinical outcomes. Randomized trials have been lacking or have suffered from design flaws that preclude sound conclusions of the effectiveness of these exercises, but these flaws have tended to underestimate rather than overestimate the usefulness of nerve gliding. The exercises are simple to perform and can be done by the patient after brief instruction. It is considered accepted therapy for CTS.

(a). Time to Produce Effect: two-four weeks

(b). Frequency: Up to five times per day by patient (patient-initiated)

(c). Optimum Duration: two sessions

(d). Maximum Duration: three sessions

ii. Instruction in Therapeutic Exercise. Instruction should focus on alleviating associated myofascial symptoms. Please refer to the Cumulative Trauma Disorder (CTD) guideline for information on therapeutic exercise techniques.

iii. Proper Work Techniques. Please refer to the "Job Site Evaluation" and "Job Site Alteration" sections of this guideline.

13. Therapy-Passive. Therapy includes those treatment modalities that do not require energy expenditure on the part of the patient. They are principally effective during the early phases of treatment and are directed at controlling symptoms such as pain, inflammation and swelling and to improve the rate of healing soft tissue injuries. They should be used in adjunct with active therapies. They may be used intermittently as a therapist deems appropriate or regularly if there are specific goals with objectively measured functional improvements during treatment. Diathermies have not been shown to be beneficial to patients with CTS and may interfere with nerve conduction.

a. Manual Therapy Techniques are passive interventions in which the providers use his or her hands to administer skilled movements designed to modulate pain; increase joint range of motion; reduce/eliminate soft tissue swelling, inflammation, or restriction; induce relaxation; and improve contractile and non-contractile tissue extensibility. These techniques are applied only after a thorough examination is performed to identify those for whom manual therapy would be contraindicated or for whom manual therapy must be applied with caution. Soft tissue mobilization/manipulation techniques are generally accepted and widely used adjunctive treatment modalities in the

treatment of myofascial symptoms related to carpal tunnel syndrome. Mobilization and manipulation can include myofascial release therapy, muscle energy techniques, neural gliding, high velocity, low amplitude (HVLA) technique, osteopathic manipulation, joint mobilization and non-force techniques.

i. Time to produce effect: two-six treatments

ii. Frequency: one-three times/week, decreasing over time

iii. Optimum duration: four-six weeks

d. Maximum duration: eight-ten weeks

b. Ultrasound: There is some evidence that ultrasound may be effective in symptom relief and in improving nerve conduction in mild to moderate cases of CTS. No studies have demonstrated long-term functional benefit. It may be used in conjunction with an active therapy program for non-surgical patients who do not improve with splinting and activity modification. It is not known if there are any long-term deleterious neurological effects from ultrasound.

c. Microcurrent TENS: There is some evidence that concurrent application of microamperage TENS applied to distinct acupuncture points and low-level laser treatment may be useful in treatment of mild to moderate CTS. This treatment may be useful for patients not responding to initial conservative treatment or who wish to avoid surgery. Patient selection criteria should include absence of denervation on EMG and motor latencies not exceeding 7 ms. The effects of microamperage TENS and low-level laser have not been differentiated; there is no evidence to suggest whether only one component is effective or the combination of both is required.

i. Time to produce effect: one week

ii. Frequency: three sessions per week

iii. Optimum duration: three weeks

iv. Maximum duration: four weeks

v. Other Passive Therapy: For associated myofascial symptoms, please refer to the Cumulative Trauma Disorder guideline.

14. Vocational Rehabilitation is a generally accepted intervention. Initiation of vocational rehabilitation requires adequate evaluation of patients for quantification highest functional level, motivation, and achievement of maximum medical improvement. Vocational rehabilitation may be as simple as returning to the original job or as complicated as being retrained for a new occupation. It may also be beneficial for full vocational rehabilitation to be started before MMI if it is evident that the injured worker will be unable to return to his/her previous occupation. A positive goal and direction may aid the patient in decreasing stress and depression and promote optimum rehabilitation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1743 (June 2011).

§2213. Therapeutic Procedures - Operative

A. Surgical Decompression is well-established, generally accepted, and widely used and includes open and endoscopic techniques. There is good evidence that surgery is more effective than splinting in producing long-term symptom relief and normalization of median nerve conduction velocity.

1. Endoscopic Techniques have had a higher incidence of serious complications (up to 5 percent) compared to open techniques (less than 1 percent). The most commonly seen serious complications are incomplete transection of the transverse carpal ligament and inadvertent nerve or vessel injuries. The incidence of complications may be lower for surgeons who have extensive experience and familiarity with certain endoscopic techniques. Choice of technique should be left to the discretion of the surgeon.

2. Indications for Surgery include positive history, abnormal electrodiagnostic studies, and/or failure of conservative management. Job modification should be considered prior to surgery. Please refer to the "Job Site Alteration" section for additional information on job modification.

3. Surgery as an Initial Therapy. Surgery should be considered as an initial therapy in situations where:

a. Median nerve trauma has occurred; "acute carpal tunnel syndrome", or

b. Electrodiagnostic evidence of moderate to severe neuropathy. EMG findings showing evidence of acute or chronic motor denervation suggest the possibility that irreversible damage may be occurring.

4. Surgery When Electrodiagnostic Testing is Normal. Surgery may be considered in cases where electrodiagnostic testing is normal. A second opinion from a hand surgeon is strongly recommended. The following criteria should be considered in deciding whether to proceed with surgery.

a. the patient experiences significant temporary relief following steroid injection into the carpal tunnel; or

b. the patient has failed 3-6 months of conservative treatment including work site change; and

c. psychosocial factors have been addressed through psychological screening requirements as defined "Adjunctive Testing" in this Section; and

d. the patient's signs and symptoms are specific for carpal tunnel syndrome

5. Suggested parameters for return-to-work are:

Time Frame	Activity Level
2 Days	Return to Work with Restrictions on utilizing the affected extremity
2-3 Weeks	Sedentary and non-repetitive work
4-6 Weeks	Case-by-case basis
6-12 Weeks	Heavy Labor, forceful and repetitive

NOTE: All return-to-work decisions are based upon clinical outcome.

B. Neurolysis has not been proven advantageous for carpal tunnel syndrome. Internal neurolysis should never be done. Very few indications exist for external neurolysis.

C. Tenosynovectomy has not proven to be of benefit in carpal tunnel syndrome.

D. Consideration for Repeat Surgery

1. The single most important factor in predicting symptomatic improvement following carpal tunnel release is the severity of preoperative neuropathy. Patients with moderate electrodiagnostic abnormalities have better results than those with either very severe or no abnormalities. Incomplete cutting of the transverse carpal ligament or iatrogenic injury to the median nerve are rare. If median nerve symptoms do not improve following initial surgery or symptoms improve initially and then recur, but are

unresponsive to non-operative therapy (see Therapeutic Procedures, Non-Operative) consider the following:

a. Recurrent synovitis;

b. Repetitive work activities may be causing "dynamic" CTS;

c. Scarring;

d. Work-up of systemic diseases

2. A second opinion by a hand surgeon is required if repeat surgery is contemplated. The decision to undertake repeat surgery must factor in all of the above possibilities. Results of surgery for recurrent carpal tunnel syndrome vary widely depending on the etiology of recurrent symptoms.

E. Post-Operative Treatment.

1. Considerations for post-operative therapy are:

a. Immobilization: There is some evidence showing that immediate mobilization of the wrist following surgery is associated with less scar pain and faster return to work. Final decisions regarding the need for splinting post-operatively should be left to the discretion of the treating physician based upon his/her understanding of the surgical technique used and the specific conditions of the patient.

b. Home Program: It is generally accepted that all patients should receive a home therapy protocol involving stretching, ROM, scar care, and resistive exercises. Patients should be encouraged to use the hand as much as possible for daily activities, allowing pain to guide their activities.

c. Supervised Therapy Program: may be helpful in patients who do not show functional improvements post-operatively or in patients with heavy or repetitive job activities. The therapy program may include some of the generally accepted elements of soft tissue healing and return to function:

i. Soft tissue healing/remodeling: May be used after the incision has healed. It may include all of the following: evaluation, whirlpool, electrical stimulation, soft tissue mobilization, scar compression pad, heat/cold application, splinting or edema control may be used as indicated. Following wound healing, ultrasound and iontophoresis with Sodium Chloride (NaCl) may be considered for soft tissue remodeling. Diathermy is a non-acceptable adjunct.

ii. Return to function: Range of motion, therapeutic exercises and stretching exercises, strengthening, activity of daily living adaptations, joint protection instruction, posture/body mechanics education; worksite modifications may be indicated.

(a). Time to produce effect: two-four weeks

(b). Frequency: two-three times/week

(c). Optimum duration: four-six weeks

(d). Maximum duration: eight weeks

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1748 (June 2011).

§2214. LWC-WC 1009. Disputed Claim for Medical Treatment

Mail to:
OWCA—Medical Services
ATTN: Medical Director
P.O. Box 94040
Baton Rouge, LA 70804

1. Social Security No.__-__-__
2. Date of Injury/Illness __-__-__
3. Parts of Body Injury_____
4. Date of Birth __-__-__
5. Date of This Request __-__-__
6. Claim Number _____

DISPUTED CLAIM FOR MEDICAL TREATMENT

NOTE: THIS REQUEST WILL NOT BE HONORED UNLESS THE INSURER HAS ISSUED A DENIAL FOR THE MEDICAL SERVICES IN DISPUTE AS PER R.S. 23:1203.1 J.

GENERAL INFORMATION
Claimant files this dispute with the Office of Workers' Compensation – Medical Services Director. This office must be notified immediately in writing of changes in address. An employee may be represented by an attorney, but it is not required.

7. This request is submitted by
___ Employee ___ Employer __ Insurer ___ Health Care Provider ___ Other ___

A. Copies of all relevant medical records must be included with this request.

B. A copy of the denial letter issued by the insurance carrier must be attached to this request.

EMPLOYEE
8. Name _____
Street or Box _____
City _____
State _____ Zip _____
Phone (____) _____

EMPLOYEE'S ATTORNEY
9. Name _____
Street or Box _____
City _____
State _____
Phone (____) _____
Fax (____) _____

EMPLOYER
10. Name _____
Street or Box _____
City _____
State _____ Zip _____
Phone (____) _____
Fax (____) _____

INSURER/ADMINISTRATOR
(circle one)
11. Name _____
Street or Box _____
City _____
State _____
Phone (____) _____
Fax (____) _____

EMPLOYER/INSURER'S ATTORNEY
12. Name _____
Street or Box _____
City _____
State _____ Zip _____
Phone (____) _____
Fax (____) _____

TREATING/REQUESTING PHYSICIAN
13. Name _____
Street or Box _____
City _____
State _____
Phone (____) _____
Fax (____) _____

LWC-WC 1009
11/2010

14. PLEASE PROVIDE A SUMMARY OF THE DETAILS REGARDING THE ISSUE AT DISPUTE:

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

You may attach a letter or petition with additional information with this disputed claim.
The information given above is true and correct to the best of my knowledge and belief.

_____ _____
SIGNATURE OF REQUESTING PARTY DATE

LWC-WC 1009
11/2010

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1749 (June 2011).

Subchapter B. Thoracic Outlet Syndrome

§2215. Introduction

A. This document has been prepared by the Louisiana Workforce Commission, Office of Workers' Compensation and should be interpreted within the context of guidelines for physicians/providers treating individuals qualifying under Louisiana's Workers' Compensation Act as injured workers with upper extremity involvement. These guidelines are enforceable under the Louisiana Workers Compensation Act. All medical care, services, and treatment owed by the employer to the employee in accordance with the Louisiana Workers' Compensation Act shall mean care, services, and treatment in accordance with these guidelines. Medical Care, services, and treatment that varies from these guidelines shall also be due by the employer when it is demonstrated to the medical director of the office by a preponderance of the scientific medical evidence, that a variance from these guidelines is reasonably required to cure or relieve the injured worker from the effects of the injury or occupational disease given the circumstances. Therefore, these guidelines are not relevant as evidence of a provider's legal standard of professional care. To properly utilize this document, the reader should not skip nor overlook any Sections.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1750 (June 2011).

§2217. General Guidelines Principles

A. The principles summarized in this section are key to the intended implementation of all Office of Workers' Compensation guidelines and critical to the reader's application of the guidelines in this document.

1. Application of Guidelines. The OWCA provides procedures to implement medical treatment guidelines and to foster communication to resolve disputes among the provider, payer, and patient through the Office of Worker's Compensation.

2. Education of the patient and family, as well as the employer, insurer, policy makers and the community should be the primary emphasis in the treatment of upper extremity pain. Currently, practitioners often think of education last, after medications, manual therapy, and surgery. Practitioners must develop and implement an effective strategy and skills to educate patients, employers, insurance systems, policy makers, and the community as a whole. An education-based paradigm should always start with inexpensive communication providing reassuring information to the patient. More in-depth education currently exists within a treatment regime employing functional restorative and innovative programs of prevention and rehabilitation. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of facilitating self-management of symptoms and prevention.

3. Treatment Parameter Duration. Time frames for specific interventions commence once treatments have been initiated, not on the date of injury. Obviously, duration will be impacted by patient compliance, as well as availability of services. Clinical judgment may substantiate the need to accelerate or decelerate the time frames discussed in this document. Such deviation shall be in accordance with La. R.S. 23:1203.1.

4. Active Interventions. Emphasizing patient responsibility, such as therapeutic exercise and/or functional treatment, are generally emphasized over passive modalities, especially as treatment progresses. Generally, passive interventions are viewed as a means to facilitate progress in an active rehabilitation program with concomitant attainment of objective functional gains.

5. Active Therapeutic Exercise Program. Exercise program goals should incorporate patient strength, endurance, flexibility, coordination, and education. This includes functional application in vocational or community settings.

6. Positive Patient zresponse. Positive results are defined primarily as functional gains that can be objectively measured. Standard measurement tools, including outcome measures, should be used. Objective functional gains include, but are not limited to, positional tolerances, range-of-motion (ROM), strength, and endurance, activities of daily living, cognition, psychological behavior, and efficiency/velocity measures that can be quantified. Subjective reports of pain and function should be considered and given relative weight when the pain has anatomic and physiologic correlation. Anatomic correlation must be based on objective findings.

7. Re-evaluation Treatment every Three to Four Weeks. If a given treatment or modality is not producing positive results within three to four weeks, the treatment should be either modified or discontinued. Reconsideration of diagnosis should also occur in the event of poor response to a seemingly rational intervention.

8. Surgical Interventions. Surgery should be contemplated within the context of expected functional outcome and not purely for the purpose of pain relief. The concept of "cure" with respect to surgical treatment by itself is generally a misnomer. All operative interventions must be based upon positive correlation of clinical findings, clinical course, and diagnostic tests. A comprehensive assimilation of these factors must lead to a specific diagnosis with positive identification of pathologic conditions.

9. Six-month Time Frame. The prognosis drops precipitously for returning an injured worker to work once he/she has been temporarily totally disabled for more than six months. The emphasis within these guidelines is to move patients along a continuum of care and return-to-work within a six-month time frame, whenever possible. It is important to note that time frames may not be pertinent to injuries that do not involve work-time loss or are not occupationally related.

10. Return-to-work is therapeutic, assuming the work is not likely to aggravate the basic problem or increase long-term pain. The practitioner must provide specific written physical limitations and the patient should never be released to "sedentary" or "light duty." The following physical limitations should be considered and modified as recommended: lifting, pushing, pulling, crouching, walking, using stairs, bending at the waist, awkward and/or sustained postures, tolerance for sitting or standing, hot and cold environments, data entry and other repetitive motion tasks, sustained grip, tool usage and vibration factors. Even if there

is residual chronic pain, return-to-work is not necessarily contraindicated.

a. The practitioner should understand all of the physical demands of the patient's job position before returning the patient to full duty and should request clarification of the patient's job duties. Clarification should be obtained from the employer or, if necessary, including, but not limited to, an occupational health nurse, occupational therapist, vocational rehabilitation specialist, or an industrial hygienist.

11. Delayed Recovery. Strongly consider a psychological evaluation, if not previously provided, as well as initiating interdisciplinary rehabilitation treatment and vocational goal setting, for those patients who are failing to make expected progress 6 to 12 weeks after an injury. The OWCA recognizes that 3 to 10 percent of all industrially injured patients will not recover within the timelines outlined in this document despite optimal care. Such individuals may require treatments beyond the limits discussed within this document, but such treatment will require clear documentation by the authorized treating practitioner focusing on objective functional gains afforded by further treatment and impact upon prognosis.

12. Guideline Recommendations and Inclusion of Medical Evidence. Guidelines are recommendations based on available evidence and/or consensus recommendations. When possible, guideline recommendations will note the level of evidence supporting the treatment recommendation. When interpreting medical evidence statements in the guideline, the following apply.

a. *Consensus*—the opinion of experienced professionals based on general medical principles. Consensus recommendations are designated in the guideline as "generally well accepted," "generally accepted," "acceptable/accepted," or "well-established."

b. *Some*—the recommendation considered at least one adequate scientific study, which reported that a treatment was effective.

c. *Good*—the recommendation considered the availability of multiple adequate scientific studies or at least one relevant high-quality scientific study, which reported that a treatment was effective.

d. *Strong*—the recommendation considered the availability of multiple relevant and high quality scientific studies, which arrived at similar conclusions about the effectiveness of a treatment.

i. All recommendations in the guideline are considered to represent reasonable care in appropriately selected cases, regardless of the level of evidence or consensus statement attached to it. Those procedures considered inappropriate, unreasonable, or unnecessary are designated in the guideline as "not recommended."

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1750 (June 2011).

§2219. Definition of Thoracic Outlet Syndrome

A. Thoracic Outlet Syndrome (TOS) may be described as a neurovascular disorder affecting the upper extremity which, on rare occasions, is caused by workplace factors, such as jobs that require repetitive activities of the upper extremities with forward head and shoulder postures. It should be emphasized that occupational TOS is a relatively uncommon disorder and other disorders with similar symptomatology need to be ruled out.

B. There are four types of thoracic outlet syndrome. The two vascular types, comprised of subclavian vein or artery pathology, are diagnosed with imaging. True or classic neurogenic TOS consists of a chronic lower trunk brachial plexopathy diagnosed by positive electrodiagnostic testing. It is usually unilateral, predominantly affects women, and results in classic electrophysiologic and physical exam findings such as hand atrophy. The two vascular types of TOS and true neurogenic are relatively rare and easily diagnosed. The most common type of TOS is non-specific neurogenic (also called disputed) TOS, which is diagnosed based on upper or lower trunk brachial plexus symptoms.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1751 (June 2011).

§2221. Initial Diagnostic Procedures

A. The OWCA recommends the following diagnostic procedures be considered, at least initially, the responsibility of the workers' compensation carrier to ensure that an accurate diagnosis and treatment plan can be established. Standard procedures that should be utilized when initially diagnosing a work-related TOS complaint are listed below.

1. History taking and physical examination (Hx and PE) are generally accepted, well-established and widely used procedures which establish the basis for diagnosis, and dictate all other diagnostic and therapeutic procedures. When findings of clinical evaluations and those of other diagnostic procedures are not complementing each other, the objective clinical findings should have preference. Neurogenic TOS will be described separately from vascular TOS, although some general symptoms may occasionally overlap. Vascular TOS usually requires emergent treatment as described in the surgical Section. Treatment for non-specific neurogenic TOS begins with jobsite alteration and therapy as described in Section F. and rarely requires surgical intervention. True neurogenic TOS may require early surgical intervention if there is significant weakness with corresponding EMG/NCV changes. The medical records should reasonably document the following.

a. History Taking. A careful history documenting exacerbating activities and positions which relieve symptoms is essential. Timing of the onset of symptoms is important. TOS has been associated with trauma and motor vehicle accidents. Avocational pursuits should also be specifically documented.

i. Symptoms Common to Neurogenic TOS. Neurological symptoms are usually intermittent in non-specific TOS. If symptoms are constant, consider other diagnoses such as true TOS or other brachial plexus injuries. Neck pain is often the first symptom with complaints within the first few days of injury. Occipital headaches may also occur early. Some patients experience coldness or color changes in the hands. Neurogenic symptoms include the following:

(a). forearm (frequently medial), or proximal upper extremity pain;

(b). numbness and paresthesia in arm, hand and fingers:

(i). fourth and fifth digits: most common pattern;

(ii). all five fingers: next most common pattern;

(iii). first, second and third digits: symptoms may occur, but one must rule out carpal tunnel syndrome;

(c). upper extremity weakness: arm and/or hand; "dropping things" may be a common complaint;

(d). exacerbating factor: arm elevation. Common complaints are trouble combing hair, putting on clothing, driving a car, or carrying objects with shoulder straps such as back packs; disturbed sleep, etc.

(i). Symptoms Common to Vascular TOS

[a]. Pain, coldness, pallor, digital ischemia and claudication in the forearm are signs of arterial compromise which is most frequently chronic and due to subclavian aneurysm or stenosis.

[b]. Swollen, cyanotic, and sometimes painful arm is indicative of a venous obstruction requiring immediate attention.

b. Occupational Relationship for Neurogenic and Vascular TOS. In many cases, trauma is the cause vascular or neurogenic TOS. Clavicular fractures, cervical strain (including whiplash), and other cases of cervical trauma injuries have been associated with TOS. Continual overhead lifting or motion may contribute as can static postures in which the shoulders droop and the head is inclined forward. Activities which cause over-developed scalene muscles such as weight-lifting and swimming may contribute. The Paget-Schroetter syndrome, or effort thrombosis of the subclavian vein, may occur in athletes or workers with repetitive overhead forceful motion and neck extension. Arterial thrombosis or symptoms from subclavian aneurysms or stenosis are usually not work-related. Both classic neurogenic TOS (usually due to a cervical or anomalous first rib) and vascular TOS due to arterial compromise from stenosis or aneurysm are rarely work-related conditions.

c. Physical Findings

i. Physical Examination Signs used to Diagnose Classic or Non-specific Neurogenic TOS. Both extremities should be examined to compare symptomatic and asymptomatic sides.

ii. Provocative maneuvers (listed below) must reproduce the symptoms of TOS to be considered positive:

(a). tenderness over scalene muscles in supraclavicular area;

(b). pressure in supraclavicular area elicits symptoms in arm/hand, or Tinel's sign over brachial plexus is positive. The supraclavicular pressure test is positive for paresthesia in approximately 15 percent of asymptomatic individuals;

(c). Elevated Arm Stress Test (EAST) is performed with the arms abducted and shoulders externally rotated to 90 degrees with elbows bent to 90 degrees for 3 minutes (some examiners use 60 seconds). The patient may also be asked to repetitively open and close fists. A positive test reproduces upper extremity symptoms. When this test is performed for 3 minutes in an asymptomatic population, approximately 35 percent experience paresthesia;

(d). some literature has suggested another provocative elevated arm stress test. The patient holds his arms over head for one minute with elbows extended, wrists in a neutral position, and forearm midway between supination and pronation. If symptoms are reproduced, the test is positive.

d. Posture related brachial tests:

i. head tilting: lateral flexion of the neck (ear to shoulder) causes radiating pain and paresthesia in the contralateral arm consistent with TOS.;

ii. Military posture or costoclavicular maneuver. Shoulders are depressed and pulled backward in an exaggerated position. Reproduction of symptoms is a positive test. Approximately 15 percent of asymptomatic individuals will report paresthesia with this test.

e. Neurological Examination: usually normal in non-specific TOS, but may be abnormal.

i. Sensory Exam: may show decreased sensation to light touch, pain, vibration, and/or temperature in lower brachial plexus distribution. The entire ring finger is usually involved. This contrasts with ulnar neuropathy, which usually involves only the ulnar side of the ring finger.

ii. Motor Exam: weakness and/or muscle atrophy in either upper or lower trunk distributions including, but not limited to, valid dynamometer readings indicative of relative weakness in the affected limb. In lower plexus injuries, the abductor pollicus brevis often demonstrates more involvement and atrophy than the intrinsic interosseous muscles.

(a). Physical exam findings for vascular TOS cases. Suspicion of vascular compromise should lead to confirmation using appropriate imaging procedures.

(i). Arterial cases usually demonstrate an absent radial pulse at rest, pale hand and often ischemic fingers.

(ii). Venous obstruction presents with visible or distended superficial veins on the effected signs involving the anterior axillary fold and chest wall. The arm is usually swollen and cyanotic.

iii. Physical Exam—other tests which are recommended and may indicate additional diagnostic considerations.

(a). Neck rotation may be restricted and can indicate the presence of additional pathology.

(b). Upper Limb Tension Test—this provocative test may be positive for cervical radiculopathy, brachial plexus pathology, or other peripheral nerve pathology. It is considered sensitive but non-specific. The test has several variations; however, they all consist of a series of systematic maneuvers performed on the upper quadrant to evaluate peripheral nerve function and pathology. Head tilting is one of the maneuvers included. Provocation of abnormal responses indicates neural tissue sensitization/irritation, and can include implication of specific peripheral nerve trunks. Performance and interpretation of this test requires specific training and experience. A negative response to the upper limb tension test makes the diagnosis of neurogenic TOS unlikely. If negative, investigate other diagnoses.

(c). Rotator cuff/acromioclavicular (AC) joint tenderness suggests rotator cuff, or biceps tendonitis or AC joint disease.

(d). Trapezius muscle, shoulder girdle muscles or paraspinal muscle tenderness suggests a myofascial component.

(e). Drooping shoulders secondary to nerve injuries can be present with TOS symptoms. If a spinal accessory, long thoracic or other nerve injury is identified, treatment should focus on therapy for the nerve injury in addition to conservative measures for TOS. Refer to the Shoulder Injury Medical Treatment Guidelines. Brachial Plexus and Shoulder Nerve Injuries.

(f). The following tests suggest carpal tunnel syndrome:

(i). carpal tunnel compression test;

(ii). flicking the wrist secondary to paresthesia;

(iii). Tinel's sign; and/or

(iv). Phalen's sign.

(g). Positive Tinel's sign at elbow (over ulnar groove) suggests ulnar nerve entrapment.

(h). Positive Tinel's sign over the pronator teres muscle suggests median nerve involvement. Positive Tinel's sign over the radial tunnel suggests radial nerve compression.

f. Cervical spine x-ray is a generally accepted, well-established procedure indicated to rule out cervical spine disease, fracture, cervical rib or rudimentary first rib when clinical findings suggest these diagnoses. Cervical spine x-rays should also be considered when there is an asymmetric diminished pulse in an arm that is symptomatic. X-rays are most useful when arterial TOS is suspected. The presence of a cervical rib does not confirm the diagnosis unless other clinical signs and symptoms are present, as many cervical ribs are asymptomatic. Therefore, routine roentgenographic evaluation of the cervical spine is frequently unnecessary early in the course of treatment for non-specific TOS.

g. Vascular Studies. Vascular laboratory studies, including duplex scanning, Doppler studies, standard and MR arteriography and venography are required for patients presenting with arterial or venous occlusion, as these patients may require immediate thrombolytic intervention. These studies are not indicated for neurogenic TOS.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1751 (June 2011).

§2223. Follow-up Diagnostic Imaging and Testing Procedures

A. Cervical computed axial tomography or magnetic resonance imaging (ct/mri) are generally accepted, well-established procedures indicated to rule out cervical disc or other cervical spine disorders when clinical findings suggest these diagnoses. It should not be routinely performed for TOS. MRI is the preferred test over a CT unless a fracture is suspected, and then CT may be superior to MRI. CT/MRI is not indicated early unless there is a neurological deficit and/or the need to rule out a space- occupying lesion, such as a tumor. Repeat cervical MRI is not indicated for TOS. If cervical spine injury is confirmed, refer to the OWCA's *Cervical Spine Injury Medical Treatment Guidelines*. If a cervical spine disorder is not suspected, conservative therapy as indicated in Section F, Non-operative Procedures should be done for at least 8 to 12 weeks, prior to ordering an MRI for persistent symptoms.

B. Electrodiagnostic Studies

1. Electromyography/Nerve Conduction Velocities (EMG/NCV) is a generally accepted, well-established procedure. EMG/NCV is primarily indicated to rule out other nerve entrapment syndromes such as carpal tunnel or cubital tunnel syndrome when indicated by clinical examination, or to establish true neurogenic TOS. Most cases of non-specific TOS have normal electrodiagnostic studies, but EMG/NCV should be considered when symptoms have been present for approximately three months or if the patient has failed eight weeks of conservative therapy. EMG/NCV may also be performed to rule out other disorders. Somato-sensory evoked potentials (SSEPs), F waves and NCV across the thoracic outlet have no diagnostic value and should not be performed. The diagnosis is usually made by comparison to the normal extremity. For bilateral disease, each EMG lab must establish its own absolute limits of latency and amplitude from volunteer controls so that measurements exceeding these limits can be noted.

2. Criteria for True Neurogenic TOS

a. reduction of the ulnar sensory nerve action potential to digits (usually less than 60 percent of unaffected side); or

b. medial antebrachial sensory action potential which is low or absent compared to the unaffected side; or

c. reduction of the median M-wave amplitude (usually less than 50 percent of unaffected side); or

d. needle EMG examination reveals neurogenic changes in intrinsic hand muscles and the abductor pollicus brevis muscle.

3. Portable automated electrodiagnostic device: (also known as surface EMG) is not a substitute for conventional EMG/NCS testing in clinical decision-making, and therefore, is not recommended.

4. Quantitative Sensory Testing (QST). Research is not currently available on the use of QST in the evaluation of TOS. QST tests the entire spectrum of the neurological system including the brain. It is not able to reliably distinguish between organic and psychogenic pathology and therefore, is not recommended.

C. Vascular Studies. Noninvasive vascular testing, such as pulse-volume recording in different positions, is not indicated in cases of neurogenic TOS. Since the presence or absence of a pulse cutoff on physical examination is not helpful in establishing a diagnosis of TOS, the recording of finer degrees of positional pulse alteration will not add to the diagnosis. Vascular laboratory studies, including duplex scanning, Doppler studies, standard and MR arteriography and venography, are not cost-effective in cases of neurogenic TOS. These studies are only indicated in patients who have arterial or venous occlusive signs. Dynamic venography with the arm in 180 degrees of abduction may be used in cases with continued swelling and/or periodic cyanosis who have not improved with conservative therapy. Approximately 20 percent of asymptomatic individuals will have an abnormal dynamic venogram. Some individuals may have a pectoralis minor syndrome which occludes the axillary vein rather than the subclavian vein. In these cases, less invasive surgery than the TOS operative procedures may be indicated.

D. Thermography is not generally accepted or widely used for TOS. It may be used if differential diagnosis includes CRPS; in such cases refer to the OWCA's Complex Regional Pain Syndrome/Reflex Sympathetic Dystrophy Medical Treatment Guidelines.

E. Anterior scalene or pectoralis muscle blocks may be performed to provide additional information prior to expected surgical intervention. It is recommended that EMG or sonography guidance be used to assure localization.

F. Personality/psychological/psychiatric/psychosocial evaluations are generally accepted and well-established diagnostic procedures with selective use in the acute TOS population and more widespread use in the sub-acute and chronic TOS population.

1. Diagnostic testing procedures may be useful for patients with symptoms of depression, delayed recovery, chronic pain, recurrent painful conditions, disability problems, and for pre-operative evaluation as well as a possible predictive value for post-operative response. Psychological testing should provide differentiation between pre-existing depression versus injury-caused depression, as well as post-traumatic stress disorder.

2. Formal psychological or psychosocial evaluation should be performed on patients not making expected progress within 6-12 weeks following injury and whose subjective symptoms do not correlate with objective signs and tests. In addition to the customary initial exam, the evaluation of the injured worker should specifically address the following areas:

a. employment history;

b. interpersonal relationships—both social and work;

c. leisure activities;

d. current perception of the medical system;

e. results of current treatment;

f. perceived locus of control; and

g. childhood history, including abuse and family history of disability.

3. This information should provide clinicians with a better understanding of the patient, and enable a more effective rehabilitation.

4. The evaluation will determine the need for further psychosocial interventions, and in those cases, a Diagnostic Statistical Manual (DSM) of Mental Disorders diagnosis should be determined and documented. An individual with a PhD, PsyD, or Psychiatric MD/DO credentials should perform initial evaluations, which are generally completed within one to two hours. A professional fluent in the primary language of the patient is strongly preferred. When such a provider is not available, services of a professional language interpreter must be provided. When issues of chronic pain are identified, the evaluation should be more extensive and follow testing procedures as outlined in the OWCA's *Chronic Pain Disorder Medical Treatment Guidelines*.

a. Frequency—one time visit for evaluation. If psychometric testing is indicated as a portion of the initial evaluation, time for such testing should not exceed an additional two hours of professional time.

G. Special tests are generally well-accepted tests and are performed as part of a skilled assessment of the patients' capacity to return to work, his/her strength capacities, and physical work demand classifications and tolerance. The procedures in this subsection are listed in alphabetical order, not by importance.

1. Computer-enhanced evaluations may include isotonic, isometric, isokinetic and/or isoinertial measurement of movement, range-of-motion, endurance or strength. Values obtained can include degrees of motion, torque forces, pressures or resistance. Indications include determining validity of effort, effectiveness of treatment and demonstrated motivation. These evaluations should not be used alone to determine return to work restrictions. The added value of computer enhanced evaluations is unclear. Targeted work tolerance screening or gradual return to work is preferred.

a. Frequency—one time for evaluation. Can monitor improvements in strength every three to four weeks up to a total of six evaluations.

2. Functional capacity evaluation (FCE) is a comprehensive or modified evaluation of the various aspects of function as they relate to the worker's ability to return to work. Areas such as endurance, lifting (dynamic and static), postural tolerance, specific range of motion, coordination and strength, worker habits, employability as well as psychosocial, cognitive, and sensory perceptual aspects of competitive employment may be evaluated. Components of this evaluation may include: musculoskeletal screen; cardiovascular profile/aerobic capacity; coordination; lift/carrying analysis; job-specific activity tolerance; maximum voluntary effort; pain assessment/psychological screening; and non-material and material handling activities.

a. When an FCE is being used to determine return to a specific jobsite, the provider is responsible for fully understanding the job duties. A jobsite evaluation is frequently necessary. FCEs cannot be used in isolation to determine work restrictions. The authorized treating physician must interpret the FCE in light of the individual patient's presentation and medical and personal perceptions. FCEs should not be used as the sole criteria to diagnose malingering.

b. Full FCEs are sometimes necessary. In many cases, a work tolerance screening will identify the ability to perform the necessary job tasks. If partial FCEs are performed, it is recognized that all parts of the FCE that are not performed are considered normal.

i. Frequency—can be used initially to determine baseline status and for case closure when patient is unlikely to return to pre-injury position and further information is desired to determine permanent work restrictions. Prior authorization is required for FCEs performed during treatment.

3. Jobsite evaluation is a comprehensive analysis of the physical, mental and sensory components of a specific job. These components may include, but are not limited to: postural tolerance (static and dynamic); aerobic requirements; range of motion; torque/force; lifting/carrying; cognitive demands; social interactions; visual perceptual; sensation; coordination; environmental requirements; repetitiveness; and essential job functions. Job descriptions provided by the employer are helpful but should not be used as a substitute for direct observation.

a. A jobsite evaluation may include observation and instruction of how work is done, what material changes (desk, chair) should be made, and determination of readiness

to return to work. Postural risk factors should be identified and awkward postures of overhead reach, hyperextension or rotation of the neck, shoulder drooped or forward-flexed and head-chin forward postures should be eliminated. Unless combined with one of the above postures, repetitiveness is not by itself a risk factor. Refer to Cumulative Trauma Disorder and Shoulder Guidelines for further suggestions.

i. Requests for a jobsite evaluation should describe the expected goals for the evaluation. Goals may include, but are not limited to the following:

(a). to determine if there are potential contributing factors to the person's condition and/or for the physician to assess causality;

(b). to make recommendations for, and to assess the potential for ergonomic changes;

(c). to provide a detailed description of the physical and cognitive job requirements;

(d). to assist the patient in their return to work by educating them on how they may be able to do their job more safely in a bio-mechanically appropriate manner;

(e). to give detailed work/activity restrictions.

(i). Frequency—one time with additional visits as needed for follow-up per jobsite.

4. Vocational Assessment. The vocational assessment should provide valuable guidance in the determination of future rehabilitation program goals. It should clarify rehabilitation goals, which optimize both patient motivation and utilization of rehabilitation resources. If prognosis for return to former occupation is determined to be poor, except in the most extenuating circumstances, vocational assessment should be implemented within 3 to 12 months post-injury. Declaration of MMI should not be delayed solely due to lack of attainment of a vocational assessment.

a. Frequency—one time with additional visits as needed for follow-up.

5. Work tolerance screening is a determination of an individual's tolerance for performing a specific job based on a job activity or task and may be used when a full functional capacity evaluation is not indicated. The screening is monitored by a therapist and may include a test or procedure to specifically identify and quantify work-relevant cardiovascular, physical fitness and postural tolerance. It may also address ergonomic issues affecting the patient's return-to-work potential.

a. Frequency—one time for initial screen. May monitor improvements in strength every three to four weeks up to a total of six visits.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1753 (June 2011).

§2225. Therapeutic Procedures—Non-Operative

NOTE: Treating providers, as well as employers and insurers are highly encouraged to reference the General Guideline Principles prior to initiation of any therapeutic procedure.

A. Initial Treatment Recommendations. Vascular cases will require surgical management and thus are not appropriate candidates for initial non-operative therapy. Cases of "non-specific" (also called disputed) TOS are treated conservatively first for a minimum of three months. Patients undergoing therapeutic procedures may return to modified or restricted duty during their rehabilitation, at the earliest appropriate time. Cessation and/or review of treatment modalities should be undertaken when no further significant subjective or objective improvement in the patient's condition is noted. Most literature of conservative therapy for TOS suggest benefit for patients with non-specific TOS. Non-surgical patients may be less likely to lose as much time from work as surgical patients. Initial treatment for TOS patients without indications for early surgery should include, patient education, jobsite alterations (especially if job activities are related to symptoms), neuromuscular education to emphasis proper breathing techniques and posture, nerve gliding and core body therapeutic exercise.

B. Postural risk factors should be identified. Awkward postures of overhead reach, hyperextension or rotation of the neck, shoulder drooped or forward-flexed and head-chin forward postures should be eliminated. Proper breathing techniques are also part of the treatment plan.

C. Therapy is primarily a daily self-managed home program developed and supervised by an appropriately trained professional. Nerve gliding and upper extremity stretching usually involves the following muscle groups: scalene, pectoralis minor, trapezius and levator scapulae. Endurance or strengthening of the upper extremities early in the course of therapy is not recommended, as this may exacerbate cervical or upper extremity symptoms.

D. Jobsite evaluation should be done early in all non-traumatic cases and should be performed by a qualified individual in all cases of suspected occupational TOS. Postural risk factors discussed above should be considered when making jobsite changes. Unless combined with one of the above postures, repetition alone is not a risk factor. Work activities need to be modified early in treatment to avoid further exposure to risk factors.

1. Acupuncture is an accepted and widely used procedure for the relief of pain and inflammation and there is some scientific evidence to support its use. The exact mode of action is only partially understood. Western medicine literature suggests that acupuncture stimulates the nervous system at the level of the brain, promotes deep relaxation, and affects the release of neurotransmitters. Acupuncture is commonly used as an alternative or in addition to traditional Western pharmaceuticals. While it is commonly used when pain medication is reduced or not tolerated, it may be used as an adjunct to physical rehabilitation and/or surgical intervention to hasten the return of functional activity. Acupuncture should be performed by licensed practitioners.

a. Acupuncture is the insertion and removal of filiform needles to stimulate acupoints (acupuncture points). Needles may be inserted, manipulated and retained for a period of time. Acupuncture can be used to reduce pain, reduce inflammation, increase blood flow, increase range of motion, decrease the side effect of medication-induced nausea, promote relaxation in an anxious patient, and reduce muscle spasm.

i. Indications include joint pain, joint stiffness, soft tissue pain and inflammation, paresthesia, post-surgical pain relief, muscle spasm, and scar tissue pain.

b. Acupuncture with electrical stimulation is the use of electrical current (micro-amperage or milli-amperage) on the needles at the acupuncture site. It is used to increase

effectiveness of the needles by continuous stimulation of the acupoint. Physiological effects (depending on location and settings) can include endorphin release for pain relief, reduction of inflammation, increased blood circulation, analgesia through interruption of pain stimulus, and muscle relaxation.

i. It is indicated to treat chronic pain conditions, radiating pain along a nerve pathway, muscle spasm, inflammation, scar tissue pain, and pain located in multiple sites.

c. Total time frames for acupuncture and acupuncture with electrical stimulation time frames are not meant to be applied to each of the above sections separately. The time frames are to be applied to all acupuncture treatments regardless of the type or combination of therapies being provided.

i. Time to Produce Effect—three to six treatments.

ii. Frequency—one to three times per week.

iii. Optimum Duration—one to two months.

iv. Maximum Duration—14 treatments.

(a). Any of the above acupuncture treatments may extend longer if objective functional gains can be documented or when symptomatic benefits facilitate progression in the patient's treatment program. Treatment beyond 14 treatments must be documented with respect to need and ability to facilitate positive symptomatic or functional gains. Such care should be re-evaluated and documented with each series of treatments.

d. Other Acupuncture Modalities. Acupuncture treatment is based on individual patient needs and therefore treatment may include a combination of procedures to enhance treatment effect. Other procedures may include the use of heat, soft tissue manipulation/massage, and exercise. Refer to Active Therapy (Therapeutic Exercise) and, Passive Therapy sections (Massage and Superficial Heat and Cold Therapy) for a description of these adjunctive acupuncture modalities and time frames.

2. Biofeedback is a form of behavioral medicine that helps patients learn self-awareness and self-regulation skills for the purpose of gaining greater control of their physiology, such as muscle activity, brain waves, and measures of autonomic nervous system activity. Electronic instrumentation is used to monitor the targeted physiology and then displayed or fed back to the patient visually, auditorily, or tactilely, with coaching by a biofeedback specialist. Biofeedback is provided by clinicians certified in biofeedback and/or who have documented specialized education, advanced training, or direct or supervised experience qualifying them to provide the specialized treatment needed (e.g., surface EMG, EEG, or other).

a. Treatment is individualized to the patient's work-related diagnosis and needs. Home practice of skills is required for mastery and may be facilitated by the use of home training tapes. The ultimate goal in biofeedback treatment is normalizing the physiology to the pre-injury status to the extent possible and involves transfer of learned skills to the workplace and daily life. Candidates for biofeedback therapy or training must be motivated to learn and practice biofeedback and self-regulation techniques.

b. Indications for biofeedback include individuals who are suffering from musculoskeletal injury where muscle dysfunction or other physiological indicators of excessive or prolonged stress response affects and/or delays recovery. Other applications include training to improve self-management of emotional stress/pain responses such as anxiety, depression, anger, sleep disturbance, and other central and autonomic nervous system imbalances. Biofeedback is often utilized along with other treatment modalities.

i. Time to Produce Effect—three to four sessions.

ii. Frequency—one to two times per week.

iii. Optimum Duration—five to six sessions.

iv. Maximum Duration: 10 to 12 sessions. Treatment beyond 12 sessions must be documented with respect to need, expectation, and ability to facilitate positive symptomatic or functional gains.

3. Injections—Therapeutic

a. Scalene blocks have no therapeutic role in the treatment of TOS.

b. Trigger point injections, although generally accepted, are not routinely used in cases of TOS. However, it is not unusual to find myofascial trigger points associated with TOS pathology, which may require injections.

i. Description. Trigger point treatment can consist of dry needling or injection of local anesthetic with or without corticosteroid into highly localized, extremely sensitive bands of skeletal muscle fibers that produce local and referred pain when activated. Medication is injected in a four-quadrant manner in the area of maximum tenderness. Injection efficacy can be enhanced if injections are immediately followed by myofascial therapeutic interventions, such as vapo-coolant spray and stretch, ischemic pressure massage (myotherapy), specific soft tissue mobilization and physical modalities. There is conflicting evidence regarding the benefit of trigger point injections. A truly blinded study comparing dry needle treatment of trigger points is not feasible. There is no evidence that injection of medications improves the results of trigger-point injections. Needling alone may account for some of the therapeutic response.

ii There is no indication for conscious sedation for patients receiving trigger point injections. The patient must be alert to help identify the site of the injection.

iii. Indications. Trigger point injections may be used to relieve myofascial pain and facilitate active therapy and stretching of the affected areas. They are to be used as an adjunctive treatment in combination with other treatment modalities such as functional restoration programs. Trigger point injections should be utilized primarily for the purpose of facilitating functional progress. Patients should continue with a therapeutic exercise program as tolerated throughout the time period they are undergoing intensive myofascial interventions. Myofascial pain is often associated with other underlying structural problems and any abnormalities need to be ruled out prior to injection.

iv. Trigger point injections are indicated in those patients where well circumscribed trigger points have been consistently observed, demonstrating a local twitch response, characteristic radiation of pain pattern and local

autonomic reaction, such as persistent hyperemia following palpation. Generally, these injections are not necessary unless consistently observed trigger points are not responding to specific, noninvasive, myofascial interventions within approximately a six-week time frame.

v. Complications. Potential but rare complications of trigger point injections include infection, pneumothorax, anaphylaxis, neurapraxia, and neuropathy. If corticosteroids are injected in addition to local anesthetic, there is a risk of local myopathy developing. Severe pain on injection suggests the possibility of an intraneural injection, and the needle should be immediately repositioned.

(a). Time to Produce Effect—local anesthetic, 30 minutes; no anesthesia, 24 to 48 hours.

(b). Frequency—weekly, suggest no more than four injection sites per session per week to avoid significant post-injection soreness.

(c). Optimal Duration—four weeks.

(d). Maximum Duration—eight weeks. Occasional patients may require two to four repetitions of trigger point injection series over a one to two year period.

4. Medications:

a. Thrombolytic agents will be required for some vascular TOS conditions.

b. Medication use is appropriate for pain control in TOS. A thorough medication history, including use of alternative and over the counter medications, should be performed at the time of the initial visit and updated periodically.

c. Acetaminophen is an effective and safe initial analgesic. Nonsteroidal anti-inflammatory drugs (NSAIDs) are useful in the treatment of inflammation, and for pain control. Pain is subjective in nature and should be evaluated using a scale to rate effectiveness of the analgesic in terms of functional gain. Other medications, including antidepressants and anti-convulsants, may be useful in selected patients with neuropathic and/or chronic pain (Refer to the OWCA's *Chronic Pain Guidelines*). Narcotics are rarely indicated for treatment of TOS, and they should be primarily reserved for the treatment of acute severe pain for a limited time on a case-by-case basis. Topical agents may be beneficial in the management of localized upper extremity pain.

d. The use of a patient completed pain drawing, Visual Analog Scale (VAS), is highly recommended to help providers track progress. Functional objective goals should be monitored regularly to determine the effectiveness of treatment. The patient should be advised regarding the interaction with prescription and over-the-counter herbal products.

e. The following medications are listed in alphabetical order.

i. Acetaminophen is an effective analgesic with antipyretic but not anti-inflammatory activity. Acetaminophen is generally well tolerated, causes little or no gastrointestinal irritation and is not associated with ulcer formation. Acetaminophen has been associated with liver toxicity in overdose situations or in chronic alcohol use. Patients may not realize that many over-the-counter preparations may contain acetaminophen. The total daily dose of acetaminophen is recommended not to exceed 2250 mg per 24 hour period, from all sources, including narcotic-acetaminophen combination preparations.

(a). Optimal Duration—7 to 10 days.

(b). Maximum Duration—chronic use as indicated on a case-by-case basis. Use of this substance long-term for three days per week or greater may be associated with rebound pain upon cessation.

ii. Anticonvulsants. Although the mechanism of action of anticonvulsant drugs in neuropathic pain states remains to be fully defined, they appear to act as nonselective sodium channel blocking agents. A large variety of sodium channels are present in nervous tissue, and some of these are important mediators of nociception, as they are found primarily in unmyelinated fibers and their density increases following nerve injury. While the pharmacodynamic effects of the various anticonvulsant drugs are similar, the pharmacokinetic effects differ significantly. Carbamazepine has important effects as an inducer of hepatic enzymes and may influence the metabolism of other drugs enough to present problems in patients taking more than one drug. Gabapentin and oxcarbazepine, by contrast, are relatively non-significant enzyme inducers, creating fewer drug interactions. Because anticonvulsant drugs may have more problematic side-effect profiles, their use should usually be deferred until antidepressant drugs have failed to relieve pain.

(a). Gabapentin (Neurontin)

(i). Description—structurally related to gamma aminobutyric acid (GABA) but does not interact with GABA receptors.

(ii). Indications—neuropathic pain.

(iii). Relative Contraindications—renal insufficiency.

iv. Dosing and Time to Therapeutic Effect—dosage may be increased over several days.

v. Major Side Effects—confusion, sedation.

vi. Drug Interactions—oral contraceptives, cimetidine, antacids.

vii. Recommended Laboratory Monitoring—renal function.

iii. Antidepressants are classified into a number of categories based on their chemical structure and their effects on neurotransmitter systems. Their effects on depression are attributed to their actions on disposition of norepinephrine and serotonin at the level of the synapse; although these synaptic actions are immediate, the symptomatic response in depression is delayed by several weeks. When used for chronic pain, the effects may in part arise from treatment of underlying depression, but may also involve additional neuromodulatory effects on endogenous opioid systems, raising pain thresholds at the level of the spinal cord.

(a). Pain responses may occur at lower drug doses with shorter times to symptomatic response than are observed when the same compounds are used in the treatment of mood disorders. Neuropathic pain, diabetic neuropathy, post-herpetic neuralgia, and cancer-related pain may respond to antidepressant doses low enough to avoid adverse effects that often complicate the treatment of depression.

(i). Tricyclics (e.g., amitryptiline [Elavil], nortriptyline [Pamelor, Aventyl], doxepin [Sinequan, Adapin])

[a]. Description—serotonergics, typically tricyclic antidepressants (TCAs), are utilized for their serotonergic properties as increasing CNS serotonergic tone can help decrease pain perception in non-antidepressant dosages. Amitriptyline is known for its ability to repair Stage 4 sleep architecture, a frequent problem found in chronic pain patients and to treat depression, frequently associated with chronic pain.

[b]. Indications—chronic musculoskeletal and/or neuropathic pain, insomnia. Second line drug treatment for depression.

[c]. Major Contraindications—cardiac disease or dysrhythmia, glaucoma, prostatic hypertrophy, seizures, suicide risk.

[d]. Dosing and Time to Therapeutic Effect—varies by specific tricyclic. Low dosages are commonly used for chronic pain and/or insomnia.

[e]. Major Side Effects—anticholinergic side effects including, but not limited to, dry mouth, sedation, orthostatic hypotension, cardiac arrhythmia, weight gain.

[f]. Drug Interactions—tramadol (may cause seizures), clonidine, cimetidine, sympathomimetics, valproic acid, warfarin, carbamazepine, bupropion, anticholinergics, quinolones.

[g]. Recommended Laboratory Monitoring—renal and hepatic function. Electrocardiogram (EKG) for those on high dosages or with cardiac risk.

iv. Minor tranquilizer/muscle relaxants are appropriate for muscle spasm, mild pain and sleep disorders.

(a). Optimum Duration—up to one week.

(b). Maximum Duration—four weeks.

v. Narcotics medications should be prescribed with strict time, quantity and duration guidelines, and with definitive cessation parameters. Adverse effects include respiratory depression, impaired alertness, and the development of physical and psychological dependence.

(a). Optimum Duration—up to seven days.

(b). Maximum Duration—two weeks. Use beyond two weeks is acceptable in appropriate cases, such as patients requiring complex surgical treatment.

vi. Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) are useful for pain and inflammation. In mild cases, they may be the only drugs required for analgesia. There are several classes of NSAIDs, and the response of the individual injured worker to a specific medication is unpredictable. For this reason, a range of NSAIDs may be tried in each case with the most effective preparation being continued. Patients should be closely monitored for adverse reactions. The US Food and Drug Administration advises that many NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. Naproxen sodium does not appear to be associated with increased risk of vascular events. Administration of proton pump inhibitors, Histamine 2 Blockers, or prostaglandin analog misoprostol along with these NSAIDs may reduce the risk of duodenal and gastric ulceration but do not impact possible cardiovascular complications. Due to the cross-reactivity between aspirin and NSAIDs, NSAIDs should not be used in aspirin-sensitive patients, and should be used with caution in all asthma patients. NSAIDs are associated with abnormal renal function, including renal failure, as well as, abnormal liver function. Certain NSAIDs may have interactions with various other medications. Individuals may have adverse events not listed above. Intervals for metabolic screening are dependent upon the patient's age, general health status and should be within parameters listed for each specific medication. Complete Blood Count (CBC), and liver and renal function should be monitored at least every six months in patients on chronic NSAIDs and initially when indicated.

(a). Non-selective Nonsteroidal Anti-Inflammatory Drugs

(i). Includes NSAIDs and acetylsalicylic acid (aspirin). Serious GI toxicity, such as bleeding, perforation, and ulceration can occur at any time, with or without warning symptoms in patients treated with traditional NSAIDs. Physicians should inform patients about the signs and/or symptoms of serious gastrointestinal toxicity and what steps to take if they occur. Anaphylactoid reactions may occur in patients taking NSAIDs. NSAIDs may interfere with platelet function. Fluid retention and edema have been observed in some patients taking NSAIDs.

[a]. Optimal Duration—one week.

[b]. Maximum Duration—one year. Use of these substances long-term (three days per week or greater) is associated with rebound pain upon cessation.

(b). Selective Cyclo-oxygenase-2 (COX-2) Inhibitors

(i). COX-2 inhibitors are more recent NSAIDs and differ in adverse side effect profiles from the traditional NSAIDs. The major advantages of selective COX-2 inhibitors over traditional NSAIDs are that they have less gastrointestinal toxicity and no platelet effects. COX-2 inhibitors can worsen renal function in patients with renal insufficiency, thus renal function may need monitoring.

(ii). COX-2 inhibitors should not be first-line for low risk patients who will be using an NSAID short-term but are indicated in select patients for whom traditional NSAIDs are not tolerated. Serious upper GI adverse events can occur even in asymptomatic patients. Patients at high risk for GI bleed include those who use alcohol, smoke, are older than 65, take corticosteroids or anti-coagulants, or have a longer duration of therapy. Celecoxib is contraindicated in sulfonamide allergic patients.

[a]. Optimal Duration—7 to 10 days.

[b]. Maximum Duration—chronic use is appropriate in individual cases. Use of these substances long-term (three days per week or greater) is associated with rebound pain upon cessation.

5. Occupational Rehabilitation Programs

a. Non-Interdisciplinary. These generally accepted programs are work-related, outcome-focused, individualized treatment programs. Objectives of the program include, but are not limited to, improvement of cardiopulmonary and neuromusculoskeletal functions (strength, endurance, movement, flexibility, stability, and motor control functions), patient education, and symptom relief. The goal is for patients to gain full or optimal function and return to work. The service may include the time-limited use of passive modalities with progression to achieve treatment and/or

simulated/real work. These programs are frequently necessary for patients who must return to physically demanding job duties or whose injury requires prolonged rehabilitation and therapy spanning several months.

i. Work Conditioning. These programs are usually initiated once reconditioning has been completed but may be offered at any time throughout the recovery phase. It should be initiated when imminent return of a patient to modified or full duty is not an option, but the prognosis for returning the patient to work at completion of the program is at least fair to good.

(a). Length of Visit—one to two hours per day.

(b). Frequency—two to five visits per week.

(c). Optimum Duration—two to four weeks.

(d). Maximum Duration—six weeks. Participation in a program beyond six weeks must be documented with respect to need and the ability to facilitate positive symptomatic or functional gains.

ii. Work Simulation. Work Simulation is a program where an individual completes specific work-related tasks for a particular job and return-to-work. Use of this program is appropriate when modified duty can only be partially accommodated in the work place, when modified duty in the work place is unavailable, or when the patient requires more structured supervision. The need for work place simulation should be based upon the results of a functional capacity evaluation and/or jobsite analysis.

(a). Length of Visit—two to six hours per day.

(b). Frequency—two to five visits per week.

(c). Optimum Duration—two to four weeks.

(d). Maximum Duration—six weeks. Participation in a program beyond six weeks must be documented with respect to need and the ability to facilitate positive symptomatic or functional gains.

b. Interdisciplinary programs are well-established treatment for patients with sub-acute and functionally impairing cervical spine pain. They are characterized by a variety of disciplines that participate in the assessment, planning, and/or implementation of an injured workers program with the goal for patients to gain full or optimal function and return to work. There should be close interaction and integration among the disciplines to ensure that all members of the team interact to achieve team goals. Programs should include cognitive-behavioral therapy as there is good evidence for its effectiveness in patients with chronic low back pain and it is probably effective in cervical spine pain. These programs are for patients with greater levels of disability, dysfunction, deconditioning and psychological involvement. For patients with chronic pain, refer to the *Chronic Pain Disorder Medical Treatment Guidelines*.

i. Work Hardening. Work hardening is an interdisciplinary program addressing a patient's employability and return to work. It includes a progressive increase in the number of hours per day that a patient completes work simulation tasks until the patient can tolerate a full workday. This is accomplished by addressing the medical, psychological, behavioral, physical, functional, and vocational components of employability and return-to-work.

(a). This can include a highly structured program involving a team approach or can involve any of the components thereof. The interdisciplinary team should, at a minimum, be comprised of a qualified medical director who is board certified with documented training in occupational rehabilitation; team physicians having experience in occupational rehabilitation; occupational therapy; physical therapy; case manager; and psychologist. As appropriate, the team may also include: chiropractor, RN, vocational specialist or certified biofeedback therapist.

(i). Length of Visit—up to eight hours/day.

(ii). Frequency—two to five visits per week.

(iii). Optimal Duration—two to four weeks.

(iv). Maximum Duration—six weeks. Participation in a program beyond six weeks must be documented with respect to need and the ability to facilitate positive symptomatic or functional gains.

6. Patient Education. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of prolonging the beneficial effects of treatment, as well as facilitating self-management of symptoms and injury prevention. The patient should be encouraged to take an active role in the establishment of functional outcome goals. They should be educated on their specific injury, assessment findings, and plan of treatment. Instruction on breathing technique, proper body mechanics and posture, positions to avoid, self-care for exacerbation of symptoms, sleep postures, and home exercise should also be addressed. Patients with TOS may find that sleeping on the affected side, with the arms overhead or prone with head to one side can increase symptoms and should be avoided. Cervical roll pillows that do not result in overextension may be useful.

a. Time to Produce Effect—varies with individual patient.

b. Frequency—should occur at each visit.

7. Personality/Psychosocial/Psychiatric/Psychological Intervention. Psychosocial treatment is generally accepted, widely used, and well-established intervention. This group of therapeutic and diagnostic modalities includes, but is not limited to, individual counseling, group therapy, stress management, psychosocial crises intervention, hypnosis and meditation. Any evaluation or diagnostic workup should clarify and distinguish between pre-existing versus aggravated versus purely causative psychological conditions. Psychosocial intervention is recommended as an important component in the total management program that should be implemented as soon as the problem is identified. This can be used alone or in conjunction with other treatment modalities. Providers treating patients with chronic pain should refer to the OWCA's *Chronic Pain Disorder Medical Treatment Guidelines*.

a. Time to Produce Effect—two to four weeks.

b. Frequency—one to three times weekly for the first four weeks (excluding hospitalization, if required), decreasing to one to two times per week for the second month. Thereafter, two to four times monthly.

c. Optimum Duration—six weeks to three months.

d. Maximum Duration—3 to 12 months. Counseling is not intended to delay but to enhance functional recovery. For select patients, longer supervised treatment may be required and if further counseling beyond 3 months is indicated, extensive documentation addressing

which pertinent issues are pre-existing versus aggravated versus causative, as well as projecting a realistic functional prognosis, should be provided by the authorized treating provider every 4 to 6 weeks during treatment.

8. Return-to-Work. Early return-to-work should be a prime goal in treating occupational injuries given the poor return-to-work prognosis for an injured worker who has been out of work for more than six months. It is imperative that the patient be educated regarding the benefits of return-to-work, work restrictions, and follow-up care if problems arise. When attempting to return a patient to work after a specific injury, clear objective restrictions of activity level should be made. An accurate job description with detailed physical duty restrictions may be necessary to assist the physician in making return-to-work recommendations. This may require a jobsite evaluation.

a. Employers should be prepared to offer transitional work. This may consist of temporary work in a less demanding position, return to the regular job with restrictions, or gradual return to the regular job. Company policies which encourage return-to-work with positive communication are most likely to have decreased worker disability.

b. *Return-to-Work*—any work or duty that the patient is able to perform safely. It may not be the patient's regular work. Due to the large spectrum of injuries of varying severity and varying physical demands in the work place, it is not possible to make specific return-to-work guidelines for each injury. Therefore, the OWCA recommends the following:

i. Establishment of a Return-to-Work Status. Ascertaining a return-to-work status is part of medical care, should be included in the treatment and rehabilitation plan, and addressed at every visit. A description of daily activity limitations is part of any treatment plan and should be the basis for restriction of work activities. In most non-surgical cases, the patient should be able to return-to-work in some capacity or in an alternate position consistent with medical treatment within several days unless there are extenuating circumstances. Injuries requiring more than two weeks off work should be thoroughly documented.

ii. Establishment of Activity Level Restrictions. Communication is essential between the patient, employer and provider to determine appropriate restrictions and return-to-work dates. It is the responsibility of the physician to provide clear concise restrictions, and it the employer's responsibility to determine if temporary duties can be provided within the restrictions. For treatment of TOS injuries, the following should be addressed when describing the patient's activity level:

(a). activities such as overhead motion, lifting, abduction;

(b). static neck and shoulder positions with regard to duration and frequency;

(c). restriction of cervical hyperextension;

(d). use of adaptive devices or equipment for proper ergonomics and to enhance capacities;

(e). maximum Lifting limits with reference to the frequency of the lifting and/or the object height level;

(f). maximum limits for pushing, pulling, with limits on bending and twisting at the waist as necessary; and

(g). testrictions on 'shoulder drooped' or 'head forward' positions.

iii. Compliance with Activity Restrictions. In some cases, compliance with restriction of activity levels may require a complete jobsite evaluation, a functional capacity evaluation (FCE), or other special testing. Refer to the special tests section of this guideline.

9. Therapy-active. The following active therapies are widely used and accepted methods of care for a variety of work-related injuries. They are based on the philosophy that therapeutic exercise and/or activity are beneficial for restoring flexibility, strength, endurance, function, range of motion, and can alleviate discomfort. Active therapy requires physical effort by the individual to complete a specific exercise or task. This form of therapy requires supervision from a therapist or medical provider such as verbal, visual, and/or tactile instruction(s). At times, the provider may help stabilize the patient or guide the movement pattern but the energy required to complete the task is predominately executed by the patient.

a. Patients should be instructed to continue active therapies at home as an extension of the treatment process in order to maintain improvement levels. Follow-up visits to reinforce and monitor progress and proper technique are recommended. Home exercise can include exercise with or without mechanical assistance or resistance and functional activities with assistive devices.

b. The use of a patient completed pain drawing, Visual Analog Scale (VAS), is highly recommended to help providers track progress. Functional objective goals should be monitored and documented regularly to determine the effectiveness of treatment.

c. The following active therapies are listed in alphabetical order.

i. Activities of daily living (ADL) are well-established interventions which involve instruction, active-assisted training, and/or adaptation of activities or equipment to improve a person's capacity in normal daily activities such as self-care, work re-integration training, homemaking, and driving.

(a). Time to Produce Effect—four to five treatments.

(b). Frequency—three to five times per week.

(c). Optimum Duration—four to six weeks.

(d). Maximum Duration—six weeks.

ii. Aquatic therapy is a well-accepted treatment which consists of the therapeutic use of aquatic immersion for therapeutic exercise to promote range-of-motion, core stabilization, endurance, flexibility, strengthening, body mechanics, and pain management. Aquatic therapy includes the implementation of active therapeutic procedures in a swimming or therapeutic pool. The water provides a buoyancy force that lessens the amount of force gravity applies to the body. The decreased gravity effect allows the patient to have a mechanical advantage and more likely have a successful trial of therapeutic exercise. Literature has shown that the muscle recruitment for aquatic therapy versus similar non–aquatic motions is significantly less. Because there is always a risk of recurrent or additional damage to the muscle tendon unit after a surgical repair, aquatic therapy may be preferred by surgeons to gain early return of range of motion. In some cases the patient will be able to do the

exercises unsupervised after the initial supervised session. Parks and recreation contacts may be used to develop less expensive facilities for patients. Indications include:

(a). postoperative therapy as ordered by the surgeon; or Intolerance for active land-based or full-weight bearing therapeutic procedures; or

(b). symptoms that are exacerbated in a dry environment; and

(c). willingness to follow through with the therapy on a regular basis.

(i). The pool should be large enough to allow full extremity range of motion and fully erect posture. Aquatic vests, belts, snorkels, and other devices may be used to provide stability, balance, buoyancy, and resistance.

[a]. Time to Produce Effect—four to five treatments.

[b]. Frequency—three to five times per week.

[c]. Optimum Duration: Four to six weeks.

[d]. Maximum Duration: eight weeks

(ii). A self-directed program is recommended after the supervised aquatics program has been established, or, alternatively a transition to a self-directed dry environment exercise program.

(iii). Functional activities are well-established interventions which involve the use of therapeutic activity to enhance mobility, body mechanics, employability, coordination, balance, and sensory motor integration.

[a]. Time to Produce Effect—four to five treatments.

[b]. Frequency—three to five times per week.

[c]. Optimum Duration—four to six weeks.

[d]. Maximum Duration—six weeks.

(iv). Nerve Gliding is an accepted therapy for TOS. Nerve Gliding exercises consist of a series of gentle movements of the neck, shoulder and arm that produce longitudinal movement along the length of the nerves of the upper extremity. These exercises are based on the principle that the tissues of the peripheral nervous system are designed for movement, and glide (excursion) of nerves may have an effect on neurophysiology through alterations in vascular and axoplasmic flow. Biomechanical principles have been more thoroughly studied than clinical outcomes. The exercises should be done by the patient after proper instruction and monitoring by the therapist.

[a]. Time to Produce Effect—two to four weeks.

[b]. Frequency—up to five times per day by patient (patient-initiated).

[c]. Optimum Duration—four to six sessions.

[d]. Maximum Duration—six to eight sessions.

(v). Neuromuscular re-education is a generally accepted treatment. Neuromuscular re-education is the skilled application of exercise with manual, mechanical, or electrical facilitation to enhance strength; movement patterns; neuromuscular response; proprioception, kinesthetic sense, coordination; education of movement, balance and posture. Indications include the need to promote neuromuscular responses through carefully timed proprioceptive stimuli to elicit and improve motor activity in patterns similar to normal neurologically developed sequences, and improve neuromotor response with independent

[a]. Time to Produce Effect—two to six treatments.

[b]. Frequency—three times per week.

[c]. Optimum Duration—four to eight weeks.

[d]. Maximum Duration—eight weeks.

(vi). Therapeutic exercise is a generally well-accepted treatment. Therapeutic exercise with or without mechanical assistance or resistance, may include isoinertial, isotonic, isometric and isokinetic types of exercises. The exact type of program and length of therapy should be determined by the treating physician with the physical or occupational therapist. In most cases the therapist instructs the patient in a supervised clinic and home program to increase motion and subsequently increase strength. Usually, isometrics are performed initially, progressing to isotonic exercises as tolerated.

[a]. time to produce effect: two to six treatments;

[b]. frequency: two to three times per week;

[c]. optimum duration: 16 to 24 sessions;

[d]. maximum duration: 36 sessions. Additional visits may be necessary in cases of re-injury, interrupted continuity of care, exacerbation of symptoms, and in those patients with comorbidities. Functional gains including increased range of motion must be demonstrated to justify continuing treatment.

10. Therapy—Passive. The following passive therapies and modalities are generally accepted methods of care for a variety of work-related injuries. Passive therapy includes those treatment modalities that do not require energy expenditure on the part of the patient. They are principally effective during the early phases of treatment and are directed at controlling symptoms such as pain, inflammation and swelling and to improve the rate of healing soft tissue injuries. They should be use adjunctively with active therapies such as postural stabilization and exercise programs to help control swelling, pain and inflammation during the rehabilitation process. Please refer to, General Guidelines Principles, Active Interventions. Passive therapies may be used intermittently as a therapist deems appropriate or regularly if there are specific goals with objectively measured functional improvements during treatment.

a. On occasion, specific diagnoses and post-surgical conditions may warrant durations of treatment beyond those listed as "maximum." Factors such as exacerbation of symptoms, re-injury, interrupted continuity of care, and comorbidities may also extend durations of care. Specific goals with objectively measured functional improvement during treatment must be cited to justify extended durations

of care. It is recommended that, if no functional gain is observed after the number of treatments under "time to produce effect" has been completed, alternative treatment interventions, further diagnostic studies, or further consultations should be pursued.

b. The following passive therapies and modalities are listed in alphabetical order.

i. Electrical stimulation (unattended) is an accepted treatment. Once applied, electrical stimulation (unattended) requires minimal on-site supervision by the physical therapists, occupational therapist or other provider. Indications include pain, inflammation, muscle spasm, atrophy, decreased circulation, and the need for osteogenic stimulation. A home unit should be purchased if treatment is effective and frequent use is recommended.

(a). Time to Produce Effect—two to four treatments.

(b). Frequency—varies, depending upon indication, between two to three times/day to one time/week;

(c). Optimum Duration—one to three months;

(d). Maximum Duration—three months.

ii. Iontophoresis is an accepted treatment which consists of the transfer of medication, including, but not limited to, steroidal anti-inflammatories and anesthetics, through the use of electrical stimulation. Indications include pain (lidocaine), inflammation (hydrocortisone, salicylate), edema (mecholyl, hyaluronidase, and salicylate), ischemia (magnesium, mecholyl, and iodine), muscle spasm (magnesium, calcium), calcifying deposits (acetate), scars, and keloids (sodium chloride, iodine, acetate).

(a). Time to Produce Effect—one to four treatments.

(b). Frequency—three times per week with at least 48 hours between treatments.

(c). Optimum Duration—8 to 10 treatments.

(d). Maximum Duration—10 treatments.

iii. Manipulation is a generally accepted treatment. Manipulative treatment (not therapy) is defined as the therapeutic application of manually guided forces by an operator to improve physiologic function and/or support homeostasis that has been altered by the injury or occupational disease, and has associated clinical significance.

(a). High velocity, low amplitude (HVLA) technique, chiropractic manipulation, osteopathic manipulation, muscle energy techniques, counter strain, and non-force techniques are all types of manipulative treatment. This may be applied by osteopathic physicians (D.O.), chiropractors (D.C.), properly trained physical therapists (P.T.), properly trained occupational therapists (O.T.), or properly trained medical physicians. Under these different types of manipulation exist many subsets of different techniques that can be described as direct- a forceful engagement of a restrictive/pathologic barrier; indirect- a gentle/non-forceful disengagement of a restrictive/pathologic barrier; the patient actively assisting in the treatment; and the patient relaxing, allowing the practitioner to move the body tissues. When the proper diagnosis is made and coupled with the appropriate technique, manipulation has no contraindications and can be applied to all tissues of the body. Pre-treatment assessment should be performed as part of each manipulative treatment visit to ensure that the correct diagnosis and correct treatment is employed.

(i). Time to Produce Effect for all Types of Manipulative Treatment—one to six treatments.

(ii). Frequency—up to three times per week for the first three weeks as indicated by the severity of involvement and the desired effect.

(iii). Optimum Duration—10 treatments.

(iv). Maximum Duration—12 treatments. Additional visits may be necessary in cases of re-injury, interrupted continuity of care, exacerbation of symptoms, and in those patients with comorbidities. Functional gains including increased range of motion must be demonstrated to justify continuing treatment.

iv. Massage, manual or mechanical, is a generally well-accepted treatment. Massage is manipulation of soft tissue with broad ranging relaxation and circulatory benefits. This may include stimulation of acupuncture points and acupuncture channels (acupressure), application of suction cups and techniques that include pressing, lifting, rubbing, pinching of soft tissues by, or with the practitioner's hands. Indications include edema (peripheral or hard and non-pliable edema), muscle spasm, adhesions, the need to improve peripheral circulation and range of motion, or to increase muscle relaxation and flexibility prior to exercise. In cases with edema, deep vein thrombosis should be ruled out prior to treatment.

(a). Time to Produce Effect—immediate.

(b). Frequency—one to two times per week.

(c). Optimum Duration—six weeks.

(d). Maximum Duration—two months.

v. Mobilization (joint) is a generally well-accepted treatment. Mobilization is passive movement, which may include passive range of motion performed in such a manner (particularly in relation to the speed of the movement) that it is, at all times, within the ability of the patient to prevent the movement if they so choose. It may include skilled manual joint tissue stretching. Indications include the need to improve joint play, improve intracapsular arthrokinematics, or reduce pain associated with tissue impingement.

(a). Time to Produce Effect—six to nine treatments.

(b). Frequency—three times per week.

(c). Optimum Duration—six weeks.

(d). Maximum Duration—two months.

vi. Mobilization (soft tissue) is a generally well-accepted treatment. Mobilization of soft tissue is the skilled application of muscle energy, strain/counter strain, myofascial release, manual trigger point release and manual therapy techniques designed to improve or normalize movement patterns through the reduction of soft tissue pain and restrictions. These can be interactive with the patient participating or can be with the patient relaxing and letting the practitioner move the body tissues. Indications include muscle spasm around a joint, trigger points, adhesions, and neural compression. Mobilization should be accompanied by active therapy.

(a). Time to Produce Effect—two to three weeks.

(b). Frequency—two to three times per week.

(c). Optimum Duration—four to six weeks.

(d). Maximum Duration—six weeks.

vii. Superficial heat and cold therapy is a generally accepted treatment. Superficial heat and cold therapies are thermal agents applied in various manners that lower or raise the body tissue temperature for the reduction of pain, inflammation, and/or effusion resulting from injury or induced by exercise. It may be used acutely with compression and elevation. Indications include acute pain, edema and hemorrhage, need to increase pain threshold, reduce muscle spasm and promote stretching/flexibility. Includes portable cryotherapy units and application of heat just above the surface of the skin at acupuncture points.

(a). Time to Produce Effect—immediate.

(b). Frequency—two to five times per week.

(c). Optimum Duration—three weeks as primary, or up to two months if used intermittently as an adjunct to other therapeutic procedures.

(d). Maximum Duration—two months.

viii. Transcutaneous electrical nerve stimulation (TENS) is a generally accepted treatment and should include at least one instructional session for proper application and use. Indications include muscle spasm, atrophy, and decreased circulation and pain control. Minimal TENS unit parameters should include pulse rate, pulse width and amplitude modulation. Consistent, measurable functional improvement must be documented prior to the purchase of a home unit.

(a). Time to Produce Effect—immediate.

(b). Frequency—variable.

(c). Optimum Duration—three sessions.

(d). Maximum Duration—three sessions. If beneficial, provide with home unit or purchase if effective.

ix. Ultrasound (including phonophoresis) is an accepted treatment and includes ultrasound with electrical stimulation and phonophoresis. Ultrasound uses sonic generators to deliver acoustic energy for therapeutic thermal and/or non-thermal soft tissue effects. Indications include scar tissue, adhesions, collagen fiber and muscle spasm, and the need to extend muscle tissue or accelerate the soft tissue healing.

(a). Ultrasound with electrical stimulation is concurrent delivery of electrical energy that involves a dispersive electrode placement. Indications include muscle spasm, scar tissue, pain modulation, and muscle facilitation.

(b). Phonophoresis is the transfer of medication to the target tissue to control inflammation and pain through the use of sonic generators. These topical medications include, but are not limited to, steroidal anti-inflammatory and anesthetics.

(i). Time to Produce Effect—6 to 15 treatments.

(ii). Frequency—3 times per week.

(iii). Optimum Duration—4 to 8 weeks.

(iv). Maximum Duration—2 months.

11. Vocational rehabilitation is a generally accepted intervention. Initiation of vocational rehabilitation requires adequate evaluation of patients for quantification highest functional level, motivation and achievement of maximum medical improvement. Vocational rehabilitation may be as simple as returning to the original job or as complicated as being retrained for a new occupation.

a. It may also be beneficial for full vocational rehabilitation to be started before MMI if it is evident that the injured worker will be unable to return to his/her previous occupation. A positive goal and direction may aid the patient in decreasing stress and depression, and promote optimum rehabilitation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1755 (June 2011).

§2227. Therapeutic Procedures—Operative

A. Operative treatment is indicated when the natural history of surgically treated lesions is better than the natural history for non-operatively treated lesions. All patients being considered for surgical intervention should first undergo a comprehensive neuro-musculoskeletal examination to identify mechanical pain generators that may respond to non-surgical techniques or may be refractory to surgical intervention.

1. Non-vascular Diagnostic Criteria for Surgical Procedures

a. True or Classic Neurogenic TOS

i. Clinical—at least two consistent clinical sign plus symptoms consistent with TOS (refer to initial diagnostic procedures).

ii. Neurophysiologic—meets criteria for neurogenic TOS (refer to follow-up diagnostic imaging and testing procedures).

b. Non-specific Neurogenic TOS (also called disputed)

i. Clinical—at least three consistent clinical signs plus symptoms consistent with TOS refer to discussion in Initial Diagnostic Procedures and alternative diagnoses have been explored and tests are negative.

ii. Neurophysiologic—may have normal EMG/NCV or a pattern not meeting criteria in EMG section.

c. Pectoralis Minor Syndrome without TOS

i. Compression of the Neurovascular Bundle by the Pectoralis Muscle. This syndrome, described by a few authors, is usually caused by neck or shoulder trauma and generally resolves with physical therapy.

ii. Clinical. Patients do not meet criteria for non-specific or true TOS. They generally have pain over the anterior chest wall near the pectoralis minor and into the axilla, arm, and forearm. They may complain of paresthesia or weakness, and have fewer complaints of headache, neck or shoulder pain. On physical exam there is tenderness with palpation over the pectoralis minor and in the axilla which reproduces the patient's symptoms in the arm. Disabling symptoms have been present for more than three months despite active participation in an appropriate therapy program and alternative diagnoses have been explored and tests are negative.

iii. Neurophysiologic and other Diagnostic Tests. EMG/NCV studies may show medial antebrachial cutaneous nerve changes compared to the normal side. The axillary vein may show some occlusion. Pectoralis minor block should be positive.

d. Non-surgical Diagnosis for Possible TOS

i. Clinical—inconsistent clinical signs plus symptoms of TOS for more than three months and alternative diagnoses have been explored and tests are negative.

ii. Neurophysiologic—may have normal EMG/NCV studies.

2. Surgical Indications

a. Early surgical intervention should be performed if there is:

i. documented EMG/NCV evidence of nerve compression with sensory loss, and weakness (with or without muscle atrophy); or

ii. acute subclavian vein thrombosis or arterial thrombosis; or

iii. subclavian artery aneurysm or stenosis secondary to a cervical or anomalous rib (Note: this condition is almost never work related.).

b. After failed conservative therapy, the following criteria must be fulfilled:

i. true neurogenic or non-specific TOS: see criteria in the preceding subsection; and

ii. a positive upper limb tension test; and

iii. failed three months of active participation in non-operative therapy including worksite changes; and

iv. disabling symptoms interfering with work, recreation, normal daily activities, sleep; and

v. pre-surgical psychiatric or psychological clearance has been obtained, demonstrating motivation and long-term commitment without major issues of secondary gain or other psychological contraindications for surgery, and with an expectation that surgical relief of pain probably would improve the patient's functioning.

c. Even if return to their prior job is unlikely, an individual may need surgical intervention to both increase activities-of-daily living and/or return-to-work in a different job.

d. It is critically important that all other pathology, especially shoulder disorders, be treated prior to surgical intervention for TOS.

e. Smoking may affect soft tissue healing through tissue hypoxia. Patients should be strongly encouraged to stop smoking and provided with appropriate counseling.

f. Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities. The patient should agree to comply with the pre- and post-operative treatment plan including home exercise requirements. The patient should understand the amount of post operative therapy required and the length of partial and full disability expected post operatively.

3. Surgical Procedures

a. Since the success rates for the various surgical procedures are similar, the OWCA suggests that the surgeon performing the procedure use the technique with which the surgeon has the most experience and is most appropriate for the patient.

b. No controlled quality literature on surgical outcome for non-specific neurogenic TOS have been published. Uncontrolled case series suggest some improvement in symptoms in the majority of patients. In one study of workers' compensation patients operated on for TOS, work disability was reported to be 60 percent at one year. Other pathologies were commonly diagnosed in this population. Comorbid conditions of the shoulder, cervical spine, and carpal tunnel should be treated or ruled out before surgery is considered. Reported repeat surgery rates vary between approximately 10 percent and 30 percent. Some literature contends that patients with non-specific TOS treated conservatively have similar long-term outcomes as those treated with surgery. Complications and/or unsatisfactory outcomes are reportedly in the range of 15 to 20 percent. Acknowledged complications depend on the procedure and include complex regional pain syndrome; Horner's syndrome; permanent brachial plexus damage; phrenic, intercostal brachial cutaneous, or long thoracic nerve damage; and pneumothorax.

c. Vascular TOS procedures include resection of the abnormal rib and repair of the involved vessel. Anticoagulation is required for thrombotic cases.

i. first rib resection;

ii. anterior and middle scalenectomy;

iii. anterior scalenectomy;

iv. combined first rib resection and scalenectomy;

v. pectoralis minor tenotomy. This procedure is done under local anesthesia, normally in an out-patient setting for patients meeting the criteria for pectoralis minor syndrome.

4. Post-Operative Treatment

a. Individualized rehabilitation programs based upon communication between the surgeon and the therapist.

b. Generally, progressive resistive exercise no earlier than two months post-operatively with gradual return to full-activity at four to six months.

c. Return-to-work and restrictions after surgery may be made by an experienced primary occupational medicine physician in consultation with the surgeon or by the surgeon. Depending upon the patient's functional response and their job requirements, return-to-work with job modifications may be considered as early as one week post operatively. The employer must be able to fully accommodate restrictions of overhead activities or heavy lifting. Work restrictions should be evaluated every four to six weeks during post-operative recovery and rehabilitation, with appropriate written communications to both the patient and the employer.

d. Should progress plateau, the provider should re-evaluate the patient's condition and make appropriate adjustments to the treatment plan.

e. Post-operative therapy will frequently require a repeat of the therapy provided pre-operatively. Refer to Therapeutic Procedures, Non-operative, and consider the first post-operative visit as visit number one for the time frame parameters provided.

f. Refer to the following areas in the non-operative therapeutic section for post-operative time parameters:

i. activities of daily living;

ii. functional activities;

iii. nerve gliding;

iv. neuromuscular re-education;

v. therapeutic exercise;

vi. proper work techniques. Refer to jobsite evaluation, and return-to-work, of these guidelines;

vii. limited passive therapies may be appropriate in some cases.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1763 (June 2011).

§2228. LWC-WC 1009 Disputed Claim for Medical Treatment.

Mail to:
OWCA—Medical Services
ATTN: Medical Director
P.O. Box 94040
Baton Rouge, LA 70804

1. Social Security No.__-__-__
2. Date of Injury/Illness __-__-__
3. Parts of Body Injury_____
4. Date of Birth __-__-__
5. Date of This Request __-__-__
6. Claim Number _____

DISPUTED CLAIM FOR MEDICAL TREATMENT

NOTE: THIS REQUEST WILL NOT BE HONORED UNLESS THE INSURER HAS ISSUED A DENIAL FOR THE MEDICAL SERVICES IN DISPUTE AS PER R.S. 23:1203.1 J.

GENERAL INFORMATION
Claimant files this dispute with the Office of Workers' Compensation – Medical Services Director. This office must be notified immediately in writing of changes in address. An employee may be represented by an attorney, but it is not required.

7. This request is submitted by
___ Employee ___ Employer __ Insurer ___ Health Care Provider ___ Other ___

A. Copies of all relevant medical records must be included with this request.

B. A copy of the denial letter issued by the insurance carrier must be attached to this request.

EMPLOYEE
8. Name _____
Street or Box _____
City _____
State _____ Zip _____
Phone (____) _____

EMPLOYEE'S ATTORNEY
9. Name _____
Street or Box _____
City _____
State _____
Phone (____) _____
Fax (____) _____

EMPLOYER
10. Name _____
Street or Box _____
City _____
State _____ Zip _____
Phone (____) _____
Fax (____) _____

INSURER/ADMINISTRATOR
(circle one)
11. Name _____
Street or Box _____
City _____
State _____
Phone (____) _____
Fax (____) _____

EMPLOYER/INSURER'S ATTORNEY
12. Name _____
Street or Box _____
City _____
State _____ Zip _____
Phone (____) _____
Fax (____) _____

TREATING/REQUESTING PHYSICIAN
13. Name _____
Street or Box _____
City _____
State _____
Phone (____) _____
Fax (____) _____

LWC-WC 1009
11/2010

14. PLEASE PROVIDE A SUMMARY OF THE DETAILS REGARDING THE ISSUE AT DISPUTE:
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

You may attach a letter or petition with additional information with this disputed claim.
The information given above is true and correct to the best of my knowledge and belief.

_____ _____
SIGNATURE OF REQUESTING PARTY DATE

LWC-WC 1009
11/2010

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1765 (June 2011).

Chapter 23. Upper and Lower Extremities Medical Treatment Guidelines

Subchapter A. Lower Extremities

§2301. Introduction

A. This document has been prepared by the Louisiana Workforce Commission, Office of Workers' Compensation and should be interpreted within the context of guidelines for physicians/providers treating individuals qualifying under Louisiana's Workers' Compensation Act as injured workers with lower extremity injuries. These guidelines are enforceable under the Louisiana Workers Compensation Act. All medical care, services, and treatment owed by the employer to the employee in accordance with the Louisiana Workers' Compensation Act shall mean care, services, and treatment in accordance with these guidelines. Medical Care, services, and treatment hat varies from these guidelines shall also be due by the employer when it is demonstrated to the medical director of the office by a preponderance of the scientific medical evidence, that a variance from these guidelines is reasonably required to cure or relieve the injured worker from the effects of the injury or occupational disease given the circumstances. Therefore, these guidelines are not relevant as evidence of a provider's legal standard of professional care. To properly utilize this document, the reader should not skip nor overlook any sections.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1765 (June 2011).

§2303. General Guidelines Principles

A. The principles summarized in this section are key to the intended implementation of all Office of Workers' Compensation guidelines and critical to the reader's application of the guidelines in this document.

1. Application of Guidelines. The OWCA provides procedures to implement medical treatment guidelines and to foster communication to resolve disputes among the provider, payer, and patient through the Office of Workers Compensation.

2. Education. Education of the patient and family, as well as the employer, insurer, policy makers and the community should be the primary emphasis in the treatment of lower extremity pain. Currently, practitioners often think of education last, after medications, manual therapy, and surgery. Practitioners must develop and implement an effective strategy and skills to educate patients, employers,

insurance systems, policy makers, and the community as a whole. An education-based paradigm should always start with inexpensive communication providing reassuring information to the patient. More in-depth education currently exists within a treatment regime employing functional restorative and innovative programs of prevention and rehabilitation. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of facilitating self-management of symptoms and prevention.

3. Treatment Parameter Duration. Time frames for specific interventions commence once treatments have been initiated, not on the date of injury. Obviously, duration will be impacted by patient compliance, as well as availability of services. Clinical judgment may substantiate the need to accelerate or decelerate the time frames discussed in this document. Such deviation shall be in accordance with La. R.S. 23:1203.1

4. Active Interventions. Emphasizing patient responsibility, such as therapeutic exercise and/or functional treatment, are generally emphasized over passive modalities, especially as treatment progresses. Generally, passive interventions are viewed as a means to facilitate progress in an active rehabilitation program with concomitant attainment of objective functional gains.

5. Active Therapeutic Exercise Program. Exercise program goals should incorporate patient strength, endurance, flexibility, coordination, and education. This includes functional application in vocational or community settings.

6. Positive Patient Response. Positive results are defined primarily as functional gains that can be objectively measured. Standard measurement tools, including outcome measures, should be used.

a. Objective functional gains include, but are not limited to, positional tolerances, range-of-motion (ROM), strength, and endurance, activities of daily living, cognition, psychological behavior, and efficiency/velocity measures that can be quantified. Subjective reports of pain and function should be considered and given relative weight when the pain has anatomic and physiologic correlation. Anatomic correlation must be based on objective findings.

7. Re-evaluation treatment every three to four weeks. If a given treatment or modality is not producing positive results within three to four weeks, the treatment should be either modified or discontinued. Reconsideration of diagnosis should also occur in the event of poor response to a seemingly rational intervention.

8. Surgical Interventions. Surgery should be contemplated within the context of expected functional outcome and not purely for the purpose of pain relief. The concept of "cure" with respect to surgical treatment by itself is generally a misnomer. All operative interventions must be based upon positive correlation of clinical findings, clinical course, and diagnostic tests. A comprehensive assimilation of these factors must lead to a specific diagnosis with positive identification of pathologic conditions.

9. Six-Month Time Frame. The prognosis drops precipitously for returning an injured worker to work once he/she has been temporarily totally disabled for more than six months. The emphasis within these guidelines is to move patients along a continuum of care and return-to-work within a six-month time frame, whenever possible. It is important to note that time frames may not be pertinent to injuries that do not involve work-time loss or are not occupationally related.

10. Return-to-Work. Return to Work is therapeutic, assuming the work is not likely to aggravate the basic problem or increase long-term pain. The practitioner must provide specific written physical limitations and the patient should never be released to "sedentary" or "light duty." The following physical limitations should be considered and modified as recommended: lifting, pushing, pulling, crouching, walking, using stairs, bending at the waist, awkward and/or sustained postures, tolerance for sitting or standing, hot and cold environments, data entry and other repetitive motion tasks, sustained grip, tool usage and vibration factors. Even if there is residual chronic pain, return-to-work is not necessarily contraindicated. The practitioner should understand all of the physical demands of the patient's job position before returning the patient to full duty and should request clarification of the patient's job duties. Clarification should be obtained from the employer or, if necessary, including, but not limited to, an occupational health nurse, occupational therapist, vocational rehabilitation specialist, or an industrial hygienist.

11. Delayed Recovery. Strongly consider a psychological evaluation, if not previously provided, as well as initiating interdisciplinary rehabilitation treatment and vocational goal setting, for those patients who are failing to make expected progress 6 to 12 weeks after an injury. The OWCA recognizes that 3 to 10 percent of all industrially injured patients will not recover within the timelines outlined in this document despite optimal care. Such individuals may require treatments beyond the limits discussed within this document, but such treatment will require clear documentation by the authorized treating practitioner focusing on objective functional gains afforded by further treatment and impact upon prognosis.

12. Guideline Recommendations and Inclusion of Medical Evidence. Guidelines are recommendations based on available evidence and/or consensus recommendations. When possible, guideline recommendations will note the level of evidence supporting the treatment recommendation. When interpreting medical evidence statements in the guideline, the following apply:

a. "Consensus" means the opinion of experienced professionals based on general medical principles. Consensus recommendations are designated in the guideline as "generally well accepted," "generally accepted," "acceptable/accepted," or "well-established."

b. "Some" means the recommendation considered at least one adequate scientific study, which reported that a treatment was effective.

c. "Good" means the recommendation considered the availability of multiple adequate scientific studies or at least one relevant high-quality scientific study, which reported that a treatment was effective.

d. "Strong" means the recommendation considered the availability of multiple relevant and high quality scientific studies, which arrived at similar conclusions about the effectiveness of a treatment.

B. All recommendations in the guideline are considered to represent reasonable care in appropriately selected cases, regardless of the level of evidence or consensus statement

attached to it. Those procedures considered inappropriate, unreasonable, or unnecessary are designated in the guideline as "not recommended."

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1765 (June 2011).

§2305. Initial diagnostic procedures

A. The OWCA recommends the following diagnostic procedures be considered, at least initially, the responsibility of the workers' compensation carrier to ensure that an accurate diagnosis and treatment plan can be established. Standard procedures that should be utilized when initially diagnosing a work-related lower extremity complaint are listed below.

1. History-taking and physical examination (Hx & PE) are generally accepted, well-established and widely used procedures that establish the foundation/basis for and dictates subsequent stages of diagnostic and therapeutic procedures. When findings of clinical evaluations and those of other diagnostic procedures are not complementing each other, the objective clinical findings should have preference. The medical records should reasonably document the following:

a. History of Present Injury

i. Mechanism of injury. This includes details of symptom onset and progression. It should include such details as: the activity at the time of the injury, patient description of the incident, and immediate and delayed symptoms. The history should elicit as much detail about these mechanisms as possible.

ii. Relationship to work. This includes a statement of the probability that the illness or injury is work-related.

iii. History of locking, clicking, popping, giving way, acute or chronic swelling, crepitation, pain while ascending or descending stairs (e.g. handrail used, 'foot by foot' instead of 'foot over foot') inability to weight bear due to pain, intolerance for standing or difficulty walking distances on varied surfaces, difficulty crouching or stooping, and wear patterns on footwear. Patients may also report instability or mechanical symptoms.

iv. Any history of pain in back as well as joints distal and proximal to the site of injury. The use of a patient completed pain drawing, Visual Analog Scale (VAS), is highly recommended, especially during the first two weeks following injury to assure that all work related symptoms are addressed.

v. Ability to perform job duties and activities of daily living; and

vi. Exacerbating and alleviating factors of the reported symptoms. The physician should explore and report on non-work related as well as, work related activities.

vii. Prior occupational and non-occupational injuries to the same area including specific prior treatment and any prior bracing devices.

viii. Discussion of any symptoms present in the uninjured extremity.

ix. Lower extremity injuries are frequently not isolated, but are accompanied by other injuries. In the setting of a traumatic brain injury (TBI), long bone fracture management must consider the effect of TBI on bone metabolism and may require more aggressive treatment. Refer to the Traumatic Brain Injury Medical Treatment Guidelines, Musculoskeletal Complications.

b. Past History

i. past medical history includes neoplasm, gout, arthritis, previous musculoskeletal injuries, and diabetes;

ii. review of systems includes symptoms of rheumatologic, neurological, endocrine, neoplastic, and other systemic diseases;

iii. History of smoking, alcohol use, and substance abuse;

iv. History of corticosteroid use; and

v. vocational and recreational pursuits.

c. Physical Examination: Examination of a joint should begin with examination of the uninjured limb and include assessment of the joint above and below the affected area of the injured limb. Physical examinations should include accepted tests as described in textbooks or other references and exam techniques applicable to the joint or region of the body being examined, including:

i. Visual inspection; Swelling: may indicate joint effusion from trauma, infection or arthritis. Swelling or bruising over ligaments or bones can indicate possible fractures or ligament damage;

ii. Palpation: for joint line tenderness, effusion, and bone or ligament pain. Palpation may be used to assess tissue tone and contour; myofascial trigger points; and may be graded for intensity of pain. Palpation may be further divided into static and motion palpation. Static palpation consists of feeling bony landmarks and soft tissue structures and consistency. Motion palpation is commonly used to assess joint movement patterns and identify joint dysfunction;

iii. Assessment of activities of daily living including gait abnormalities, especially after ambulating a distance and difficulties ascending/descending stairs; Assessment of activities such as the inability to crouch or stoop, may give important indications of the patient's pathology and restrictions;

iv. range-of-motion/quality-of-motion; should be assessed actively and passively;

v. strength;

vi. joint stability;

vii. Hip exam: In general multiple tests are needed to reliably establish a clinical diagnosis. Spinal pathology and groin problems should always be considered and ruled out as a cause of pain for patients with hip symptomatology. The following is a list of commonly performed tests;

(a). Flexion-Abduction-External Rotation (FABER-aka Patrick's) test - is frequently used as a test for sacral pathology;

(b). Log roll test - may be used to assess iliofemoral joint laxity;

(c). Ober's is used to test the iliotibial band;

(d). Greater trochanter bursitis is aggravated by external rotation and adduction and resisted hip abduction or external rotation;

(e). Iliopectineal bursitis may be aggravated by stretching the tendon in hip extension;

(f). Internal and external rotation is usually painful in osteoarthritis;

(g). The maneuvers of flexion, adduction and internal rotation (FADIR) will generally reproduce pain in cases of labral tears and with piriformis strain/irritation.

viii. Knee exam: In general multiple tests are needed to reliably establish a clinical diagnosis. The expertise of the physician performing the exam influences the predictability of the exam findings. Providers should be aware that patients with osteoarthritis may have positive pain complaints with various maneuvers based on their osteoarthritis rather than ligamentous or meniscal damage. The following is a partial list of commonly performed tests.

(a). Bilateral thigh circumference measurement: assesses for quadriceps wasting which may occur soon after a knee injury. The circumferences of both thighs should be documented approximately 15 cm above a reference point, either the joint line or patella.

(b). Anterior Cruciate Ligament tests:

(i). Lachman's test;

(ii). Anterior drawer test;

(iii). Lateral pivot shift test.

(c). Meniscus tests. Joint line tenderness and effusions are common with acute meniscal tears. Degenerative meniscal tears are fairly common in older patients with degenerative changes and may be asymptomatic.

(i). McMurray test;

(ii). Apley compression test;

(iii). Medial lateral grind test;

(iv). Weight-bearing tests - include Thessaly and Ege's test.

(d). Posterior Cruciate Ligament tests:

(i). Posterior drawer test;

(ii). Extension lag may also be measured passively by documenting the heel height difference with the patient prone.

(e). Collateral Ligaments tests:

(i). Medial stress test – A positive test in full extension may include both medial collateral ligament and cruciate ligament pathology;

(ii). Lateral stress test.

(f). Patellar Instability tests:

(i). Apprehension test;

(ii). J sign;

(iii). Q angle.

ix. Foot and ankle exam: In general multiple tests are needed to reliably establish a clinical diagnosis. The expertise of the physician performing the exam influences the predictability of the exam findings. Ankle assessments may include anterior drawer exam, talar tilt test, external rotation stress test, ankle ligament stress test and the tibia-fibula squeeze test. Achilles tendon may be assessed with the Thompson's test. Foot examinations may include, assessment of or for: subtalar, midtarsal, and metatarsal-phalangeal joints; tarsal tunnel; and posterior tibial tendon; Morton's neuroma; the piano key test and Lisfranc injury.

x. If applicable, full neurological exam including muscle atrophy and gait abnormality.

xi. If applicable to injury, integrity of distal circulation, sensory, and motor function.

2. Radiographic imaging of the lower extremities is a generally accepted, well-established and widely used diagnostic procedure when specific indications based on history and/or physical examination are present. It should not be routinely performed. The mechanism of injury and specific indications for the radiograph should be listed on the request form to aid the radiologist and x-ray technician. For additional specific clinical indications, refer to "Specific Lower Extremity Injury Diagnosis, Testing and Treatment." Indications for initial imaging include any of the following:

a. The inability to flex knee to 90 degrees or to transfer weight for four steps at the time of the immediate injury and at the initial visit, regardless of limping;

b. Bony tenderness on any of the following areas: over the head of the fibula; isolated to the patella; of the lateral or medial malleolus from the tip to the distal 6 cm; at the base of the 5th metatarsal; or at the navicular;

c. History of significant trauma, especially blunt trauma or fall from a height;

d. Age over 55 years;

e. History or exam suggestive of intravenous drug abuse or osteomyelitis;

f. Pain with swelling and/or range of motion (ROM) limitation localizing to an area of prior fracture, internal fixation, or joint prosthesis; or

g. Unexplained or persistent lower extremity pain over two weeks.

i. Occult fractures, especially stress fractures, may not be visible on initial x-ray. A follow-up radiograph, MRI and/or bone scan may be required to make the diagnosis.

ii. Weight-bearing radiographs are used to assess osteoarthritis and alignment prior to some surgical procedures.

3. Laboratory testing. Laboratory tests are generally accepted, well-established and widely used procedures. They are, however, rarely indicated at the time of initial evaluation, unless there is suspicion of systemic illness, infection, neoplasia, connective tissue disorder, or underlying arthritis or rheumatologic disorder based on history and/or physical examination. Laboratory tests can provide useful diagnostic information. The OWCA recommends that lab diagnostic procedures be initially considered the responsibility of the workers' compensation carrier to ensure that an accurate diagnosis and treatment plan can be established. Tests include, but are not limited to:

a. Complete blood count (CBC) with differential can detect infection, blood dyscrasias, and medication side effects;

b. Erythrocyte sedimentation rate, rheumatoid factor, antinuclear antigen (ANA), human leukocyte antigen (HLA), and C-reactive protein (CRP) can be used to detect evidence of a rheumatologic, infection, or connective tissue disorder;

c. Serum calcium, phosphorous, uric acid, alkaline phosphatase, and acid phosphatase can detect metabolic bone disease;

d. Liver and kidney function may be performed for prolonged anti-inflammatory use or other medications requiring monitoring; and

e. Analysis of joint aspiration for bacteria, white cell count, red cell count, fat globules, crystalline birefringence and chemistry to evaluate joint effusion.

4. Other procedures

a. Joint Aspiration is a generally accepted, well-established and widely used procedure when specifically indicated and performed by individuals properly trained in these techniques. This is true at the initial evaluation when history and/or physical examination are of concern for a septic joint or bursitis and for some acute injuries. Particularly at the knee, aspiration of a large effusion can help to decrease pain and speed functional recovery. Persistent or unexplained effusions may be examined for evidence of infection, rheumatologic, or inflammatory processes. The presence of fat globules in the effusion strongly suggests occult fracture.

i. Risk factors for septic arthritis include joint surgery, knee arthritis, joint replacement, skin infection, diabetes, age greater than 80, immunocompromised states, and rheumatoid arthritis. More than 50 percent of patients with septic joints have a fever greater than 37.5 degrees centigrade and joint swelling. Synovial white counts of greater than 25,000 and polymorphonuclear cells of at least 90 percent increase the likelihood of a septic joint.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1767 (June 2011).

§2307. Follow-up diagnostic imaging and testing procedures

A. One diagnostic imaging procedure may provide the same or distinctive information as obtained by other procedures. Therefore, prudent choice of procedure(s) for a single diagnostic procedure, a complementary procedure in combination with other procedures(s), or a proper sequential order in multiple procedures will ensure maximum diagnostic accuracy; minimize adverse effect to patients and cost effectiveness by avoiding duplication or redundancy.

B. All diagnostic imaging procedures have a significant percentage of specificity and sensitivity for various diagnoses. None is specifically characteristic of a certain diagnosis. Clinical information obtained by history taking and physical examination should be the basis for selection and interpretation of imaging procedure results.

C. When a diagnostic procedure, in conjunction with clinical information, provides sufficient information to establish an accurate diagnosis, the second diagnostic procedure will become a redundant procedure. At the same time, a subsequent diagnostic procedure can be a complementary diagnostic procedure if the first or preceding procedures, in conjunction with clinical information, cannot provide an accurate diagnosis. Usually, preference of a procedure over others depends upon availability, a patient's tolerance, and/or the treating practitioner's familiarity with the procedure.

1. Imaging studies. When indicated, the following additional imaging studies can be utilized for further evaluation of the lower extremity, based upon the mechanism of injury, symptoms, and patient history. For specific clinical indications, see Section E, Specific Lower Extremity Injury Diagnosis, Testing, and Treatment. The studies below are listed in frequency of use, not importance.

a. Magnetic Resonance Imaging (MRI) are generally accepted, well-established, and widely used diagnostic procedures. It provides a more definitive visualization of soft tissue structures, including ligaments, tendons, joint capsule, menisci and joint cartilage structures, than x-ray or Computed Axial Tomography in the evaluation of traumatic or degenerative injuries. The addition of intravenous or intra-articular contrast can enhance definition of selected pathologies.

i. The high field, closed MRI with 1.5 or higher tesla provides better resolution. A lower field scan may be indicated when a patient cannot fit into a high field scanner or is too claustrophobic despite sedation. Inadequate resolution on the first scan may require a second MRI using a different technique or with a reading by a musculoskeletal radiologist. All questions in this regard should be discussed with the MRI center and/or radiologist.

ii. MRIs have high sensitivity and specificity for meniscal tears and ligamentous injuries although in some cases when physical exam findings and functional deficits indicate the need for surgery an MRI may not be necessary. MRI is less accurate for articular cartilage defects (sensitivity 76 percent) than for meniscal and ligamentous injury (sensitivity greater than 90 percent).

iii. MRIs have not been shown to be reliable for diagnosing symptomatic hip bursitis.

b. MR Arthrography (MRA): This accepted investigation uses the paramagnetic properties of gadolinium to shorten T1 relaxation times and provide a more intense MRI signal. It should be used to diagnose hip labral tears. Pelvic MRIs are not sufficient for this purpose. Arthrograms are also useful to evaluate mechanical pathology in knees with prior injuries and/or surgery.

c. Computed Axial Tomography (CT) is generally accepted and provides excellent visualization of bone. It is used to further evaluate bony masses and suspected fractures not clearly identified on radiographic window evaluation. Instrument scatter-reduction software provides better resolution when metallic artifact is of concern.

d. Diagnostic Sonography is an accepted diagnostic procedure. The performance of sonography is operator-dependent, and is best when done by a specialist in musculoskeletal radiology. It may also be useful for post-operative pain after total knee arthroplasty (TKA), and for dynamic testing especially of the foot or ankle.

e. Lineal Tomography is infrequently used, yet may be helpful in the evaluation of joint surfaces and bone healing.

f. Bone Scan (Radioisotope Bone Scanning) is generally accepted, well-established and widely used. 99MTechnecium diphosphonate uptake reflects osteoblastic activity and may be useful in metastatic/primary bone tumors, stress fractures, osteomyelitis, and inflammatory lesions, but cannot distinguish between these entities.

i. Bone scanning is more sensitive but less specific than MRI. It is useful for the investigation of trauma, infection, stress fracture, occult fracture, Charcot joint, Complex Regional Pain Syndrome and suspected neoplastic conditions of the lower extremity.

g. Other Radionuclide Scanning: Indium and gallium scans are generally accepted, well-established, and widely used procedures usually to help diagnose lesions seen

on other diagnostic imaging studies. 67Gallium citrate scans are used to localize tumor, infection, and abscesses. 111Indium-labeled leukocyte scanning is utilized for localization of infection or inflammation.

h. Arthrogram is an accepted diagnostic procedure. It may be useful in the evaluation of internal derangement of a joint, including when MRI or other tests are contraindicated or not available. Potential complications of this more invasive technique include pain, infection, and allergic reaction. Arthrography gains additional sensitivity when combined with CT in the evaluation of internal derangement, loose bodies, and articular cartilage surface lesions. Diagnostic arthroscopy should be considered before arthrogram when there are strong clinical indications.

2. Other diagnostic tests. The following diagnostic procedures listed in this subsection are listed in alphabetical order.

a. Compartment Pressure Testing and Measurement Devices: such as pressure manometer, are useful in the evaluation of patients who present symptoms consistent with a compartment syndrome.

b. Diagnostic Arthroscopy (DA) allows direct visualization of the interior of a joint, enabling the diagnosis of conditions when other diagnostic tests have failed to reveal an accurate diagnosis; however, it should generally not be employed for exploration purposes only. In order to perform a diagnostic arthroscopy, the patient must have completed at least some conservative therapy without sufficient functional recovery per Section E, Specific Lower Extremity Injury Diagnosis, Testing, and Treatment, and meet criteria for arthroscopic repair.

i. DA may also be employed in the treatment of acute joint disorders. In some cases, the mechanism of injury and physical examination findings will strongly suggest the presence of a surgical lesion. In those cases, it is appropriate to proceed directly with the interventional arthroscopy.

c. Doppler Ultrasonography/Plethysmography is useful in establishing the diagnosis of arterial and venous disease in the lower extremity and should usually be considered prior to the more invasive venogram or arteriogram study. Doppler is less sensitive in detecting deep vein thrombosis in the calf muscle area. If the test is initially negative and symptoms continue, an ultrasound should usually be repeated seven days later to rule out popliteal thrombosis. It is also useful for the diagnosis of popliteal mass when MRI is not available or contraindicated.

d. Electrodiagnostic Testing. Electrodiagnostic tests include, but are not limited to Electromyography (EMG), Nerve Conduction Studies (NCS) and Somatosensory Evoked Potentials (SSEP). These are generally accepted, well-established and widely used diagnostic procedures. The SSEP study, although generally accepted, has limited use. Electrodiagnostic studies may be useful in the evaluation of patients with suspected involvement of the neuromuscular system, including disorder of the anterior horn cell, radiculopathies, peripheral nerve entrapments, peripheral neuropathies, neuromuscular junction and primary muscle disease.

i. In general, these diagnostic procedures are complementary to imaging procedures such as CT, MRI, and/or myelography or diagnostic injection procedures. Electrodiagnostic studies may provide useful, correlative neuropathophysiological information that would be otherwise unobtainable from standard radiologic studies.

e. Personality/Psychological/Psychiatric/ Psychosocial Evaluations. These are generally accepted and well-established diagnostic procedures with selective use in the upper extremity population, but have more widespread use in subacute and chronic upper extremity populations. Diagnostic testing procedures may be useful for patients with symptoms of depression, delayed recovery, chronic pain, recurrent painful conditions, disability problems, and for preoperative evaluation. Psychological/psychosocial and measures have been shown to have predictive value for postoperative response, and therefore should be strongly considered for use pre-operatively when the surgeon has concerns about the relationship between symptoms and findings, or when the surgeon is aware of indications of psychological complication or risk factors for psychological complication (e.g. childhood psychological trauma). Psychological testing should provide differentiation between pre-existing conditions versus injury caused psychological conditions, including depression and posttraumatic stress disorder. Psychological testing should incorporate measures that have been shown, empirically, to identify comorbidities or risk factors that are linked to poor outcome or delayed recovery.

i. Formal psychological or psychosocial evaluation should be performed on patients not making expected progress within 6 to 12 weeks following injury and whose subjective symptoms do not correlate with objective signs and test results. In addition to the customary initial exam, the evaluation of the injured worker should specifically address the following areas:

(a). employment history;

(b). interpersonal relationships-both social and work;

(c). patient activities;

(d). current perception of the medical system;

(e). current perception/attitudes toward employer/job;

(f). results of current treatment;

(g). risk factors and psychological comorbidities that may influence outcome and that may require treatment.

(h). Childhood history, including history of childhood psychological trauma, abuse and family history of disability.

ii. Personality/psychological/psychosocial evaluations consist of two components, clinical interview and psychological testing. Results should help clinicians with a better understanding of the patient in a number of ways. Thus the evaluation result will determine the need for further psychosocial interventions; and in those cases, Diagnostic and Statistical Manual of Mental Disorders (DSM) diagnosis should be determined and documented. The evaluation should also include examination of both psychological comorbidities and psychological risk factors that are empirically associated with poor outcome and/or delayed recovery. An individual with a Ph.D., Psy.D, or psychiatric M.D./D.O. credentials should perform initial evaluations, which are generally completed within one to two hours. A professional fluent in the primary language of the patient is preferred. When such a provider is not

available, services of a professional language interpreter should be provided.

(a). Frequency. one-time visit for the clinical interview. If psychometric testing is indicated as a part of the initial evaluation, time for such testing should not exceed an additional two hours of professional time.

f. Venogram/Arteriogram is useful for investigation of vascular injuries or disease, including deep venous thrombosis. Potential complications may include pain, allergic reaction, and deep vein thrombosis.

3. Special tests are generally well-accepted tests and are performed as part of a skilled assessment of the patient's capacity to return-to-work, his/her strength capacities, and physical work demand classifications and tolerances. The procedures in this subsection are listed in alphabetical order.

a. Computer-Enhanced Evaluations may include isotonic, isometric, isokinetic and/or isoinertial measurement of movement, range of motion, balance, endurance or strength. Values obtained can include degrees of motion, torque forces, pressures or resistance. Indications include determining validity of effort, effectiveness of treatment and demonstrated motivation. These evaluations should not be used alone to determine return-to-work restrictions.

i. Frequency: One time for evaluation. Can monitor improvements in strength every three to four weeks up to a total of six evaluations.

b. Functional Capacity Evaluation (FCE) is a comprehensive or modified evaluation of the various aspects of function as they relate to the worker's ability to return-to-work. Areas such as endurance, lifting (dynamic and static), postural tolerance, specific range of motion, coordination and strength, worker habits, employability, as well as psychosocial aspects of competitive employment may be evaluated. Components of this evaluation may include: musculoskeletal screen; cardiovascular profile/aerobic capacity; coordination; lift/carrying analysis; job-specific activity tolerance; maximum voluntary effort; pain assessment/psychological screening; and non-material and material handling activities.

i. When an FCE is being used to determine return to a specific jobsite, the provider is responsible for fully understanding the job duties. A jobsite evaluation is frequently necessary. FCEs cannot be used in isolation to determine work restrictions. The authorized treating physician must interpret the FCE in light of the individual patient's presentation and medical and personal perceptions. FCEs should not be used as the sole criteria to diagnose malingering. Full FCEs are sometimes necessary. In many cases, a work tolerance screening will identify the ability to perform the necessary job tasks. FCEs are not necessary to assign permanent impairment ratings in the Colorado workers' compensation system. If Partial FCEs are performed, it is recognized that all parts of the FCE that are not performed are considered normal.

(a). Frequency: Can be used initially to determine baseline status; and for case closure when patient is unable to return to pre-injury position and further information is desired to determine permanent work restrictions. Prior authorization is required for FCEs performed during treatment.

c. Jobsite Evaluation is a comprehensive analysis of the physical, mental and sensory components of a specific job. These components may include, but are not limited to: postural tolerance (static and dynamic); aerobic requirements; range of motion; torque/force; lifting/carrying; cognitive demands; social interactions; visual perceptual; sensation; coordination; environmental requirements of a job; repetitiveness; and essential job functions including job licensing requirements. Job descriptions provided by the employer are helpful but should not be used as a substitute for direct observation.

i. A jobsite evaluation may include observation and instruction of how work is done, what material changes (desk, chair) should be made, and determination of readiness to return to work.

(a). Requests for a jobsite evaluation should describe the expected goals for the evaluation. Goals may include, but are not limited to the following:

(i). To determine if there are potential contributing factors to the person's condition and/or for the physician to assess causality;

(ii). To make recommendations for, and to assess the potential for ergonomic changes;

(iii). To provide a detailed description of the physical and cognitive job requirements;

(iv). To assist the patient in their return to work by educating them on how they may be able to do their job more safely in a bio-mechanically appropriate manner; and/or

(v). To give detailed work/activity restrictions.

[a]. Frequency: One time with additional visits as needed for follow-up visits per jobsite.

d. Vocational Assessment: The vocational assessment should provide valuable guidance in the determination of future rehabilitation program goals. It should clarify rehabilitation goals, which optimize both patient motivation and utilization of rehabilitation resources. If prognosis for return to former occupation is determined to be poor, except in the most extenuating circumstances, vocational assessment should be implemented within 3 to 12 months post-injury. Declaration of MMI should not be delayed solely due to lack of attainment of a vocational assessment.

i. Frequency: One time with additional visits as needed for follow-up

e. Work Tolerance Screening (Fitness for Duty) is a determination of an individual's tolerance for performing a specific job based on a job activity or task. It may include a test or procedure to specifically identify and quantify work-relevant cardiovascular, physical fitness and postural tolerance. It may also address ergonomic issues affecting the patient's return-to-work potential. May be used when a full FCE is not indicated.

i. Frequency: One time for initial screen. May monitor improvements in strength every three to four weeks up to a total of six visits.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1769 (June 2011).

§2309. Specific Lower Extremity Injury Diagnosis, Testing, and Treatment

1. Foot and Ankle

a. Achilles Tendonopathy/or Injury and Rupture (ALTERNATE SPELLING: "TENDINOPATHY"):

i. Description/Definition: Rupture or tear of Achilles tendon or insertional or non-insertional tendonopathy.

ii. Occupational Relationship: Tears or ruptures are related to a fall, twisting, jumping, or sudden load on ankle with dorsiflexion. Tendonopathy may be exacerbated by continually walking on hard surfaces.

iii. Specific Physical Exam Findings: Swelling and pain at tendon, sometimes accompanied by crepitus and pain with passive motion. Rupture or partial tear may present with palpable deficit in tendon. If there is a full tear, Thompson test will usually be positive. A positive Thompson's test is lack of plantar flexion with compression of the calf when the patient is prone with the knee flexed.

iv. Diagnostic Testing Procedures: Radiography may be performed to identify Haglund's deformity; however, many Haglund's deformities are asymptomatic. MRI or ultrasound may be performed if surgery is being considered for tendonopathy or rupture.

v. Non-operative Treatment Procedures:

(a). Initial Treatment: Cast in non weight-bearing for tears. Protected weight-bearing for other injuries.

(b). Medications such as analgesics and anti-inflammatories may be helpful. Refer to medication discussions in Medications and Medical Management.

(c). Patient education should include instruction in self-management techniques, ergonomics, body mechanics, home exercise, joint protection, and weight management.

(d). Benefits may be achieved through therapeutic rehabilitation and rehabilitation interventions. Eccentric training alone or with specific bracing may be used for tendonopathy. Manual therapy may also be used. Therapy will usually include range-of-motion (ROM), active therapies, and a home exercise program. Active therapies include, proprioception training, restoring normal joint mechanics, and clearing dysfunctions from adjacent structures. Passive as well as active therapies may be used for control of pain and swelling. Therapy should progress to strengthening and an independent home exercise program targeted to further improve ROM, strength, and normal joint mechanics influenced by distal and proximal structures. Refer to Therapeutic Procedures, Non-operative.

(i). Passive modalities are most effective as adjunctive treatments to improve the results of active treatment. They may be used as found in Therapeutic Procedures, Non-operative.

(e). Steroid injections should generally be avoided in these patients since this is a risk for later rupture.

(f). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(g). Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

vi. Surgical Indications/Considerations: Total or partial rupture.

(a). Smoking may affect soft tissue healing through tissue hypoxia. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician.

vii. Operative Procedures: Repair of tendons open or percutaneously with or without anchors may be required. Tendon grafts are used for chronic cases or primary surgery failures when tendon tissue is poor.

viii. Post-operative Treatment:

(a). An individualized rehabilitation program based upon communication between the surgeon and the therapist using therapies as outlined in Section F, Therapeutic Procedures, Non-operative.

(b). Treatment may include the following: restricted weight-bearing, bracing, active therapy with or without passive therapy.

(c). Range of motion may begin at three weeks depending on wound healing. Therapy and some restrictions will usually continue for six to eight weeks.

(d). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

b. Aggravated Osteoarthritis:

i. Description/Definition: Internal joint pathology of ankle.

ii. Occupational Relationship: The provider must establish the occupational relationship by establishing a change in the patient's baseline condition and a relationship to work activities, for example frequent jumping, climbing, or squatting.

(a). Other causative factors to consider: Prior significant injury to the ankle may predispose the joint to osteoarthritis. In order to entertain previous trauma as a cause, the patient should have a medically documented injury with radiographs or MRI showing the level of anatomic change. The prior injury should have been at least two years from the presentation for the new complaints and there should be a significant increase of pathology on the affected side in comparison to the original imaging or operative reports and/or the opposite un-injured extremity.

iii. Specific Physical Exam Findings: Pain within joint, swelling. Crepitus, locking of the joint, reduced range of motion, pain with stress tests, angular deformities.

iv. Diagnostic Testing Procedures: X-ray – mechanical axis views, CT, MRI, diagnostic injection.

v. Non-operative Treatment Procedures:

(a). Initial Treatment: May include orthoses, custom shoes with rocker bottom shoe inserts, and braces. Cane may also be useful.

(b). Medications such as analgesics and anti-inflammatories may be helpful. Refer to medication discussions in Medications and Medical Management.

(c). Patient education should include instruction in self-management techniques, ergonomics, body mechanics, home exercise, joint protection, and weight management.

(d). Benefits may be achieved through therapeutic rehabilitation and rehabilitation interventions. They should include range-of-motion (ROM), active

therapies, and a home exercise program. Active therapies include, proprioception training, restoring normal joint mechanics, and clearing dysfunctions from adjacent structures. Passive as well as active therapies may be used for control of pain and swelling. Therapy should progress to strengthening and an independent home exercise program targeted to further improve ROM, strength, and normal joint mechanics influenced by distal and proximal structures. Refer to Therapeutic Procedures, Non-operative.

(i). Passive modalities are most effective as adjunctive treatments to improve the results of active treatment. They may be used as found in Therapeutic Procedures, Non-operative.

(e). Steroid injections may decrease inflammation and allow the therapist to progress with functional exercise and range of motion. Steroid injections under significant pressure should be avoided as the needle may be penetrating the tendon and injection into the tendon can cause possible tendon breakdown, tendon degeneration, or rupture. Injections should be minimized for patients under 30 years of age.

(i). Time to Produce Effect: One injection.

(ii). Maximum Duration: Three injections in one year spaced at least four to eight weeks apart.

(iii). Steroid injections should be used cautiously in diabetic patients. Diabetic patients should be reminded to check their blood glucose levels at least daily for two weeks after injections.

(f). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(g). Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

vi. Surgical Indications/Considerations:

(a). The patient is a good surgical candidate and pain continues to interfere with ADLs after non-surgical interventions including weight control, therapy with active patient participation, and medication.

(b). Refer to Therapeutic Procedures-Operative, for specific indications for osteotomy, ankle fusion or arthroplasty.

(c). Implants are less successful than similar procedures in the knee or hip. There are no quality studies comparing arthrodesis and ankle replacement. Patients with ankle fusions generally have good return to function and fewer complications than those with joint replacements. Salvage procedures for ankle replacement include revision with stemmed implant or allograft fusion. Given these factors, an ankle arthroplasty requires prior authorization and a second opinion by a surgeon specializing in lower extremity surgery.

(d). Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities and the patient should agree to comply with the pre- and post-operative treatment plan including home exercise. The provider should be especially careful to make sure the patient understands the amount of post-operative therapy required and the length of partial- and full-disability expected post-operatively.

(e). In cases where surgery is contraindicated due to obesity, it may be appropriate to recommend a weight loss program if the patient is unsuccessful losing weight on their own. Coverage for weight loss would continue only for motivated patients who have demonstrated continual progress with weight loss.

(f). Because smokers have a higher risk of non-union and post-operative costs, it is recommended that carriers cover a smoking cessation program peri-operatively. Physicians may monitor smoking cessation with laboratory tests such as cotinine levels for long-term cessation.

vii. Operative Procedures: Arthroscopy, ankle arthroplasty or fusion. Supramalleolar osteotomies can be considered for patients with deformities or pre-existing hind foot varus or valgus deformities.

viii. Post-operative Treatment

(a). An individualized rehabilitation program based upon communication between the surgeon and the therapist using therapies as outlined in Section F, Therapeutic Procedures, Non-operative.

(b). In all cases, communication between the physician and therapist is important to the timing of weight-bearing and exercise progressions.

(c). Treatment may include the following: restricted weight-bearing, bracing, gait training and other active therapy with or without passive therapy.

(d). Refer to Ankle Fusion, Osteotomy, or Arthroplasty for further specific information.

(e). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

c. Ankle or Subtalar Joint Dislocation:

i. Description/Definition: Dislocation of ankle or subtalar joint.

ii. Occupational Relationship: Usually occurs with falling or twisting.

iii. Specific Physical Exam Findings: Disruption of articular arrangements of ankle, subtalar joint may be tested using ligamentous laxity tests.

iv. Diagnostic Testing Procedures: Radiographs, CT scans. MRI may be used to assess for avascular necrosis of the talus which may occur secondary to a dislocation.

v. Non-operative Treatment Procedures:

(a). Initial Treatment: Closed reduction under anesthesia with pre- and post-reduction neurovascular assessment followed by casting and weight-bearing limitations.

(b). Medications such as analgesics and anti-inflammatories may be helpful. Refer to medication discussions in Medications and Medical Management.

(c). Patient education should include instruction in self-management techniques, ergonomics, body mechanics, home exercise, joint protection, and weight management.

(d). Benefits may be achieved through therapeutic rehabilitation and rehabilitation interventions. They should include range of motion (ROM), active therapies, and a home exercise program. Active therapies include, proprioception training, restoring normal joint mechanics, and clearing dysfunctions from adjacent structures. Passive as well as active therapies may be used for control of pain and swelling. Therapy should progress to strengthening and an independent home exercise program

targeted to further improve ROM, strength, and normal joint mechanics influenced by distal and proximal structures. Refer to Therapeutic Procedures, Non-operative.

(i). Passive modalities are most effective as adjunctive treatments to improve the results of active treatment. They may be used as found in Therapeutic Procedures, Non-operative.

(e). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(f). Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

vi. Surgical Indications/Considerations: Inability to reduce closed fracture, association with unstable fractures

vii. Operative Procedures: Open or closed reduction of dislocation.

viii. Post-operative Treatment:

(a). An individualized rehabilitation program based upon communication between the surgeon and the therapist using therapies as outlined in Therapeutic Procedures, Non-operative.

(b). Treatment usually includes initial immobilization with restricted weight-bearing, followed by bracing and active therapy with or without passive therapy.

(c). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

d. Ankle Sprain/Fracture

i. Description/Definition. An injury to the ankle joint due to abnormal motion of the talus that causes a stress on the malleolus and the ligaments. Injured ligaments in order of disruption include the anterior talofibular ligament (ATFL), calcaneofibular ligament (CFL), posterior talofibular ligament (PTFL), deltoid ligaments, and syndesmotic ligaments. Instability can result from a fracture of a malleolus (malleolli), rupture of ligaments, or a combination. Circumstances surrounding the injury, including consideration of location and additional injuries are of importance. Additionally, the position of the foot at the time of injury is helpful in determining the extent and type of injury. Grading of soft tissue injuries includes:

(a). Grade 1 Injury: those with overstretching or microscopic tears of the ligament, minimal swelling, normal stress testing, and the ability to bear weight.

(b). Grade 2 Injury: have partial disruption of the ligament, significant swelling, indeterminate results on stress testing, and difficulty bearing weight.

(c). Grade 3 Injury: have a ruptured ligament, swelling and ecchymosis, abnormal results on stress testing, and the inability to bear weight. May also include a chip avulsion fracture on x-ray.

ii. Occupational Relationship: sudden twisting, direct blunt trauma and falls. Inversion of the ankle with a plantar-flexed foot is the most common mechanism of injury.

iii. Specific Physical Exam Findings: varies with individual. With lower grade sprains the ankle may be normal appearing with minimal tenderness on examination. The ability/inability to bear weight, pain, swelling, or ecchymosis should be noted. If the patient is able to transfer weight from one foot onto the affected foot and has normal physical findings, then likelihood of fracture is reduced. Stress testing using the anterior drawer stress test, the talar tilt test and the external rotation stress test may be normal or abnormal depending on the involved ligament.

(a). Syndesmotic injury can occur with external rotation injuries and requires additional treatment. Specific physical exam tests include the squeeze test and external rotation at neutral.

iv. Diagnostic Testing Procedures: Radiographs. Refer to Initial Diagnostic Section which generally follows the Ottawa Ankle Rules. The Ottawa Ankle Rules are a decision aid for radiography. Commonly missed conditions include ankle syndesmosis or fractures. The instrument has a sensitivity of almost 100 percent and a modest specificity, and its use should reduce the number of unnecessary radiographs by 30 to 40 percent.

(a). For an acute, unstable ankle or a repeat or chronic ankle injury, a MRI and/or diagnostic injection may be ordered. Arthroscopy can be used in unusual cases with persistent functional instability and giving way of the ankle, after conservative treatment, to directly visualize the ruptured ligament(s).

v. Non-operative Treatment Procedures

(a). Initial treatment for patients able to bear weight: NSAIDs, RICE (rest, ice, compression and elevation), and early functional bracing is used. In addition, crutches may be beneficial for comfort. Early functional treatment including range of motion and strengthening exercises along with limited weight-bearing, are preferable to strict immobilization with rigid casting for improving outcome and reducing time to return to work.

(b). Initial treatment for patients unable to bear weight: bracing plus NSAIDs and RICE are used. When patient becomes able to bear weight a walker boot is frequently employed. There is no clear evidence favoring ten days of casting over pneumatic bracing as initial treatment for patients who cannot bear weight three days post injury. There is good evidence that use of either device combined with functional therapy results in similar long-term recovery.

(i). There is some evidence that functional rehabilitation has results superior to six weeks of immobilization.

(ii). Small avulsion fractures of the fibula with minimal or no displacement can be treated as an ankle sprain.

(iii). For patients with a clearly unstable joint, immobilize with a short leg plaster cast or splint for two to six weeks along with early weight-bearing.

(c). Balance/coordination training is a well-established treatment which improves proprioception and may decrease incidence of recurrent sprains.

(d). Medications such as analgesics and anti-inflammatories may be helpful. Refer to medication discussions in Medications and Medical Management.

(e). Patient education should include instruction in self-management techniques, ergonomics, body mechanics, home exercise, joint protection, and weight management.

(f). Heel wedges or other orthotics may be used for rear foot varus or valgus deformities.

(i). There is good evidence that semi-rigid orthoses or pneumatic braces prevent ankle sprains during

high risk physical activities and they should be used as appropriate after acute sprains.

(g). When fractures are involved refer to comments related to osteoporosis in Therapeutic Procedures, Non-operative, Osteoporosis Management.

(h). Smoking may affect fracture healing. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician.

(i). Return-to-work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(j). Other therapies in Therapeutic Procedures, Non-operative, including manual therapy may be employed in individual cases.

(k). Hyperbaric oxygen therapy is not recommended.

vi. Surgical Indications/Considerations:

(a). Acute surgical indications include sprains with displaced fractures, syndesmotic disruption or ligament sprain associated with a fracture causing instability.

(b). There is no conclusive evidence that surgery as opposed to functional treatment for an uncomplicated Grade I-III ankle sprain improves patient outcome.

(c). Chronic indications are functional problems, such as recurrent instability, remaining after at least 2 months of appropriate therapy including active participation in a non-operative therapy program including balance training.

(d). Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities and the patient should agree to comply with the pre- and post-operative treatment plan including home exercise. The provider should be especially careful to make sure the patient understands the amount of post-operative therapy required and the length of partial- and full-disability expected post-operatively.

(e). If injury is a sprain: Smoking may affect soft tissue healing through tissue hypoxia. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician.

(f). If injury is a fracture: Because smokers have a higher risk of non-union and post-operative costs, it is recommended that carriers cover a smoking cessation program peri-operatively. Physicians may monitor smoking cessation with laboratory tests such as cotinine levels for long-term cessation.

vii. Operative Treatment: Repair of fractures or other acute pathology as necessary. Primary ligament ankle reconstruction with possible tendon transplant.

viii. Post-operative Treatment

(a). An individualized rehabilitation program based upon communication between the surgeon and the therapist using therapies as outlined in Therapeutic Procedures, Non-operative. Treatment may include short-term post surgical casting. In all cases, communication between the physician and therapist is important to the timing of weight-bearing and exercise progressions.

(i). There is some evidence that more rapid recovery occurs with functional rehabilitation compared to six weeks of immobilization in a cast.

(b). The surgical procedures and the patient's individual results dictate the amount of time a patient has non weight-bearing restrictions. Fractures usually require six to eight weeks while tendon transfers may be six weeks. Other soft tissue repairs, such as the Brostrom lateral ankle stabilization, may be as short as three weeks.

(c). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

e. Calcaneal Fracture:

i. Description/Definition: Osseous fragmentation/separation confirmed by diagnostic studies.

ii. Occupational Relationship: Usually occurs by fall or crush injury.

iii. Specific Physical Exam Findings: Pain with range of motion and palpation of calcaneus. Inability to bear weight, mal-positioning of heel, possible impingement of sural nerve.

iv. Diagnostic Testing Procedures: Radiographs and CT scan to assess for intra-articular involvement. Lumbar films and urinalysis are usually performed to rule out lumbar crush fractures when the mechanism of injury is a fall from a height.

v. Non-operative Treatment Procedures:

(a). Initial Treatment: Non weight-bearing six to eight weeks, followed by weight-bearing cast at physician's discretion and active therapy with or without passive therapy.

(b). Medications such as analgesics and anti-inflammatories may be helpful. Refer to medication discussions in Medications and Medical Management.

(c). Patient education should include instruction in self-management techniques, ergonomics, body mechanics, home exercise, joint protection, and weight management.

(d). Refer to comments related to osteoporosis in Therapeutic Procedures, Non-operative, Osteoporosis Management.

(e). Smoking may affect fracture healing. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician.

(f). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(g). Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

vi. Surgical Indications/Considerations: Displacement of fragments, joint depression, intra-articular involvement, mal-position of heel. Sanders Types II and III are generally repaired surgically. However, the need for surgery will depend on the individual case. Relative contraindications: smoking, diabetes, or immunosuppressive disease.

(a). Because smokers have a higher risk of non-union and post-operative costs, it is recommended that carriers cover a smoking cessation program peri-operatively. Physicians may monitor smoking cessation with laboratory tests such as cotinine levels for long-term cessation.

vii. Operative Procedures: Open reduction internal fixation. Subtalar fusion may be necessary in some cases

when the calcaneus is extremely comminuted. External fixation has been used when the skin condition is poor.

(a). Complications may include wound infections requiring skin graft.

viii. Post-operative Treatment:

(a). An individualized rehabilitation program based upon communication between the surgeon and the therapist using the therapies as outlined in Section F, Therapeutic Procedures, Non-operative. In all cases, communication between the physician and therapist is important to the timing of weight-bearing and exercise progressions.

(b). The patient is usually non weight-bearing for six to eight weeks followed by weight-bearing for approximately six to eight weeks at physician's discretion.

(c). Treatment may include the following: restricted weight-bearing, bracing, active therapy with or without passive therapy.

(d). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

f. Chondral and Osteochondral Defects:

i. Description/Definition: Cartilage or cartilage and bone defect of the talar surface. May be associated with ankle sprain or other injuries.

ii. Occupational Relationship: Usually caused by a traumatic ankle injury.

iii. Specific Physical Exam Findings: Ankle effusion, pain in joint and with walking.

iv. Diagnostic Testing Procedures: MRI may show bone bruising, osteochondral lesion, or possibly articular cartilage injury. Radiographs, contrast radiography, CT may also be used.

v. Non-Operative Treatment Procedures:

(a). Initial Treatment: Acute injuries may require immobilization followed by active therapy with or without passive therapy.

(b). Medications such as analgesics and anti-inflammatories may be helpful. Refer to medication discussions in Medications and Medical Management.

(c). Patient education should include instruction in self-management techniques, ergonomics, body mechanics, home exercise, joint protection, and weight management.

(d). Benefits may be achieved through therapeutic rehabilitation and rehabilitation interventions. They should include range-of-motion (ROM), active therapies, and a home exercise program. Active therapies include, proprioception training, restoring normal joint mechanics, and clearing dysfunctions from adjacent structures. Passive as well as active therapies may be used for control of pain and swelling. Therapy should progress to strengthening and an independent home exercise program targeted to further improve ROM, strength, and normal joint mechanics influenced by distal and proximal structures. Refer to Therapeutic Procedures, Non-operative.

(i). Passive modalities are most effective as adjunctive treatments to improve the results of active treatment. They may be used as found in Therapeutic Procedures, Non-operative.

(e). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(f). Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

vi. Surgical Indications/Considerations

(a). Functional deficits not responsive to conservative therapy. Identification of an osteochondral lesion by diagnostic testing procedures should be done to determine the size of the lesion and stability of the joint.

(b). Microfracture is the initial treatment unless there are other anatomic variants such as a cyst under the bone.

(c). Osteochondral Autograft Transfer System (OATS) may be effective in patients without other areas of osteoarthritis, a BMI of less than 35 and a failed microfracture. This procedure may be indicated when functional deficits interfere with activities of daily living and/or job duties 6 to 12 weeks after a failed microfracture with active patient participation in non-operative therapy. This procedure is only appropriate in a small subset of patients and requires prior authorization.

(d). Autologous cartilage cell implant is not FDA approved for the ankle and therefore not recommended.

(e). Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities and the patient should agree to comply with the pre- and post-operative treatment plan including home exercise. The provider should be especially careful to make sure the patient understands the amount of post-operative therapy required and the length of partial- and full-disability expected post-operatively.

(f). Smoking may affect tissue healing through tissue hypoxia. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician.

vii. Operative Procedures: Arthroscopy with debridement or shaving of cartilage, microfracture, mosiacplasty, fixation of loose osteochondral fragments.

viii. Post-operative Treatment

(a). An individualized rehabilitation program based upon communication between the surgeon and the therapist and using therapies as outlined in Therapeutic Procedures, Non-operative. In all cases, communication between the physician and therapist is important to the timing of weight-bearing and exercise progressions.

(b). Treatment may include the following: restricted weight-bearing, bracing, active therapy with or without passive therapy.

(c). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

g. Heel Spur Syndrome/Plantar Fasciitis:

i. Description: Pain along the inferior aspect of the heel at the calcaneal attachment of the plantar fascia and/or along the course of the plantar fascia.

ii. Occupational Relationship: Condition may be exacerbated by prolonged standing or walking on hard surfaces. Acute injury may be caused by trauma. This may

include jumping from a height or hyperextension of the forefoot upon the rear foot.

iii. Specific Physical Exam Findings: Pain with palpation at the inferior attachment of the plantar fascia to the os calcis may be associated with calcaneal spur. Gastrocnemius tightness may be tested with the Silfverskiöld test. The foot is dorsiflexed with the knee extended and then with the knee flexed. The test for gastrocnemius tightness is considered positive if dorsiflexion is greater with the knee flexed than with the knee extended.

iv. Diagnostic Testing Procedures: Standard radiographs to rule out fracture, identify spur after conservative therapy. Bone scans and/or MRI may be used to rule out stress fractures in chronic cases.

v. Non-operative Treatment Procedures:

(a). Initial Treatment: This condition usually responds to conservative management consisting of eccentric exercise of the gastrocnemius, plantar fascial stretching, taping, soft-tissue mobilization, night splints, and orthotics. Therapy may include passive therapy, taping, and injection therapy.

(b). Shock absorbing shoe inserts may prevent back and lower extremity problems in some work settings.

(c). Medications such as analgesics and anti-inflammatories may be helpful. Refer to medication discussions in Medications and Medical Management.

(d). Patient education should include instruction in self-management techniques, ergonomics, body mechanics, home exercise, joint protection, and weight management.

(e). Steroid injections may decrease inflammation and allow the therapist to progress with functional exercise and range of motion. Steroid injections under significant pressure should be avoided as the needle may be penetrating the tendon and injection into the tendon can cause possible tendon breakdown, tendon degeneration, or rupture. Injections should be minimized for patients under 30 years of age.

(i). Time to Produce Effect: One injection.

(ii). Maximum Duration: Three injections in one year spaced at least four to eight weeks apart.

(iii). Steroid injections should be used cautiously in diabetic patients. Diabetic patients should be reminded to check their blood glucose levels at least daily for two weeks after injections.

(f). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(g). After four months of failed therapy, Extracorporeal Shock Wave Therapy (ESWT) trial may be considered prior to surgery. Refer to Therapeutic Procedures, Non-operative.

(h). Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

vi. Surgical Indications/Considerations:

(a). Surgery is employed only after failure of at least four to six months of active patient participation in non-operative treatment.

(b). Indications for a gastrocnemius recession include a positive Silfverskiöld test. This procedure does not weaken the arch as may occur with a plantar fascial procedure, however, there is a paucity of literature on this procedure.

(c). Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities and the patient should agree to comply with the pre- and post-operative treatment plan including home exercise. The provider should be especially careful to make sure the patient understands the amount of post-operative therapy required and the length of partial- and full-disability expected post-operatively.

(d). Smoking may affect soft tissue healing through tissue hypoxia. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician.

vii. Operative Treatment Procedures: Plantar fascial release with or without calcaneal spur removal, endoscopic or open gastrocnemius recession.

viii. Post-operative Treatment

(a). An individualized rehabilitation program based upon communication between the surgeon and the therapist using therapies as outlined in Therapeutic Procedures, Non-operative.

(b). Treatment may include the following: restricted weight-bearing, bracing, active therapy with or without passive therapy. Usually non weight-bearing for 7 to 10 days followed by weight-bearing cast or shoe for four weeks; however, depending on the procedure some patients may be restricted from weight-bearing for four to six weeks.

(c). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

h. Metatarsal-Phalangeal, Tarsal-Metatarsal and Interphalangeal Joint Arthropathy:

i. Description/Definition: Internal derangement of joint.

ii. Occupational Relationship: Jamming, contusion, crush injury, repetitive impact, or post-traumatic arthrosis.

iii. Specific Physical Exam Findings. Pain with palpation and ROM of joint, effusion. The piano key test may be used, where the examiner stabilizes the heel with one hand and presses down on the distal head of the metatarsals, assessing for pain proximally.

iv. Diagnostic Testing Procedures. Radiographs, diagnostic joint injection, CT, MRI.

v. Non-operative Treatment Procedures

(a). Medications such as analgesics and anti-inflammatories may be helpful. Refer to medication discussions in Medications and Medical Management.

(b). Patient education should include instruction in self-management techniques, ergonomics, body mechanics, home exercise, joint protection, and weight management.

(c). Benefits may be achieved through therapeutic rehabilitation and rehabilitation interventions. They should include range-of-motion (ROM), active therapies, and a home exercise program. Active therapies include, proprioception training, restoring normal joint mechanics, and clearing dysfunctions from adjacent structures. Passive as well as active therapies may be used

for control of pain and swelling. Orthotics and iontophoresis are usually included. A carbon fiber Morton extension may be useful. Therapy should progress to strengthening and an independent home exercise program targeted to further improve ROM, strength, and normal joint mechanics influenced by distal and proximal structures. Refer to Therapeutic Procedures, Non-operative.

(i). Passive modalities are most effective as adjunctive treatments to improve the results of active treatment. They may be used as found in Therapeutic Procedures, Non-operative.

(d). Steroid injections may decrease inflammation and allow the therapist to progress with functional exercise and range of motion. Steroid injections under significant pressure should be avoided as the needle may be penetrating the tendon and injection into the tendon can cause possible tendon breakdown, tendon degeneration, or rupture. Injections should be minimized for patients under 30 years of age.

(i). Time to Produce Effect: One injection.

(ii). Maximum Duration: Three injections in one year spaced at least four to eight weeks apart.

(iii). Steroid injections should be used cautiously in diabetic patients. Diabetic patients should be reminded to check their blood glucose levels at least daily for two weeks after injections.

(e). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(f). Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

vi. Surgical Indications/Considerations

(a). Pain, unresponsive to conservative care and interfering with activities of daily living.

(b). First metatarsal arthritis or avascular necrosis can interfere with function and gait.

(c). Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities and the patient should agree to comply with the pre- and post-operative treatment plan including home exercise. The provider should be especially careful to make sure the patient understands the amount of post-operative therapy required and the length of partial- and full-disability expected post-operatively.

(d). Smoking may affect soft tissue healing through tissue hypoxia. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician.

vii. Operative Procedures: if debridement of the arthritic joint and other conservative treatment is unsuccessful in correcting gait and walking tolerance, other procedures may be considered. Other procedures include: fusion of first metatarsal-phalangeal joint, chilectomy, osteotomies, Keller arthroplasty and soft tissue procedures.

(a). There is some evidence that the first metatarsal-phalangeal joint arthritis is better treated with arthrodesis than arthroplasty for pain and functional improvement. Therefore, total joint arthroplasties are not recommended for any metatarsal-phalangeal joints due to less successful outcomes than fusions. There may be an exception for first and second metatarsal-phalangeal joint arthroplasties when a patient is older than 60, has low activity levels, and cannot tolerate non weight-bearing for prolonged periods or is at high risk for non-union.

(b). Metallic hemi-arthroplasties are still considered experimental as long-term outcomes remain unknown in comparison to arthrodesis, and there is a significant incidence of subsidence. Therefore, these are not recommended at this time.

viii. Post-Operative Treatment

(a). An individualized rehabilitation program based upon communication between the surgeon and the therapist using therapies as outlined in Therapeutic Procedures, Non-operative. In all cases, communication between the physician and therapist is important to the timing of weight-bearing and exercise progressions.

(b). For fusions and osteotomies, reduced weight-bearing and the use of special shoes will be necessary for at least ix weeks post operative. For other procedures early range-of-motion, bracing, and/or orthotics. Treatment usually also includes other active therapy with or without passive therapy.

(c). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

i. Midfoot (Lisfranc) Fracture/Dislocation

i. Description/Definition: Fracture/ligamentous disruption of the tarsal-metatarsal joints, i.e., metatarsal-cuneiform and metatarsal-cuboid bones.

ii. Occupational Relationship: Usually occurs from a fall, crush, axial load with a plantar flexed foot, or abductory force on the forefoot.

iii. Specific Physical Exam Findings. Pain and swelling at the Lisfranc joint, first and/or second metatarsal cuneiform articulation, palpable dorsal dislocation, pain on forced abduction.

(a). Dislocation may not always be apparent. Pronation and supination of the forefoot with the calcaneus fixed in the examiners opposite hand may elicit pain in a Lisfranc injury, distinguishing it from an ankle sprain, in which this maneuver is expected to be painless. The piano key test may be used, where the examiner stabilizes the heel with one hand and presses down on the distal head of the metatarsal, assessing for pain proximally. The dorsalis pedis artery crosses the second metatarsal and may be disrupted. Therefore, the dorsalis pedis pulse and capillary filling should be assessed.

iv. Diagnostic Testing Procedures: X-rays, CT scans, MRI, mid-foot stress x-rays.

v. Non-operative Treatment Procedures:

(a). Initial Treatment: If minimal or no displacement then casting, non weight-bearing six to eight weeks. Orthoses may be used later.

(b). Medications such as analgesics and anti-inflammatories may be helpful. Refer to medication discussions in Medications and Medical Management.

(c). Patient education should include instruction in self-management techniques, ergonomics, body mechanics, home exercise, joint protection, and weight management.

(d). Refer to comments related to osteoporosis in Therapeutic Procedures, Non-operative, Osteoporosis Management.

(e). Smoking may affect fracture healing. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician.

(f). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(g). Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

vi. Surgical Indications/Considerations: Displacement of fragments or intra-articular fracture. Most Lisfranc fracture/dislocations are treated surgically.

(a). Because smokers have a higher risk of non-union and post-operative costs, it is recommended that carriers cover a smoking cessation program peri-operatively. Physicians may monitor smoking cessation with laboratory tests such as cotinine levels for long-term cessation.

vii. Operative Procedures: Open reduction internal fixation with possible removal of hardware at approximately three to six months, pending healing status. Alternatively, arthrodesis of the medial two or three metatarsals.

viii. Post-Operative Treatment

(a). An individualized rehabilitation program based upon communication between the surgeon and the therapist using treatments as outlined in Therapeutic Procedures, Non-operative. In all cases, communication between the physician and therapist is important to the timing of weight-bearing and exercise progressions.

(b). The patient is usually in cast or fracture walker for six to eight weeks non weight-bearing. Orthoses may be indicated after healing.

(c). Treatment may include the following: restricted weight-bearing, bracing, active therapy with or without passive therapy.

(d). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

j. Morton's Neuroma

i. Description. This condition is a perineural fibrosis of the intermetatarsal nerve creating pain and/or paresthesias in the forefoot region. Symptoms appear with weight-bearing activities. Usually occurs between the third and fourth metatarsals or between the second and third metatarsals.

ii. Occupational Relationship. Acute injuries may include excessive loading of the forefoot region caused from jumping or pushing down on the ball of the foot. Non-traumatic occurrences are determined at physician's discretion after review of environmental and biomechanical risk factors.

iii. Specific Physical Exam Findings. Paresthesias and/or pain with palpation of the inter-metatarsal nerve. Mulder's sign, a palpable click from compression of the nerve, or Tinel's sign.

iv. Diagnostic Testing Procedures. Radiographs to rule out osseous involvement. Diagnostic and therapeutic injections. Diagnosis is usually based on clinical judgment; however, MRI and ultrasound imaging have also been employed in difficult cases.

v. Non-operative Treatment Procedures

(a). Initial Treatment: Nonsteroidal anti-inflammatories and foot orthoses are primary treatments.

(b). Medications such as analgesics and anti-inflammatories are usually helpful. Refer to medication discussions in Medications and Medical Management.

(c). Patient education should include instruction in self-management techniques, ergonomics, body mechanics, home exercise, joint protection, and weight management.

(d). Steroid injections may decrease inflammation and allow the therapist to progress with functional exercise and range of motion. Steroid injections under significant pressure should be avoided as the needle may be penetrating the tendon and injection into the tendon can cause possible tendon breakdown, tendon degeneration, or rupture. Injections should be minimized for patients under 30 years of age.

(i). Time to Produce Effect: One injection.

(ii). Maximum Duration: Three injections in one year spaced at least four to eight weeks apart.

(iii). Steroid injections should be used cautiously in diabetic patients. Diabetic patients should be reminded to check their blood glucose levels at least daily for two weeks after injections.

(e). Alcohol injections are thought to produce a chemical neurolysis. Alcohol injection with ultrasound guidance may be used to decrease symptoms.

(i). Optimum Duration: Four treatments.

(ii). Maximum Duration: Seven treatments.

(f). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(g). Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

vi. Surgical Indications/Considerations:

(a). Functional deficits persisting after two to three months of active participation in therapy.

(b). Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities and the patient should agree to comply with the pre- and post-operative treatment plan including home exercise. The provider should be especially careful to make sure the patient understands the amount of post-operative therapy required and the length of partial- and full-disability expected post-operatively.

(c). Smoking may affect soft tissue healing through tissue hypoxia. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician.

vii. Operative Procedures: Excision of the neuroma; nerve transection or transposition.

viii. Post-Operative Treatment

(a). An individualized rehabilitation program based upon communication between the surgeon and the therapist using therapies as outlined in Therapeutic Procedures, Non-operative.

(b). Treatment may involve a period of non weight-bearing for up to two weeks, followed by gradual protected weight-bearing four to six weeks.

(c). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

k. Pilon Fracture

i. Description/Definition: Crush/comminution fracture of distal metaphyseal tibia that has intra-articular extensions into the weight-bearing surface of the tibio-talar joint.

ii. Occupational Relationship: Usually from a fall.

iii. Specific Physical Exam Findings: Swelling, pain with weight-bearing, ecchymosis, and palpable tenderness.

iv. Diagnostic Testing Procedures: Radiographs, CT scans.

v. Non-operative Treatment Procedures

(a). Initial Treatment: Prolonged non weight-bearing at physician's discretion.

(b). Medications such as analgesics and anti-inflammatories may be helpful. Refer to medication discussions in Medications and Medical Management.

(c). Patient education should include instruction in self-management techniques, ergonomics, body mechanics, home exercise, joint protection, and weight management.

(d). Refer to comments related to osteoporosis in Therapeutic Procedures, Non-operative, Osteoporosis Management.

(e). Smoking may affect fracture healing. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician.

(f). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(g). Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

vi. Surgical Indications/Considerations: Displacement of fracture, severe comminution necessitating primary fusion.

(a). Because smokers have a higher risk of non-union and post-operative costs, it is recommended that insurers cover a smoking cessation program peri-operatively. Physicians may monitor smoking cessation with laboratory tests such as cotinine levels for long-term cessation.

vii. Operative Procedures: Open reduction internal fixation, fusion, external fixation. In some cases staged procedures may be necessary beginning with external fixation.

viii. Post-operative Treatment

(a). An individualized rehabilitation program based upon communication between the surgeon and the therapist using treatment as outlined in Therapeutic Procedures, Non-operative. In all cases, communication between the physician and therapist is important to the timing of weight-bearing and exercise progressions.

(b). Treatment may include the following: restricted weight-bearing, bracing, active therapy with or without passive therapy.

(c). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

l. Posterior Tibial Tendon Dysfunction

i. Description/Definition: Pain in the posteromedial ankle with plantar flexion.

ii. Occupational Relationship: Repetitive or forced plantar flexion after an ankle sprain or athletic activity.

iii. Specific Physical Exam Findings: Painful posterior tibial tendon with active and passive non weight-bearing motion, reproduction of pain with forced plantar flexion and inversion of the ankle, difficulty performing single heel raise, pain with palpation from the posterior medial foot along the medial malleous to the navicular greater tuberosity. The patient should also be evaluated for a possible weak gluteus medius as a contributing factor.

iv. Diagnostic Testing Procedures: X-ray, MRI may be used to rule out other diagnoses.

v. Non-operative Treatment Procedures:

(a). Initial Treatment: Short ankle articulated orthosis and therapy including low-load strengthening exercises with progression to home program. Other active and passive therapy including iontophoresis, orthotics and possible strengthening for the gluteus medius.

(b). Medications such as analgesics and anti-inflammatories may be helpful. Refer to medication discussions in Medications and Medical Management.

(c). Patient education should include instruction in self-management techniques, ergonomics, body mechanics, home exercise, joint protection, and weight management.

(d). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(e). Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

vi. Surgical Indications/Considerations:

(a). Failure of non-operative treatment. Surgery is rarely necessary as success rate for non-operative treatment is around 90 percent.

(b). Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities and the patient should agree to comply with the pre- and post-operative treatment plan including home exercise. The provider should be especially careful to make sure the patient understands the amount of post-operative therapy required and the length of partial- and full-disability expected post-operatively.

(c). Smoking may affect soft tissue healing through tissue hypoxia. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician.

vii. Operative Procedures: Resection of anomolous muscle segments or tenolysis. In severe cases, tendon transfer, osteotomies and/or arthrodesis may be necessary.

viii. Post-operative Treatment:

(a). An individualized rehabilitation program based upon communication between the surgeon and the therapist and using therapies as outlined in Therapeutic Procedures, Non-Operative.

(b). Treatment may include the following: restricted weight-bearing, bracing, active therapy with or without passive therapy.

(c). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

m. Puncture Wounds of the Foot

i. Description/Definition: Penetration of skin by foreign object.

ii. Occupational Relationship: Usually by stepping on foreign object, open wound.

iii. Specific Physical Exam Findings: Site penetration by foreign object consistent with history. In early onset, may show classic signs of infection.

iv. Diagnostic Testing Procedures: X-ray, MRI, ultrasound.

v. Non-operative Treatment Procedures

(a). Initial Treatment: Appropriate antibiotic therapy, tetanus toxoid booster, non weight-bearing at physician's discretion.

(b). Medications such as analgesics and anti-inflammatories may be helpful. Refer to medication discussions in Medications and Medical Management.

(c). Patient education should include instruction in self-management techniques, ergonomics, body mechanics, home exercise, joint protection, and weight management.

(d). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(e). Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

vi. Surgical Indications/Considerations: Cellulitis, retained foreign body suspected, abscess, compartmental syndrome, and bone involvement.

(a). Smoking may affect soft tissue healing through tissue hypoxia. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician.

vii. Operative Procedures: Incision and drainage with cultures.

viii. Post-operative Treatment

(a). Patient is usually non-weight-bearing with antibiotic therapy based upon cultures. Follow-up x-rays and/or MRI may be needed to evaluate for osseous involvement.

(b). An individualized rehabilitation program based upon communication between the surgeon and the therapist using treatment as outlined in Therapeutic Procedures, Non-operative.

(c). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

n. Severe Soft Tissue Crush Injuries:

i. Description/Definition: Soft tissue damage to the foot.

ii. Occupational Relationship: Crush injury or heavy impact to the foot or ankle.

iii. Specific Physical Exam Findings: Pain and swelling over the foot.

iv. Diagnostic Testing Procedures: X-ray and other tests as necessary to rule out other possible diagnoses such as compartment syndrome which requires emergent compartment pressure assessment.

v. Non-operative Treatment Procedures:

(a). Initial Treatment: Usually needs initial rest from work with foot elevation and compression wraps.

(b). Medications such as analgesics and anti-inflammatories may be helpful. Refer to medication discussions in Medications and Medical Management.

(c). Patient education should include instruction in self-management techniques, ergonomics, body mechanics, home exercise, joint protection, and weight management.

(d). Benefits may be achieved through therapeutic rehabilitation and rehabilitation interventions. They should include range-of-motion (ROM), active therapies, and a home exercise program. Active therapies include, proprioception training, restoring normal joint mechanics, and clearing dysfunctions from adjacent structures. Passive as well as active therapies may be used for control of pain and swelling. Therapy should progress to strengthening and an independent home exercise program targeted to further improve ROM, strength, and normal joint mechanics influenced by distal and proximal structures. Refer to Therapeutic Procedures, Non-operative.

(i). Passive modalities are most effective as adjunctive treatments to improve the results of active treatment. They may be used as found in Therapeutic Procedures, Non-operative.

(e). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(f). Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

vi. Surgical Indications/Considerations: If compartmental pressures are elevated, emergent fasciotomy is warranted.

(a). Smoking may affect soft tissue healing through tissue hypoxia. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician.

vii. Operative Procedures: Emergency fasciotomy. In some cases a delayed primary closure is necessary.

viii. Post-operative Treatment

(a). An individualized rehabilitation program based upon communication between the surgeon and the therapist and using therapies as outlined in Section F, Therapeutic Procedures, Non-operative.

(b). Treatment may include the following: elevation, restricted weight-bearing, active therapy with or without passive therapy.

(c). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

o. Stress Fracture

i. Description/Definition: Fracture without displacement usually to metatarsals, talus, navicular or calcaneus.

ii. Occupational Relationship: May be related to repetitive, high impact walking; running; or jumping.

iii.Specific Physical Exam Findings: Pain over the affected bone with palpation or weight-bearing.

iv. Diagnostic Testing Procedures: X-ray, CT, MRI, bone scan

v. Non-Operative Treatment Procedures

(a). Initial Treatment: Immobilization for four to eight weeks with limited weight-bearing may be appropriate.

(b). Medications such as analgesics and anti-inflammatories may be helpful. Refer to medication discussions in Medications and Medical Management.

(c). Patient education should include instruction in self-management techniques, ergonomics, body mechanics, home exercise, joint protection, and weight management.

(d). Refer to comments related to osteoporosis in Therapeutic Procedures, Non-operative, Osteoporosis Management.

(e). Smoking may affect fracture healing. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician.

(f). There is some evidence that shock absorbing boot inserts may decrease the incidence of stress fractures in military training. Shock absorbing boot inserts of other orthotics may be used in some cases after a stress fracture has occurred or to prevent stress fractures in appropriate work settings.

(g). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(h). Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

vi. Surgical Indications/Considerations: Fractures that have not responded to conservative therapy.

(a). Because smokers have a higher risk of non-union and post-operative costs, it is recommended that insurers cover a smoking cessation program peri-operatively. Physicians may monitor smoking cessation with laboratory tests such as cotinine levels for long-term cessation.

vii. Operative Procedures: Most commonly percutaneous screws or plate fixation.

viii. Post-operative Treatment

(a). An individualized rehabilitation program based upon communication between the surgeon and the therapist and using therapies as outlined in Section F, Therapeutic Procedures, Non-operative. In all cases, communication between the physician and therapist is important to the timing of weight-bearing and exercise progressions.

(b). Treatment may include the following: restricted weight-bearing, bracing, active therapy with or without passive therapy.

(c). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

p. Talar Fracture

i. Description/Definition: Osseous fragmentation of talus confirmed by radiographic, CT or MRI evaluation.

ii. Occupational Relationship: Usually occurs from a fall or crush injury.

iii. Specific Physical Exam Findings: Clinical findings consistent with fracture of talus: pain with range of motion, palpation, swelling, ecchymosis. Pain with weight-bearing attempt.

iv. Diagnostic Testing Procedures: Radiographs, CT scans, MRI. CT scans preferred for spatial alignment.

v. Non-Operative Treatment Procedures

(a). Initial Treatment: Non weight-bearing for six to eight weeks for non-displaced fractures.

(b). Medications such as analgesics and anti-inflammatories may be helpful. Refer to medication discussions in Medications and Medical Management.

(c). Patient education should include instruction in self-management techniques, ergonomics, body mechanics, home exercise, joint protection, and weight management.

(d). Refer to comments related to osteoporosis in Therapeutic Procedures, Non-operative, Osteoporosis Management.

(e). Smoking may affect fracture healing. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician.

(f). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(g). Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

vi. Surgical Indications/Considerations: Osseous displacement, joint involvement and instability.

(a). Because smokers have a higher risk of non-union and post-operative costs, it is recommended that carriers cover a smoking cessation program peri-operatively. Physicians may monitor smoking cessation with laboratory tests such as cotinine levels for long-term cessation.

vii. Operative Procedures: Open reduction internal fixation.

viii. Post-operative Treatment

(a). An individualized rehabilitation program based upon communication between the surgeon and the therapist and using therapies as outlined in Therapeutic Procedures, Non-operative. In all cases, communication between the physician and therapist is important to the timing of weight-bearing and exercise progressions.

(b). Treatment may include the following: Non weight-bearing six to eight weeks followed by weight-bearing cast. MRI follow-up if avascular necrosis is suspected. Active therapy with or without passive therapy.

(c). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

q. Tarsal Tunnel Syndrome

i. Description: Pain and paresthesias along the medial aspect of the ankle and foot due to nerve irritation and entrapment of the tibial nerve or its branches. These symptoms can also be caused by radiculopathy.

ii. Occupational Relationship: Acute injuries may occur after blunt trauma along the medial aspect of the foot. Non-traumatic occurrences are determined at physician's discretion after review of environmental and biomechanical risk factors. Non work related causes include space occupying lesions.

iii. Specific Physical Exam Findings: Positive Tinel's sign. Pain with percussion of the tibial nerve

radiating distally or proximally. Pain and paresthesias with weight-bearing activities.

iv. Diagnostic Testing Procedures: Nerve conduction velocity studies of both sides for comparison to normal side. EMGs may be needed to rule out radiculopathy. MRI to rule out space occupying lesions. Diagnostic injections to confirm the diagnosis.

v. Non-operative Treatment Procedures:

(a). Initial Treatment: Cast or bracing, immobilization and foot orthoses are appropriate initial management.

(b). Medications such as analgesics and anti-inflammatories may be helpful. Refer to medication discussions in Medications and Medical Management.

(c). Patient education should include instruction in self-management techniques, ergonomics, body mechanics, home exercise, joint protection, and weight management.

(d). Return to work with appropriate restrictions should be considered early in the course of treatment.

(i). Orthotics or accommodative footwear is usually necessary before workers can be returned to walking on hard surfaces. Refer to Return to Work.

(e). Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

vi. Surgical Indications/Considerations

(a). Continued functional deficits after active participation in therapy for three to six months.

(b). Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities and the patient should agree to comply with the pre- and post-operative treatment plan including home exercise. The provider should be especially careful to make sure the patient understands the amount of post-operative therapy required and the length of partial- and full-disability expected post-operatively.

(c). Smoking may affect soft tissue healing through tissue hypoxia. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician.

vii. Operative Procedures: Tarsal tunnel release with or without a plantar fascial release.

viii. Post-operative Treatment:

(a). An individualized rehabilitation program based upon communication between the surgeon and the therapist and using therapies as outlined in Therapeutic Procedures, Non-Operative.

(b). Treatment may include the following: restricted weight-bearing, orthotics, bracing, active therapy with or without passive therapy.

(c). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

r. Tendonopathy: For Achilles Tendonopathy, Refer to Specific Lower Extremity Injury Diagnosis, Testing and Treatment for other types of tendonopathy of the foot and ankle, General recommendations can be found in Tendonopathy of the Knee.

2. Knee

a. Aggravated Osteoarthritis

i. Description/Definition: Swelling and/or pain in a joint due to an aggravating activity in a patient with pre-existing degenerative change in a joint. Age greater than 50 and morning stiffness lasting less than 30 minutes are frequently associated. The lifetime risk for symptomatic knee arthritis is probably around 45 percent and is higher among obese persons.

ii. Occupational Relationship: The provider must establish the occupational relationship by establishing a change in the patient's baseline condition and a relationship to work activities including but not limited to physical activities such as repetitive kneeling or crawling, squatting and climbing, or heavy lifting.

(a). Other causative factors to consider - Previous meniscus or ACL damage may predispose a joint to degenerative changes. In order to entertain previous trauma as a cause, the patient should have medical documentation of the following: menisectomy; hemarthrosis at the time of the original injury; or evidence of MRI or arthroscopic meniscus or ACL damage. The prior injury should have been at least two years from the presentation for the new complaints and there should be a significant increase of pathology on the affected side in comparison to the original imaging or operative reports and/or the opposite un-injured side or extremity.

(b). Body mass index (BMI) of 25 or greater is a significant risk factor for eventual knee replacement.

iii. Specific Physical Exam Findings: Increased pain and/or swelling in a joint with joint line tenderness; joint crepitus; and/or joint deformity.

iv. Diagnostic Testing Procedures: Radiographs, The Kellgren-Lawrence Scale is the standard radiographic scale for knee osteoarthritis. It is based on the development of osteophytes, on bone sclerosis, and on joint space narrowing. The degree of joint space narrowing may not predict disability.

(a). Grade 1: doubtful narrowing of joint space, and possible osteophytic lipping.

(b). Grade 2: definite osteophytes, definite narrowing of joint space.

(c). Grade 3: moderate multiple osteophytes, definite narrowing of joint space, some sclerosis and possible deformity of bone contour.

(d). Grade 4: large osteophytes, marked narrowing of joint space, severe sclerosis and definite deformity of bone contour.

(e). MRI to rule out degenerative menisci tears. MRI may identify bone marrow lesions which are correlated with knee pain. These lesions may reflect increased water, blood, or other fluid inside bone and may contribute to the causal pathway of pain. These are incidental findings and should not be used to determine a final diagnosis nor make decisions regarding surgery.

v. Non-Operative Treatment Procedures

(a). Medications such as analgesics and anti-inflammatories may be helpful. Refer to medication discussions in Medications and Medical Management.

(b). Patient education should include instruction in self-management techniques, ergonomics, body mechanics, home exercise, joint protection, and weight management. There is good evidence for self-management

using weight loss, exercise, pacing of activities, unloading the joint with braces, insoles and possibly taping, and medications as needed. Patients should be encouraged to perform aerobic activity such as walking or biking. However, activities such as ladders, stairs and kneeling may be restricted.

(c). Benefits may be achieved through therapeutic rehabilitation and rehabilitation interventions. They should include range-of-motion (ROM), active therapies, and a home exercise program. Active therapies include, proprioception training, restoring normal joint mechanics, and clearing dysfunctions from distal to proximal structures. Passive as well as active therapies may be used for control of pain and swelling. Therapy should progress to strengthening and an independent home exercise program targeted to further improve ROM, strength, and normal joint mechanics influenced by structures distal and proximal to the knee. Bracing may be appropriate in some instances. Refer to Therapeutic Procedures, Non-operative. There is good evidence that there is a small functional advantage for patients involved in exercise with physical therapy supervision over home exercise.

(i). There is some evidence that active physical therapy improves knee function more effectively than medication alone.

(ii). Aquatic therapy may be used as a type of active intervention when land-based therapy is not well-tolerated.

(iii). Passive modalities are most effective as adjunctive treatments to improve the results of active treatment. They may be used as found in Therapeutic Procedures, Non-operative. There is some evidence that ice massage can improve ROM, strengthening of the knee and function. Ice can be used with proper instruction at home or under supervision for up to 20 minute periods 3 times per week or more frequently.

(d). Therapeutic Injections—both steroids and viscosupplementation may be used.

(i). There is good evidence that intra-articular corticosteroid injection is more effective than placebo in reducing pain from osteoarthritis. Optimum dosage is not known.

(ii). Steroid injections may decrease inflammation and allow the therapist to progress with functional exercise and ROM.

[a]. Time to Produce Effect: One injection.

[b]. Maximum Duration: Three injections in one year at least four to eight weeks apart.

(iii). Steroid injections should be used cautiously in diabetic patients. Diabetic patients should be reminded to check their blood glucose levels at least daily for two weeks after injections.

(iv). Viscosupplementation appears to have a longer lasting effect than intra-articular corticosteroids, however, the overall effect varies depending on the timing and the effect studied. Refer to Therapeutic Procedures.

(e). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(f). Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

(g). Bracing such as knee immobilizer or hinge brace may be used for acute ACL injuries.

vi. Surgical Indications/Considerations.

(a). Arthroscopic Debridement and/or Lavage. There is good evidence from a randomized controlled trial that arthroscopic debridement alone provides no benefit over recommended therapy for patients with uncomplicated Grade 2 or higher arthritis. The comparison recommended treatment in the study followed the American College of Rheumatology guidelines which includes: patient education, and supervised therapy with a home program, instruction on ADLs, stepwise use of analgesics and hyaluronic acid injections if desired. Complicated arthritic patients excluded from the study included patients who required other forms of intervention due to the following associated conditions: large meniscal bucket handle tears, inflammatory or infectious arthritis, more than 5 degrees of varus or valgus deformity, previous major knee trauma, or Grade 4 arthritis in two or more compartments.

(i). Therefore, arthroscopic debridement and/or lavage are not recommended for patients with arthritic findings and continual pain and functional deficits unless there is meniscal or cruciate pathology. Refer to the specific conditions in Specific Lower Extremity Injury Diagnosis, Testing and Treatment, for specific diagnostic recommendations.

(b). Osteotomy and joint replacement are indicated when conservative treatment, including active participation in non-operative treatment has failed to result in sufficient functional improvement (Refer to Knee Arthroplasty, and Osteotomy). Tibial osteotomy is a choice for younger patients with unicompartmental disease who have failed conservative therapy.

(c). In cases where surgery is contraindicated due to obesity, it may be appropriate to recommend a weight loss program if the patient is unsuccessful losing weight on their own. Coverage for weight loss would continue only for motivated patients who have demonstrated continual progress with weight loss.

(d). Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities and the patient should agree to comply with the pre- and post-operative treatment plan including home exercise. The provider should be especially careful to make sure the patient understands the amount of post-operative therapy required and the length of partial- and full-disability expected post-operatively.

(e). Because smokers have a higher risk of non-union and post-operative costs, it is recommended that carriers cover a smoking cessation program peri-operatively. Physicians may monitor smoking cessation with laboratory tests such as cotinine levels for long-term cessation.

vii. Operative Procedures: Total or compartmental joint replacement, and osteotomy.

(a). Free-floating interpositional unicompartmental replacement is not recommended for any patients due to high revision rate at two years and less than optimal pain relief.

viii. Post-Operative Treatment

(a). An individualized rehabilitation program based upon communication between the surgeon and

therapist and using the treatments found in Therapeutic Procedures, Non-operative. In all cases, communication between the physician and therapist is important to the timing of weight-bearing and exercise progressions.

(b). Refer also to Knee Arthroplasty, or Osteotomy as appropriate.

(c). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

b. Anterior Cruciate Ligament (ACL) Injury

i. Description/Definition: Rupture or partial rupture of the anterior cruciate ligament; may be associated with other internal derangement of the knee.

ii. Occupational Relationship: May be caused by virtually any traumatic force to the knee but most often caused by a twisting or a hyperextension force, with a valgus stress. The foot is usually planted and the patient frequently experiences a "popping" feeling.

iii. Specific Physical Exam Findings: Findings on physical exam include effusion or hemarthrosis, instability, positive Lachman's test, positive pivot shift test, and positive anterior drawer test.

iv. Diagnostic Testing Procedures: MRI. Radiographs may show avulsed portion of tibial spine but this is a rare finding.

v. Non-operative Treatment Procedures:

(a). Initial Treatment: Acute injuries may require immobilization followed by active therapy with or without passive therapy.

(b). Medications such as analgesics and anti-inflammatories may be helpful. Refer to Medications and Medical Management.

(c). Patient education should include instruction in self-management techniques, ergonomics, body mechanics, home exercise, joint protection, and weight management.

(d). Benefits may be achieved through therapeutic rehabilitation and rehabilitation interventions. They should include range-of-motion (ROM), active therapies, and a home exercise program. Active therapies include proprioception training, restoring normal joint mechanics, and clearing dysfunctions from distal and proximal structures bracing may be beneficial. Passive as well as active therapies may be used for control of pain and swelling. Therapy should progress to strengthening and an independent home exercise program targeted to further improve ROM, strength, and normal joint mechanics influenced by structures distal and proximal to the knee (Refer to Therapeutic Procedures, Non-operative). Passive modalities are most effective as adjunctive treatments to improve the results of active treatment. They may be used as found in Therapeutic Procedures, Non-operative.

(i). There is no evidence that any particular exercise regime is better for ACL injuries in combination with collateral or meniscus injuries. There is no evidence that knee bracing for non operated ACL improves outcomes although patients may feel that they have greater stability. Non surgical treatment may provide acceptable results in some patients.

(e). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(f). Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

iv. Surgical Indications/Considerations: any individual with complaints of recurrent instability interfering with function and physical findings with imaging consistent with an ACL injury.

(a). Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities and the patient should agree to comply with the pre- and post-operative treatment plan including home exercise. The provider should be especially careful to make sure the patient understands the amount of post-operative therapy required and the length of partial- and full-disability expected post-operatively.

(b). Smoking may affect soft tissue healing through tissue hypoxia. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician.

v. Operative Procedures

(a). Diagnostic/surgical arthroscopy followed by ACL reconstruction using autograft or allograft. If meniscus repair is performed, an ACL repair should be performed concurrently.

(b). Patients tend to have more pain associated with patellar grafts while patients with hamstring replacement seem to have an easier rehabilitation. Choice of graft is made by the surgeon and patient on an individual basis.

vi. Post-Operative Treatment

(a). An individualized rehabilitation program based upon communication between the surgeon and the therapist and using therapies as outlined in Therapeutic Procedures, Non-operative.

(b). Treatment may include the following: active therapy with or without passive therapy and bracing. Early active extension does not cause increased laxity at two years.

(c). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

c. Bursitis of the Lower Extremity

i. Description/Definition: Inflammation of bursa tissue. Bursitis can be precipitated by tendonitis, bone spurs, foreign bodies, gout, arthritis, muscle tears, or infection.

ii. Occupational Relationship: Soft tissue trauma, contusion, or physical activities of the job such as sustained direct compression force, or other repetitive forceful activities affecting the knee.

iii. Specific Physical Exam Findings: Palpable, tender and enlarged bursa, decreased ROM, warmth. The patient may have increased pain with ROM.

iv. Diagnostic Testing Procedures: Lab work may be done to rule out inflammatory disease. Bursal fluid aspiration with testing for connective tissue, rheumatic disease, and infection may be necessary. Radiographs, CT, MRI are rarely indicated.

v. Non-operative Treatment Procedures

(a). Initial Treatment: Diagnostic/therapeutic aspiration, ice, therapeutic injection, treatment of an underlying infection, if present. Aspirations may be repeated as clinically indicated.

(b). Medications such as analgesics and anti-inflammatories may be helpful. Refer to medication discussions in Medications and Medical Management.

(c). Patient education should include instruction in self-management techniques, ergonomics, body mechanics, home exercise, joint protection, and weight management.

(d). Benefits may be achieved through therapeutic rehabilitation and rehabilitation interventions. They should include range-of-motion (ROM), active therapies, including a home exercise program. Active therapies include, proprioception training, restoring normal joint mechanics, and clearing dysfunctions from distal and proximal joints. Passive as well as active therapies may be used for control of pain and swelling. Therapy should progress to strengthening and an independent home exercise program targeted to further improve ROM, strength, and normal joint mechanics influenced by structures distal and proximal to the knee. Refer to Therapeutic Procedures, Non-operative.

(i). Passive modalities are most effective as adjunctive treatments to improve the results of active treatment. They may be used as found as adjunctive in Therapeutic Procedures, Non-operative.

(e). Steroid Injections. Steroid injections may decrease inflammation and allow the therapist to progress with functional exercise and ROM.

(i). Time to Produce Effect: One injection.

(ii). Maximum Duration: Three injections in one year spaced at least four to eight weeks apart.

(iii). Steroid injections should be used cautiously in diabetic patients. Diabetic patients should be reminded to check their blood glucose levels at least daily for two weeks after injections.

(f). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(g). Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

vi. Surgical indications/Considerations:

(a). Failure of conservative therapy.

(b). Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities and the patient should agree to comply with the pre- and post-operative treatment plan including home exercise. The provider should be especially careful to make sure the patient understands the amount of post-operative therapy required and the length of partial- and full-disability expected post-operatively.

(c). Smoking may affect soft tissue healing through tissue hypoxia. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician.

vii. Operative Procedures: Surgical excision of the bursa.

viii. Post-operative Treatment

(a). An individualized rehabilitation program based upon communication between the surgeon and the therapist and using the therapies as outlined in Therapeutic Procedures, Non-operative.

(b). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

d. Chondral and Osteochondral Defects

i. Description/Definition: Cartilage or cartilage and bone defect at the articular surface of a joint. Deficits may be identified in up to 60 percent of arthroscopies; however, only around 30 percent of these lesions are isolated deficits and even fewer are Grade III or IV deficits which might qualify for cartilage grafts.

(a). Defects in cartilage and bone are common at the femoral condyles and patella. The Outerbridge classification grades these defects according to their size and depth.

(i). Grade 0: normal cartilage.

(ii). Grade I: softening and swelling of cartilage.

(iii). Grade II: partial-thickness defects with surface fissures that do not exceed 1.5 cm in diameter and do not reaiih subchondral bone.

(iv). Grade III: fissuring that reaches subchondral bone in an area with a diameter greater than 1.5 cm.

(v). Grade IV: exposed subchondral bone.

ii. Occupational Relationship: Typically caused by a traumatic knee injury. Chondral deficits can also be present secondary to osteoarthritis.

iii. Specific Physical Exam Findings: Knee effusion, joint line tenderness.

iv. Diagnostic Testing Procedures: MRI may show bone bruising, osteochondral lesion, or possibly articular cartilage injury. Radiographs, contrast radiography, CT may also be used. Diagnostic arthroscopy may be performed when surgical indications as stated in Section VI are met.

v. Non-Operative Treatment Procedures:

(a). Initial Treatment: Non-operative treatment may be indicated for chondral lesions associated with degenerative changes, refer to aggravated osteoarthritis; other knee lesions not requiring surgery (refer to Specific Diagnosis); and/or non-displaced stable lesions. Acute injuries may require immobilization followed by active therapy with or without passive therapy.

(b). Medications such as analgesics and anti-inflammatories may be helpful. Refer to medication discussions in Medications and Medical Management.

(c). Patient education should include instruction in self-management techniques, ergonomics, body mechanics, home exercise, joint protection, and weight management.

(d). Benefits may be achieved through therapeutic rehabilitation and rehabilitation interventions. They should include range-of-motion (ROM), active therapies, and a home exercise program. Active therapies include, proprioception training, restoring normal joint mechanics, and clearing dysfunctions from distal and proximal structures. Passive as well as active therapies may be used for control of pain and swelling. Therapy should

progress to strengthening and an independent home exercise program targeted to further improve ROM, strength, and normal joint mechanics influenced by structures distal and proximal to the knee. Refer to Therapeutic Procedures, Non-operative.

(i). Passive modalities are most effective as adjunctive treatments to improve the results of active treatment. They may be used as found in Therapeutic Procedures, Non-operative.

(e). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(f). Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

vi. Surgical Indications/Considerations: Surgery for isolated chondral defects may be indicated when functional deficits interfere with activities of daily living and/or job duties after 6 to 12 weeks of active patient participation in non-operative therapy. Identification of the lesion should have been accomplished by diagnostic testing procedures which describe the size of the lesion and stability of the joint. If a lesion is detached or has fluid underlying the bone on MRI, surgery may be necessary before a trial of conservative therapy is completed. Early surgery may consist of fixation or microfracture.

(a). Microfractures: Normally the first line of surgical treatment.

(i). Indications: An isolated small full-thickness articular chondral defect with normal joint space, when the patient has not recovered functionally after active participation in therapy. Patients 45 or younger are likely to have better results.

(b). Osteochondral Autograft Transfer System (OATS)

(i). Indications: The knee must be stable with intact ligaments and menisci, normal joint space and a large full-thickness defect less than 3 square cm and 1 cm depth. They should be 45 or younger, with a BMI less than 35, and engaged in athletics and/or an equally physically demanding occupation. Surgery may be indicated when functional deficits interfere with activities of daily living and/or job duties after 6 to 12 weeks of active patient participation in non-operative therapy. This procedure may be appropriate in a small subset of patients and requires prior authorization.

(c). Autologous chondrocyte implantation (ACI): These procedures are technically difficult and require specific physician expertise. Cartilage transplantation requires the harvesting and growth of patients' cartilage cells in a highly specialized lab and incurs significant laboratory charges. There is some evidence that transplants and microfractures do not differ on long-term effects. There is some evidence that autologous chrondrocyte implantation is not better than microfracture five years after surgery in patients younger than 45 presenting with Grade III -IV lesions. This procedure is controversial but may be appropriate in a small subset of patients with physically rigorous employment or recreational activities. It requires prior authorization.

(i). Indications: The area of the lesion should be between 2 square cm and 10 square cm. The patient should have failed four or more months of active participation in therapy and a microfracture, abrasion, arthroplasty or drilling with sufficient healing time, which may be from four months to over one year. The knee must be stable with intact ligaments and meniscus, and normal joint space. Patients should be 45 or younger, with a BMI less than 35, and engaged in athletics and/or an equally physically demanding occupation.

(d). Contraindications: General contraindications for grafts and transplants are individuals with obesity, inflammatory or osteoarthritis with multiple chondral defects, associated ligamentous or meniscus pathology, or who are older than 55 years of age.

(e). Prior to either graft or implantation intervention the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities and the patient should agree to comply with the pre- and post-operative treatment plan including home exercise. The provider should be especially careful to make sure the patient understands the amount of post-operative therapy required and the length of partial- and full-disability expected post-operatively.

(f). Smoking may affect soft tissue healing through tissue hypoxia. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician.

vii. Operative Procedures: Arthroscopy with debridement or shaving of cartilage, microfracture, drilling, abrasion arthroplasty, mosiacplasty or osteochondral autograft (OATS), fixation of loose osteochondral fragments and autologous chondrocyte implantation (ACI).

(a). Radiofrequency treatment is not recommended.

viii. Post-Operative Treatment

(a). An individualized rehabilitation program based upon communication between the surgeon and the therapist and using therapies as outlined in Therapeutic Procedures, Non-operative. In all cases, communication between the physician and therapist is important to the timing of weight-bearing and exercise progressions.

(b). Treatment may include the following: restricted weight-bearing, bracing, active therapy with or without passive therapy. Full weight-bearing usually occurs by or before 8 weeks.

(c). Continuous passive motion may be used after chondral procedures.

(d). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon. Return to full-duty usually occurs by between four and six months.

(e). Collateral Ligament Pathology

(i). Description/Definition: Strain or tear of medial or lateral collateral ligaments which provide some stabilization for the knee.

(ii). Occupational Relationship: Typically a result of forced abduction and external rotation to an extended or slightly flexed knee.

(iii). Specific Physical Exam Findings: Swelling or ecchymosis over the collateral ligaments and increased laxity or pain with applied stress.

(iv). Diagnostic Testing Procedures: X-rays to rule out fracture. Imaging is more commonly ordered when internal derangement is suspected.

(v). Non-Operative Treatment Procedures

[a]. Initial Treatment: braces, ice, and protected weight-bearing.

[b]. Medications such as analgesics and anti-inflammatories may be helpful. Refer to medication discussions area in Medications and Medical Management.

[c]. Patient education should include instruction in self-management techniques, ergonomics, body mechanics, home exercise, joint protection, and weight management.

[d]. Benefits may be achieved through therapeutic rehabilitation and rehabilitation interventions. They should include range-of-motion (ROM), active therapies, and a home exercise program. Active therapies include proprioception training, restoring normal joint mechanics, and clearing dysfunctions from distal and proximal structures. Bracing may be beneficial. Passive as well as active therapies may be used for control of pain and swelling. Therapy should progress to strengthening and an independent home exercise program targeted to further improve ROM, strength, and normal joint mechanics influenced by structures distal and proximal to the knee. Refer to Therapeutic Procedures, Non-operative.

[i]. Passive modalities are most effective as adjunctive treatments to improve the results of active treatment. They may be used as found in Therapeutic Procedures, Non-operative.

[e]. Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

[f]. Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

vi. Surgical Indications/Considerations: Surgery is rarely necessary except when functional instability persists after active participation in non-operative treatment or indications for surgery exist due to other accompanying injuries.

(a). Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities and the patient should agree to comply with the pre- and post-operative treatment plan including home exercise. The provider should be especially careful to make sure the patient understands the amount of post-operative therapy required and the length of partial- and full-disability expected post-operatively.

(b). Smoking may affect soft tissue healing through tissue hypoxia. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician.

vii. Operative Procedures: Surgical repair.

viii. Post-operative Treatment

(a). An individualized rehabilitation program based upon communication between the surgeon and the therapist and using procedures as outlined in Therapeutic Procedures, Non-Operative.

(b). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

f. Meniscus Injury

i. Description/Definition—a tear, disruption, or avulsion of medial or lateral meniscus tissue. Locking of the knee or clicking is frequently reported. Patients may describe a popping, tearing, or catching sensation followed by stiffness.

ii. Occupational Relationship—trauma to the menisci from rotational shearing, torsion, and/or impact injuries while in a flexed position.

iii. Specific Physical Exam Findings: Joint line tenderness, Positive McMurray's test locked joint, or occasionally, effusion. The presence of joint line tenderness has a sensitivity of 85 percent and a specificity of 31 percent. The Apley's compression test is also used.

iv. Diagnostic Testing Procedures. Radiographs including standing Posterior/Anterior (PA), lateral, tunnel, and skyline views. MRI is the definitive imaging test. MRI is sensitive and specific for meniscal tear. However, meniscal MRI is frequently abnormal in asymptomatic injuries. In one study of volunteers without a history of knee pain, swelling, locking, giving way, or any knee injury, 16 percent of the volunteers had MRI-evident meniscal tears; among volunteers older than 45, 36 percent had MRI-evident meniscal tears. Therefore, clinical correlation with history and physical exam findings specific for meniscus injury is critically important.

(a). Providers planning treatment should therefore consider the patient's complaints and presence of arthritis on MRI carefully, knowing that not all meniscus tears in the middle aged and older population are related to the patients' complaints of pain.

(b). MRI arthrograms are used to diagnose recurrent meniscal tears particularly after previous surgery.

v. Non-operative Treatment

(a). Initial Treatment: ice, bracing, and protected weight-bearing.

(b). Medications such as analgesics and anti-inflammatories may be helpful. Refer to medication discussions in Medications and Medical Management.

(c). Patient education should include instruction in self-management techniques, ergonomics, body mechanics, home exercise, joint protection, and weight management.

(d). Benefits may be achieved through therapeutic rehabilitation and rehabilitation interventions. They should include range-of-motion (ROM), active therapies, and a home exercise program. Active therapies include, proprioception training, restoring normal joint mechanics, and clearing dysfunctions from distal and proximal structures. Passive as well as active therapies may be used for control of pain and swelling. Therapy should progress to strengthening and an independent home exercise program targeted to further improve ROM, strength, and normal joint mechanics influenced by structures distal and proximal to the knee. Refer to Therapeutic Procedures, Non-operative.

(i). Passive modalities are most effective as adjunctive treatments to improve the results of active treatment. They may be used as found as adjunctive in Therapeutic Procedures, Non-Operative.

(e). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(f). Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

vi. Surgical Indications/Considerations: Locked or blocked knee precluding active therapy; Isolated acute meniscus tear with appropriate physical exam findings; Meniscus pathology combined with osteoarthritis in a patient with functional deficits interfering with activities of daily living and/or job duties after 6 to 12 weeks of active patient participation in non-operative therapy.

(a). It is not clear that partial meniscectomy for a chronic degenerative meniscal tear is beneficial. Middle aged patients may do as well without arthroscopy and with therapy.

(b). Meniscal allograft should only be performed on patients between 20 and 45 with an otherwise stable knee, previous meniscectomy with 2/3 removed, lack of function despite active therapy, BMI less than 35, and sufficient joint surface to support repair.

(c). Medial collagen meniscus implants are considered experimental and not generally recommended. No studies have been done to compare this procedure to medial meniscus repair. There is some evidence to support the fact that collagen meniscal implant may slightly improve function and decrease risk of reoperation in patients with previous medial meniscal surgery. It remains unclear as to the extent that the procedure may decrease future degenerative disease. The procedure can only be considered for individuals with previous medial meniscal surgery and intact meniscus rim; without lateral meniscus lesions or Grade 4 Outerbridge lesions; and who need to return to heavy physical labor employment or demanding recreational activities. A second concurring opinion from an orthopedic surgeon specializing in knee surgery and prior authorization is required. Full weight-bearing is not allowed for 6 weeks and most patients return to normal daily activity after three months.

(d). Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities and the patient should agree to comply with the pre- and post-operative treatment plan including home exercise. The provider should be especially careful to make sure the patient understands the amount of post-operative therapy required and the length of partial- and full-disability expected post-operatively.

(e). Smoking may affect soft tissue healing through tissue hypoxia. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician.

vii. Operative Treatment: Repair of meniscus, partial or complete excision of meniscus or meniscus allograft or implant. Debridement of the meniscus is not recommended in patients with severe arthritis as it is unlikely to alleviate symptoms. Complete excision of meniscus should only be performed when clearly indicated due to the long-term risk of arthritis in these patients. Partial meniscectomy or meniscus repair is preferred to total meniscectomy due to easier recovery, less instability, and short-term functional gains.

viii. Post-operative Treatment

(a). An individualized rehabilitation program based upon communication between the surgeon and the therapist using the treatments found in Therapeutic Procedures, Non-operative.

(b). Treatment may include the following: Passive therapy progressively moving toward active therapy, bracing, cryotherapy and other treatments found in Therapeutic procedures Non-Operative.

(c). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

g. Patellar Fracture

i. Description/Definition: Fracture of the patella.

ii. Occupational Relationship: Usually from a traumatic injury such as a fall or direct blow

iii. Specific Physical Exam Findings: Significant hemarthrosis/effusion usually present. Extension may be limited and may indicate disruption of the extensor mechanism. It is essential to rule out open fractures; therefore a thorough search for lacerations is important.

iv. Diagnostic Testing Procedures. Aspiration of the joint and injection of local anesthetic may aid the diagnosis. A saline load injected in the joint can also help rule out an open joint injury. Radiographs may be performed, including tangential (sunrise) or axial views and x-ray of the opposite knee in many cases. CT or MRI is rarely needed.

v. Non-Operative Treatment Procedures

(a). Initial Treatment: For non-displaced closed fractures, protected weight-bearing and splinting for four to six weeks. Hinged knee braces can be used. When radiographs demonstrate consolidation, active motion and strengthening exercise may begin.

(b). Medications such as analgesics and anti-inflammatories may be helpful. Refer to medication discussions in Medications and Medical Management.

(c). Patient education should include instruction in self-management techniques, ergonomics, body mechanics, home exercise, joint protection, and weight management.

(d). Refer to comments related to osteoporosis in Therapeutic Procedures, Non-operative, Osteoporosis Management.

(e). Smoking may affect fracture healing. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician.

(f). Benefits may be achieved through therapeutic rehabilitation and rehabilitation interventions, after boney union has been achieved. They should include bracing then range-of-motion (ROM), active therapies including proprioception training, restoring normal joint mechanics, and clearing dysfunctions from adjacent structures, and a home exercise program. Passive as well as active therapies may be used for control of pain and swelling. Therapy should progress to strengthening and an independent home exercise program targeted to further improve ROM, strength, restoring normal joint mechanics, influenced by proximal and distal structures. Therapy should include training on the use of adaptive equipment and home and work site evaluations when appropriate. Bracing may be

appropriate. Refer to Therapeutic Procedures, Non-operative.

(i). Passive modalities are most effective as adjunctive treatments to improve the results of active treatment. They may be used as found as adjunctive in Therapeutic Procedures, Non-operative.

(h). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(i). Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

vi. Surgical Indications/Considerations: Open fractures require immediate intervention and may need repeat debridement. Internal fixation is usually required for comminuted or displaced fractures. Non-union may also require surgery.

(a). Because smokers have a higher risk of non-union and post-operative costs, it is recommended that insurers cover a smoking cessation program peri-operatively. Physicians may monitor smoking cessation with laboratory tests such as cotinine levels for long-term cessation.

vii. Operative Procedures: internal fixation; partial patellectomy or total patellectomy. Total patellectomy results in instability with running or stairs and significant loss of extensor strength. Therefore, this is usually a salvage procedure.

viii. Post-Operative Treatment

(a). An individualized rehabilitation program based upon communication between the surgeon and the therapist and using therapies as outlined in Therapeutic Procedures, Non-operative. In all cases, communication between the physician and therapist is important to the timing of weight-bearing and exercise progressions. Continuous passive motion may be used post operatively.

(b). Treatment may include protected weight-bearing and active therapy with or without passive therapy for early range of motion if joint involvement.

(c). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

(d). Hardware removal may be necessary after three to six months.

h. Patellar Subluxation:

i. Description/Definition: Incomplete subluxation or dislocation of the patella. Recurrent episodes can lead to subluxation syndrome that can cause frank dislocation of the patella. Patient may report a buckling sensation, pain with extension, or a locking of the knee with exertion.

ii. Occupational Relationship: Primarily associated with a direct contact lateral force. Secondary causes associated with shearing forces on the patella.

iii. Specific Physical Exam Findings: Lateral retinacular tightness with associated medial retinacular weakness, swelling, effusion, and marked pain with patellofemoral tracking/compression and glides. In addition, other findings may include atrophy of muscles, positive patellar apprehension test, and patella alta.

iv. Diagnostic Testing Procedures: CT or Radiographs including Merchant views, Q-angle, and MRI for loose bodies.

v. Non-Operative Treatment Procedures

(a). Initial Treatment: Reduction if necessary, ice, taping, and bracing followed by active therapy.

(b). Medications such as analgesics and anti-inflammatories may be helpful. Refer to medication discussions in Medications and Medical Management.

(c). Patient education should include instruction in self-management techniques, ergonomics, body mechanics, home exercise, joint protection, and weight management.

(d). Benefits may be achieved through therapeutic rehabilitation and rehabilitation interventions. They should include range-of-motion (ROM), active therapies, and a home exercise program. Active therapies include, proprioception training, restoring normal joint mechanics, and clearing dysfunctions from distal and proximal structures. Taping the patella or bracing may be beneficial. Passive as well as active therapies can be used for control of pain and swelling. Therapy should progress to strengthening and an independent home exercise program targeted to further improve ROM, strength, and normal joint mechanics influenced by structures distal and proximal to the knee. Specific strengthening should be done to optimize patellofemoral mechanics and address distal foot mechanics that influence the patellofemoral joint. Refer to Therapeutic Procedures, Non-operative.

(i). Passive modalities are most effective as adjunctive treatments to improve the results of active treatment. They may be used as found in Therapeutic Procedures, Non-operative.

(e). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(f). Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

vi. Surgical Indications/Considerations

(a). Fracture, loose bodies, and recurrent dislocation. Surgical repair of first-time dislocation in young adults generally is not recommended. Retinacular release, quadriceps reefing, and patellar tendon transfer should only be considered for subluxation after four to six months of active patient participation in non-operative treatment.

(b). Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities and the patient should agree to comply with the pre- and post-operative treatment plan including home exercise. The provider should be especially careful to make sure the patient understands the amount of post-operative therapy required and the length of partial- and full-disability expected post-operatively.

(c). Smoking may affect soft tissue healing through tissue hypoxia. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician.

vii. Operative Procedures: arthroscopy with possible arthrotomy; debridement of soft tissue and articular cartilage disruption; open reduction internal fixation with fracture; retinacular release, quadriceps reefing, and patellar tendon or lateral release with or without medial soft-tissue realignment.

viii. Post-operative Treatment

(a). Individualized rehabilitation program based upon communication between the surgeon and the therapist using the treatments found in Therapeutic Procedures, Non-operative.

(b). Treatment may include active therapy with or without passive therapy, bracing.

(c). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

i. Patellofemoral Pain Syndrome (aka Retropatellar Pain Syndrome)

i. Description/Definition. Patellofemoral pathologies are associated with resultant weakening, instability, and pain of the patellofemoral mechanism. Diagnoses can include patellofemoral chondromalacia, malalignment, persistent quadriceps tendonitis, distal patellar tendonitis, patellofemoral arthrosis, and symptomatic plica syndrome. Patient complains of pain, instability and tenderness that interfere with daily living and work functions such as sitting with bent knees, climbing stairs, squatting, running or cycling.

ii. Occupational Relationship: Usually associated with contusion; repetitive patellar compressive forces; shearing articular injuries associated with subluxation or dislocation of patella, fractures, and/or infection.

iii. Specific Physical Exam Findings: Findings on physical exam may include retinacular tenderness, pain with patellar compressive ranging, positive patellar glide test, atrophy of quadriceps muscles, positive patellar apprehensive test. Associated anatomical findings may include increased Q angle; ligament laxity, and effusion. Some studies suggest that the patellar tilt test (assessing the patella for medial tilt) and looking for active instability with the patient supine and knee flexed to 15 degrees and an isometric quad contraction, may be most useful for distinguishing normal from abnormal. Most patellar tests are more specific than sensitive.

iv. Diagnostic Testing Procedures: Radiographs including tunnel view, axial view of patella at 30 degrees, lateral view and Merchant views. MRI rarely identifies pathology. Occasional CT or bone scans.

v. Non-Operative Treatment Procedures

(a). Medications such as analgesics and anti-inflammatories may be helpful. Refer to medication discussions in Medications and Medical Management.

(b). Patient education should include instruction in self-management techniques, ergonomics, body mechanics, home exercise, joint protection, and weight management.

(c). Benefits may be achieved through therapeutic rehabilitation and rehabilitation interventions. The program should include bracing and/or patellar taping, prone quad stretches, hip external rotation, balanced strengthening, range-of-motion (ROM), active therapies and a home exercise program. Active therapies include proprioception training, restoring normal joint mechanics, and clearing dysfunctions from distal and proximal structures. Passive as well as active therapies may be used for control of pain and swelling. Active therapeutic exercise appears to decrease pain; however, the expected functional benefits are unclear. Therapy should progress to strengthening and an independent home exercise program targeted to further improve ROM strength, and normal joint mechanics influenced by structures distal and proximal to the knee. Refer to Therapeutic Procedures, Non-operative.

(i). Passive modalities are most effective as adjunctive treatments to improve the results of active treatment. They may be used as found as adjunctive in Section F., Therapeutic Procedures, Non-operative. Orthotics may be useful in some cases.

(d). Knee pain, when associated with abnormal foot mechanics, may be favorably treated with appropriate orthotics.

(i). There is some evidence that pre-fabricated commercially available foot orthotic devices are more beneficial for patients with patellofemoral pain syndrome than flat shoe inserts. They may produce mild side effects such as rubbing or blistering which can be reduced with additional empirical measures such as heat molding or addition, and removal of wedges and inserts until patient comfort is achieved. In some cases, custom semi-rigid or rigid orthotics is necessary to decrease pronation or ensure a proper fit. There is no evidence regarding which orthotic design might be useful.

(e). Botulinum toxin injections for the relief of patellofemoral pain are considered experimental and are not recommended.

(f). Steroid Injections

(i). Steroid injections may decrease inflammation and allow the therapist to progress with functional exercise and ROM. Steroid injections under significant pressure should be avoided as the needle may be penetrating the tendon and injection into the tendon can cause possible tendon breakdown, tendon degeneration, or rupture. Injections near the patellar tendon should generally be avoided. Injections should be minimized for patients less than 30 years of age.

[a]. Time to Produce Effect: One injection.

[b]. Maximum Duration: Three injections in one year spaced at least four to eight weeks apart.

(ii). Steroid injections should be used cautiously in diabetic patients. Diabetic patients should be reminded to check their blood glucose levels at least daily for two weeks after injections.

(g). Extracorporeal Shock Wave Therapy (ESWT): There is no good research to support ESWT and therefore, it is not recommended.

(h). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(i). Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

vi. Surgical Indications/Considerations: patellar tendon disruption, quadriceps tendon rupture/avulsion, fracture. There is no evidence that surgery is better than eccentric training for patellar tendonopathy of the inferior pole (jumper's knee).

(a). Retinacular release, quadriceps reefing, and tibial transfer procedures should only be considered after four to six months of active patient participation in non-operative treatment in young active patients. There is no

evidence that arthroscopy for patellofemoral syndrome is more efficacious than exercise.

(b). Lateral release and reconstruction is not recommended for patellofemoral arthritis or middle aged adults.

(c). In cases of severe Grade III-IV isolated patellofemoral arthritis where walking, steps, and other functional activities are significantly impacted after adequate conservative treatment, prosthesis may be considered in those less than 55 years. A patellofemoral arthroplasty is generally contraindicated if there is patellofemoral instability or malalignment, tibiofemoral mechanical malalignment, fixed loss of knee motion (greater than 10 degrees extension or less than 110 degrees flexion), inflammatory arthritis, and other systemic related issues. For patellar resurfacing, refer to Knee Arthroplasty.

(d). Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities and the patient should agree to comply with the pre- and post-operative treatment plan including home exercise. The provider should be especially careful to make sure the patient understands the amount of post-operative therapy required and the length of partial- and full-disability expected post-operatively.

(e). Smoking may affect soft tissue healing through tissue hypoxia. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician.

vii Operative Procedures: Arthroscopic debridement of articular surface, plica, synovial tissue, loose bodies; arthrotomy; open reduction internal fixation with fracture; patellar prosthesis with isolated Grade III-IV OA, and possible patellectomy for young active patients with isolated arthritis.

viii. Post-Operative Treatment

(a). An individualized rehabilitation program based upon communication between the surgeon and the therapist and using therapies as outlined in Therapeutic Procedures, Non-operative.

(b). Treatment may include active therapy with or without passive therapy; and bracing.

(c). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

j. Posterior Cruciate Ligament (PCL) Injury

i. Description/Definition: Rupture of PCL. May be associated with concurrent ACL rupture or collateral ligament injury.

ii. Occupational Relationship. Most often caused by a posterior force directed to flexed knee.

iii. Specific Physical Exam Findings: Findings on physical exam include acute effusion, instability, reverse Lachman's test, reverse pivot shift, posterior drawer test.

iv. Diagnostic Testing Procedures: MRI, radiographs including kneeling view, may reveal avulsed bone.

v. Non-operative Treatment Procedures:

(a). Initial Treatment: Ice, bracing, and protected weight-bearing followed by active therapy.

(b). Medications such as analgesics and anti-inflammatories may be helpful. Refer to medication discussions in Medications and Medical Management.

(c). Patient education should include instruction in self-management techniques, ergonomics, body mechanics, home exercise, joint protection, and weight management.

(d). Benefits may be achieved through therapeutic rehabilitation and rehabilitation interventions. They should include bracing then range-of-motion (ROM), active therapies, and a home exercise program. Active therapies include proprioception training, restoring normal joint mechanics, and clearing dysfunctions from distal and proximal structures. Passive as well as active therapies may be used for control of pain and swelling. Therapy should progress to strengthening and an independent home exercise program targeted to further improve ROM, strength, and normal joint structures distal and proximal to the knee. Refer to Therapeutic Procedures, Non-operative.

(i). Passive modalities are most effective as adjunctive treatments to improve the results of active treatment. They may be used as found in Therapeutic Procedures, Non-operative.

(e). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(f). Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

vi. Surgical Indications/Considerations:

(a). Carefully consider the patients' normal daily activity level before initiation of surgical intervention. Isolated Grade 1 instability does not require surgical intervention. Grades 2 or 3 may have surgical intervention if there remains demonstrable instability which interferes with athletic or work pursuits of the patient. In a second degree strain there is significant posterior motion of the tibia on the femur in active testing. A third degree strain demonstrates rotary instability due to medial or lateral structural damage. Surgery is most commonly done when the PCL rupture is accompanied by multi-ligament injury. Not recommended as an isolated procedure in patients over 50 with Grade 3 or 4 osteoarthritis.

(b). Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities and the patient should agree to comply with the pre- and post-operative treatment plan including home exercise. The provider should be especially careful to make sure the patient understands the amount of post-operative therapy required and the length of partial- and full-disability expected post-operatively.

(c). Smoking may affect soft tissue healing through tissue hypoxia. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician.

vi. Operative Procedures: Autograft or allograft reconstruction.

vii. Post-Operative Treatment

(a). An individualized rehabilitation program based upon communication between the surgeon and the therapist and using therapies as outlined in Section F. Therapeutic Procedures, Non-operative.

(b). Treatment may include active therapy with or without passive therapy, bracing.

(c). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

k. Tendonopathy

i. Description/Definition. Inflammation of the lining of the tendon sheath or of the enclosed tendon. Usually occurs at the point of insertion into bone or a point of muscular origin. Can be associated with bursitis, calcium deposits, or systemic connective diseases.

ii. Occupational Relationship: Extreme or repetitive trauma, strain, or excessive unaccustomed exercise or work.

iii. Specific Physical Exam Findings: Involved tendons may be visibly swollen with possible fluid accumulation and inflammation; popping or crepitus; and decreased ROM.

iv. Diagnostic Testing Procedures. Lab work may be done to rule out inflammatory disease. Other tests are rarely indicated.

v. Non-Operative Treatment Procedures

(a). Initial Treatment: Ice, protected weight-bearing and/or restricted activity, possible taping and/or bracing.

(b). Medications such as analgesics and anti-inflammatories may be helpful. Refer to medication discussions in Medications and Medical Management.

(c). Patient education should include instruction in self-management techniques, ergonomics, body mechanics, home exercise, joint protection, and weight management.

(d). Benefits may be achieved through therapeutic rehabilitation and rehabilitation interventions. They should include range-of-motion (ROM), active therapies, including a home exercise program. Active therapies include, proprioception training, restoring normal joint mechanics, and clearing dysfunctions from distal and proximal structures. Passive as well as active therapies may be used for control of pain and swelling. Therapy should progress to strengthening and an independent home exercise program targeted to further improve ROM, strength, and normal joint mechanics influenced by structures distal and proximal to the knee. Refer to Therapeutic Procedures, Non-operative.

(i). Passive modalities are most effective as adjunctive treatments to improve the results of active treatment. They may be used as found as adjunctive in Therapeutic Procedures, Non-operative.

(e). For isolated patellar tendonopathy, patellar tendon strapping or taping may be appropriate.

(f). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(g). Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

(h). Therapeutic Injections: Steroid injections may decrease inflammation and allow the therapist to progress with functional exercise and ROM. Steroid injections under significant pressure should be avoided as the needle may be penetrating the tendon and injection into the tendon can cause possible tendon breakdown, tendon degeneration, or rupture. Injections should be minimized for patients less than 30 years of age.

(i). Time to Produce Effect: One injection.

(ii). Maximum Duration: Three injections in one year spaced at least four to eight weeks apart.

(iii). Steroid injections should be used cautiously in diabetic patients. Diabetic patients should be reminded to check their blood glucose levels at least daily for two weeks after injections.

vi. Surgical Indications/Considerations:

(a). Suspected avulsion fracture, or severe functional impairment unresponsive to a minimum of four months of active patient participation in non-operative treatment.

(b). Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities and the patient should agree to comply with the pre- and post-operative treatment plan including home exercise. The provider should be especially careful to make sure the patient understands the amount of post-operative therapy required and the length of partial- and full-disability expected post-operatively.

(c). Smoking may affect soft tissue healing through tissue hypoxia. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician.

vii. Operative Procedures: Tendon repair. Rarely indicated and only after extensive conservative therapy.

viii. Post-Operative Treatment

(a). An individualized rehabilitation program based upon communication between the surgeon and the therapist and using therapies as outlined in Therapeutic Procedures, Non-Operative.

(b). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

3. Hip and Leg

a. Acetabular Fracture

i. Description/Definition: Subgroup of pelvic fractures with involvement of the hip articulation.

ii. Occupational Relationship: Usually from a traumatic injury such as a fall or crush.

iii. Specific Physical Exam Findings: Displaced fractures may have short and/or abnormally rotated lower extremity.

iv. Diagnostic Testing Procedures: Radiographs, CT scanning.

v. Non-Operative Treatment Procedures

(a). Initial Treatment: Although surgery is frequently required, protected weight-bearing may be considered for un-displaced fractures or minimally displaced fractures that do not involve the weight-bearing surface of the acetabular dome.

(b). Medications such as analgesics and anti-inflammatories may be helpful. Refer to medication discussions in Medications and Medical Management.

(c). Patient education should include instruction in self-management techniques, ergonomics, body

mechanics, home exercise, joint protection, and weight management.

(d). Refer to comments on osteoporosis in Ankle Sprain/Fracture.

(e). Smoking may affect fracture healing. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician.

(f). Benefits may be achieved through therapeutic rehabilitation and rehabilitation interventions, after boney union has been achieved. They should include bracing then range-of-motion (ROM), active therapies, and a home exercise program. Active therapies include ambulation with appropriate assistive device, proprioception training, restoring normal joint mechanics, and clearing dysfunctions from adjacent structures. Passive as well as active therapies may be used for control of pain and swelling. Therapy should progress to strengthening and an independent home exercise program targeted to further improve ROM, strength, and normal joint mechanics influenced by proximal and distal structures. Therapy should include training on the use of adaptive equipment and home and work site evaluations when appropriate. Bracing may be appropriate. Refer to Therapeutic Procedures, Non-Operative.

(i). Passive modalities are most effective as adjunctive treatments to improve the results of active treatment. They may be used as found as adjunctive in Therapeutic Procedures, Non-operative.

(g). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(h). Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

vi. Surgical Indications/Considerations. Displaced or unstable fracture.

(a). Because smokers have a higher risk of non-union and post-operative costs, it is recommended that insurers cover a smoking cessation program peri-operatively. Physicians may monitor smoking cessation with laboratory tests such as cotinine levels for long-term cessation.

vii. Operative Procedures: Usually open reduction and internal fixation or total hip replacement.

viii. Post-Operative Treatment

(a). An individualized rehabilitation program based upon communication between the surgeon and the therapist, and using therapies as outlined in Therapeutic Procedures, Non-operative. In all cases, communication between the physician and therapist is important to the timing of weight-bearing, and exercise progressions.

(b). Treatment usually includes active therapy with or without passive therapy for early range of motion and weight-bearing then progression to, strengthening, flexibility, neuromuscular training, and gait training with appropriate assistive devices.

(c). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

b. Aggravated Osteoarthritis

i. Description/Definition: hip pain with radiographic evidence of joint space narrowing or femoral acetabular osteophytes, and sedimentation rate less than 20mm/hr with symptoms. Patients usually have gradual onset of pain increasing with use and relieved with rest, progressing to morning stiffness and then to night pain.

ii. Occupational Relationship: The provider must establish the occupational relationship by establishing a change in the patient's baseline condition and a relationship to work activities including but not limited to repetitive heavy lifting or specific injury to the hip.

(a). Other causative factors to consider: Prior significant injury to the hip may predispose the joint to osteoarthritis. In order to entertain previous trauma as a cause, the patient should have a medically documented injury with radiographs or MRI showing the level of anatomic change. The prior injury should have been at least two years from the presentation for the new complaints and there should be a significant increase of pathology on the affected side in comparison to the original imaging or operative reports and/or the opposite un-injured side or extremity.

iii. Specific Physical Exam Findings: Bilateral exam including knees and low back is necessary to rule out other diagnoses. Pain with the hip in external and/or internal hip rotation with the knee in extension is the strongest indicator.

iv. Diagnostic Testing Procedures: standing pelvic radiographs demonstrating joint space narrowing to 2 mm or less, osteophytes or sclerosis at the joint. MRI may be ordered to rule out other more serious disease.

v. Non-Operative Treatment Procedures

(a). Medications such as analgesics and anti-inflammatories may be helpful. Refer to medication discussions in Medications and Medical Management.

(b). Patient education should include instruction in self-management techniques, ergonomics, body mechanics, home exercise, joint protection, and weight management. Patient education may also include videos, telephone, follow-up, and pamphlets.

(c). Benefits may be achieved through therapeutic rehabilitation and rehabilitation interventions. They should include range-of-motion (ROM), active therapies and a home exercise program. Active therapies include gait training with appropriate assistive devices, proprioception training restoring normal joint mechanics, and clearing dysfunctions from adjacent structures. Passive as well as active therapies may be used for control of pain and swelling. Therapy should progress to strengthening and an independent home exercise program targeted to further improve ROM, strength, and normal joint mechanics influenced by proximal and distal structures. Therapy should include training on the use of adaptive equipment and home and work site evaluations when appropriate Refer to Therapeutic Procedures, Non-operative. There is good evidence that a supervised therapeutic exercise program with an element of strengthening is an effective treatment for hip osteoarthritis.

(i). Passive modalities are most effective as adjunctive treatments to improve the results of active treatment. They may be used as found as adjunctive in Therapeutic Procedures, Non-operative. There is some evidence that manual therapy, including stretching and traction manipulation by a trained provider, produces functional improvement in hip osteoarthritis and may be a suitable treatment option.

[a]. Aquatic therapy may be used as a type of active intervention to improve muscle strength and range of motion when land-based therapy is not well-tolerated.

[b]. The use of insoles, adaptive equipment, cane, may be beneficial.

[c]. There is some evidence that acupuncture may produce improvement in hip pain and function, making it a suitable treatment option for patients. Refer to Therapeutic Procedures, Non-operative.

[d]. Steroid Injections - Steroid injections may decrease inflammation and allow the therapist to progress with functional exercise and ROM.

[i]. Time to Produce Effect: One injection.

[ii]. Maximum Duration: Three injections in one year spaced at least four to eight weeks apart.

[iii].Steroid injections should be used cautiously in diabetic patients. Diabetic patients should be reminded to check their blood glucose levels at least daily for two weeks after injections.

[e]. Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

[f]. Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

vi. Surgical Indications/Considerations

(a). When pain interferes with ADLs and the patient meets the following: low surgical risk, adequate bone quality, and failure of previous non-surgical interventions including weight control, therapy with active patient participation, and medication. Refer to Therapeutic Procedures-operative, Hip Arthroplasty, for indications specific to the procedure.

(b). Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities and the patient should agree to comply with the pre- and post-operative treatment plan including home exercise. The provider should be especially careful to make sure the patient understands the amount of post-operative therapy required and the length of partial- and full-disability expected post-operatively.

(c). In cases where surgery is contraindicated due to obesity, it may be appropriate to recommend a weight loss program if the patient is unsuccessful losing weight on their own. Coverage for weight loss would continue only for motivated patients who have demonstrated continual progress with weight loss.

(d). Because smokers have a higher risk of non-union and post-operative costs, it is recommended that carriers cover a smoking cessation program peri-operatively. Physicians may monitor smoking cessation with laboratory tests such as cotinine levels for long-term cessation.

vii. Operative Procedures: Prosthetic replacement (traditional or minimally invasive), or resurfacing.

viii. Post-Operative Treatment

(a). In all cases, communication between the physician and therapist is important to the timing of weight-bearing and exercise progressions.

(b). For prosthetic replacement, refer to Hip Arthroplasty.

(c). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

c. Femoral Osteonecrosis (Avascular Necrosis (AVN) of the Femoral Head)

i. Description/Definition. Death of the bone tissue of the femoral head following loss of blood supply to the area. Destruction of the articular surfaces of the hip joint may lead to arthritis.

ii. Occupational Relationship. Trauma resulting in displaced subcapital fracture of the hip or hip dislocation may cause AVN. Previous surgical procedures and systemic steroids may lead to AVN. In the general population risk factors include, but are not limited to alcohol abuse, smoking, Caisson disease (also known as the bends), sickle cell anemia, autoimmune disease, and hypercoagulable states. Often, the cause cannot be identified. Involvement of the opposite hip may occur in more than half of cases not caused by trauma.

iii. Specific Physical Exam Findings. Hip or groin pain made worse by motion or weight-bearing and alleviated by rest is the classical presentation. Symptoms may begin gradually, often months after the vascular compromise of blood flow. A limp may result from the limited toleration of weight-bearing.

iv. Diagnostic Testing Procedures. X-ray abnormalities include sclerotic changes, cystic lesions, joint space narrowing, and degeneration of the acetabulum. The x-ray may be normal in the first several months of the disease process. AVN should be suspected when hip pain occurs and risk factors are present. X-rays should be done first, but may be followed by an MRI. When AVN is not due to trauma, both hips should be imaged.

v. Non-operative Treatment Procedures

(a). Initial Treatment: protected weight-bearing and bracing followed by active therapy with or without passive therapy. Conservative approaches may suffice when the lesion is small, but larger lesions are expected to require surgical intervention when symptoms are disabling.

(b). Medications such as analgesics and anti-inflammatories may be helpful. Refer to medication discussions in Medications and Medical Management.

(c). Patient education should include instruction in self-management techniques, ergonomics, body mechanics, home exercise, joint protection, and weight management. Weight-bearing restrictions may be appropriate.

(d). Smoking may affect bone healing. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician.

(e). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(f). Other therapies in Therapeutic Procedures, Non-operative, may be employed in individual cases.

vi. Surgical Indications/Considerations: Core decompression may appropriate for some patients with early disease (Stages 1 and 2A) who have functionally disabling symptoms. Femoral head osteotomies or resurfacing hemiarthroplasties may also be appropriate for younger patients when disease is limited to the femoral head. Those

50 or older and patients with total joint collapse or severely limiting disease will usually require an implant arthroplasty.

(a). Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities and the patient should agree to comply with the pre- and post-operative treatment plan including home exercise. The provider should be especially careful to make sure the patient understands the amount of post-operative therapy required and the length of partial- and full-disability expected post-operatively.

(b). Because smokers have a higher risk of non-union and post-operative costs, it is recommended that insurers cover a smoking cessation program peri-operatively. Physicians may monitor smoking cessation with laboratory tests such as cotinine levels for long-term cessation.

vii. Operative Procedures. Osteotomy, core decompression with or without bone graft, prosthetic replacement. Refer to Therapeutic Procedures-operative for details.

viii. Post-operative Treatment

(a). Anticoagulant therapy to prevent deep venous thrombosis for most procedures. Refer to Therapeutic Procedures, Non-operative.

(b). Treatment usually includes active therapy with or without passive therapy. Refer to Therapeutic Procedures-Operative and specific procedures for further details.

(c). An individualized rehabilitation program based upon communication between the surgeon and the therapist using the treatments found in Therapeutic Procedures, Non-operative.

(d). Treatment should include gait training with appropriate assistive devices.

(e). Therapy should include training on the use of adaptive equipment and home and work site evaluation when appropriate.

(f). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon

d. Femur Fracture

i. Description/Definition. Fracture of the femur distal to the lesser trochanter.

ii. Occupational Relationship. Usually from a traumatic injury such as a fall or crush.

iii. Specific Physical Exam Findings: May have a short, abnormally rotated extremity. Effusion if the knee joint is involved.

iv. Diagnostic Testing Procedures: Radiographs. Occasionally CT scan or MRI particularly if the knee joint is involved.

v. Non-operative Treatment Procedures

(a). Initial Treatment. Although surgery is usually required, non-operative procedures may be considered in stable, non-displaced fractures and will require protected weight-bearing.

(b). Medications such as analgesics and anti-inflammatories may be helpful. Refer to medication discussions in Medications and Medical Management.

(c). Back pain may occur after femur fracture and should be addressed and treated as necessary.

(d). Patient education should include instruction in self-management techniques, ergonomics, body mechanics, home exercise, joint protection, weight management. Weight-bearing restrictions may be appropriate.

(e). Refer to comments related to osteoporosis in Therapeutic Procedures, Non-operative, Osteoporosis Management.

(f). Smoking may affect fracture healing. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician.

(g). Orthotics such as heel lifts and custom shoe build-ups may be required when leg-length discrepancy persists.

(h). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(i). Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

vi. Surgical Indications/Considerations. Femoral neck fracture or supracondylar femur fracture with joint incongruity.

(a). Because smokers have a higher risk of non-union and post-operative costs, it is recommended that insurers cover a smoking cessation program peri-operatively. Physicians may monitor smoking cessation with laboratory tests such as cotinine levels for long-term cessation.

vii. Operative Procedures: Rod placement or open internal fixation.

viii. Post-Operative Treatment

(a). An individualized rehabilitation program based upon communication between the surgeon and the therapist, using therapies as outlined in Therapeutic Procedures, Non-operative. In all cases, communication between the physician and the therapist is important to the timing of weight-bearing and exercise progression.

(b). Treatment usually includes active therapy with or without passive therapy for protected weight-bearing, early range of motion if joint involvement.

(c). Refer to bone-growth stimulators in Therapeutic Procedures, Non-operative.

(d). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

(e). Hamstring Tendon Rupture

(i). Description/Definition. Most commonly, a disruption of the muscular portion of the hamstring. Extent of the tear is variable. Occasionally a proximal tear or avulsion. Rarely a distal injury.

(ii). Occupational Relationship: Excessive tension on the hamstring either from an injury or from a rapid, forceful contraction of the muscle.

(iii). Specific Physical Exam Findings: Local tenderness, swelling, ecchymosis.

(iv). Diagnostic Testing Procedures: Occasionally radiographs or MRI for proximal tears/possible avulsion.

(v). Non-operative Treatment Procedures

[a]. Initial Treatment: Protected weight-bearing and ice.

[b]. Medications such as analgesics and anti-inflammatories may be helpful. Refer to medication discussions in Medications and Medical Management.

[c]. Patient education should include instruction in self-management techniques, ergonomics, body mechanics, home exercise, and weight management.

[d]. Benefits may be achieved through therapeutic rehabilitation and rehabilitation interventions. They may include range-of-motion (ROM), active therapies, and a home exercise program. Active therapies include proprioception training, restoring normal joint mechanics, and clearing dysfunctions from adjacent structures. Passive as well as active therapies may be used for control of pain and swelling. Therapy should progress to strengthening and an independent home exercise program targeted to further improve ROM, strength, and normal joint mechanics influenced by proximal and distal structures. Bracing may be appropriate. Refer to Therapeutic Procedures, Non-operative.

[i]. Passive modalities are most effective as adjunctive treatments to improve the results of active treatment. They may be used as found as adjunctive in Therapeutic Procedures, Non-operative.

[e]. Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

[f]. Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

vi. Surgical Indications/Considerations

(a). Surgery is indicated for proximal or distal injuries only when significant functional impairment is expected without repair. If surgery is indicated, it is preferably performed within three months.

(b). Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities and the patient should agree to comply with the pre- and post-operative treatment plan including home exercise. The provider should be especially careful to make sure the patient understands the amount of post-operative therapy required and the length of partial- and full-disability expected post-operatively.

(c). Smoking may affect soft tissue healing through tissue hypoxia. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician.

vii. Operative Procedures: Re-attachment of proximal avulsions and repair of distal tendon disruption.

viii. Post-Operative Treatment

(a). An individualized rehabilitation program based upon communication between the surgeon and the therapist using therapies as outlined in Therapeutic Procedures, Non-operative. In all cases, communication between the physician and therapist is important to the timing of weight-bearing and exercise progressions.

(b). Treatment may include protected weight-bearing and active therapy with or without passive therapy. Splinting in a functional brace may reduce time off work.

(c). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

f. Hip Dislocation

i. Description/Definition. Disengagement of the femoral head from the acetabulum.

ii. Occupational Relationship. Usually from a traumatic injury such as a fall or crush.

iii. Specific Physical Exam Findings: Most commonly a short, internally rotated, adducted lower extremity with a posterior dislocation and a short externally rotated extremity with an anterior dislocation.

iv. Diagnostic Testing Procedures: Radiographs, CT scanning.

v. Non-operative Treatment Procedures

(a). Initial Treatment: Urgent closed reduction with sedation or general anesthesia.

(b). Medications such as analgesics and anti-inflammatories may be helpful. Refer to medication discussions in Medications and Medical Management.

(c). Patient education should include instruction in self-management techniques, ergonomics, body mechanics, home exercise, joint protection, and weight management.

(d). Benefits may be achieved through therapeutic rehabilitation and rehabilitation interventions. They should include bracing then range-of-motion (ROM), active therapies, and a home exercise program. Active therapies include proprioception training, gait training with appropriate assistive devices, restoring normal joint mechanics, and clearing dysfunctions from adjacent structures. Passive as well as active therapies may be used for control of pain and swelling. Therapy should progress to strengthening and an independent home exercise program targeted to further improve ROM, strength, and normal joint mechanics influenced by proximal and distal structures. Therapy should include training on the use of adaptive equipment and home and work site evaluations when appropriate. Bracing may be appropriate Refer to Therapeutic Procedures, Non-operative.

(i). Passive modalities are most effective as adjunctive treatments to improve the results of active treatment. They may be used as found as adjunctive in Therapeutic Procedures, Non-operative.

(e). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(f). Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

vi. Surgical Indications/Considerations: Failure of closed reduction. Associated fracture of the acetabulum or femoral head, loose fragments in joint or open fracture.

(a). Because smokers have a higher risk of non-union and post-operative costs, when a fracture is involved it is recommended that insurers cover a smoking cessation program peri-operatively. Physicians may monitor smoking cessation with laboratory tests such as cotinine levels for long-term cessation.

vii. Operative Procedures. Open reduction of the femoral head or acetabulum and possible internal fixation.

viii. Post-operative Treatment Procedures

(a). An individualized rehabilitation program based upon communication between the surgeon and the

therapist using therapies as outlined in Therapeutic Procedures, Non-operative. In all cases, communication between the physician and therapist is important to the timing of weight-bearing and exercise progressions.

(b). Treatment should include gait training with appropriate assistive devices.

(c). Treatment may include protected weight-bearing and active therapy with or without passive therapy for early range of motion.

(d). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

g. Hip Fracture

i. Description/Definition. Fractures of the neck and peri-trochanteric regions of the proximal femur.

ii. Occupational Relationship: Usually from a traumatic injury such as a fall or crush. Patients with intracapsular femoral fractures have a risk of developing avascular necrosis of the femoral head requiring treatment months to years after the initial injury.

iii. Specific Physical Exam Findings. Often a short and externally rotated lower extremity.

iv. Diagnostic Testing Procedures: Radiographs. Occasional use of CT scan or MRI.

v. Non-operative Treatment Procedures

(a). Initial Treatment: protected weight-bearing and bracing followed by active therapy with or without passive therapy. Although surgery is usually required, non-operative procedures may be considered in stable, non-displaced fractures.

(b). Medications such as analgesics and anti-inflammatories may be helpful. Refer to medication discussions in Medications and Medical Management.

(c). Back pain may occur after hip fracture and should be addressed and treated as necessary.

(d). Patient education should include instruction in self-management techniques, ergonomics, body mechanics, home exercise, joint protection, and weight management. Weight-bearing restrictions may be appropriate.

(e). Refer to comments on osteoporosis in Ankle Sprain/Fracture.

(f). Smoking may affect fracture healing. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician.

(g). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(h). Other therapies in Therapeutic Procedures, Non-operative, may be employed in individual cases.

vi. Surgical Indications/Considerations. Surgery is indicated for unstable peritrochanteric fractures and femoral neck fractures.

(a). Because smokers have a higher risk of non-union and post-operative costs, it is recommended that insurers cover a smoking cessation program peri-operatively. Physicians may monitor smoking cessation with laboratory tests such as cotinine levels for long-term cessation.

vii. Operative Procedures: Prosthetic replacement for displaced femoral neck fractures. Reduction and internal fixation for peritrochanteric fractures, and un-displaced, or minimally-displaced neck fractures.

viii. Post-operative Treatment

(a). Anti coagulant therapy to prevent deep venous thrombosis. Refer to Therapeutic Procedures, Non-operative.

(b). Treatment usually includes active therapy with or without passive therapy.

(c). An individualized rehabilitation program based upon communication between the surgeon and the therapist using the treatments found in Therapeutic Procedures, Non-operative.

(d). Treatment should include gait training with appropriate assistive devices.

(e). Therapy should include training on the use of adaptive equipment and home and work site evaluation when appropriate.

(f). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

h. Impingement/Labral Tears

i. Description/Definition: Two types of impingement are described pincer; resulting from over coverage of the acetabulum and/or cam; resulting from aspherical portion of the head and neck junction. Persistence of these abnormalities can cause early arthritis or labral tears. Labral tears can also be isolated; however, they are frequently accompanied by bony abnormalities. Patients usually complain of catching or painful clicking which should be distinguished from a snapping iliopsoas tibial tendon. A pinch while sitting may be reported and hip or groin pain.

ii. Occupational Relationship: Impingement abnormalities are usually congenital; however, they may be aggravated by repetitive rotational force or trauma. Labral tears may accompany impingement or result from high energy trauma.

iii. Specific Physical Exam Findings. Positive labral tests.

iv. Diagnostic Testing Procedures. Cross table laterals, standing AP pelvis and frog leg lateral x-rays. MRI may reveal abnormality; however, false positives and false negatives are also possible. MRI arthrogram with gadolinium should be performed to diagnose labral tears, not a pelvic MRI. Intra-articular injection should help rule out extra-articular pain generators. To confirm the diagnosis, the patient should demonstrate changes on a pain scale accompanied by recorded functional improvement post-injection. This is important, as labral tears do not always cause pain and over-diagnosis is possible using imaging alone.

v. Non-Operative Treatment Procedures

(a). Medications such as analgesics and anti-inflammatories may be helpful. Refer to medication discussions in Medications and Medical Management.

(b). Patient education should include instruction in self-management techniques, ergonomics, body mechanics, reducing hip adduction and internal rotation home exercise, joint protection, and weight management.

(c). Benefits may be achieved through therapeutic rehabilitation and rehabilitation interventions.

They should include range-of-motion (ROM), active therapies and a home exercise program. Active therapies include proprioception training, restoring normal joint mechanics, and clearing dysfunctions from adjacent structures. Passive as well as active therapies may be used for control of pain and swelling. Therapy should progress to strengthening and an independent home exercise program targeted to further improve ROM, strength, and normal joint mechanics influenced by proximal and distal structures. Refer to Therapeutic Procedures, Non-operative.

(i). Passive modalities are most effective as adjunctive treatments to improve the results of active treatment. They may be used as found as adjunctive in Therapeutic Procedures, Non-operative.

(d). Steroid Injections. Steroid injections may decrease inflammation and allow the therapist to progress with functional exercise and ROM.

(i). Time to Produce Effect: One injection.

(ii). Maximum Duration: Three injections in one year spaced at least four to eight weeks apart.

(iii). Steroid injections should be used cautiously in diabetic patients. Diabetic patients should be reminded to check their blood glucose levels at least daily for two weeks after injections.

(e). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(f). Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

vi. Surgical Indications/Considerations:

(a). Surgery is indicated when functional limitations persist after eight weeks of active patient participation in treatment, there are clinical signs and symptoms suggestive of the diagnosis and other diagnoses have been ruled out.

(b). Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities and the patient should agree to comply with the pre- and post-operative treatment plan including home exercise. The provider should be especially careful to make sure the patient understands the amount of post-operative therapy required and the length of partial- and full-disability expected post-operatively.

(c). In cases where surgery is contraindicated due to obesity, it may be appropriate to recommend a weight loss program if the patient is unsuccessful losing weight on their own. Coverage for weight loss would continue only for motivated patients who have demonstrated continual progress with weight loss.

(d). Smoking may affect soft tissue healing through tissue hypoxia. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician.

vii. Operative Procedures: Debridement or repair of labrum and removal of excessive bone.

viii. Post-operative Treatment

(a). When bone is removed and/or the labrum is repaired, weight-bearing restrictions usually apply.

(b). An individualized rehabilitation program based upon communication between the surgeon and the therapist that should include gait training with appropriate assistive devices. Refer to Therapeutic Procedures Non-operative.

(c). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

i. Pelvic Fracture

i. Description/Definition. Fracture of one or more components of the pelvic ring (sacrum and iliac wings).

ii. Occupational Relationship. Usually from a traumatic injury such as a fall or crush.

iii. Specific Physical Exam Findings. Displaced fractures may cause pelvic deformity and shortening, or rotation of the lower extremities.

iv. Diagnostic Testing Procedures: Radiographs, CT scanning. Occasionally MRI, angiogram, urethrogram, emergent sonogram.

v. Non-operative Treatment Procedures

(a). Initial Treatment: Protected weight-bearing. Although surgery is usually required, non-operative procedures may be considered in a stable, non-displaced fracture.

(b). Medications such as analgesics and anti-inflammatories may be helpful. Refer to medication discussions in Medications and Medical Management.

(c). Patient education should include instruction in self-management techniques, ergonomics, body mechanics, home exercise, joint protection, and weight management.

(d). Refer to comments related to osteoporosis in Therapeutic Procedures, Non-operative, Osteoporosis Management.

(e). Smoking may affect fracture healing. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician.

(f). Benefits may be achieved through therapeutic rehabilitation and rehabilitation interventions, after boney union has been achieved. They should include bracing then range-of-motion (ROM), active therapies, and a home exercise program. Active therapies include, proprioception training, gait training with appropriate assistive devices, restoring normal joint mechanics, and clearing dysfunctions from adjacent structures. Passive as well as active therapies may be used for control of pain and swelling. Therapy should progress to strengthening and an independent home exercise program targeted to further improve ROM, strength, and normal joint mechanics influenced by proximal and distal structures. Therapy should include training on the use of adaptive equipment and home and work site evaluations when appropriate. Refer to Therapeutic Procedures, Non-operative.

(i). Passive modalities are most effective as adjunctive treatments to improve the results of active treatment. They may be used as found as adjunctive in Therapeutic Procedures, Non-operative.

(g). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(h). Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

vi. Surgical Indications/Considerations. Unstable fracture pattern, or open fracture.

(a). Because smokers have a higher risk of non-union and post-operative costs, it is recommended that insurers cover a smoking cessation program peri-operatively. Physicians may monitor smoking cessation with laboratory tests such as cotinine levels for long-term cessation.

vii. Operative Procedures. External or internal fixation dictated by fracture pattern.

viii. Post-Operative Treatment

(a). An individualized rehabilitation program based upon communication between the surgeon and the therapist using therapies as outlined in Therapeutic Procedures, Non-operative. In all cases, communication between the physician and therapist is important to the timing of weight-bearing and exercise progressions.

(b). Treatment usually includes active therapy with or without passive therapy for gait, pelvic stability, strengthening, and restoration of joint and extremity function. Treatment should include gait training with appropriate assistive devices.

(c). Graduated weight-bearing according to fracture healing.

(d). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

j. Tendonopathy: Refer to Tendonopathy for general recommendations.

k. Tibial Fracture

i. Description/Definition. Fracture of the tibia proximal to the malleoli.

(a). Open tibial fractures are graded in severity according to the Gustilo-Anderson Classification:

(i). Type I: Less than 1 cm (puncture wounds).

(ii). Type II: 1 to 10 cm.

(iii). Type III-A: Greater than 10 cm, sufficient soft tissue preserved to cover the wound (includes gunshot wounds and any injury in a contaminated environment).

(iv). Type III-B: Greater than 10 cm, requiring a soft tissue coverage procedure.

(v). Type III-C: With vascular injury requiring repair.

ii. Occupational Relationship. Usually from a traumatic injury such as a fall or crush.

iii. Specific Physical Exam Findings. May have a short, abnormally rotated extremity. Effusion if the knee joint involved.

iv. Diagnostic Testing Procedures: Radiographs. CT scanning or MRI.

v. Non-operative Treatment Procedures:

(a). Initial Treatment—protected weight-bearing; functional bracing. There is some evidence for use of pneumatic braces with stress fractures.

(b). Medications such as analgesics and anti-inflammatories may be helpful. Refer to medication discussions in Medications and Medical Management.

(c). Patient education should include instruction in self-management techniques, ergonomics, body mechanics, home exercise, joint protection, and weight management.

(d). Refer to comments related to osteoporosis in Therapeutic Procedures, Non-operative, Osteoporosis Management.

(e). Smoking may affect fracture healing. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician.

(f). Benefits may be achieved through therapeutic rehabilitation and rehabilitation interventions, after boney union has been achieved. They should include bracing then range-of-motion (ROM), active therapies including proprioception training, restoring normal joint mechanics, and clearing dysfunctions from adjacent structures, and a home exercise program. Passive as well as active therapies may be used for control of pain and swelling. Therapy should progress to strengthening and an independent home exercise program targeted to further improve ROM, strength, restoring normal joint mechanics, influenced by proximal and distal structures. Therapy should include training on the use of adaptive equipment and home and work site evaluations when appropriate. Bracing may be appropriate. Refer to Therapeutic Procedures, Non-operative.

(i). Passive modalities are most effective as adjunctive treatments to improve the results of active treatment. They may be used as found as adjunctive in Therapeutic Procedures, Non-operative.

(g). Orthotics such as heel lifts and custom shoe build-ups may be required when leg-length discrepancy persists.

(h). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(i). Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

vi. Surgical Indications/Considerations. Unstable fracture pattern, displaced fracture (especially if the knee joint is involved), open fracture, and non-union.

(a). Because smokers have a higher risk of non-union and post-operative costs, it is recommended that insurers cover a smoking cessation program peri-operatively. Physicians may monitor smoking cessation with laboratory tests such as cotinine levels for long-term cessation.

vii. Operative Procedures. Often closed rodding for shaft fractures. Open reduction and internal fixation more common for fractures involving the knee joint or pilon fractures of the distal tibia.

(a). Human bone morphogenetic protein (RhBMP): this material is used for surgical repair of open tibial fractures. Refer to Therapeutic Procedures, Operative for further specific information.

(b). Stem cell use - stem cells have been added to allograft to increase fracture union. Their use is considered experimental and is not recommended at this time.

viii. Post-operative Treatment

(a). An individualized rehabilitation program based upon communication between the surgeon and the therapist and using therapies as outlined in Therapeutic Procedures, Non-operative. In all cases, communication between the physician and therapist is important to the timing of weight-bearing and exercise progressions.

(b). Treatment may include protected weight-bearing and active therapy with or without passive therapy for early range of motion if joint involvement.

(c). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

l. Trochanteric Fracture

i. Description/Definition: Fracture of the greater trochanter of the proximal femur.

ii. Occupational Relationship. Usually from a traumatic injury such as a fall or crush.

iii. Specific Physical Exam Findings: Local tenderness over the greater trochanter. Sometimes associated swelling, ecchymosis.

iv. Diagnostic Testing Procedures. Radiographs, CT scans or MRI.

v. Non-operative Treatment Procedures:

(a). Initial Treatment: protected weight-bearing.

(b.) Medications such as analgesics and anti-inflammatories may be helpful. Refer to medication discussions in Medications and Medical Management.

(c). Patient education should include instruction in self-management techniques, ergonomics, body mechanics, home exercise, joint protection, and weight management.

(d). Refer to comments related to osteoporosis in Therapeutic Procedures, Non-operative, Osteoporosis Management.

(e). Smoking may affect fracture healing. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician.

(f). Benefits may be achieved through therapeutic rehabilitation and rehabilitation interventions, after boney union has been achieved. They should include bracing then range-of-motion (ROM), active therapies, and a home exercise program. Active therapies include proprioception training, restoring normal joint mechanics, and clearing dysfunctions from adjacent structures, and a home exercise program. Passive as well as active therapies may be used for control of pain and swelling. Therapy should progress to strengthening and an independent home exercise program targeted to further improve ROM, strength, and normal joint mechanics influenced by proximal and distal structures. Bracing may be appropriate. Refer to Therapeutic Procedures, Non-operative.

(i). Passive modalities are most effective as adjunctive treatments to improve the results of active treatment. They may be used as found as adjunctive in Therapeutic Procedures, Non-operative.

(g). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(h). Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

vi. Surgical Indications/Considerations. Large, displaced fragment, open fracture.

(a). Because smokers have a higher risk of non-union and post-operative costs, it is recommended that insurers cover a smoking cessation program peri-operatively. Physicians may monitor smoking cessation with laboratory tests such as cotinine levels for long-term cessation.

vii. Operative Procedures: Open reduction, internal fixation.

viii. Post-operative Treatment

(a). An individualized rehabilitation program based upon communication between the surgeon and the therapist using therapies as outlined in Therapeutic Procedures, Non-operative. In all cases, communication between the physician and therapist is important to the timing of weight-bearing and exercise progressions.

(b). Protected weight-bearing is usually needed. Full weight-bearing with radiographic and clinical signs of healing.

(c). Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1772 (June 2011).

§2311. Therapeutic Procedures—Non-Operative

A. Treating providers, as well as employers and insurers are highly encouraged to reference the General Guidelines Principles (Section B) prior to initiation of any therapeutic procedure. Before initiation of any therapeutic procedure, the authorized treating provider, employer and insurer must consider these important issues in the care of the injured worker.

B. First, patients undergoing therapeutic procedure(s) should be released or returned to modified, restricted duty during their rehabilitation at the earliest appropriate time. Refer to Return-to-Work in this section for detailed information.

C. Second, cessation and/or review of treatment modalities should be undertaken when no further significant subjective or objective improvement in the patient's condition is noted. If patients are not responding within the recommended duration periods, alternative treatment interventions, further diagnostic studies or consultations should be pursued.

D. Third, providers should provide and document education to the patient. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of facilitating self-management of symptoms.

E. Lastly, formal psychological or psychosocial evaluation should be performed on patients not making expected progress within 6 to 12 weeks following injury and whose subjective symptoms do not correlate with objective signs and tests.

F. In cases where a patient is unable to attend an outpatient center, home therapy may be necessary. Home therapy may include active and passive therapeutic procedures as well as other modalities to assist in alleviating pain, swelling, and abnormal muscle tone. Home therapy is usually of short duration and continues until the patient is able to tolerate coming to an outpatient center.

G. The following procedures are listed in alphabetical order.

1. Acupuncture is an accepted and widely used procedure for the relief of pain and inflammation in the lower extremity. There is some scientific evidence to support

its use for hip and knee osteoarthritis. The exact mode of action is only partially understood. Western medicine studies suggest that acupuncture stimulates the nervous system at the level of the brain, promotes deep relaxation, and affects the release of neurotransmitters. Acupuncture is commonly used as an alternative or in addition to traditional Western pharmaceuticals. While it is commonly used when pain medication is reduced or not tolerated, it may be used as an adjunct to physical rehabilitation and/or surgical intervention to hasten the return of functional activity. Acupuncture should be performed by licensed practitioners.

a. Acupuncture is the insertion and removal of filiform needles to stimulate acupoints (acupuncture points). Needles may be inserted, manipulated and retained for a period of time. Acupuncture can be used to reduce pain, reduce inflammation, increase blood flow, increase range-of-motion, decrease the side effect of medication-induced nausea, promote relaxation in an anxious patient, and reduce muscle spasm.

i. Indications include joint pain, joint stiffness, soft tissue pain and inflammation, paresthesia, post-surgical pain relief, muscle spasm, and scar tissue pain.

b. Acupuncture with Electrical Stimulation is the use of electrical current (micro-amperage or milli-amperage) on the needles at the acupuncture site. It is used to increase effectiveness of the needles by continuous stimulation of the acupoint. Physiological effects (depending on location and settings) can include endorphin release for pain relief, reduction of inflammation, increased blood circulation, analgesia through interruption of pain stimulus, and muscle relaxation.

i. It is indicated to treat chronic pain conditions, radiating pain along a nerve pathway, muscle spasm, inflammation, scar tissue pain, and pain located in multiple sites.

c. Total Time Frames for Acupuncture and Acupuncture with Electrical Stimulation: Time frames are not meant to be applied to each of the above sections separately. The time frames are to be applied to all acupuncture treatments regardless of the type or combination of therapies being provided.

i. Time to Produce Effect: three to six treatments.

ii. Frequency: One to three times per week.

iii. Optimum Duration: One to two months.

iv. Maximum Duration: 14 treatments.

v. Any of the above acupuncture treatments may extend longer if objective functional gains can be documented or when symptomatic benefits facilitate progression in the patient's treatment program. Treatment beyond 14 treatments must be documented with respect to need and ability to facilitate positive symptomatic or functional gains. Such care should be re-evaluated and documented with each series of treatments.

d. Other Acupuncture Modalities: Acupuncture treatment is based on individual patient needs and therefore treatment may include a combination of procedures to enhance treatment effect. Other procedures may include the use of heat, soft tissue manipulation/massage, and exercise. Refer to Active Therapy (Therapeutic Exercise) and Passive Therapy sections (Massage and Superficial Heat and Cold Therapy) for a description of these adjunctive acupuncture modalities and time frames.

2. Biofeedback is a form of behavioral medicine that helps patients learn self-awareness and self-regulation skills for the purpose of gaining greater control of their physiology, such as muscle activity, brain waves, and measures of autonomic nervous system activity. Electronic instrumentation is used to monitor the targeted physiology and then displayed or fed back to the patient visually, auditorially, or tactilely, with coaching by a biofeedback specialist. Biofeedback is provided by clinicians certified in biofeedback and/or who have documented specialized education, advanced training, or direct or supervised experience qualifying them to provide the specialized treatment needed (e.g., surface EMG, EEG, or other).

a. Treatment is individualized to the patient's work-related diagnosis and needs. Home practice of skills is required for mastery and may be facilitated by the use of home training tapes. The ultimate goal in biofeedback treatment is normalizing the physiology to the pre-injury status to the extent possible and involves transfer of learned skills to the workplace and daily life. Candidates for biofeedback therapy or training must be motivated to learn and practice biofeedback and self-regulation techniques.

b. Indications for biofeedback include individuals who are suffering from musculoskeletal injury in which muscle dysfunction or other physiological indicators of excessive or prolonged stress response affects and/or delays recovery. Other applications include training to improve self-management of emotional stress/pain responses such as anxiety, depression, anger, sleep disturbance, and other central and autonomic nervous system imbalances. Biofeedback is often utilized along with other treatment modalities.

i. Time to Produce Effect: Three to four sessions.

ii. Frequency: One to two times per week.

iii. Optimum Duration: Five to six sessions.

iv. Maximum Duration: 10 to 12 sessions. Treatment beyond 12 sessions must be documented with respect to need, expectation, and ability to facilitate functional gains.

3. Bone-Growth Stimulators

a. Electrical. Pre-clinical and experimental literature has shown a stimulatory effect of externally applied electrical fields on the proliferation and calcification of osteoblasts and periosteal cells. All of the studies on bone growth stimulators, however, have some methodological deficiencies and high-quality literature of electrical bone growth stimulation is lacking for lower extremity injuries.

i. These acceptable nonsurgical techniques include Capacitive Coupling (CC), which places skin electrodes on opposite sides of the bone being treated and Pulsed Electromagnetic Field (PEMF) which uses a current-carrying coil which induces a secondary electrical field in bone.

ii. There is insufficient evidence to conclude a benefit of electrical stimulation for delayed union, non-union, long bone fracture healing, fresh fractures, or tibial stress fractures.

b. Low-intensity Pulsed Ultrasound: There is some evidence that low-intensity pulsed ultrasound, applied by the patient at home and administered as initial treatment of the fracture, reduces the time required for cortical bridging in tibial fractures. Non-union and delayed unions were not

included in these clinical trials. Possible indications for Low-Intensity Pulsed Ultrasound are non-unions or fractures that are expected to require longer healing time.

i. FDA approved bone-growth stimulators of any type may be appropriate for patients with non-union after initial fracture care or for patients with acute fractures or osteotomies who are at high risk for delayed union or non-union. Patients at high risk include, but are not limited to, smokers, diabetics, and those on chemotherapeutic agents or other long-term medication affecting bone growth. Due to lack of supporting scientific evidence, stimulators require prior authorization.

4. Extracorporeal Shock Wave Therapy (ESWT)

a. Extracorporeal shock wave therapy (ESWT) delivers an externally applied acoustic pulse to the plantar fascia. It has been hypothesized that ESWT causes microtrauma to the fascia, inducing a repair process involving the formation of new blood vessels and delivery of nutrients to the affected area. High energy ESWT is delivered in one session and may be painful requiring some form of anesthesia. It is not generally recommended for the treatment of plantar heel pain due to increased cost when it is performed with conscious sedation. It may also be performed with local blocks. Low energy ESWT does not require anesthetics. It is given in a series of treatments, generally three sessions.

b. There is conflicting evidence concerning low energy ESWT for plantar heel pain. Focused ESWT concentrates the acoustic pulse on a single point in the heel, while radial ESWT distributes the pulse along the entire plantar fascia. Focused low energy ESWT has not been shown to produce clinically important reductions in plantar heel pain. There is some evidence that radial ESWT may reduce plantar pain more effectively than placebo, but a successful response may occur in only 60 percent of patients. There is some evidence supporting high-energy ESWT.

c. Low energy radial or high energy ESWT with local blocks are accepted treatments. It should only be used on patients who have had plantar pain for four months or more; have tried NSAIDs, ice, stretching exercises, shoe inserts; and have significant functional deficits. These patients should meet the indications for surgery found in heel spurs, plantar fascia pain. Tarsal tunnel syndrome should be ruled out. Peripheral vascular disease, lower extremity neuropathy and diabetes are all relative contraindications. Diagnostic testing may be needed to rule out these conditions.

i. Time to Effect: Two sessions.

ii. Optimum Duration: Three sessions one week or more apart.

iii. Maximum Duration: Treatment may be continued for up to five total sessions if functional improvement has been demonstrated after three treatment sessions. Functional improvement is preferably demonstrated using direct testing or functional scales validated in clinical research settings.

5. Injections-Therapeutic

a. Description. Therapeutic injection procedures may play a significant role in the treatment of patients with lower extremity pain or pathology. Therapeutic injections involve the delivery of anesthetic and/or anti-inflammatory medications to the painful structure. Therapeutic injections have many potential benefits. Ideally, a therapeutic injection will: reduce inflammation in a specific target area; relieve secondary muscle spasm; allow a break from pain; and support therapy directed to functional recovery. Diagnostic and therapeutic injections should be used early and selectively to establish a diagnosis and support rehabilitation. If injections are overused or used outside the context of a monitored rehabilitation program, they may be of significantly less value.

b. Indications. Diagnostic injections are procedures which may be used to identify pain generators or pathology. For additional specific clinical indications see Specific Lower Extremity Injury Diagnosis, Testing and Treatment.

c. Special Considerations. The use of injections has become progressively sophisticated. Each procedure considered has an inherent risk, and risk versus benefit should be evaluated when considering injection therapy. In addition, all injections must include sterile technique.

d. Contraindications. General contraindications include local or systemic infection, bleeding disorders, allergy to medications used, and patient refusal. Specific contraindications may apply to individual injections.

e. Joint Injections: are generally accepted, well-established procedures that can be performed as analgesic or anti-inflammatory procedures.

i. Time to Produce Effect: Immediate with local anesthesia, or within three days if no anesthesia.

ii. Optimum Duration: Usually one to two injections is adequate.

iii. Maximum Duration: Not more than three to four times annually.

iv. Steroid injections should be used cautiously in diabetic patients. Diabetic patients should be reminded to check their blood-glucose level at least twice daily for two weeks post-injections.

f. Soft Tissue Injections: include bursa and tendon insertions. Injections under significant pressure should be avoided as the needle may be penetrating the tendon. Injection into the tendon can cause tendon degeneration, tendon breakdown, or rupture. Injections should be minimized for patients under 30 years of age.

i. When performing tendon insertion injections, the risk of tendon rupture should be discussed with the patient and the need for restricted duty emphasized.

(a). Time to Produce Effect: Immediate with local anesthesia, or within three days if no anesthesia.

(b). Optimum Duration: Usually one to two injections is adequate.

(c). Maximum Duration: Not more than three to four times annually.

ii. Steroid injections should be used cautiously in diabetic patients. Diabetic patients should be reminded to check their blood-glucose level at least twice daily for two weeks post-injections.

g. Trigger Point Injections: although generally accepted, have only rare indications in the treatment of lower extremity disorders. Therefore, the OWCA does not recommend their routine use in the treatment of lower extremity injuries.

i. Description. Trigger point treatment can consist of dry needling or injection of local anesthetic with

or without corticosteroid into highly localized, extremely sensitive bands of skeletal muscle fibers that produce local and referred pain when activated. Medication is injected in a four-quadrant manner in the area of maximum tenderness. Injection efficacy can be enhanced if injections are immediately followed by myofascial therapeutic interventions, such as vapo-coolant spray and stretch, ischemic pressure massage (myotherapy), specific soft tissue mobilization and physical modalities. There is conflicting evidence regarding the benefit of trigger point injections. A truly blinded study comparing dry needle treatment of trigger points is not feasible. There is no evidence that injection of medications improves the results of trigger-point injections. Needling alone may account for some of the therapeutic response.

ii. There is no indication for conscious sedation for patients receiving trigger point injections. The patient must be alert to help identify the site of the injection.

iii. Indications. Trigger point injections may be used to relieve myofascial pain and facilitate active therapy and stretching of the affected areas. They are to be used as an adjunctive treatment in combination with other treatment modalities such as functional restoration programs. Trigger point injections should be utilized primarily for the purpose of facilitating functional progress. Patients should continue with a therapeutic exercise program as tolerated throughout the time period they are undergoing intensive myofascial interventions. Myofascial pain is often associated with other underlying structural problems, and any abnormalities need to be ruled out prior to injection.

iv. Trigger point injections are indicated in those patients where well circumscribed trigger points have been consistently observed, demonstrating a local twitch response, characteristic radiation of pain pattern and local autonomic reaction, such as persistent hyperemia following palpation. Generally, these injections are not necessary unless consistently observed trigger points are not responding to specific, noninvasive, myofascial interventions within approximately a six week time frame.

v. Complications. Potential but rare complications of trigger point injections include infection, anaphylaxis, neurapraxia, and neuropathy. If corticosteroids are injected in addition to local anesthetic, there is a risk of developing local myopathy. Severe pain on injection suggests the possibility of an intraneural injection, and the needle should be immediately repositioned.

(a). Time to Produce Effect: Local anesthetic 30 minutes; no anesthesia 24 to 48 hours.

(b). Frequency: Weekly, suggest no more than four injection sites per session per week to avoid significant post-injection soreness.

(c). Optimum Duration: Four Weeks.

(d). Maximum Duration: Eight weeks. Occasional patients may require two to four repetitions of trigger point injection series over a one to two year period.

h. Viscosupplementation/Intracapsular Acid Salts: is an accepted form of treatment for osteoarthritis or degenerative changes in the knee joint. There is good evidence that intra-articular hyaluronic acid injections have only a small effect on knee pain and function. Therefore, the patient and treating physician should identify functional goals and the likelihood of achieving improved ability to perform activities of daily living or work activities with injections versus other treatments. The patient should agree to comply with the treatment plan including home exercise. These injections may be considered an alternative in patients who have failed non-operative treatment and surgery is not an option, particularly, if non-steroidal anti-inflammatory drug treatment is contraindicated or has been unsuccessful. Viscosupplementation is not recommended for patients with severe osteoarthritis who are surgical candidates. Its efficacy beyond six months is not well-established. There is no evidence that one product significantly outperforms another, prior authorization is required to approve product choice and for repeat series of injections.

i. One injection of 6 ml of Hylan G-F 20 may be effective and is an option for knee injections.

ii. Viscosupplementation is not recommended for ankle osteoarthritis due to the small effect size documented in knee conditions and the lack of evidence supporting its use in the ankle. Viscosupplementation is not recommended for hip arthritis given the probable superiority of corticosteroid injections. In rare cases a patient with significant hip osteoarthritis who does not qualify for surgical intervention may try viscosupplementation. It should be done with ultrasound or fluoroscopic guidance and will not necessarily require a series of three injections. The patient may choose to have repeat injections when the first injection was successful.

(a). Time to Produce Effect: After one series or one injection as discussed above, there must be a functional gain lasting three months to justify repeat injections.

(b). Frequency: One injection or one series (three to five injections generally spaced one week apart).

(c). Optimum/Maximum Duration: Varies. Efficacy beyond six months is not well-established.

i. Prolotherapy (also known as sclerotherapy) consists of peri-articular injections of hypertonic dextrose with or without phenol with the goal of inducing an inflammatory response that will recruit cytokine growth factors involved in the proliferation of connective tissue. Advocates of prolotherapy propose that these injections will alleviate complaints related to joint laxity by promoting the growth of connective tissue and stabilizing the involved joint.

i. Laboratory studies may lend some biological plausibility to claims of connective tissue growth, but high quality published clinical studies are lacking. The dependence of the therapeutic effect on the inflammatory response is poorly defined, raising concerns about the use of conventional anti-inflammatory drugs when proliferant injections are given. The evidence in support of prolotherapy is insufficient and therefore, its use is not recommended in lower extremity injuries.

6. Jobsite Alteration. Early evaluation and training of body mechanics are essential for every injured worker. Risk factors to be addressed include: repetitive work, lifting, and forces that have an impact on the lower extremity. In some cases, this requires a jobsite evaluation. There is no single factor or combination of factors that is proven to prevent or ameliorate lower extremity pain, but a combination of ergonomic and psychosocial factors are generally considered to be important. Physical factors that may be considered include use of force, repetitive work, squatting, climbing,

kneeling, crouching, crawling, prolonged standing, walking a distance or on uneven surfaces, jumping, running, awkward positions requiring use of force, and lower extremity vibration. Psychosocial factors to be considered include pacing, degree of control over job duties, perception of job stress, and supervisory support.

a. The job analysis and modification should include input from the employee, employer, and a medical professional familiar with work place evaluation. An ergonomist may also provide useful information. The employee must be observed performing all job functions in order for the jobsite analysis to be valid. Periodic follow-up is recommended to evaluate effectiveness of the intervention and need for additional ergonomic changes.

i. Ergonomic Changes may be made to modify the hazards identified. In addition, workers should be counseled to vary tasks throughout the day. When possible, employees performing repetitive tasks should take 15 to 30 second breaks every 10 to 20 minutes, or 5-minute breaks every hour. Mini-breaks should include stretching exercises.

ii. Interventions should consider engineering controls (e.g., mechanizing the task, changing the tool used, or adjusting the jobsite), or administrative controls (e.g., adjusting the time an individual performs the task).

7. Medications and medical management. Use of medications will vary widely due to the spectrum of injuries from simple strains to complicated fractures. A thorough medication history, including use of alternative and over-the-counter medications, should be performed at the time of the initial visit and updated periodically. Treatment for pain control is initially accomplished with acetaminophen and/or NSAIDs. The patient should be educated regarding the interaction with prescription and over-the-counter medications as well as the contents of over-the-counter herbal products.

a. Nonsteroidal anti-inflammatory drugs (NSAIDs) and acetaminophen are useful in the treatment of injuries associated with degenerative joint disease and/or inflammation. These same medications can be used for pain control.

b. Topical agents can be beneficial for pain management in lower extremity injuries. This includes topical capsaicin, nonsteroidals, as well as topical iontphoretics/phonophoretics, such as steroid creams and lidocaine.

c. Glucosamine and chondroitin are sold in the United States as dietary supplements. Their dosage, manufacture, and purity are not regulated by the Food and Drug Administration. For moderate to severe knee osteoarthritis, there is good evidence for the effectiveness of a pharmaceutical grade combination of 500 mg glucosamine hydrochloride and 400 mg chondroitin sulfate three times per day. Effectiveness for mild disease is unknown. Recent literature suggests that chondroitin sulfate in a dose of 800 mg once daily may reduce the rate of joint degradation as demonstrated by joint space loss on serial x-rays.

d. For mild-to-moderate osteoarthritis confined to the hip, there is good evidence that a pharmaceutical-grade glucosamine sulfate is unlikely to produce a clinically significant improvement in pain and joint function.

e. When osteoarthritis is identified as a contributing factor to a work–related injury, pharmaceutical grade glucosamine and chondroitin may be tried. Long-term coverage for these medications would fall under Workers' Compensation only when the arthritic condition is primarily related to the work injury.

f. S-adenosyl methionine (SAM-e), like glucosamine and chondroitin, is sold as a dietary supplement in the United States, with a similar lack of standard preparations of dose and manufacture. There is some evidence that a pharmaceutical-grade SAM-e is as effective as celecoxib in improving pain and function in knee osteoarthritis, but its onset of action is slower. Studies using liquid chromatography have shown that it may lose its potency after several weeks of storage. In addition, SAM-e has multiple additional systemic effects. It is not currently recommended due to lack of availability of pharmaceutical quality, systemic effects, and loss of potency with storage.

i. The following are listed in alphabetical order.

(a). Acetaminophen: is an effective analgesic with antipyretic but not anti-inflammatory activity. Acetaminophen is generally well tolerated, causes little or no gastrointestinal irritation and is not associated with ulcer formation. Acetaminophen has been associated with liver toxicity in overdose situations or in chronic alcohol use. Patients may not realize that many over-the-counter preparations may contain acetaminophen. The total daily dose of acetaminophen is recommended not to exceed 2250 mg per 24 hour period, from all sources, including narcotic-acetaminophen combination preparations.

(i). Optimal Duration: 7 to 10 days.

(ii). Maximum Duration: Chronic use as indicated on a case-by-case basis. Use of this substance long-term for three days per week or greater may be associated with rebound pain upon cessation.

b. Bisphosphonates may be used for those qualifying under osteoporosis guidelines. Long-term use for the purpose of increasing prosthetic fixation is not recommended as long-term improvement in fixation is not expected. See Osteoporosis Management Section below.

c. Deep Venous Thrombosis Prophylaxis is a complex issue involving many variables such as individual patient characteristics, the type of surgery, anesthesia used and agent(s) used for prophylaxis. Final decisions regarding prophylaxis will depend on the surgeon's clinical judgment. The following are provided as generally accepted concepts regarding prophylaxis at the time of writing of these guidelines.

i. All patients undergoing lower extremity surgery or prolonged lower extremity immobilization should be evaluated for elevated risk for DVT and should receive education on prevention. Possible symptoms should be discussed. Patients at higher risk than the normal population include, but are not limited to, those with known hypercoagulable states and those with previous pulmonary embolism or DVT. Those considered at higher risk for bleeding, which may alter thromboprophylaxis protocols, include patients with a history of a bleeding disorder, recent gastrointestinal bleed, or hemorrhagic stroke.

ii. There is no evidence to support mandatory prophylaxis for all patients who are immobilized or undergo lower extremity procedures, outside of hip or knee arthroplasties or hip fracture repair.

iii. Hip and knee arthroplasties and hip fracture repair are standard risk factors requiring thromboprophylaxis. Commonly used agents are low molecular weight heparin, low dose un-fractionated heparin (LDUH), synthetic pentasaccaride fondaparinux, or warfarin. If aspirin is used, it should be accompanied by aggressive mechanical prophylaxis.

iv. All patients should be mobilized as soon as possible after surgery. Mechanical prophylaxis such as pneumatic devices that are thigh calf, calf only, or foot pumps may be considered immediately post-operatively and/or until the patient is discharged home. Thigh length or knee high graduated compression stockings are used for most patients. With prolonged prophylaxis, lab tests must be drawn regularly. These may be accomplished with home health care or outpatient laboratories when appropriate.

d. Minor Tranquilizer/Muscle Relaxants are appropriate for muscle spasm, mild pain and sleep disorders. When prescribing these agents, physicians must seriously consider side effects of drowsiness or dizziness and the fact that benzodiazepines may be habit-forming.

i. Optimal Duration: One week.

ii. Maximum Duration: Four weeks.

e. Narcotics: should be primarily reserved for the treatment of severe lower extremity pain. There are circumstances where prolonged use of narcotics is justified based upon specific diagnosis, and in these cases, it should be documented and justified. In mild-to-moderate cases of lower extremity pain, narcotic medication should be used cautiously on a case-by-case basis. Adverse effects include respiratory depression, the development of physical and psychological dependence, and impaired alertness.

i. Narcotic medications should be prescribed with strict time, quantity, and duration guidelines, and with definitive cessation parameters. Pain is subjective in nature and should be evaluated using a pain scale and assessment of function to rate effectiveness of the narcotic prescribed. Any use beyond the maximum duration should be documented and justified based on the diagnosis and/or invasive procedures.

(a). Optimal Duration: Three to seven days.

(b). Maximum Duration: Two weeks. Use beyond two weeks is acceptable in appropriate cases. Refer to Chronic Pain Guidelines which gives a detailed discussion regarding medication use in chronic pain management. When prescribing beyond the maximum duration, it is recommended physicians access the Colorado PDMP (Prescription Drug Monitoring Program). This system allows the prescribing physician to see all controlled substances prescribed by other physicians for an individual patient.

f. Nonsteroidal Anti-Inflammatory Drugs (NSAIDs): are useful for pain and inflammation. In mild cases, they may be the only drugs required for analgesia. There are several classes of NSAIDs, and the response of the individual injured worker to a specific medication is unpredictable. For this reason, a range of NSAIDs may be tried in each case with the most effective preparation being continued. Patients should be closely monitored for adverse reactions. The US Food and Drug Administration advise that many NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. Naproxen sodium does not appear to be associated with increased risk of vascular events. Administration of proton pump inhibitors, histamine 2 blockers, or prostaglandin analog misoprostol along with these NSAIDs may reduce the risk of duodenal and gastric ulceration but do not impact possible cardiovascular complications. Due to the cross-reactivity between aspirin and NSAIDs, NSAIDs should not be used in aspirin-sensitive patients, and should be used with caution in all asthma patients. NSAIDs are associated with abnormal renal function, including renal failure, as well as, abnormal liver function. Certain NSAIDs may have interactions with various other medications. Individuals may have adverse events not listed above. Intervals for metabolic screening are dependent upon the patient's age, general health status and should be within parameters listed for each specific medication. Complete Blood Count (CBC) and liver and renal function should be monitored at least every six months in patients on chronic NSAIDs and initially when indicated.

i. NSAIDs may be used for pain management after joint replacement. They have also been used to reduce heterotopic ossification after arthroplasty. NSAIDs do reduce the radiographically documented heterotopic ossification in this setting, but there is some evidence that they do not improve functional outcomes and they may increase the risk of bleeding events in the post-operative period. Their routine use for prevention of heterotopic bone formation is not recommended.

(a). Non-Selective Nonsteroidal Anti-Inflammatory Drugs: Includes NSAIDs and acetylsalicylic acid (aspirin). Serious GI toxicity, such as bleeding, perforation, and ulceration can occur at any time, with or without warning symptoms in patients treated with traditional NSAIDs. Physicians should inform patients about the signs and/or symptoms of serious gastrointestinal toxicity and what steps to take if they occur. Anaphylactoid reactions may occur in patients taking NSAIDs. NSAIDs may interfere with platelet function. Fluid retention and edema have been observed in some patients taking NSAIDs.

i. Optimal Duration: One week.

ii. Maximum Duration: One year. Use of these substances long-term (Three days per week or greater) is associated with rebound pain upon cessation.

b. Selective Cyclo-oxygenase-2 (COX-2) Inhibitors:

i. COX-2 inhibitors are more recent NSAIDs and differ in adverse side effect profiles from the traditional NSAIDs. The major advantages of selective COX-2 inhibitors over traditional NSAIDs are that they have less gastrointestinal toxicity and no platelet effects. COX-2 inhibitors can worsen renal function in patients with renal insufficiency, thus renal function may need monitoring.

ii. COX-2 inhibitors should not be first-line for low risk patients who will be using a NSAID short-term but are indicated in select patients for whom traditional NSAIDs are not tolerated. Serious upper GI adverse events can occur even in asymptomatic patients. Patients at high risk for GI bleed include those who use alcohol, smoke, are older than 65, take corticosteroids or anti-coagulants, or have a longer duration of therapy. Celecoxib is contraindicated in sulfonamide allergic patients.

(a). Optimal Duration: 7 to 10 days.

(b). Maximum Duration: Chronic use is appropriate in individual cases. Use of these substances long-term (Three days per week or greater) is associated with rebound pain upon cessation.

g. Oral Steroids: have limited use but are accepted in cases requiring potent anti-inflammatory drug effect in carefully selected patients. A one-week regime of steroids may be considered in the treatment of patients who have arthritic flare-ups with significant inflammation of the joint. The physician must be fully aware of potential contraindications for the use of all steroids such as hypertension, diabetes, glaucoma, peptic ulcer disease, etc., which should be discussed with the patient.

i. Optimal Duration: Three to seven days.

ii. Maximum Duration: Seven days.

h. Osteoporosis Management. All patients with conditions which require bone healing, especially those over 50, should be encouraged to ingest at least 1200 mg of Calcium and 800 IU of Vitamin D per day. There is some evidence that, for women in the older age group (58 to 88) with low hip bone density, greater callus forms for those who adhere to these recommendations than those who do not. Although the clinical implications of this are not known, there is greater non-union in this age group and thus, coverage for these medications during the fracture healing time period is recommended. At this time there is no evidence that bisphosphonates increase acute fracture healing.

i. Female patients over 65 should be referred for an osteoporosis evaluation if one has not been completed the previous year. Patients who have been on prednisone at a dose of 5 to 7.5 mg for more than 3 months should be evaluated for glucocorticoid induced osteoporosis. An osteoporosis evaluation may be considered for males who: are over 70, are physically inactive, have previous fragility fracture, have a BMI less than 20, or have been hypogonadal for 5 years. Evaluation may also be considered for patients on medications that can cause bone loss, patients who have suffered a fracture due to a low-impact fall or with minimum to no provocation, and women under 65 with one of the following: menopause before 40, current smoker, or body mass index less than 20. Low body weight appears to be the best predictor of osteoporosis in women younger that 65. In one adequate study, all patients aged 50 to 75 referred to an orthopaedic department for treatment of wrist, vertebral, proximal humerus, or hip fractures received bone mass density testing. 97 percent of patients had either osteoporosis (45 percent) or osteopenia (42 percent). Referral is important to prevent future factures in these groups. Long-term care for osteoporosis is not covered under workers compensation even though it may be discovered due to an injury-related acute fracture.

i. Psychotropic/Anti-anxiety/Hypnotic Agents may be useful for treatment of mild and chronic pain, dysesthesias, sleep disorders, and depression. Post-operative patients may receive medication to assure normal sleep cycles. Antidepressant medications, such as tricyclics and Selective Serotonin Reuptake Inhibitors (SSRIs), are useful for affective disorder and chronic pain management. Tricyclic antidepressant agents, in low dose, are useful for chronic pain but have more frequent side effects.

i. Anti-anxiety medications are best used for short-term treatment (i.e., less than six months). Accompanying sleep disorders are best treated with sedating antidepressants prior to bedtime. Frequently, combinations of the above agents are useful. As a general rule, physicians should access the patient's prior history of substance abuse or depression prior to prescribing any of these agents.

ii. Due to the habit-forming potential of the benzodiazepines and other drugs found in this class, they are not routinely recommended. Refer to the Chronic Pain Guidelines which give a detailed discussion regarding medication use in chronic pain management.

(a). Optimal Duration: One to six months.

(b). Maximum Duration: 6 to 12 months, with monitoring.

j. Topical Drug Delivery: Creams and patches may be an alternative treatment of localized musculoskeletal disorders. It is necessary that all topical agents be used with strict instructions for application as well as the maximum number of applications per day to obtain the desired benefit and avoid potential toxicity. As with all medications, patient selection must be rigorous to select those patients with the highest probability of compliance. Refer to "Iontophoresis" in the Passive Therapy of this section for information regarding topical iontophoretic agents.

i. Topical Salicylates and Nonsalicylates: have been shown to be effective in relieving pain in acute and chronic musculoskeletal conditions. Topical salicylate and nonsalicylates achieve tissue levels that are potentially therapeutic, at least with regard to COX inhibition. Other than local skin reactions, the side effects of therapy are minimal, although not non-existent, and the usual contraindications to use of these compounds needs to be considered. Local skin reactions are rare and systemic effects were even less common. Their use in patients receiving warfarin therapy may result in alterations in bleeding time. Overall, the low level of systemic absorption can be advantageous; allowing the topical use of these medications when systemic administration is relatively contraindicated such as is the case in patients with hypertension, cardiac failure, or renal insufficiency.

(a). There is no evidence that topical agents are more or less effective than oral medications.

(i). Optimal Duration: One week.

(ii). Maximal Duration: Two weeks per episode.

ii. Capsaicin: is another medication option for topical drug use in lower extremity injury. Capsaicin offers a safe and effective alternative to systemic NSAID therapy. Although it is quite safe, effective use of capsaicin is limited by the local stinging or burning sensation that typically dissipates with regular use, usually after the first 7 to 10 days of treatment. Patients should be advised to apply the cream on the affected area with a plastic glove or cotton applicator and to avoid inadvertent contact with eyes and mucous membranes.

(a). Optimal Duration: One week.

(b). Maximal Duration: Two weeks per episode.

iii. Iontophoretic Agents: Refer to "Iontophoresis," under Passive Therapy of this section.

k. Tramadol is useful in relief of lower extremity pain and has been shown to provide pain relief equivalent to that of commonly prescribed NSAIDs. Tramadol is an atypical opioid with norepinephrine and serotonin reuptake inhibition. It is not considered a controlled substance in the U.S. Although Tramadol may cause impaired alertness, it is generally well tolerated, does not cause gastrointestinal ulceration, or exacerbate hypertension or congestive heart failure. Tramadol should be used cautiously in patients who have a history of seizures or who are taking medication that may lower the seizure threshold, such as MAO inhibitors, SSRIs, and tricyclic antidepressants. This medication has physically addictive properties and withdrawal may follow abrupt discontinuation and is not recommended for patients with prior opioid addiction.

i. Optimal Duration: Three to seven days.

ii. Maximum Duration: Two weeks. Use beyond two weeks is acceptable in appropriate cases.

8. Occupational Rehabilitation Programs

a. Interdisciplinary: programs are well-established treatment for patients with sub-acute and functionally impairing cervical spine pain. They are characterized by a variety of disciplines that participate in the assessment, planning, and/or implementation of an injured workers program with the goal for patients to gain full or optimal function and return to work. There should be close interaction and integration among the disciplines to ensure that all members of the team interact to achieve team goals. Programs should include cognitive-behavioral therapy as there is good evidence for its effectiveness in patients with chronic low back pain and it is probably effective in cervical spine pain. These programs are for patients with greater levels of disability, dysfunction, deconditioning and psychological involvement. For patients with chronic pain, refer to the Chronic Pain Disorder Medical Treatment Guidelines.

i. Work Hardening

(a). Work Hardening is an interdisciplinary program addressing a patient's employability and return to work. It includes a progressive increase in the number of hours per day that a patient completes work simulation tasks until the patient can tolerate a full workday. This is accomplished by addressing the medical, psychological, behavioral, physical, functional, and vocational components of employability and return-to-work.

(b). This can include a highly structured program involving a team approach or can involve any of the components thereof. The interdisciplinary team should, at a minimum, be comprised of a qualified medical director who is board certified with documented training in occupational rehabilitation; team physicians having experience in occupational rehabilitation; occupational therapy; physical therapy; case manager; and psychologist. As appropriate, the team may also include: chiropractor, RN, vocational specialist or Certified Biofeedback Therapist.

(i). Length of Visit: up to eight hours/day

(ii). Frequency: Two to five visits per week

(iii). Optimal Duration: Two to four weeks

(iv). Maximum Duration: Six weeks. Participation in a program beyond six weeks must be documented with respect to need and the ability to facilitate positive symptomatic or functional gains.

b. Non-Interdisciplinary. These generally accepted programs are work-related, outcome-focused, individualized treatment programs. Objectives of the program include, but are not limited to, improvement of cardiopulmonary and neuromusculoskeletal functions (strength, endurance, movement, flexibility, stability, and motor control functions), patient education, and symptom relief. The goal is for patients to gain full or optimal function and return to work. The service may include the time-limited use of passive modalities with progression to achieve treatment and/or simulated/real work.

i. Work Conditioning. These programs are usually initiated once reconditioning has been completed but may be offered at any time throughout the recovery phase. It should be initiated when imminent return of a patient to modified- or full-duty is not an option, but the prognosis for returning the patient to work at completion of the program is at least fair to good.

(a). Length of visit: One to two hours per day.

(b). Frequency: Two to five visits per week.

(c). Optimum Duration: Two to four weeks.

(d). Maximum Duration: Six weeks. Participation in a program beyond six weeks must be documented with respect to need and the ability to facilitate positive symptomatic or functional gains.

ii. Work Simulation is a program where an individual completes specific work-related tasks for a particular job and return-to-work. Use of this program is appropriate when modified duty can only be partially accommodated in the work place, when modified duty in the work place is unavailable, or when the patient requires more structured supervision. The need for work place simulation should be based upon the results of a Functional Capacity Evaluation and/or Jobsite Analysis.

(a). Length of visit: two to six hours per day.

(b). Frequency: two to five visits per week.

(c). Optimum Duration: two to four weeks.

(d). Maximum Duration: Six weeks. Participation in a program beyond six weeks must be documented with respect to need and the ability to facilitate positive symptomatic or functional gains.

9. Orthotics and prosthetics

a. Fabrication/Modification of Orthotics: would be used when there is need to normalize weight-bearing, facilitate better motion response, stabilize a joint with insufficient muscle or proprioceptive/reflex competencies, to protect subacute conditions as needed during movement, and correct biomechanical problems. Footwear modifications may be necessary for work shoes and everyday shoes. Replacement is needed every six months to one year. For specific types of orthotics/prosthetics see Section e, "Specific Lower Extremity Injury Diagnosis, Testing and Treatment."

i. Time to Produce Effect: One to three sessions (includes wearing schedule and evaluation).

ii. Frequency: One to two times per week.

iii. Optimum/Maximum Duration: Over a period of approximately four to six weeks for casting, fitting, and re-evaluation.

b. Orthotic/Prosthetic Training: is the skilled instruction (by qualified providers) in the proper use of orthotic devices and/or prosthetic limbs including stump

preparation, donning and doffing limbs, instruction in wearing schedule and orthotic/prosthetic maintenance training. Training can include gait, mobility, transfer and self-care techniques.

i. Time to Produce Effect: Two to six sessions.

ii. Frequency: Three times per week.

iii. Optimum/Maximum Duration: two to four months.

c. Splints or Adaptive Equipment—design, fabrication and/or modification indications include the need to control neurological and orthopedic injuries for reduced stress during functional activities and modify tasks through instruction in the use of a device or physical modification of a device, which reduces stress on the injury. Equipment should improve safety and reduce risk of re-injury. This includes high and low technology assistive options such as workplace modifications, crutch or walker training, and self-care aids.

i. Time to Produce Effect: Immediate.

ii. Frequency: One to three sessions or as indicated to establish independent use.

iii. Optimum/Maximum Duration: One to three sessions.

10. Patient Education. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of prolonging the beneficial effects of treatment, as well as facilitating self-management of symptoms and injury prevention. The patient should be encouraged to take an active role in the establishment of functional outcome goals. They should be educated on their specific injury, assessment findings, and plan of treatment. Instruction on proper body mechanics and posture, positions to avoid, self-care for exacerbation of symptoms, and home exercise should also be addressed.

a. Time to Produce Effect: Varies with individual patient.

b. Frequency: Should occur at each visit.

11. Personality/psychosocial/psychiatric/psychological intervention. Psychosocial treatment is a generally accepted, widely used and well-established intervention. This group of therapeutic and diagnostic modalities includes, but is not limited to: individual counseling, group therapy, stress management, psychosocial crises intervention, hypnosis and meditation. Any screening or diagnostic workup should clarify and distinguish between pre-existing versus aggravated versus purely causative psychological conditions. Psychosocial intervention is recommended as an important component in the total management program that should be implemented as soon as the problem is identified. This can be used alone or in conjunction with other treatment modalities. Providers treating patients with chronic pain should refer to the OWCA's Chronic Pain Disorder Medical Treatment Guidelines.

a. Time to Produce Effect: Two to four weeks.

b. Frequency: One to three times weekly for the first four weeks (excluding hospitalization, if required), decreasing to one to two times per week for the second month. Thereafter, two to four times monthly.

c. Optimum Duration: Six weeks to three months.

d. Maximum Duration: 3 to 12 months. Counseling is not intended to delay but to enhance functional recovery. For select patients, longer supervised treatment may be required, and if further counseling beyond three months is indicated, documentation addressing which pertinent issues are pre-existing versus aggravated versus causative, as well as projecting a realistic functional prognosis, should be provided by the authorized treating provider every four to six weeks during treatment.

12. Restriction of activities varies according to the specific diagnosis and the severity of the condition. Job modification/modified duty are frequently required to avoid exacerbation of the injured lower extremity. Complete work cessation should be avoided, if possible, since it often further aggravates the pain presentation. Modified return-to-work is almost always more efficacious and rarely contraindicated in the vast majority of injured workers with lower extremity injuries.

13. Return-to-Work. Early return-to-work should be a prime goal in treating occupational injuries given the poor return-to-work prognosis for an injured worker who has been out of work for more than six months. It is imperative that the patient be educated regarding the benefits of return-to-work, work restrictions, and follow-up if problems arise. When attempting to return a patient to work after a specific injury, clear objective restrictions of activity level should be made. An accurate job description with detailed physical duty restrictions is often necessary to assist the physician in making return-to-work recommendations. This may require a jobsite evaluation.

a. Employers should be prepared to offer transitional work. This may consist of temporary work in a less demanding position, return to the regular job with restrictions, or gradual return to the regular job. Company policies which encourage return-to-work with positive communication are most likely to have decreased worker disability.

b. Return-to-work is defined as any work or duty that the patient is able to perform safely. It may not be the patient's regular work. Due to the large spectrum of injuries of varying severity and varying physical demands in the work place, it is not possible to make specific return-to-work guidelines for each injury. Therefore, the OWCA recommends the following:

c. Compliance with Activity Restrictions: In some cases, compliance with restriction of activity levels may require a complete jobsite evaluation, a functional capacity evaluation (FCE), or other special testing. Refer to the "Special Tests" section of these guidelines.

d. Establishment of a Return-to-Work Status: Ascertaining a return-to-work status is part of medical care, should be included in the treatment and rehabilitation plan, and addressed at every visit. A description of daily activity limitations is part of any treatment plan and should be the basis for restriction of work activities. In most cases non-surgical the patient should be able to return to work in some capacity or in an alternate position consistent with medical treatment within several days unless there are extenuating circumstances. Injuries requiring more than two weeks off work should be thoroughly documented (Some of these diagnoses are listed in Specific Lower Extremity Injury Diagnosis, Testing and Treatment).

e. Establishment of Activity Level Restrictions: Communication is essential between the patient, employer and provider to determine appropriate restrictions and

return-to-work dates. It is the responsibility of the physician to provide clear concise restrictions, and it the employer's responsibility to determine if temporary duties can be provided within the restrictions. For lower extremity injuries, the following should be addressed when describing the patient's activity level:

i. lower body postures such as squatting, kneeling, crawling, stooping, or climbing, including duration and frequency;

ii. ambulatory level for distance, frequency and terrain;

iii. static and dynamic standing including duration and frequency;

iv. ability to maintain balance;

v. use of adaptive devices, including cane and walker, to accomplish basic job duties.

14. Therapy-Active. The following active therapies are widely used and accepted methods of care for a variety of work-related injuries. They are based on the philosophy that therapeutic exercise and/or activity are beneficial for restoring flexibility, strength, endurance, function, range-of-motion, and can alleviate discomfort. Active therapy requires an internal effort by the individual to complete a specific exercise or task. This form of therapy requires supervision from a therapist or medical provider such as verbal, visual and/or tactile instruction(s). At times, the provider may help stabilize the patient or guide the movement pattern but the energy required to complete the task is predominately executed by the patient.

a. Patients should be instructed to continue active therapies at home as an extension of the treatment process in order to maintain improvement levels. Follow-up visits to reinforce and monitor progress and proper technique are recommended. Home exercise can include exercise with or without mechanical assistance or resistance and functional activities with assistive devices.

i. The following active therapies are listed in alphabetical order:

(a). Activities of Daily Living (ADL) are well-established interventions which involve instruction, active-assisted training, and/or adaptation of activities or equipment to improve a person's capacity in normal daily activities such as self-care, work re-integration training, homemaking, and driving.

(i). Time to Produce Effect: Four to five treatments.

(ii). Frequency: Three to five times per week.

(iii). Optimum Duration: Four to six weeks.

(iv). Maximum Duration: Six weeks.

(b). Aquatic Therapy is a well-accepted treatment which consists of the therapeutic use of aquatic immersion for therapeutic exercise to promote ROM, flexibility, core stabilization, endurance, strengthening, body mechanics, and pain management. Aquatic therapy includes the implementation of active therapeutic procedures in a swimming or therapeutic pool. The water provides a buoyancy force that lessens the amount of force gravity applies to the body. The decreased gravity effect allows the patient to have a mechanical advantage and more likely to have a successful trial of therapeutic exercise. Studies have shown that the muscle recruitment for aquatic therapy versus similar non–aquatic motions is significantly less. Because there is always a risk of recurrent or additional damage to the muscle tendon unit after a surgical repair, aquatic therapy may be preferred by surgeons to gain early return of ROM. In some cases the patient will be able to do the exercises unsupervised after the initial supervised session. Parks and recreation contacts may be used to locate less expensive facilities for patients. Indications include:

(i). Post-operative therapy as ordered by the surgeon; or

(ii). Intolerance for active land-based or full-weight-bearing therapeutic procedures; or

(iii). Symptoms that are exacerbated in a dry environment; and

(iv). Willingness to follow through with the therapy on a regular basis.

(v). The pool should be large enough to allow full extremity ROM and fully erect posture. Aquatic vests, belts, snorkels, and other devices may be used to provide stability, balance, buoyancy, and resistance.

[a]. Time to Produce Effect: Four to five treatments.

[b]. Frequency: Three to five times per week.

[c]. Optimum Duration: Four to six weeks.

[d]. Maximum Duration: Eight weeks.

(vi). A self-directed program is recommended after the supervised aquatics program has been established, or alternatively a transition to a self-directed dry environment exercise program.

(vii). There is some evidence that for osteoarthritis of the hip or knee, aquatic exercise probably slightly reduces pain and slightly improves function over three months.

(c.) Functional Activities are the use of therapeutic activity to enhance mobility, body mechanics, employability, coordination, balance, and sensory motor integration.

(i). Time to Produce Effect: Four to five treatments

(ii). Frequency: Three to five times per week.

(iii). Optimum Duration: Four to six weeks.

(iv). Maximum Duration: Six weeks

(d). Functional Electrical Stimulation is the application of electrical current to elicit involuntary or assisted contractions of atrophied and/or impaired muscles. Indications include muscle atrophy, weakness, sluggish muscle contraction, neuromuscular dysfunction or peripheral nerve lesion. Indications also may include an individual who is precluded from active therapy.

(i). Time to Produce Effect: Two to six treatments.

(ii). Frequency: Three times per week.

(iii). Optimum Duration: Eight weeks.

(iv). Maximum Duration: Eight weeks. If beneficial, provide with home unit. Home use is not recommended for neuromuscularly intact patients.

(e). Gait Training is crutch walking, cane or walker instruction to a person with lower extremity injury or surgery. Indications include the need to promote normal gait

pattern with assistive devices; instruct in the safety and proper use of assistive devices; instruct in progressive use of more independent devices (i.e., platform-walker, to walker, to crutches, to cane); instruct in gait on uneven surfaces and steps (with and without railings) to reduce risk of fall, or loss of balance; and/or instruct in equipment to limit weight-bearing for the protection of a healing injury or surgery.

(i). Time to Produce Effect: Two to six treatments.

(ii). Frequency: Two to three times per week.

(iii). Optimum Duration: Two weeks.

(iv). Maximum Duration: Two weeks.

(f). Neuromuscular Re-education: is the skilled application of exercise with manual, mechanical, or electrical facilitation to enhance strength; movement patterns; neuromuscular response; proprioception; kinesthetic sense; coordination; education of movement, balance and posture. Indications include the need to promote neuromuscular responses through carefully timed proprioceptive stimuli to elicit and improve motor activity in patterns similar to normal neurologically developed sequences, and improve neuromotor response with independent control.

(i). Time to Produce Effect: Two to six treatments.

(ii). Frequency: Three times per week.

(iii). Optimum Duration: Four to eight weeks.

(iv). Maximum Duration: Eight weeks.

(g). Therapeutic Exercise is a generally accepted treatment with or without mechanical assistance or resistance, may include isoinertial, isotonic, isometric and isokinetic types of exercises. There is good evidence to support the functional benefits of manual therapy with exercise, walking programs, conditioning, and other combined therapy programs. Indications include the need for cardiovascular fitness, reduced edema, improved muscle strength, improved connective tissue strength and integrity, increased bone density, promotion of circulation to enhance soft tissue healing, improvement of muscle recruitment, increased range of motion and are used to promote normal movement patterns. May also include complementary/alternative exercise movement therapy.

(i). Time to Produce Effect: Two to six treatments.

(ii). Frequency: Three to five times per week.

(iii). Optimum Duration: Four to eight weeks.

(iv). Maximum Duration: Eight weeks.

(h). Wheelchair Management and Propulsion is the instruction and training of self-propulsion and proper use of a wheelchair. This includes transferring and safety instruction. This is indicated in individuals who are not able to ambulate due to bilateral lower extremity injuries, inability to use ambulatory assistive devices, and in cases of multiple traumas.

(i). Time to Produce Effect: Two to six treatments.

(ii). Frequency: Two to three times per week.

(iii). Optimum Duration: Two weeks.

(iv). Maximum Duration: Two weeks.

15. Therapy-passive. Most of the following passive therapies and modalities are generally well-accepted methods of care for a variety of work-related injuries. Passive therapy includes those treatment modalities that do not require energy expenditure on the part of the patient. They are principally effective during the early phases of treatment and are directed at controlling symptoms such as pain, inflammation and swelling and to improve the rate of healing soft tissue injuries. They should be use adjunctively with active therapies to help control swelling, pain, and inflammation during the rehabilitation process. They may be used intermittently as a therapist deems appropriate or regularly if there are specific goals with objectively measured functional improvements during treatment.

a. On occasion, specific diagnoses and post-surgical conditions may warrant durations of treatment beyond those listed as "maximum." Factors such as exacerbation of symptoms, re-injury, interrupted continuity of care and comorbidities may also extend durations of care. Specific goals with objectively measured functional improvement during treatment must be cited to justify extended durations of care. It is recommended that, if no functional gain is observed after the number of treatments under "time to produce effect" has been completed alternative treatment interventions, further diagnostic studies, or further consultations should be pursued.

i. The following passive therapies and modalities are listed in alphabetical order.

(a). Continuous Passive Motion (CPM) is a form of passive motion using specialized machinery that acts to move a joint and may also pump blood and edema fluid away from the joint and periarticular tissues. CPM is effective in preventing the development of joint stiffness if applied immediately following surgery. It should be continued until the swelling that limits motion of the joint no longer develops. ROM for the joint begins at the level of patient tolerance and is increased twice a day as tolerated. Home use of CPM is expected after chondral defect surgery. CPM may be necessary for cases with ACL repair, manipulation, joint replacement or other knee surgery if the patient has been non compliant with pre-operative ROM exercises. Use of this equipment may require home visits.

(i). Time to Produce Effect: Immediate.

(ii). Frequency: Up to four times a day.

(iii). Optimum Duration: Up to three weeks post surgical.

(iv). Maximum Duration: Three weeks.

(b). Contrast Baths can be used for alternating immersion of extremities in hot and cold water. Indications include edema in the sub-acute stage of healing, the need to improve peripheral circulation and decrease joint pain and stiffness.

(i). Time to Produce Effect: Three treatments.

(ii). Frequency: Three times per week.

(iii). Optimum Duration: Four weeks.

(iv). Maximum Duration: One month.

(c). Electrical Stimulation (Unattended): once applied, requires minimal on-site supervision by the physician or non-physician provider. Indications include

pain, inflammation, muscle spasm, atrophy, decreased circulation, and the need for osteogenic stimulation.

(i). Time to Produce Effect: Two to four treatments.

(ii). Frequency: Varies, depending upon indication, between two to three times per day to one time a week. Provide home unit if treatment is effective and frequent use is recommended.

(iii). Optimum Duration: One to three months.

(iv). Maximum Duration: Three months.

(d). Fluidotherapy: employs a stream of dry, heated air that passes over the injured body part. The injured body part can be exercised during the application of dry heat. Indications include the need to enhance collagen extensibility before stretching, reduce muscle guarding, or reduce inflammatory response.

(i). Time to Produce Effect: One to four treatments.

(ii). Frequency: One to three times per week.

(iii). Optimum Duration: Four weeks.

(iv). Maximum Duration: One month.

(e). Hyperbaric Oxygen Therapy. There is no evidence to support long-term benefit of hyperbaric oxygen therapy for non-union lower extremity fractures. It is not recommended.

(f). Infrared Therapy is a radiant form of heat application. Indications include the need to elevate the pain threshold before exercise and to alleviate muscle spasm to promote increased movement.

(i). Time to Produce Effect: Two to four treatments.

(ii). Frequency: Three to five times per week.

(iii). Optimum Duration: Three weeks as primary, or up to two months if used intermittently as an adjunct to other therapeutic procedures.

(iv). Maximum Duration: Two months.

(g). Iontophoresis: is the transfer of medication, including, but not limited to, steroidal anti-inflammatory and anesthetics, through the use of electrical stimulation. Indications include pain (Lidocaine), inflammation (hydrocortisone, salicylate), edema (mecholyl, hyaluronidase, and salicylate), ischemia (magnesium, mecholyl, and iodine), muscle spasm (magnesium, calcium); calcific deposits (acetate), scars, and keloids (chlorine, iodine, acetate).

(i). Time to Produce Effect: One to four treatments.

(ii). Frequency: 3 times per week with at least 48 hours between treatments.

(iii). Optimum Duration: 8 to 10 treatments.

(iv). Maximum Duration: 10 treatments.

(h). Manipulation: is a generally accepted, well-established and widely used therapeutic intervention for lower extremity injuries. Manipulative treatment (not therapy) is defined as the therapeutic application of manually guided forces by an operator to improve physiologic function and/or support homeostasis that has been altered by the injury or occupational disease, and has associated clinical significance.

(i). High velocity, low amplitude (HVLA) technique, chiropractic manipulation, osteopathic manipulation, muscle energy techniques, counter strain, and non-force techniques are all types of manipulative treatment. This may be applied by osteopathic physicians (D.O.), chiropractors (D.C.), properly trained physical therapists (P.T.), properly trained occupational therapists (O.T.), or properly trained medical physicians. Under these different types of manipulation exist many subsets of different techniques that can be described as a) direct a forceful engagement of a restrictive/pathologic barrier, b) indirect a gentle/non-forceful disengagement of a restrictive/pathologic barrier, c) the patient actively assists in the treatment and d) the patient relaxing, allowing the practitioner to move the body tissues. When the proper diagnosis is made and coupled with the appropriate technique, manipulation has no contraindications and can be applied to all tissues of the body. Pre-treatment assessment should be performed as part of each manipulative treatment visit to ensure that the correct diagnosis and correct treatment is employed.

[a]. Time to Produce Effect (for all types of manipulative treatment): One to six treatments.

[b]. Frequency: Up to three times per week for the first three weeks as indicated by the severity of involvement and the desired effect.

[c]. Optimum Duration: 10 treatments.

[d]. Maximum Duration: 12 treatments. Additional visits may be necessary in cases of re-injury, interrupted continuity of care, exacerbation of symptoms, and in those patients with co-morbidities. Functional gains including increased ROM must be demonstrated to justify continuing treatment.

(i). Manual Electrical Stimulation is used for peripheral nerve injuries or pain reduction that requires continuous application, supervision, or involves extensive teaching. Indications include muscle spasm (including TENS), atrophy, decreased circulation, osteogenic stimulation, inflammation, and the need to facilitate muscle hypertrophy, muscle strengthening, muscle responsiveness in Spinal Cord Injury/Brain Injury (SCI/BI), and peripheral neuropathies.

(i). Time to Produce Effect: Variable, depending upon use.

(ii). Frequency: Three to seven times per week.

(iii). Optimum Duration: Eight weeks.

(iv). Maximum Duration: Two months.

(j). Massage. Manual or Mechanical: Massage is manipulation of soft tissue with broad ranging relaxation and circulatory benefits. This may include stimulation of acupuncture points and acupuncture channels (acupressure), application of suction cups and techniques that include pressing, lifting, rubbing, pinching of soft tissues by, or with, the practitioners' hands. Indications include edema (peripheral or hard and non-pliable edema), muscle spasm, adhesions, the need to improve peripheral circulation and range of motion, or to increase muscle relaxation, and flexibility prior to exercise. In cases with edema, deep vein thrombosis should be ruled out prior to treatment.

(i). Time to Produce Effect: Immediate.

(ii). Frequency: One to two times per week.

(iii). Optimum Duration: Six weeks.

(iv). Maximum Duration: Two months.

(k). Mobilization (Joint). Mobilization is passive movement, which may include passive range of motion performed in such a manner (particularly in relation to the speed of the movement) that it is, at all times, within the ability of the patient to prevent the movement if they so choose. It may include skilled manual joint tissue stretching. Indications include the need to improve joint play, improve intracapsular arthrokinematics, or reduce pain associated with tissue impingement.

(i). Time to Produce Effect: Six to nine treatments.

(ii). Frequency: three times per week.

(iii). Optimum Duration: Six weeks.

(iv). Maximum Duration: Two months.

(l). Mobilization (Soft Tissue) is a generally well-accepted treatment. Mobilization of soft tissue is the skilled application of muscle energy, strain/counter strain, myofascial release, manual trigger point release and manual therapy techniques designed to improve or normalize movement patterns through the reduction of soft tissue pain and restrictions. These can be interactive with the patient participating or can be with the patient relaxing and letting the practitioner move the body tissues. Indications include muscle spasm around a joint, trigger points, adhesions, and neural compression. Mobilization should be accompanied by active therapy.

(i). Time to Produce Effect: Two to three weeks.

(ii). Frequency: Two to three times per week.

(iii). Optimum Duration: Four to six weeks.

(iv). Maximum Duration: Six weeks.

(m). Paraffin Bath is a superficial heating modality that uses melted paraffin (candle wax) to treat irregular surfaces such as the foot or ankle. Indications include the need to enhance collagen extensibility before stretching, reduce muscle guarding, or reduce inflammatory response.

(i). Time to Produce Effect: One to four treatments.

(ii). Frequency: One to three times per week.

(iii). Optimum Duration: Four weeks.

(iv). Maximum Duration: One month. If beneficial, provide with home unit or purchase if effective.

(n). Superficial Heat and Cold Therapy: Superficial heat and cold therapies are thermal agents applied in various manners that lower or raise the body tissue temperature for the reduction of pain, inflammation, and/or effusion resulting from injury or induced by exercise. It may be used acutely with compression and elevation. Indications include acute pain, edema and hemorrhage, need to increase pain threshold, reduce muscle spasm and promote stretching/flexibility. It includes portable cryotherapy units and application of heat just above the surface of the skin at acupuncture points.

(i). Time to Produce Effect: Immediate.

(ii). Frequency: Two to five times per week.

(iii). Optimum Duration: Three weeks as primary, or up to two months if used intermittently as an adjunct to other therapeutic procedures.

(iv). Maximum Duration: Two months.

(o). Short-Wave Diathermy involves the use of equipment that exposes soft tissue to a magnetic or electrical field. Indications include enhanced collagen extensibility before stretching, reduced muscle guarding, reduced inflammatory response, and enhanced re-absorption of hemorrhage, hematoma, or edema.

(i). Time to Produce Effect: Two to four treatments.

(ii). Frequency: Two to three times per week up to three weeks.

(iii). Optimum Duration: Three to five weeks.

(iv). Maximum Duration: 5 weeks.

(p). Traction. Manual traction is an integral part of manual manipulation or joint mobilization. Indications include decreased joint space, muscle spasm around joints, and the need for increased synovial nutrition and response.

(i). Time to Produce Effect: One to three sessions.

(ii). Frequency: Two to three times per week.

(iii). Optimum Duration: 30 days.

(iv). Maximum Duration: One month.

(q). Transcutaneous Electrical Nerve Stimulation (TENS) is a generally accepted treatment. TENS should include at least one instructional session for proper application and use. Indications include muscle spasm, atrophy, and decreased circulation and pain control. Minimal TENS unit parameters should include pulse rate, pulse width and amplitude modulation. Consistent, measurable functional improvement must be documented prior to the purchase of a home unit.

(i). Time to Produce Effect: Immediate.

(ii). Frequency: Variable.

(iii). Optimum Duration: Three sessions.

(iv). Maximum Duration: Three sessions. If beneficial, provide with home unit or purchase if effective. Due to variations in costs and in models, prior authorization for home units is required.

(r). Ultrasound is an accepted treatment which includes ultrasound with electrical stimulation and Phonophoresis. Ultrasound uses sonic generators to deliver acoustic energy for therapeutic thermal and/or non-thermal soft tissue effects. Indications include scar tissue, adhesions, collagen fiber and muscle spasm, and the need to extend muscle tissue or accelerate the soft tissue healing.

(i). Ultrasound with electrical stimulation is concurrent delivery of electrical energy that involves a dispersive electrode placement. Indications include muscle spasm, scar tissue, pain modulation, and muscle facilitation.

(ii). Phonophoresis is the transfer of medication to the target tissue to control inflammation and pain through the use of sonic generators. These topical medications include, but are not limited to, steroidal anti-inflammatory and anesthetics.

[a]. Time to Produce Effect: 6 to 15 treatments.

[b]. Frequency: Three times per week.

[c]. Optimum Duration: Four to eight weeks.

[d]. Maximum Duration: Two months.

(s). Vasopneumatic Devices are mechanical compressive devices used in both inpatient and outpatient settings to reduce various types of edema. Indications include pitting edema, lymphedema and venostasis. Maximum compression should not exceed minimal diastolic blood pressure. Use of a unit at home should be considered if expected treatment is greater than two weeks.

(i). Time to Produce Effect: One to three treatments.

(ii). Frequency: Three to five times per week.

(iii). Optimum Duration: One month.

(iv). Maximum Duration: One month. If beneficial, provide with home unit.

(t). Whirlpool/Hubbard tank is conductive exposure to water at temperatures that best elicits the desired effect (cold vs. heat). It generally includes massage by water propelled by a turbine or Jacuzzi jet system and has the same thermal effects as hot packs if higher than tissue temperature. It has the same thermal effects as cold application if comparable temperature water used. Indications include the need for analgesia, relaxing muscle spasm, reducing joint stiffness, enhancing mechanical debridement and facilitating and preparing for exercise.

(i). Time to Produce Effect: Two to four treatments.

(ii). Frequency: Three to five times per week.

(iii). Optimum Duration: Three weeks as primary, or up to two months if used intermittently as an adjunct to other therapeutic procedures.

(iv). Maximum Duration: Two months.

16. Vocational rehabilitation is a generally accepted intervention. Initiation of vocational rehabilitation requires adequate evaluation of patients for quantification of highest functional level, motivation and achievement of maximum medical improvement (MMI). Vocational rehabilitation may be as simple as returning to the original job or as complicated as being retrained for a new occupation. The effectiveness of vocational rehabilitation may be enhanced when performed in combination with work hardening or work conditioning.

a. It may also be beneficial for full vocational rehabilitation to be started before MMI if it is evident that the injured worker will be unable to return to his/her previous occupation. A positive goal and direction may aid the patient in decreasing stress and depression, and promote optimum rehabilitation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1801 (June 2011).

§2313. Therapeutic Procedures—Operative

A. All operative interventions must be based upon positive correlation of clinical findings, clinical course and diagnostic tests. A comprehensive assimilation of these factors must lead to a specific diagnosis with positive identification of pathologic condition(s). It is imperative to rule out non-physiologic modifiers of pain presentation or non-operative conditions mimicking radiculopathy or instability (e.g., peripheral neuropathy, piriformis syndrome, myofascial pain, complex regional pain syndrome or sympathetically mediated pain syndromes, sacroiliac dysfunction, psychological conditions, etc.) prior to consideration of elective surgical intervention.

B. In addition, operative treatment is indicated when the natural history of surgically treated lesions is better than the natural history for non-operatively treated lesions. All patients being considered for surgical intervention should first undergo a comprehensive neuromusculoskeletal examination to identify mechanical pain generators that may respond to non-surgical techniques or may be refractory to surgical intervention.

C. Structured rehabilitation interventions are necessary for all of the following procedures except in some cases of hardware removal.

D. Return-to-work restrictions should be specific according to the recommendation in the Therapeutic Procedures, Non-Operative.

1. Ankle and Subtalar Fusion

a. Description/Definition: Surgical fusion of the ankle or subtalar joint.

b. Occupational Relationship: Usually post-traumatic arthritis or residual deformity.

c. Specific Physical Exam Findings: Painful, limited range of motion of the joint(s). Possible fixed deformity.

d. Diagnostic Testing Procedures: Radiographs. Diagnostic injections, MRI, CT scan, and/or bone scan.

e. Surgical Indications/Considerations: All reasonable conservative measures have been exhausted and other reasonable surgical options have been seriously considered or implemented. Patient has disabling pain or deformity. Fusion is the procedure of choice for individuals with osteoarthritis who plan to return to physically demanding activities.

i. Prior to surgical intervention, the patient and treating physician should identify functional operative goals, and the likelihood of achieving improved ability to perform activities of daily living or work activities and the patient should agree to comply with the pre- and post-operative treatment plan including home exercise. The provider should be especially careful to make sure the patient understands the amount of post-operative therapy required and the length of partial- and full-disability expected post-operatively.

ii. Because smokers have a higher risk of delayed bone healing and post-operative costs, it is recommended that insurers cover a smoking cessation program peri-operatively. Physicians may monitor smoking cessation with laboratory tests such as cotinine levels for long-term cessation.

f. Operative Procedures. Open reduction internal fixation (ORIF) with possible bone grafting. External fixation may be used in some cases.

g. Post-Operative Treatment

i. An individualized rehabilitation program based upon communication between the surgeon and the therapist and using therapies as outlined in Therapeutic Procedures, Non-operative. In all cases, communication between the physician and therapist is important to the timing of weight-bearing, and exercise progressions.

ii. When boney union is achieved, treatment usually includes active therapy with or without passive therapy, including gait training and ADLs.

iii. Rocker bottom soles or shoe lifts may be required. A cast is usually in place for six to eight weeks followed by graduated weight-bearing. Modified duty may last up to four to six months.

iv. Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

2. Knee Fusion

a. Description/Definition: Surgical fusion of femur to the tibia at the knee joint.

b. Occupational Relationship: Usually from post-traumatic arthritis or deformity.

c. Specific Physical Exam Findings: Stiff, painful, sometime deformed limb at the knee joint.

d. Diagnostic Testing Procedures: Radiographs. MRI, CT, diagnostic injections or bone scan.

e. Surgical Indications/Considerations: All reasonable conservative measures have been exhausted and other reasonable surgical options have been seriously considered or implemented, e.g. failure of arthroplasty. Fusion is a consideration particularly in the young patient who desires a lifestyle that would subject the knee to high mechanical stresses. The patient should understand that the leg will be shortened and there may be difficulty with sitting in confined spaces, and climbing stairs. Although there is generally a painless knee, up to 50 percent of cases may have complications.

i. Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities and the patient should agree to comply with the pre- and post-operative treatment plan including home exercise. The provider should be especially careful to make sure the patient understands the amount of post-operative therapy required and the length of partial- and full-disability expected post-operatively.

ii. Because smokers have a higher risk of delayed bone healing and post-operative costs, it is recommended that insurers cover a smoking cessation program peri-operatively. Physicians may monitor smoking cessation with laboratory tests such as cotinine levels for long-term cessation.

f. Operative Procedures. Open reduction internal fixation (ORIF) with possible bone grafting. External fixation or intramedullary rodding may also be used.

g. Post-operative Treatment

i. An individualized rehabilitation program based upon communication between the surgeon and the therapist and using therapies as outlined in Therapeutic Procedures, Non-operative. In all cases, communication between the physician and therapist is important to the timing of weight-bearing, and exercise progressions.

ii. When boney union is achieved, treatment usually includes active therapy with or without passive therapy, including gait training and ADLs. Non weight-bearing or limited weight-bearing and modified duty may last up to four and six months.

iii. Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

3. Ankle Arthroplasty

a. Description/Definition: Prosthetic replacement of the articulating surfaces of the ankle joint.

b. Occupational Relationship: Usually from post-traumatic arthritis.

c. Specific Physical Exam Findings: Stiff, painful ankle. Limited range-of-motion of the ankle joint.

d. Diagnostic Testing Procedures: Radiographs, MRI, diagnostic injections, CT scan, bone scan.

e. Surgical Indications/Considerations: When pain interferes with ADLs, and all reasonable conservative measures have been exhausted and other reasonable surgical options have been considered or implemented. A very limited population of patients are appropriate for ankle arthroplasty.

i. Requirements include:

(a). Good bone quality;

(b). BMI less than 35;

(c). Non-smoker currently;

(d). Patient is 60 or older;

(e). No lower extremity neuropathy;

(f). Patient does not pursue physically demanding work or recreational activities.

ii. The following issues should be addressed when determining appropriateness for surgery: ankle laxity, bone alignment, surrounding soft tissue quality, vascular status, presence of avascular necrosis, history of open fracture or infection, motor dysfunction, and treatment of significant knee or hip pathology.

iii. Ankle implants are less successful than similar procedures in the knee or hip. There are no good studies comparing arthrodesis and ankle replacement. Patients with ankle fusions generally have good return to function and fewer complications than those with joint replacements. Re-operation rates may be higher in ankle arthroplasty than in ankle arthrodesis. Long-term performance beyond ten years for current devices is still unclear. Salvage procedures for ankle replacement include revision with stemmed implant or allograft fusion. Given these factors, an ankle arthroplasty requires prior authorization and a second opinion by a surgeon specializing in lower extremity surgery.

iv. Contraindications—severe osteoporosis, significant general disability due to other medical conditions, psychiatric issues.

v. In cases where surgery is contraindicated due to obesity, it may be appropriate to recommend a weight loss program if the patient is unsuccessful losing weight on their own. Coverage for weight loss would continue only for motivated patients who have demonstrated continual progress with weight loss.

vi. Prior to surgery, patients may be assessed for any associated mental health or low back pain issues that may affect rehabilitation.

vii. Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities and the patient should agree to comply with the pre- and post-operative

treatment plan including home exercise. The provider should be especially careful to make sure the patient understands the amount of post-operative therapy required and the length of partial- and full-disability expected post-operatively.

viii. Because smokers have a higher risk of delayed bone healing and post-operative costs, it is recommended that insurers cover a smoking cessation program peri-operatively. Physicians may monitor smoking cessation with laboratory tests such as cotinine levels for long-term cessation.

f. Operative Procedures: Prosthetic replacement of the articular surfaces of the ankle; DVT prophylaxis is not always required but should be considered for patients who have any risk factors for thrombosis.

i. Complications include pulmonary embolism, infection, bony lysis, polyethylene wear, tibial loosening, instability, malalignment, stiffness, nerve-vessel injury, and peri-prosthetic fracture.

g. Post-Operative Treatment

i. An individualized rehabilitation program based upon communication between the surgeon and the therapist while using therapies as outlined in Therapeutic Procedures, Non-operative. In all cases, communication between the physician and therapist is important to the timing of weight-bearing, and exercise progressions.

ii. NSAIDs may be used for pain management after joint replacement. They have also been used to reduce heterotopic ossification after ankle arthroplasty. NSAIDs do reduce the radiographically documented heterotopic ossification in this setting, but there is some evidence (in literature on hip arthroplasty) that they do not improve functional outcomes and they may increase the risk of bleeding events in the post-operative period. Their routine use for prevention of heterotopic bone formation is not recommended.

iii. Treatment may include the following: bracing, active therapy with or without passive therapy, gait training, and ADLs. Rehabilitation post-operatively may need to be specifically focused based on the following problems: contracture, gastrocnemius muscle weakness, and foot and ankle malalignment. Thus, therapies may include braces, shoe lifts, orthoses, and electrical stimulation accompanied by focused therapy.

iv. In some cases aquatic therapy may be used. Refer to Therapeutic Procedures, Non-operative Aquatic Therapy. Pool exercises may be done initially under therapist's or surgeon's direction then progressed to an independent pool program.

v. Prior to revision surgery there should be an evaluation to rule out infection.

vi. Return to work and restrictions after surgery may be made by a treating physician experienced in occupational medicine in consultation with the surgeon or by the surgeon. Patient should be able to return to sedentary work within four to six weeks. Some patients may have permanent restrictions based on their job duties.

vii. Patients are usually seen annually after initial recovery to check plain x-rays for signs of loosening.

4. Knee Arthroplasty

a. Description/Definition: Prosthetic replacement of the articulating surfaces of the knee joint.

b. Occupational Relationship: Usually from post-traumatic osteoarthritis.

c. Specific Physical Exam Findings: Stiff, painful knee, and possible effusion.

d. Diagnostic Testing Procedures: Radiographs.

e. Surgical Indications/Considerations: Severe osteoarthritis and all reasonable conservative measures have been exhausted and other reasonable surgical options have been considered or implemented. Significant changes such as advanced joint line narrowing are expected. Refer to subsection Aggravated Osteoarthritis.

i. Younger patients, less than 50 years of age, may be considered for unicompartmental replacement if there is little or no arthritis in the lateral compartment, there is no inflammatory disease and/or deformity and BMI is less than 35. They may be considered for lateral unicompartmental disease when the patient is not a candidate for osteotomy. Outcome is better for patients with social support.

ii. Contraindications—severe osteoporosis, significant general disability due to other medical conditions, psychiatric issues.

iii. In cases where surgery is contraindicated due to obesity, it may be appropriate to recommend a weight loss program if the patient is unsuccessful losing weight on their own. Coverage for weight loss would continue only for motivated patients who have demonstrated continual progress with weight loss.

iv. Prior to surgery, patients may be assessed for any associated mental health or low back pain issues that may affect rehabilitation.

v. Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities and the patient should agree to comply with the pre- and post-operative treatment plan including home exercise. The provider should be especially careful to make sure the patient understands the amount of post-operative therapy required and the length of partial- and full-disability expected post-operatively.

vi. Because smokers have a higher risk of delayed bone healing and post-operative costs, it is recommended that insurers cover a smoking cessation program peri-operatively. Physicians may monitor smoking cessation with laboratory tests such as cotinine levels for long-term cessation.

f. Operative Procedures: Prosthetic replacement of the articular surfaces of the knee; total or uni-compartmental with DVT prophylaxis. May include patellar resurfacing and computer assistance.

i. There is currently conflicting evidence on the effectiveness of patellar resurfacing. Isolated patellofemoral resurfacing is performed on patients under 60 only after diagnostic arthroscopy does not reveal any arthritic changes in other compartments. The diagnostic arthroscopy is generally performed at the same time as the resurfacing. Resurfacing may accompany a total knee replacement at the discretion of the surgeon.

ii. Computer guided implants are more likely to be correctly aligned. The overall long-term functional result using computer guidance is unclear. Decisions to use computer assisted methods depend on surgeon preference

and age of the patient as it is more likely to have an impact on younger patients with longer expected use and wear of the implant. Alignment is only one of many factors that may affect the implant longevity.

iii. Complications occur in around 3 percent and include pulmonary embolism; infection, bony lysis, polyethylene wear, tibial loosening, instability, malalignment, stiffness, patellar tracking abnormality, nerve-vessel injury, and peri-prosthetic fracture.

g. Post-operative Treatment:

i. Anti coagulant therapy to prevent deep vein thrombosis. Refer to Therapeutic Procedures, Non-operative.

ii. NSAIDs may be used for pain management after joint replacement. They have also been used to reduce heterotopic ossification after knee arthroplasty. NSAIDs do reduce the radiographically documented heterotopic ossification in this setting, but there is some evidence (in literature on total hip arthroplasty) that they do not improve functional outcomes and they may increase the risk of bleeding events in the post-operative period. Their routine use for prevention of heterotopic bone formation is not recommended.

iii. An individualized rehabilitation program based upon communication between the surgeon and the therapist and using therapies as outlined in Therapeutic Procedures, Non-operative. In all cases, communication between the physician and therapist is important to the timing of weight-bearing, and exercise progressions.

iv. Treatment may include the following: bracing and active therapy with or without passive therapy. Rehabilitation post-operatively may need to be specifically focused based on the following problems: knee flexion contracture, quadriceps muscle weakness, knee flexion deficit, and foot, and ankle malalignment. Thus, therapies may include, knee braces, shoe lifts, orthoses, and electrical stimulation, accompanied by focused active therapy.

v. In some cases aquatic therapy may be used. Refer to Therapeutic Procedures, Non-operative, Aquatic Therapy. Pool exercises may be done initially under therapist's or surgeon's direction then progressed to an independent pool program.

vi. Continuous passive motion is frequently prescribed. The length of time it is used will depend on the patient and their ability to return to progressive exercise.

vii. Consider need for manipulation under anesthesia if there is less than 90 degrees of knee flexion after six weeks.

viii. Prior to revision surgery there should be an evaluation to rule out infection.

ix. Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon. Patient should be able to return to sedentary work within four to six weeks. Some patients may have permanent restrictions based on their job duties.

x. Patients are usually seen annually after initial recovery to check plain x-rays for signs of loosening.

5. Hip Arthroplasty

a. Description/Definition: Prosthetic replacement of the articulating surfaces of the hip joint. In some cases, hip resurfacing may be performed.

b. Occupational Relationship: Usually from post-traumatic arthritis, hip dislocations and femur or acetabular fractures. Patients with intracapsular femoral fractures have a risk of developing avascular necrosis of the femoral head requiring treatment months to years after the initial injury.

c. Specific Physical Exam Findings: Stiff, painful hip.

d. Diagnostic Testing Procedures: Standing pelvic radiographs demonstrating joint space narrowing to 2 mm or less, osteophytes or sclerosis at the joint. MRI may be ordered to rule out other more serious disease.

e. Surgical Indications/Considerations: Severe osteoarthritis and all reasonable conservative measures have been exhausted and other reasonable surgical options have been considered or implemented. Refer to subsection Aggravated Osteoarthritis.

i. Possible contraindications - inadequate bone density, prior hip surgery, and obesity.

ii. In cases where surgery is contraindicated due to obesity, it may be appropriate to recommend a weight loss program if the patient is unsuccessful losing weight on their own. Coverage for weight loss would continue only for motivated patients who have demonstrated continual progress with weight loss.

iii. Prior to surgery, patients may be assessed for any associated mental health or low back pain issues that may affect rehabilitation.

iv. For patients undergoing total hip arthroplasty, there is some evidence that a pre-operative exercise conditioning program, including aquatic and land-based exercise, results in quicker discharge to home than pre-operative education alone without an exercise program.

v. Aseptic loosening of the joint requiring revision surgery occurs in some patients. Prior to revision the joint should be checked to rule out possible infection which may require a bone scan as well as laboratory procedures, including a radiologically directed joint aspiration.

vi. Because smokers have a higher risk of non-union and post-operative costs, it is recommended that carriers cover a smoking cessation program peri-operatively. Physicians may monitor smoking cessation with laboratory tests such as cotinine levels for long-term cessation.

f. Operative Procedures: Prosthetic replacement of the articular surfaces of the hip, ceramic or metal prosthesis, with DVT prophylaxis. Ceramic prosthesis is more expensive; however, it is expected to have greater longevity and may be appropriate in some younger patients. Hip resurfacing, metal on metal, is an option for younger or active patients likely to out-live traditional total hip replacements.

i. Complications include, leg length inequality, deep venous thrombosis with possible pulmonary embolus, hip dislocation, possible renal effects, need for transfusions, future infection, need for revisions, fracture at implant site.

ii. The long-term benefit for computer assisted hip replacements is unknown. It may be useful in younger patients. Prior authorization is required.

iii. Robotic assisted surgery is considered experimental and not recommended due to technical difficulties.

g. Post-operative Treatment:

i. Anti coagulant therapy is used to prevent deep vein thrombosis. Refer to Therapeutic Procedures, Non-operative.

ii. NSAIDs may be used for pain management after joint replacement. They have also been used to reduce heterotopic ossification after hip arthroplasty. NSAIDs do reduce the radiographically documented heterotopic ossification in this setting, but there is some evidence that they do not improve functional outcomes and they may increase the risk of bleeding events in the post-operative period. Their routine use for prevention of heterotopic bone formation is not recommended.

iii. An individualized rehabilitation program based upon communication between the surgeon and the therapist and using the therapies as outlined in Therapeutic Procedures Non-operative. In all cases, communication between the physician and therapist is important to the timing of weight-bearing and exercise progressions.

iv. Treatment usually includes active therapy with or without passive therapy with emphasis on gait training with appropriate assistive devices. Patients with accelerated return to therapy appear to do better. Therapy should include training on the use of adaptive equipment and home and work site evaluation when appropriate.

(a). There is good evidence for the use of aquatic therapy. Refer to Therapeutic Procedures, Non-operative. Pool exercises may be done initially under a therapist's or surgeon's direction then progressed to an independent pool program.

(b). There is some evidence that, for patients older than 60, early multidisciplinary therapy may shorten hospital stay and improve activity level for those receiving hip replacement. Therefore, this may be used for selected patients.

v. Return to activities at four to six weeks with appropriate restrictions by the surgeon. Initially range of motion is usually restricted. Return to activity after full recovery depends on the surgical approach. Patients can usually lift, but jogging and other high impact activities are avoided.

vi. Helical CT or MRI with artifact minimization may be used to investigate prosthetic complications. The need for implant revision is determined by age, size of osteolytic lesion, type of lesion and functional status. Revision surgery may be performed by an orthopedic surgeon in cases with chronic pain and stiffness or difficulty with activities of daily living. Prior authorization is required and a second opinion by a surgeon with special expertise in hip/knee replacement surgery should usually be performed.

vii. Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

viii. Patients are usually seen annually after the initial recovery to check plain x-rays for signs of loosening.

6. Amputation

a. Description/Definition: Surgical removal of a portion of the lower extremity.

b. Occupational Relationship: Usually secondary to post-traumatic bone, soft tissue, vascular or neurologic compromise of part of the extremity.

c. Specific Physical Exam Findings: Non-useful or non-viable portion of the lower extremity.

d. Diagnostic Testing Procedures: Radiographs, vascular studies, MRI, bone scan.

e. Surgical Indications/Considerations: Non-useful or non-viable portion of the extremity.

i. Smoking may affect soft tissue healing through tissue hypoxia. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician.

f. Operative Procedures: Amputation.

g. Post-Operative Treatment

i. An individualized rehabilitation program based upon communication between the surgeon and the therapist and using therapies as outlined in Therapeutic Procedures, Non-operative.

ii. Rigid removable dressings are used initially.

iii. Therapies usually include active therapy with or without passive therapy for prosthetic fitting, construction and training, protected weight-bearing, training on the use of adaptive equipment, and home and jobsite evaluation. Temporary prosthetics are used initially with a final prosthesis fitted by the second year. Multiple fittings and trials may be necessary to assure the best functional result.

iv. For prosthesis with special adaptive devices, e.g. computerized prosthesis; prior authorization and a second opinion from a physician knowledgeable in prosthetic rehabilitation and who has a clear description of the patients expected job duties and daily living activities are required.

v. Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

6. Manipulation under anesthesia

a. Description/Definition: Passive range of motion of a joint under anesthesia.

b. Occupational Relationship: Joint stiffness that usually results from a traumatic injury, compensation related surgery, or other treatment.

c. Specific Physical Exam Findings: Joint stiffness in both active and passive modes.

d. Diagnostic Testing Procedures: Radiographs. CT, MRI, diagnostic injections.

e. Surgical Indications/Considerations: Consider if routine therapeutic modalities, including therapy and/or dynamic bracing, do not restore the degree of motion that should be expected after a reasonable period of time, usually at least 12 weeks.

f. Operative Treatment: Not applicable.

g. Post-Operative Treatment:

i. An individualized rehabilitation program based upon communication between the surgeon and the therapist and using therapies as outlined in Therapeutic Procedures, Non-operative. Therapy includes a temporary increase in frequency of both active and passive therapy to maintain the range of motion gains from surgery.

ii. Continuous passive motion is frequently used post-operatively.

iii. Return to work and restrictions after surgery may be made by an attending physician experienced in

occupational medicine in consultation with the surgeon or by the surgeon.

7. Osteotomy

a. Description/Definition: A reconstructive procedure involving the surgical cutting of bone for realignment. It is useful for patients that would benefit from realignment in lieu of total joint replacement.

b. Occupational Relationship: Post-traumatic arthritis or deformity.

c. Specific Physical Exam Findings: Painful decreased range of motion and/or deformity.

d. Diagnostic Testing Procedures: Radiographs, MRI scan, CT scan.

e. Surgical Indications/Considerations: Failure of non-surgical treatment when avoidance of total joint arthroplasty is desirable. For the knee, joint femoral osteotomy may be desirable for young or middle age patients with varus alignment and medial arthritis or valgus alignment and lateral compartment arthritis. High tibial osteotomy is also used for medial compartment arthritis. Multi-compartmental degeneration is a contraindication. Patients should have a range of motion of at least 90 degrees of knee flexion. For the ankle supra malleolar osteotomy may be appropriate. High body mass is a relative contraindication.

i. Because smokers have a higher risk of non-union and post-operative costs, it is recommended that carriers cover a smoking cessation program peri-operatively. Physicians may monitor smoking cessation with laboratory tests such as cotinine levels for long-term cessation.

f. Operative Procedures: Peri-articular opening or closing wedge of bone, usually with grafting and internal or external fixation.

i. Complications—new fractures, lateral peroneal nerve palsy, infection, delayed unions, compartment syndrome, or pulmonary embolism.

g. Post-Operative Treatment

i. An individualized rehabilitation program based upon communication between the surgeon and the therapist and using therapies as outlined in Therapeutic Procedures, Non-operative. In all cases, communication between the physician and therapist is important to the timing of weight-bearing, and exercise progressions.

ii. Weight-bearing and range-of-motion exercises depend on the type of procedure performed. Partial or full weight-bearing restrictions can range from six weeks partial weight-bearing, to three months full weight-bearing. It is usually six months before return to sports or other rigorous physical activity.

iii. If femoral intertrochanteric osteotomy has been performed, there is some evidence that electrical bone growth stimulation may improve bone density. Refer to Therapeutic Procedures, Non-operative, Bone Growth Stimulators for description.

iv. Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

8. Hardware removal. Hardware removal frequently occurs after initial MMI. Physicians should document the possible need for hardware removal and include this as treatment in their final report.

a. Description/Definition: Surgical removal of internal or external fixation device, commonly related to fracture repairs.

b. Occupational Relationship: Usually following healing of a post-traumatic injury that required fixation or reconstruction using instrumentation.

c. Specific Physical Exam Findings: Local pain to palpation, swelling, erythema.

d. Diagnostic Testing Procedures: Radiographs, tomography, CT scan, MRI.

e. Surgical Indications/Considerations: Persistent local pain, irritation around hardware.

f. Operative Procedures: Removal of hardware may be accompanied by scar release/resection, and/or manipulation. Some instrumentation may be removed in the course of standard treatment without symptoms of local irritation.

g. Post-Operative Treatment

i. An individualized rehabilitation program based upon communication between the surgeon and the therapist and using therapies as outlined in Therapeutic Procedures, Non-operative.

ii. Treatment may include therapy with or without passive therapy for progressive weight-bearing, range of motion.

iii. Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

9. Release of Contracture

a. Description/Definition: Surgical incision or lengthening of contracted tendon or peri-articular soft tissue.

b. Occupational Relationship: Usually following a post-traumatic complication.

c. Specific Physical Exam Findings: Shortened tendon or stiff joint.

d. Diagnostic Testing Procedures: Radiographs, CT scan, MRI scan.

e. Surgical Indications/Considerations: Persistent shortening or stiffness associated with pain and/or altered function.

i. Smoking may affect soft tissue healing through tissue hypoxia. Patients should be strongly encouraged to stop smoking and be provided with appropriate counseling by the physician.

f. Operative Procedures: Surgical incision or lengthening of involved soft tissue.

g. Post-operative Treatment:

i. An individualized rehabilitation program based upon communication between the surgeon and the therapist and using therapies as outlined in Therapeutic Procedures, Non-operative.

ii. Treatments may include active therapy with or without passive therapy for stretching, range of motion exercises.

iii. Return to work and restrictions after surgery may be made by an attending physician experienced in occupational medicine in consultation with the surgeon or by the surgeon.

10. Human Bone Morphogenetic Protein (RhBMP)

a. (RhBMP) is a member of a family of proteins which are involved in the growth, remodeling, and regeneration of bone tissue. It has become available as a recombinant biomaterial with osteo-inductive potential for application in long bone fracture non-union and other situations in which the promotion of bone formation is desired. RhBMP may be used with intramedullary rod treatment for open tibial fractures an open tibial Type III A and B fracture treated with an intramedullary rod. There is some evidence that it decreases the need for further procedures when used within 14 days of the injury. It should not be used in those with allergies to the preparation, or in females with the possibility of child bearing, or those without adequate neurovascular status or those less than 18 years old. Ectopic ossification into adjacent muscle has been reported to restrict motion in periarticular fractures. Other than for tibial open fractures as described above, it should be used principally for non-union of fractures that have not healed with conventional surgical management or peri-prosthetic fractures. Due to the lack of information on the incidence of complications and overall success rate in these situations, its use requires prior authorization. Refer to Tibial Fracture.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1814 (June 2011).

§2314. LWC-WC 1009. Disputed Claim for Medical Treatment

Mail to:
OWCA—Medical Services
ATTN: Medical Director
P.O. Box 94040
Baton Rouge, LA 70804

1. Social Security No.__-__-__
2. Date of Injury/Illness __-__-__
3. Parts of Body Injury_____
4. Date of Birth __-__-__
5. Date of This Request __-__-__
6. Claim Number _____

DISPUTED CLAIM FOR MEDICAL TREATMENT

NOTE: THIS REQUEST WILL NOT BE HONORED UNLESS THE INSURER HAS ISSUED A DENIAL FOR THE MEDICAL SERVICES IN DISPUTE AS PER R.S. 23:1203.1 J.

GENERAL INFORMATION
Claimant files this dispute with the Office of Workers' Compensation – Medical Services Director. This office must be notified immediately in writing of changes in address. An employee may be represented by an attorney, but it is not required.

7. This request is submitted by
___ Employee ___ Employer __ Insurer ___ Health Care Provider ___ Other ___

A. Copies of all relevant medical records must be included with this request.

B. A copy of the denial letter issued by the insurance carrier must be attached to this request.

EMPLOYEE
8. Name _____
Street or Box _____
City _____
State _____ Zip _____
Phone (____) _____

EMPLOYEE'S ATTORNEY
9. Name _____
Street or Box _____
City _____
State _____
Phone (____) _____
Fax (____) _____

EMPLOYER
10. Name _____
Street or Box _____
City _____
State _____ Zip _____
Phone (____) _____
Fax (____) _____

INSURER/ADMINISTRATOR
(circle one)
11. Name _____
Street or Box _____
City _____
State _____
Phone (____) _____
Fax (____) _____

EMPLOYER/INSURER'S ATTORNEY
12. Name _____
Street or Box _____
City _____
State _____ Zip _____
Phone (____) _____
Fax (____) _____

TREATING/REQUESTING PHYSICIAN
13. Name _____
Street or Box _____
City _____
State _____
Phone (____) _____
Fax (____) _____

LWC-WC 1009
11/2010

14. PLEASE PROVIDE A SUMMARY OF THE DETAILS REGARDING THE ISSUE AT DISPUTE:
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

You may attach a letter or petition with additional information with this disputed claim.
The information given above is true and correct to the best of my knowledge and belief.

_____ _____
SIGNATURE OF REQUESTING PARTY DATE

LWC-WC 1009
11/2010

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1820 (June 2011).

Subchapter B. Shoulder Injury Medical Treatment Guidelines

§2315. Introduction

A. This document has been prepared by the Louisiana Workforce Commission, Office of Workers' Compensation and should be interpreted within the context of guidelines for physicians/providers treating individuals qualifying under Louisiana's Workers' Compensation Act as injured workers with shoulder injuries. These guidelines are enforceable under the Louisiana Workers Compensation Act. All medical care, services, and treatment owed by the employer to the employee in accordance with the Louisiana Workers' Compensation Act shall mean care, services, and treatment in accordance with these guidelines. Medical Care, services, and treatment hat varies from these guidelines shall also be due by the employer when it is demonstrated to the medical director of the office by a preponderance of the scientific medical evidence, that a variance from these guidelines is reasonably required to cure or relieve the injured worker from the effects of the injury or occupational disease given

the circumstances. Therefore, these guidelines are not relevant as evidence of a provider's legal standard of professional care. To properly utilize this document, the reader should not skip nor overlook any sections.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1820 (June 2011).

§2317. General Guideline Principles

A. The principles summarized in this section are key to the intended implementation of all Office of Workers' Compensation guidelines and critical to the reader's application of the guidelines in this document.

1. Application of Guidelines. The OWCA provides procedures to implement medical treatment guidelines and to foster communication to resolve disputes among the provider, payer, and patient through the Office of Workers Compensation.

2. Education. Education of the patient and family, as well as the employer, insurer, policy makers and the community should be the primary emphasis in the treatment of shoulder injuries. Currently, practitioners often think of education last, after medications, manual therapy, and surgery. Practitioners must develop and implement an effective strategy and skills to educate patients, employers, insurance systems, policy makers, and the community as a whole. An education-based paradigm should always start with inexpensive communication providing reassuring information to the patient. More in-depth education currently exists within a treatment regime employing functional restorative and innovative programs of prevention and rehabilitation. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of facilitating self-management of symptoms and prevention.

3. Treatment Parameter Duration. Time frames for specific interventions commence once treatments have been initiated, not on the date of injury. Obviously, duration will be impacted by patient compliance, as well as availability of services. Clinical judgment may substantiate the need to accelerate or decelerate the time frames discussed in this document. Such deviation shall be in accordance with La. R.S. 23:1203.1

4. Active Interventions. Emphasizing patient responsibility, such as therapeutic exercise and/or functional treatment, are generally emphasized over passive modalities, especially as treatment progresses. Generally, passive interventions are viewed as a means to facilitate progress in an active rehabilitation program with concomitant attainment of objective functional gains.

5. Active Therapeutic Exercise Program. Exercise program goals should incorporate patient strength, endurance, flexibility, coordination, and education. This includes functional application in vocational or community settings.

6. Positive Patient Response. Positive results are defined primarily as functional gains that can be objectively measured. Standard measurement tools, including outcome measures, should be used.

a. Objective functional gains include, but are not limited to, positional tolerances, range-of-motion (ROM), strength, and endurance, activities of daily living, cognition, psychological behavior, and efficiency/velocity measures that can be quantified. Subjective reports of pain and function should be considered and given relative weight when the pain has anatomic and physiologic correlation. Anatomic correlation must be based on objective findings.

7. Re-evaluation treatment every three to four weeks. If a given treatment or modality is not producing positive results within three to four weeks, the treatment should be either modified or discontinued. Reconsideration of diagnosis should also occur in the event of poor response to a seemingly rational intervention.

8. Surgical Interventions. Surgery should be contemplated within the context of expected functional outcome and not purely for the purpose of pain relief. The concept of "cure" with respect to surgical treatment by itself is generally a misnomer. All operative interventions must be based upon positive correlation of clinical findings, clinical course, and diagnostic tests. A comprehensive assimilation of these factors must lead to a specific diagnosis with positive identification of pathologic conditions.

9. Six-Month Time Frame. The prognosis drops precipitously for returning an injured worker to work once he/she has been temporarily totally disabled for more than six months. The emphasis within these guidelines is to move patients along a continuum of care and return-to-work within a six-month time frame, whenever possible. It is important to note that time frames may not be pertinent to injuries that do not involve work-time loss or are not occupationally related.

10. Return-to-Work. Return to Work is therapeutic, assuming the work is not likely to aggravate the basic problem or increase long-term pain. The practitioner must provide specific written physical limitations and the patient should never be released to "sedentary" or "light duty." The following physical limitations should be considered and modified as recommended: lifting, pushing, pulling, crouching, walking, using stairs, bending at the waist, awkward and/or sustained postures, tolerance for sitting or standing, hot and cold environments, data entry and other repetitive motion tasks, sustained grip, tool usage and vibration factors. Even if there is residual chronic pain, return-to-work is not necessarily contraindicated. The practitioner should understand all of the physical demands of the patient's job position before returning the patient to full duty and should request clarification of the patient's job duties. Clarification should be obtained from the employer or, if necessary, including, but not limited to, an occupational health nurse, occupational therapist, vocational rehabilitation specialist, or an industrial hygienist.

11. Delayed Recovery. Strongly consider a psychological evaluation, if not previously provided, as well as initiating interdisciplinary rehabilitation treatment and vocational goal setting, for those patients who are failing to make expected progress 6 to 12 weeks after an injury. The OWCA recognizes that 3 to 10 percent of all industrially injured patients will not recover within the timelines outlined in this document despite optimal care. Such individuals may require treatments beyond the limits discussed within this document, but such treatment will require clear documentation by the authorized treating practitioner focusing on objective functional gains afforded by further treatment and impact upon prognosis.

12. Guideline Recommendations and Inclusion of Medical Evidence. Guidelines are recommendations based on available evidence and/or consensus recommendations. When possible, guideline recommendations will note the level of evidence supporting the treatment recommendation. When interpreting medical evidence statements in the guideline, the following apply:

a. "Consensus" means the opinion of experienced professionals based on general medical principles. Consensus recommendations are designated in the guideline as "generally well accepted," "generally accepted," "acceptable/accepted," or "well-established."

b. "Some" means the recommendation considered at least one adequate scientific study, which reported that a treatment was effective.

c. "Good" means the recommendation considered the availability of multiple adequate scientific studies or at least one relevant high-quality scientific study, which reported that a treatment was effective.

d. "Strong" means the recommendation considered the availability of multiple relevant and high quality scientific studies, which arrived at similar conclusions about the effectiveness of a treatment.

B. All recommendations in the guideline are considered to represent reasonable care in appropriately selected cases, regardless of the level of evidence or consensus statement attached to it. Those procedures considered inappropriate, unreasonable, or unnecessary are designated in the guideline as "not recommended."

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1821 (June 2011).

§2319. Initial diagnostic procedures

A. The OWCA recommends the following diagnostic procedures be considered, at least initially, the responsibility of the workers' compensation carrier to ensure that an accurate diagnosis and treatment plan can be established. Standard procedures that should be utilized when initially diagnosing a work-related shoulder complaint are listed below.

1. History Taking and Physical Examination (Hx & PE) are generally accepted, well-established and widely used procedures that establish the foundation/basis for and dictates subsequent stages of diagnostic and therapeutic procedures. When findings of clinical evaluations and those of other diagnostic procedures are not complementing each other, the objective clinical findings should have preference. The medical records should reasonably document the following:

a. History of Present Injury

i. Mechanism of injury. This includes details of symptom onset and progression, and documentation of right or left dominance;

ii. Relationship to work. This includes a statement of the probability that the illness or injury is work-related;

iii. Prior occupational and non-occupational injuries to the same area including specific prior treatment;

iv. History of locking, clicking, weakness, acute or chronic swelling, crepitation, pain while lifting or performing overhead work, dislocation or popping. Pain or catching with overhead motion may indicate a labral tear. Night time pain can be associated with specific shoulder pathology. Anterior joint pain, such as that seen in throwing athletes, may indicate glenohumeral instability. Pain radiating below the elbow, may indicate cervical disc problems or proximal entrapment neuropathy.

v. Ability to perform job duties and activities of daily living; and

vi. Exacerbating and alleviating factors of the reported symptoms. The physician should explore and report on non-work related as well as, work related activities.

b. Past History

i. Past medical history includes previous shoulder conditions, neoplasm, gout, arthritis, diabetes and previous shoulder symptoms;

ii. Review of systems includes symptoms of rheumatologic, neurologic, endocrine, neoplastic, and other systemic diseases;

iii. Smoking history; and

iv. Vocational and recreational pursuits.

c. Physical Examination: Examination should include the elbow and neck. Both shoulders should be examined to compare asymptomatic and symptomatic sides and identify individuals with non-pathological joint laxity or degenerative rotator cuff pathology. Physical examinations should consist of accepted tests and exam techniques applicable to the joint or area being examined, including:

i. visual inspection;

ii. palpation, including the acromio-clavicular (AC) joint, sternoclavicular joint, and the subacromial bursa in the region of the acromiohumeral sulcus;

iii. range-of-motion/quality of motion;

iv. strength, shoulder girdle weakness may indicate musculoskeletal or neurogenic pathology;

v. joint stability;

vi. integrity of distal circulation and limited neurologic exam;

vii. cervical spine evaluation; and

viii. if applicable, full neurological exam including muscle atrophy and gait abnormality.

ix. specific shoulder tests

(a). This section contains a description of common clinical shoulder tests. Generally, more than one test is needed to make a diagnosis. Clinical judgment should be applied when considering which tests to perform, as it is not necessary to perform all of the listed tests on every patient. The physical examination may be non-specific secondary to multi-faceted pathology in many patients, and because some tests may be positive for more than one condition. Given the multitude of tests available, the physician is encouraged to document the specific patient response, rather than report that a test is 'positive.' The tests are listed for informational purposes, and are also referenced in Specific Diagnostic, Testing and Treatment Procedures.

(i). Rotator cuff/Impingement tests/Signs - Most published clinical examination studies assess rotator cuff pathology. There is some evidence that tests are reliable for ruling out diagnoses, but not necessarily defining the pathology accurately. Some studies indicate that the Neer test, Hawkins test, Jobe test, crossed-arm adduction test, impingement sign and arc of pain are approximately 80 percent sensitive for impingement or rotator cuff pathology. The drop arm, Yergason's, Speed, and passive external

Rotation Tests are thought to have specificity of 60 percent or higher. (Questions remain about interrater reliability.)

[a]. Weakness with abduction.

[b]. Arc of pain – Pain with 60 to 120 degrees of abduction.

[c]. Neer impingement sign – Examiner flexes arm anteriorly to reproduce impingement. Positive if pain is reproduced.

[d]. Neer impingement test – When the Neer impingement sign is positive, the subacromial bursa is injected with local anesthetic. If, after 40 minutes, the patient has sufficient pain relief so that the examiner can perform the Neer impingement sign without recreating the initial pain, the test suggests impingement.

[e]. Hawkins - arm is abducted to 90 degrees, forward flexed by 90 degrees with elbow flexed. Examiner internally rotates the humerus. Pain suggests impingement.

[f]. Drop arm - Patient slowly lowers arm from full abduction. If the arm drops, or if the patient is unable to maintain slow progress from approximately 90 degrees, the test suggests rotator cuff tear.

[g]. Lift off - patient's hand is placed against back of waist with 90 degrees flexion of elbow. The patient is asked to lift the hand off of his back at waist level. If the hand drops to the initial position against the back, this suggests subscapularis tear or weakness. Some patients may not be able to perform the initial hand placement due to pain or limited range-of-motion.

[h]. Subscapularis strength test - Patient places hand on mid-abdomen, and then applies pressure. If the elbow moves posteriorly or the wrist flexes, the test suggests subscapularis weakness or tear.

[i]. Empty Can test - Patient's arm abducted to 60 to 90 degrees with 30 degrees forward flexion and with forearm pronated. Thumbs are pointing toward the floor. Patient resists examiner's downward pressure on the elbow. Weakness of the affected side, compared to the opposite side, or pain in subacromial area suggests supraspinatus tear, tendonitis or tendonosis.

[j]. External rotation lag test - the patient's arm is abducted to 20 degrees with elbow flexed at 90 degrees, and almost fully externally rotated. If the patient cannot maintain the arm in external rotation, this suggests a supraspinatus and/or infraspinatus tear.

[k]. External rotation weakness – Elbows are flexed with arms at side, and patient attempts to externally rotate against resistance. Weakness suggests infraspinatus and teres minor pathology.

[l]. Impingement sign – Patient extends shoulder, then abducts and reports any pain

(ii). Acromioclavicular Joint Tests

[a]. Crossed arm adduction – Examiner adducts arm across the body as far as possible toward the opposite shoulder. If patient reports pain in the AC joint, this suggests AC joint pathology. Examiner may measure the distance between antecubital fossa and the opposite acromion of the opposite shoulder. If one shoulder demonstrates increased distance compared to the other shoulder, this suggests a tight posterior capsule.

[b]. Paxino's - The examiner's thumb is placed under the posterolateral aspect of the acromion, with the index and long fingers on the superior aspect of middle part of the clavicle. Examiner applies anterior superior pressure to acromion with thumb, and pushes inferiorly on the middle of the clavicle with index and long fingers. If the patient reports increased pain in the AC joint, the test suggests AC joint pathology.

(iii). Labral Tears

[a]. Labral tears which may require treatment usually occur with concurrent bicipital tendon disorders pathology and/or glenohumeral instability. Therefore, tests for labral pathology are included in these sections.

(iv). Bicipital Tendon Disorders

[a]. Yergason's Test - The patient has the elbow flexed to 90 degrees. The examiner faces the patient, grasps the patient's hand with one hand and palpates the bicipital groove with the other. The patient supinates the forearm against resistance. If the patient complains of pain in the biceps tendon with resistance, it suggests a positive finding.

[b]. Ludington's - The patient's hands are placed behind the head, with the shoulders in abduction and external rotation. If biceps contraction recreates pain, the test suggests biceps tendon pathology.

[c]. Speed Test - The patient's shoulder is flexed to 90 degrees and supinated. The examiner provides resistance to forward flexion. If pain is produced with resistance, the test suggests biceps tendon instability or tendonitis.

[d]. Biceps Load Test II - The patient is supine with the arm elevated to 120 degrees, externally rotated to maximum point, with elbow in 90 degrees of flexion and the forearm supinated. The examiner sits adjacent to the patient on the same side, and grasps the patient's wrist and elbow. The patient flexes the elbow, while the examiner resists. If the patient complains of pain with resistance to elbow flexion, or if the pain is increased with resisted elbow flexion, this may suggest a biceps related SLAP lesion in young patients.

(v). Glenohumeral Instability/Labral Tears/SLAP Lesions. Many of the following tests are also used to test for associated labral tears. The majority of the tests/signs should be performed on both shoulders for comparison. Some individuals have increased laxity in all joints, and therefore, tests/signs which might indicate instability in one individual may not be pathologic in individuals whose asymptomatic joint is equally lax.

[a]. Sulcus sign – With the patient's arm at the side, the examiner pulls inferiorly and checks for deepening of the sulcus, a large dimple on the lateral side of the shoulder. Deepening of the sulcus suggests instability.

[b]. Inferior instability – With patient's arm abducted to 90 degrees, examiner pushes down directly on mid-humerus. Patient may try to drop the arm to the side to avoid dislocation.

[c]. Posterior instability – The patient's arm is flexed to 90 degrees anteriorly and examiner applies posterior force to the humerus. The examiner then checks for instability.

[d]. Apprehension – Patient's shoulder is in 90 degrees of abduction and in external rotation. Examiner continues to externally rotate and apply axial force

to the humerus. If there is pain, or if patient asks to stop, the test suggests anterior instability.

[e]. Relocation – Examiner applies posterior force on humerus while externally rotating. This is performed in conjunction with the apprehension test. If symptoms are reduced, the test suggests anterior instability.

[f]. Load and shift or anterior and posterior drawer – Patient is supine or seated with arm abducted from shoulder from 20 to 90 degrees and elbow flexed. Humerus is loaded by examiner, then examiner attempts to shift the humeral head anterior, posterior, or inferior. Both shoulders should be tested. Results are graded using:

[i]. Grade 0, little or no movement;

[ii]. Grade 1, humeral head glides beyond the glenoid labrum; and

[iii]. Grades 2 & 3 actual dislocation of the humeral head off the glenoid.

[g]. Anterior slide or Kibler test – Patient places hands on hips with thumb directed posteriorly. Examiner applies force superiorly and anteriorly on the humerus, while the patient resists. If a click or deep pain results, test suggests labral tear.

[h]. Active compression (O'Brien) test – The patient has the shoulder in 90 degrees flexion and 10 to 15 degrees adduction. The arm is internally rotated so the thumb is pointing downward. The patient elevates the arm while the examiner resists. If the patient experiences deep anterior shoulder pain that is relieved when the same process is repeated with external rotation of the arm, the test suggests labral tear or AC joint pathology.

[i]. Crank test – The patient is standing and has arm elevated to 160 degrees in the scapular plane. The examiner loads the glenohumeral joint while the arm is passively rotated internally and externally. The test is repeated in the supine position. Pain, clicking, popping, or other mechanical grinding suggests labral tear and possible instability.

[j]. Compression rotation test – The patient is supine with shoulder abducted at 90 degrees. The examiner applies an axial load across the glenohumeral joint while simultaneously passively rotating the patient's arm in internal and external rotation. Pain, clicking, popping, or other mechanical grinding suggests a labral tear and possible instability.

[k]. Pain provocation or Mimori test – The patient is seated upright with the shoulder in 90 degrees abduction. The examiner maximally pronates and supinates the forearm while maintaining the shoulder at 90 degrees abduction. A positive test is suggested when pain or pain severity, is greater with the forearm pronated.

(vi). Functional assessment. The provider should assess the patient's functional skills initially and periodically during treatment. The initial exam will form the baseline for the patient's functional abilities post- injury. This assessment will help the physician and patient determine when progress is being made and whether specific therapies are having a beneficial effect. A number of functional scales are available that have been validated in clinical research settings. Many of these scales were developed to evaluate specific diagnoses and will not be useful for all patients with shoulder pain. The following areas are examples of functional activities the provider may assess:

[a]. interference with sleep;

[b]. difficulty getting dressed or combing or washing hair;

[c]. ability to do the household shopping alone;

[d]. ability to shower or bath and dry oneself using both hands;

[e]. ability to carry a tray of food across a room with both hands;

[f]. ability to hang up clothes in the closet;

[g]. ability to reach high shelves with the affected shoulder;

[h]. difficulty with any other activities including sports and work duties;

[i]. concerns about putting on overhead clothing;

[j]. concerns that a specific activity might cause the shoulder to "go out";

[k]. a detailed description of ability to perform job duties.

[l]. any positive historical information should be validated by the provider's physical exam.

2. Radiographic Imaging of the shoulder is a generally accepted, well-established and widely used diagnostic procedure when specific indications based on history and/or physical examination are present. It should not be routinely performed for most non-traumatic diagnoses. The mechanism of injury and specific indications for the radiograph should be listed on the request form to aid the radiologist and x-ray technician. For additional specific clinical indications, Specific Diagnosis, Testing and Treatment Procedures. Indications include:

a. inability to actively move arm through range-of-motion;

b. history of significant trauma, especially blunt trauma or fall from a height;

c. history of dislocation;

d. age over 55 years;

e. unexplained or persistent shoulder pain over two weeks. (Occult fractures, may not be visible on initial x-ray. A follow-up radiograph and/or bone scan may be required to make the diagnosis);

f. history or exam suggestive of intravenous drug abuse or osteomyelitis; and

g. pain with swelling and/or range-of-motion (ROM) limitation localizing to an area of prior fracture, internal fixation, or joint prosthesis.

3. Laboratory tests are generally accepted, well-established and widely used procedures. They are, however, rarely indicated at the time of initial evaluation, unless there is suspicion of systemic illness, infection, neoplasia, connective tissue disorder, or underlying arthritis or rheumatologic disorder based on history and/or physical examination. Laboratory tests can provide useful diagnostic information. The OWCA recommends that lab diagnostic procedures be initially considered the responsibility of the workers' compensation carrier to ensure that an accurate diagnosis and treatment plan can be established. Tests include, but are not limited to:

a. Completed Blood Count (CBC) with differential can detect infection, blood dyscrasias, and medication side effects;

b. Erythrocyte sedimentation rate, rheumatoid factor, antinuclear antigen (ANA), human leukocyte antigen (HLA), and C-reactive protein can be used to detect evidence of a rheumatologic, infection, or connective tissue disorder;

c. Serum calcium, phosphorous, uric acid, alkaline phosphatase, and acid phosphatase can detect metabolic bone disease;

d. Liver and kidney function may be performed for prolonged anti-inflammatory use or other medications requiring monitoring; and

e. Analysis of joint aspiration for bacteria, white cell count, red cell count, fat globules, crystalline birefringence and chemistry to evaluate joint effusion.

7. Other Procedures

a. Joint Aspiration: is a generally accepted, well-established and widely used procedure when specifically indicated and performed by individuals properly trained in these techniques. Especially, when history and/or physical examination are of concern for a septic joint or bursitis. Aspiration of a large effusion can help to decrease pain and speed functional recovery. Persistent or unexplained effusions may be examined for evidence of infection, rheumatologic, or inflammatory processes. The presence of fat globules in the effusion strongly suggests occult fracture.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1822 (June 2011).

§2321. Follow-Up diagnostic imaging and testing procedures

A. One diagnostic imaging procedure may provide the same or distinctive information as does another procedure. Therefore, the prudent choice of a single diagnostic procedure, a complement of procedures or a sequence of procedures will optimize diagnostic accuracy; maximize cost effectiveness (by avoiding redundancy), and minimize potential adverse effects to patients.

B. All diagnostic imaging procedures have a significant percentage of specificity and sensitivity for various diagnoses. None is specifically characteristic of a certain diagnosis. Clinical information obtained by history taking and physical examination should form the basis for selecting an imaging procedure and interpreting its results.

C. When a diagnostic procedure, in conjunction with clinical information, can provide sufficient information to establish an accurate diagnosis, the second diagnostic procedure will become a redundant procedure. At the same time, a subsequent diagnostic procedure can be a complementary diagnostic procedure if the first or preceding procedures, in conjunction with clinical information, cannot provide an accurate diagnosis. Usually, preference of a procedure over others depends upon availability, a patient's tolerance, and/or the treating practitioner's familiarity with the procedure.

1. Imaging Studies are generally accepted, well-established and widely used diagnostic procedures. When indicated, the following additional imaging studies can be utilized for further evaluation of the shoulder, based upon the mechanism of injury, symptoms, and patient history. For specific clinical indications, refer to Specific Diagnosis, Testing and Treatment Procedures. The studies below are listed by frequency of use, not importance. Diagnostic imaging may be useful in resolving the diagnostic uncertainties that remain after the clinical examination. Even a thorough history and physical examination may not define the shoulder pathology that produces the patient's symptoms. Therefore, additional investigations should be considered as an accepted part of the patient evaluation when surgery is being considered or clarification of diagnosis is necessary to formulate a treatment plan.

a. X-ray is widely accepted and frequently the first imaging study performed. Three radiographically distinguishable acromion types have been described: Type I (flat), Type II (curved), and Type III (hooked). Historically, acromion type was correlated with incidence of rotator cuff pathologies and with outcome of nonsurgical treatment of shoulder pain. However, there is considerable variation between observers regarding the acromial types, both in interpreting plain x-rays and in classifying anatomical specimens. Acromial morphology should not be used to assess the likelihood of rotator cuff pathology. Acromial morphology alone should not be considered an indication for acromioplasty, as up to 40 percent of asymptomatic adults may have a Type II acromion. Appropriate soft tissue imaging techniques such as sonography and MRI should be used to assess rotator cuff or bursa status.

b. Diagnostic Sonography is an accepted technique for suspected full-thickness tears. A positive sonogram has a high specificity of 96 percent and provides convincing confirmation of the diagnosis. Sensitivity is high, 87 percent, however, negative sonography does not rule out a full-thickness tear. For partial thickness tears, a positive sonogram has high specificity, 94 percent, but is only moderately sensitive, 67 percent. A negative sonogram does not exclude the diagnosis of a partial thickness tear. The performance of sonography is operator-dependent, and is best when done by a specialist in musculoskeletal radiology. It is preferable to MRI when the patient is claustrophobic or has inserted medical devices.

c. Magnetic Resonance Imaging (MRI) is generally accepted and widely used to provide a more definitive visualization of soft tissue structures, including ligaments, tendons, joint capsule, and joint cartilage structures, than x-ray or Computed Axial Tomography (CT) in the evaluation of traumatic or degenerative injuries. The addition of intravenous or intra-articular contrast can enhance definition of selected pathologies. In general, the high field, conventional, MRI provides better resolution than a low field scan. A lower field scan may be indicated when a patient cannot fit into a high field scanner or is too claustrophobic despite sedation. Inadequate resolution on the first scan may require a second MRI using a different technique. All questions in this regard should be discussed with the MRI center and/or radiologist. MRI provides excellent soft tissue detail, but interpretation of the image is problematic and depends on operator skill. A positive MRI has high specificity of 93 percent and provides supporting evidence that a clinical suspicion of a full-thickness tear is correct. Sensitivity of MRI for full-thickness tears is also high at 89 percent. However, it may not identify the

pathology in some cases. For partial thickness tears, sensitivity of MRI is below 50 percent but its specificity is high at 90 percent.

d. Computed Axial Tomography (CT): is generally accepted and provides excellent visualization of bone and is used to further evaluate bony masses and suspected fractures not clearly identified on radiographic window evaluation. Instrument scatter-reduction software provides better resolution when metallic artifact is of concern.

e. MR Arthrography (MRA): This accepted investigation uses the paramagnetic properties of gadolinium to shorten T1 relaxation times and provide a more intense MRI signal. It can accurately demonstrate and rule out full-thickness tears as well as non-contrast MRI, but it is invasive and its place in the evaluation of rotator cuff pathology has not been determined. In select populations of highly active athletes, it may uncover unsuspected labral pathology such as SLAP lesions, but the arthroscopically normal labrum may produce an abnormal signal in half of MRA studies. Its contribution to the diagnosis of SLAP lesions has not been determined. An MRA is not necessary if the patient has already met indications for arthroscopy or surgery as outlined in Specific Diagnosis, Testing and Treatment. However, an MRA may be ordered when the surgeon desires further information prior to surgery.

f. Venogram/Arteriogram is a generally accepted test is useful for investigation of vascular injuries or disease, including deep-venous thrombosis. Potential complications may include pain, allergic reaction, and deep-vein thrombosis.

g. Bone Scan (Radioisotope Bone Scanning): is generally accepted, well-established and widely used. Bone scanning is more sensitive but less specific than MRI. 99MTechnecium diphosphonate uptake reflects osteoblastic activity and may be useful in metastatic/primary bone tumors, stress fractures, osteomyelitis, and inflammatory lesions, but cannot distinguish between these entities. Bone scanning is more sensitive but less specific than MRI. It is useful for the investigation of trauma, infection, stress fracture, occult fracture, Complex Regional Pain Syndrome, and suspected neoplastic conditions of the upper extremity.

h. Other Radioisotope Scanning Indium and gallium scans are generally accepted procedures usually to help diagnose lesions seen on other diagnostic imaging studies. 67Gallium citrate scans are used to localize tumor, infection, and abscesses. 111Indium-labeled leukocyte scanning is utilized for localization of infection or inflammation.

i. Arthrograms are accepted; however, rarely used except for evaluation of patients with metal implants and previous shoulder surgery.

j. If the patient has a positive ultrasound, MRI, or Arthrogram—only one of these tests are necessary to diagnose a rotator cuff tear. Any additional tests must be for additional diagnosis.

3. Other Tests. The following diagnostic procedures in this subsection are listed in alphabetical order.

a. Compartment Pressure Testing and Measurement Devices: such as pressure manometer, are generally accepted and useful in the evaluation of patients who present uncommon but reported symptoms consistent with a compartment syndrome.

b. Doppler Ultrasonography/Plethysmography: is useful in establishing the diagnosis of arterial and venous disease in the upper extremity and should be considered prior to the more invasive venogram or arteriogram study.

c. Electrodiagnostic Testing: Electrodiagnostic tests include but are not limited to, Electromyography (EMG), and Nerve Conduction Studies (NCS). These are generally accepted, well-established and widely used diagnostic procedures. Electrodiagnostic studies may be useful in the evaluation of patients with suspected involvement of the neuromuscular system, including radiculopathies, peripheral nerve entrapments, peripheral neuropathies, disorders of the neuromuscular junction and primary muscle disease. EMGs should not be routinely performed for shoulder injuries unless there are findings to suggest new diagnostic pathology (Refer to Brachial Plexus). In general, these diagnostic procedures are complementary to imaging procedures such as CT, MRI, and/or myelography or diagnostic injection procedures. Electrodiagnostic studies may provide useful, correlative neuropathophysiological information that would not be obtainable from standard radiologic studies. Portable Automated Electrodiagnostic Device (also known as Surface EMG) is not a substitute for conventional EMG/NCS testing in clinical decision-making, and therefore, is not recommended.

d. Personality/Psychological/Psychiatric/Psycho-social Evaluation: These are generally accepted and well-established diagnostic procedures with selective use in the upper extremity population, but have more widespread use in subacute and chronic upper extremity populations. Diagnostic testing procedures may be useful for patients with symptoms of depression, delayed recovery, chronic pain, recurrent painful conditions, disability problems, and for preoperative evaluation. Psychological/psychosocial and measures have been shown to have predictive value for postoperative response, and therefore should be strongly considered for use pre-operatively when the surgeon has concerns about the relationship between symptoms and findings, or when the surgeon is aware of indications of psychological complication or risk factors for psychological complication (e.g. childhood psychological trauma). Psychological testing should provide differentiation between pre-existing conditions versus injury caused psychological conditions, including depression and posttraumatic stress disorder. Psychological testing should incorporate measures that have been shown, empirically, to identify comorbidities or risk factors that are linked to poor outcome or delayed recovery. Formal psychological or psychosocial evaluation should be performed on patients not making expected progress within 6 to 12 weeks following injury and whose subjective symptoms do not correlate with objective signs and test results. In addition to the customary initial exam, the evaluation of the injured worker should specifically address the following areas:

i. employment history;

ii. interpersonal relationships-both social and work;

iii. patient activities;

iv. current perception of the medical system;

v. current perception/attitudes toward employer/job

vi. results of current treatment

vii. risk factors and psychological comorbidities that may influence outcome and that may require treatment

viii. childhood history, including history of childhood psychological trauma, abuse and family history of disability.

(a). Personality/ psychological/ psychosocial evaluations consist of two components, clinical interview and psychological testing. Results should help clinicians with a better understanding of the patient in a number of ways. Thus the evaluation result will determine the need for further psychosocial interventions; and in those cases, Diagnostic and Statistical Manual of Mental Disorders (DSM) diagnosis should be determined and documented. The evaluation should also include examination of both psychological comorbidities and psychological risk factors that are empirically associated with poor outcome and/or delayed recovery. An individual with a Ph.D., Psy.D, or psychiatric M.D./D.O. credentials should perform initial evaluations, which are generally completed within one to two hours. A professional fluent in the primary language of the patient is preferred. When such a provider is not available, services of a professional language interpreter should be provided.

(i). Frequency: one-time visit for the clinical interview. If psychometric testing is indicated as a part of the initial evaluation, time for such testing should not exceed an additional two hours of professional time.

4. Special Tests are generally well-accepted tests and are performed as part of a skilled assessment of the patient's capacity to return-to-work, his/her strength capacities, and physical work demand classifications and tolerances. The procedures in this subsection are listed in alphabetical order.

a. Computer Enhanced Evaluations: may include isotonic, isometric, isokinetic and/or isoinertial measurement of movement, range-of-motion (ROM), endurance or strength. Values obtained can include degrees of motion, torque forces, pressures, or resistance. Indications include determining validity of effort, effectiveness of treatment and demonstrated motivation. These evaluations should not be used alone to determine return to work restrictions. The added value of computer enhanced evaluations is unclear. Targeted work tolerance screening or gradual return to work is preferred.

i. Frequency: One time for evaluation. Can monitor improvements in strength every three to four weeks up to a total of six evaluations.

b. Functional Capacity Evaluation (FCE): is a comprehensive or modified evaluation of the various aspects of function as they relate to the worker's ability to return-to-work. Areas such as endurance, lifting (dynamic and static), postural tolerance, specific range of motion, coordination and strength, worker habits, employability, as well as psychosocial aspects of competitive employment may be evaluated. Components of this evaluation may include: musculoskeletal screen; cardiovascular profile/aerobic capacity; coordination; lift/carrying analysis; job-specific activity tolerance; maximum voluntary effort; pain assessment/psychological screening; and non-material and material handling activities. When an FCE is being used to determine return to a specific jobsite, the provider is responsible for fully understanding the job duties. A jobsite evaluation is frequently necessary. FCEs cannot be used in isolation to determine work restrictions. The authorized treating physician must interpret the FCE in light of the individual patient's presentation and medical and personal perceptions. FCEs should not be used as the sole criteria to diagnose malingering. Full FCEs are sometimes not necessary. If Partial FCEs are performed, it is recognized that all parts of the FCE that are not performed are considered normal. In many cases, a work tolerance screening will identify the ability to perform the necessary job tasks.

i. Frequency: Can be used initially to determine baseline status and for case closure when patient is unable to return to pre-injury position and further information is desired to determine permanent work restrictions. Prior authorization is required for FCEs performed during treatment.

c. Jobsite Evaluation: is a comprehensive analysis of the physical, mental, and sensory components of a specific job. These components may include, but are not limited to; postural tolerance (static and dynamic); aerobic requirements; range of motion; torque/force; lifting/carrying; cognitive demands; social interactions; visual perceptual; sensation; coordination; environmental requirements of a job; repetitiveness; and essential job functions. Job descriptions provided by the employer are helpful but should not be used as a substitute for direct observation. A jobsite evaluation may include observation and instruction of how work is done, what material changes (desk, chair) should be made, and determination of readiness to return to work. Requests for a jobsite evaluation should describe the expected goals for the evaluation. Goals may include, but are not limited to the following:

i. To determine if there are potential contributing factors to the person's condition and/or for the physician to assess causality;

ii. To make recommendations for, and to assess the potential for ergonomic changes;

iii. To provide a detailed description of the physical and cognitive job requirements;

iv. To assist the patient in their return to work by educating them on how they may be able to do their job more safely in a bio-mechanically appropriate manner; and/or

v. To give detailed work/activity restrictions.

(a). Frequency: One time with additional visits as needed for follow-up visits per jobsite.

d. Vocational Assessment: The vocational assessment should provide valuable guidance in the determination of future rehabilitation program goals. It should clarify rehabilitation goals, which optimize both patient motivation and utilization of rehabilitation resources. If prognosis for return to former occupation idetermined to be poor, except in the most extenuating circumstances, vocational assessment should be implemented within 3 to 12 months post-injury. Declaration of MMI should not be delayed solely due to lack of attainment of a vocational assessment.

i. Frequency: One time with additional visits as needed for follow-up

e. Work Tolerance Screening: is a determination of an individual's tolerance for performing a specific job based on a job activity or task and may be used when a full

Functional Capacity Evaluation is not indicated. The screening is monitored by a therapist and may include a test or procedure to specifically identify and quantify work-relevant cardiovascular, physical fitness and postural tolerance. It may also address ergonomic issues affecting the patient's return-to-work potential.

i. Frequency: One time for initial screen. May monitor improvements in strength every three to four weeks up to a total of six visits.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1825 (June 2011).

§2323. Specific Diagnosis, Testing and Treatment

A. Acromioclavicular joint sprains/dislocations. An acute acromioclavicular (AC) joint injury is frequently referred to as a shoulder separation. There are six classifications of AC joint separation, which are based upon the extent of ligament damage and bony displacement:

1. Description/Definition:

a. Type I - Sprain of the AC ligament and capsule; x-ray usually normal.

b. Type II - Sprains consisting of a ruptured AC ligament and capsule with incomplete injury to the coracoclavicular (CC) ligament, resulting in mild AC joint subluxation. X-ray shows clavicle slightly elevated.

c. Type III - Dislocation of the clavicle above the acromion with complete tear of the AC ligament and/or CC ligaments; abnormal stress x-rays.

d. Type IV. - Dislocation consisting of a displaced clavicle that penetrates posteriorly through or into the trapezius muscle. The sterno-clavicular joint may also be dislocated.

e. Type V - Dislocation consisting of complete separation of the AC and CC ligaments and dislocation of the acromioclavicular joint with a large coracoclavicular interval.

f. Type VI - Dislocation consisting of a displaced clavicle that penetrates inferior to the coracoid.

2. Type I-III are common, while Types IV-VI are not, and when found require surgical consultation. For AC joint degeneration from repetitive motion that is found to be work-related, refer to Impingement Syndrome.

3. Occupational Relationship: Generally, workers sustain an AC joint injury when they fall landing on the point of the shoulder, driving the acromion downward; or fall on an outstretched hand or elbow with an adducted arm, creating a backward and outward force on the shoulder. It is important to rule out other sources of shoulder pain from the acute injury, including rotator cuff tear, fracture, and nerve injury.

4. Specific Physical Exam Findings may include the following:

a. At times, tenderness at the AC joint with contusions and/or abrasions at the joint area; and/or prominence/asymmetry of the shoulder can be seen;

b. The patient usually demonstrates decreased shoulder motion, and with palpation, the distal end of the clavicle is painful. There may be increased clavicular translation and cross-body adduction that causes exquisite pain at the AC joint. Cross-body adduction with the arm elevated to 90 degrees can also cause posterior pain with a tight posterior capsule, or lateral pain with impingement. Injection of local anesthetic in the AC joint should relieve pain when performing this maneuver.

5. Diagnostic Testing Procedures: Plain x-rays may include:

a. AP view;

b. AP radiograph of the shoulder with the beam angled 10 degrees cephalad (Zanca view) and a beam strength that is under-penetrating;

c. Axillary lateral views; and

d. Stress view; side-to-side comparison with 10 to 15 lb. of weight in each hand.

6. Non-operative Treatment Procedures may include:

a. Procedures outlined in Section F. Immobilization in some cases (up to 6 weeks for Type I-III AC joint separations). Treatments for Type III injuries are controversial and may range from a sling to surgery.

b. Medication, such as non-steroidal anti-inflammatories and analgesics would be indicated. Narcotics are not normally indicated. Lidocaine patches may be used for pain relief. In chronic acromioclavicular joint pain, a series of injections with or without cortisone may be performed up to three times per year. Benefits may be achieved through therapeutic rehabilitation. It should emphasize a progressive increase in range-of-motion (ROM) without exacerbation of the AC joint injury. Full recovery of AC joint dislocation may require up to twelve weeks. With increasing motion and pain control, a strengthening program should be instituted. Refer to Therapeutic Procedures, Non-operative.

c. Return to appropriate modified duty should begin within the first week. Refer to Return to Work. With restoration of full-motion, return to full-duty should be anticipated within three months.

d. Other therapies in Therapeutic Procedures, Non-operative, may be employed in individual cases.

7. Surgical Indications: Patients who have Type III AC joint dislocations will usually recover well without surgical intervention. Surgical intervention may be considered when functional deficits interfere with activities of daily living and/or job duties after three to four months of active patient participation in non-operative therapy. For patients with particularly high physical demands on their shoulder, immediate orthopaedic consultation with surgical intervention as early as two weeks from the date of injury may be considered. Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities. The patient should also agree to comply with the pre- and post-operative treatment plan and home exercise requirements and understand the length of partial and full-disability expected post-operatively. With a Type IV-VI AC joint injury, an orthopedic surgical consultation is recommended.

8. Operative Procedures:

a. AC joint stabilization with or without distal clavicle resection. Distal clavicle resection may prevent painful arthritis but can compromise post-operative AC joint stabilization.

9. Post-operative Treatment:

a. An individualized rehabilitation program based upon communication between the surgeon and the therapist

using the treatments found in Therapeutic Procedures, Non-operative.

b. Early therapeutic rehabilitation interventions are recommended to maintain ROM with progressive strengthening.

i. Frequency: Three to five times per week for the first two weeks, three times per week for the following two weeks, then one to two times per week.

ii. Optimum Duration: Six to eight weeks with progression to home exercise and/or pool therapy.

iii. Maximum Duration: 12 weeks. Occasional follow-up visits may be justified to reinforce exercise patterns or to reach final functional goals if the therapy to date has demonstrated objective functional gains.

c. Return to work and restrictions after surgery may be made by an experienced primary occupational medicine physician in consultation with the surgeon or by the surgeon.

10. Adhesive Capsulitis/Frozen Shoulder Disorder

a. Description/Definition: Adhesive capsulitis of the shoulder, also known as frozen shoulder disorder, is a soft tissue lesion of the glenohumeral joint resulting in global restrictions of passive and active ROM. Lack of passive ROM can persist even with therapy, for an average of 30 months. The disorder progresses through stages, specifically:

i. Stage 1—Consists of acute pain with some limitation in range-of-motion; generally lasting two to nine months.

ii. Stage 2—Characterized by progressive stiffness, loss of passive range-of-motion, muscular atrophy, and decreased pain; generally lasting an additional 3 to 12 months beyond Stage 1.

iii. Stage 3—Characterized by partial or complete resolution of symptoms and restoration of ROM and strength; it usually takes an additional 5 to 26 months beyond Stage 2.

iv. Patients will usually complain of pain in the sub-deltoid region, but occasionally over the long head of the biceps or radiating down the lateral aspect of the arm to the forearm. Pain is often worse at night, with difficulty sleeping on the involved side. Motion is restricted and painful.

v. In Stages 2 and 3, patients may also experience peri-scapular and neck pain from compensatory scapular thoracic motion.

vi. Idiopathic adhesive capsulitis usually occurs spontaneously without any specific inciting injury. This occurs most frequently in diabetic, middle aged patients. This type of adhesive capsulitis is likely to remit over time and is usually not work related.

vii. Capsulitis or stiffness may occur secondary to trauma or surgery from another condition. Therapy and additional treatment recommendations for other specific diagnoses should be strictly followed to decrease the occurrence of secondary restricted ROM.

b. Occupational Relationship: There should be some history of work related injury. Occupational adhesive capsulitis may arise secondary to any chest or upper extremity trauma. Primary adhesive capsulitis is rarely occupational in origin.

c. Specific Physical Exam Findings may include: Restricted active and passive glenohumeral ROM in multiple planes is the primary physical finding. It may be useful for the examiner to inject the subacromial space with lidocaine and then repeat ROM testing to rule out stiffness secondary to rotator cuff or bursal pathology. Lack of improvement of ROM usually confirms the diagnosis. Postural changes and secondary trigger points along with atrophy of the deltoid and supraspinatus muscles may be seen.

d. Diagnostic Testing Procedures:

i. Plain x-rays should be done to rule out concomitant pathology such as subluxation or tumor.

ii. Other diagnostic testing may be indicated to rule out associated pathology. Refer to Follow-up Diagnostic Procedures and to Specific Diagnosis, Testing, and Treatment. Dynamic sonography may be useful to specifically identify the movements most affected and rule out other pathology.

iii. Laboratory tests should be considered to rule out systemic diseases.

e. Non-operative Treatment Procedures: Address the goal to restore and maintain function and may include the following:

i. Therapeutic interventions are the mainstay of treatment. They should include ROM, active therapies, and a home exercise program. Passive as well as active therapies may be used for control of pain and swelling. Therapy should progress to strengthening and instruction in a home exercise program targeted to further improve ROM and strength of the shoulder girdle musculature. There is some evidence that a home exercise program will have similar results to fully-supervised physical therapy in non-workers compensation populations; however, to facilitate return to work, supervised therapy is generally recommended for at least several sessions to assure proper performance of home exercise and to evaluate continued progress. These sessions are in addition to any sessions already performed for the original primary related diagnosis. Refer to Therapeutic Procedures, Non-operative for all other therapies as well as a description of active and passive therapies.

(a). Time to Produce Effect: Four sessions.

(b). Frequency: Two times per week for the first two weeks and one time or less thereafter.

(c). Optimum Duration: 8 to 12 sessions.

(d). Maximum Duration: 20 sessions per year. Additional follow-up visits may be justified to reinforce exercise patterns or to reach final functional goals if therapy to date has demonstrated objective functional gains.

ii. Return to work duties with increased ROM as tolerated are also helpful to increase function. Refer to Return to Work.

iii. Medications, such as NSAIDS and analgesics, may be helpful. Narcotics are indicated for post-manipulation or post-operative cases. Judicious use of pain medications to optimize function may be indicated. Refer to Medications.

iv. Subacromial bursal and/or glenohumeral steroid injections can decrease inflammation and allow the therapist to progress with functional exercise and ROM. There is strong evidence that intra-articular injection of a corticosteroid produces pain relief and increases ROM in the short-term for individuals with restriction of both active and passive ROM in more than one direction. There is good evidence that the addition of a physical therapy or home exercise program is more effective than steroid injections

alone. Injections under significant pressure should be avoided as the needle may be penetrating the tendon and injection into the tendon can cause possible tendon breakdown, tendon degeneration, or rupture. Injections should be minimized for patients under 30 years of age. Steroid injections should be used cautiously in diabetic patients. Diabetic patients should be reminded to check their blood glucose level at least daily for 2 weeks after injections.

(a). Time to Produce Effect: One injection.

(b). Maximum Duration: Three injections in one year at least four to eight weeks apart, when functional benefits are demonstrated with each injection.

v. There is no clear long-term benefit for suprascapular nerve blocks, however, blocks may be appropriate for patients when pain is not well-controlled and injections improve function.

(a). Time to Produce Effect: One block should demonstrate increased ability to perform exercises and/or range-of-motion.

(b). Maximum Duration: Three per year.

vi. In cases that are refractory to conservative therapy lasting at least three to six months, and in whom ROM remains significantly restricted (abduction usually less than 90 degrees), the following treatment may be considered:

(a). Distension arthrography or "brisement" in which saline, an anesthetic and usually a steroid are forcefully injected into the shoulder joint causing disruption of the capsule. There is good evidence that distension arthrogram with steroid and saline improves function in patients with decreased passive ROM after three months of treatment. Early therapy to maintain ROM, and restore strength and function should follow distension arthrography. Return to work with restrictions should be expected within one week of the procedure; return to full-duty is expected within four to six weeks.

(b). Dynamic splinting may be appropriate for rare cases when a functional ROM has not been achieved with the treatment listed above.

vii. There is no evidence that hyaluronate injections are superior to physical therapy in this condition and are not recommended.

viii. Other therapies in Therapeutic Procedures, Non-operative, may be employed in individual cases.

f. Surgical Indications: Surgery may be considered when functional deficits interfere with activities of daily living and/or job duties after three to six months of active patient participation in non-operative therapy. For most individuals this constitutes limitations in the range of 130 degrees elevation and 120 degrees abduction; with significant functional limitations; however, individuals who must perform overhead work and lifting may require a greater ROM. Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities. The patient should also agree to comply with the pre- and post-operative treatment plan and home exercise requirements. The patient should understand the length of partial and full disability expected post-operatively.

g. Operative Procedures: Manipulation under anesthesia which may be done in combination with steroid injection, distension arthrography, or arthroscopy. Contraindications to closed manipulation under anesthesia include anti-coagulation or bleeding diatheses, significant osteopenia, or recent surgical repair of shoulder soft tissue, fracture or neurological lesion. Complications may include humeral fracture, dislocation, cuff injuries, labral tears or brachial plexus injury. Arthroscopic capsular release or open surgical release may be appropriate in rare cases with failure of previous methods and when the patient has demonstrated ability to follow through with required physical and occupational therapy. Other disorders, such as impingement syndrome, may also be treated at the same time. Radiofrequency is not recommended due to reported complications from chondrolyis.

h. Post-operative Treatment. An individualized rehabilitation program based upon communication between the surgeon and the therapist using the treatments found in Therapeutic Procedures, Non-operative. Therapy may include the following:

i. Early therapeutic rehabilitation interventions are recommended to maintain ROM and should progress to strengthening exercises.

ii. Frequency: Suggested frequency pattern is three to five times per week for the first two weeks, three times per week for the following two weeks, then one to two times per week. The exact frequency per week will depend on the severity.

iii. Optimum Duration: Six to eight weeks with progression to home exercise and/or pool therapy.

iv. Maximum Duration: Up to 12 weeks. Additional follow-up visits may be justified to reinforce exercise patterns or to reach final functional goals if the therapy to date has demonstrated objective functional gains.

v. Return to work and restrictions after surgery may be made by an experienced primary occupational medicine physician in consultation with the surgeon or by the surgeon.

vi. Patient should be approaching MMI within 8 to 12 weeks post-operatively; however, co-existence of other pathology should be taken into consideration.

B. Bicipital Tendon Disorders

1. Description/Definition:

a. Disorders may include: primary bicipital tendonopathy, which is exceedingly rare; secondary bicipital tendonopathy, which is generally associated with rotator cuff tendonitis or impingement syndrome (see appropriate diagnosis subsections); subluxation of the biceps tendon, which occurs with dysfunction of the transverse inter-tubercular ligament and rotator cuff tears; and acute disruption of the tendon, which can result from an acute distractive force or transection of the tendon from direct trauma.

b. Symptoms may include aching, burning and/or stabbing pain in the shoulder, usually involving the anterior medial portion of the shoulder girdle. The symptoms are exacerbated with above-the-shoulder activities and those specifically engaging the biceps (flexion at the shoulder, flexion at the elbow and supination of the forearm). Relief occurs with rest. Patients may report nocturnal symptoms which interfere with sleep during the acute stages of inflammation; pain and weakness in shoulder during activities; repeated snapping phenomenon with a subluxing

tendon; immediate sharp pain and tenderness along the course of the long head of the biceps following a sudden trauma which would raise suspicions of acute disruption of the tendon; and/or with predominant pain at the shoulder accompanied by referral patterns which may extend pain into the cervical or distal structures, including the arm, elbow, forearm, and wrist.

2. Occupational Relationship.

a. Bicipital tendon disorders may include symptoms of pain and/or achiness that occur after repetitive use of the shoulder and/or blunt trauma to the shoulder. Secondary bicipital tendonitis may be associated with prolonged above-the-shoulder activities, and/or repeated shoulder flexion, external rotation and abduction. Acute trauma to the biceps tendon of the shoulder girdle may also give rise to occupational injury of the biceps tendon.

b. Occupational disorders of the biceps tendon may accompany scapulothoracic dyskinesis, rotator cuff injury, AC joint separation, sub deltoid bursitis, shoulder instability or other shoulder pathology. Symptoms should be exacerbated or provoked by work that activated the biceps muscle. Symptoms may be exacerbated by other activities that are not necessarily work related and the physician should explore and report these areas.

3. Specific Physical Exam Findings may include the following:

a. If continuity of the tendon has been lost (biceps tendon rupture), inspection of the shoulder would reveal deformity (biceps bunching/Popeye deformity). It is important to differentiate between distal and proximal tendon rupture, as distal biceps ruptures often require urgent intervention.

b. Palpation demonstrates tenderness along the course of the bicipital tendon.

c. Pain at end range of flexion and abduction as well as with biceps tendon activation.

d. Provocative testing may include the following (a detailed description of the signs and tests is located in initial diagnostic procedures):

i. Yergeson's sign.

ii. Speed's Test.

iii. Ludington's Test.

iv. Diagnostic Testing Procedures:

(a). Plain x-rays include:

(i). Anterior/Posterior (AP) view. Elevation of the humeral head is indicative of a rotator cuff tear;

(ii). Lateral view in the plane of the scapula or an axillary view determines an anterior or posterior dislocation or the presence of a defect in the humeral head (a Hill-Sachs lesion);

(iii). Axillary view is also useful to demonstrate arthritis and spurs on the anterior inferior acromion; and

(iv). Outlet view determines if there is a downwardly tipped acromion.

(b). Adjunctive testing, such as sonography, or MRI should be considered when shoulder pain is refractory to four to six weeks of non-operative conservative treatment and the diagnosis is not readily identified by standard radiographic and clinical techniques.

4. Non-Operative Treatment Procedures:

a. Benefit may be achieved through procedures outlined in Non-operative Treatment Procedures, such as appropriate modalities, limited acute immobilization, exercise and evaluation of occupational workstation. Therapy should emphasize progressive increase in ROM. With increasing motion and pain control, a strengthening program should be instituted.

i. Time to Produce Effect: Four sessions.

ii. Frequency: Two times per week for the first two weeks and one time or less thereafter.

iii. Optimum Duration: 8 to 12 sessions.

iv. Maximum Duration: 20 sessions per year.

b. Medication, such as nonsteroidal anti-inflammatory and analgesics would be indicated. Narcotics are not normally indicated.

c. Biceps tendon sheath or subacromial steroid injections may be therapeutic. Injections under significant pressure should be avoided as the needle may be penetrating the tendon. Injection into the tendon can cause tendon degeneration, tendon breakdown, or rupture. Caution should be used in patients with a clinical suspicion of a partial tear. Injections should be minimized for patients under 30 years of age.

d. Steroid injections should be used cautiously in diabetic patients. Diabetic patients should be reminded to check their blood glucose level at least daily for two weeks after injections.

i. Time to Produce Effect: One injection should provide demonstratable functional benefit.

ii. Maximum Duration: Three injections per year at the same site when functional benefits are demonstrated with each injection.

e. Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work. By 8 to 11 weeks, with restoration of full-motion, return to full-duty should be anticipated.

f. Other therapies in Therapeutic Procedures, Non-operative, may be employed in individual cases.

5. Surgical Indications:

a. Acute Distal Biceps Tendon Rupture: normally requires urgent surgical repair.

b. Acute Proximal Long Head Biceps Tendon Rupture: active patient participation in non-operative treatment is often successful; however, operative intervention may be indicated for young patients, manual laborers or others who require forceful supination regularly for their work.

c. Bicipital Tendonitis: Conservative care prior to potential surgery must address flexibility and strength imbalances. Surgery may be considered when functional deficits interfere with activities of daily living and/or job duties after 12 weeks of active patient participation in non-operative therapy.

d. Subluxing Bicipital Tendon: Most patients with this condition also have a subscapularis tear. Surgical stabilization of the bicipital tendon is not commonly indicated. Good outcome may be achieved through successful rehabilitation procedures. Surgery may be considered when functional deficits interfere with activities of daily living and/or job duties after 12 weeks of active patient participation in non-operative therapy.

e. Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities and the patient should agree to comply with the pre- and post-operative treatment plan and home exercise requirements. The patient should understand the length of partial and full disability expected post-operatively.

6. Operative Procedures:

a. Distal Biceps tendon repair.

b. Repair of rotator cuff pulley lesion.

c. Proximal tenodesis or tenotomy: Impingement of the biceps tendon can cause continued irritation, and pain preventing shoulder elevation. Tenodesis or tenotomy has been used for decreased elevation after therapy in conjunction with a sub scapular repair or irreparable rotator cuff tear.

7. Post-operative Treatment:

a. An individualized rehabilitation program based upon communication between the surgeon and the therapist using the treatments found in Therapeutic Procedures, Non-operative. Therapy may include the following:

b. It is reasonable to restrict ROM for two months for tenodesis or distal biceps tendon repair. Early loading of the tendon should be avoided. Surgical patients may not recover sufficiently to perform full activity for 3 to 12 months. Rehabilitation, lasting at least 6 to 12 weeks, is necessary to facilitate Maximum Medical Improvement (MMI).

i. Frequency: Three to five times per week for the first two weeks, three times per week for the following two weeks, then one to two times per week.

ii. Optimum Duration: Six to eight weeks with progression to home exercise and/or pool therapy.

iii. Maximum Duration: 12 weeks. Occasional follow-up visits may be justified to reinforce exercise patterns or to reach final functional goals if the therapy to date has demonstrated objective functional gains.

c. Return to work and restrictions after surgery may be made by an experienced primary occupational medicine physician in consultation with the surgeon or by the surgeon.

C. Brachial Plexus and Shoulder Peripheral Nerve Injuries. Injuries to the brachial plexus and nerves of the shoulder girdle region may result in loss of motor and sensory function, pain, and instability of the shoulder. Signs and symptoms vary with the degree and mechanism of injury. The two modes of injury are: acute direct or indirect traumatic injuries to the shoulder region, and repetitive motion or overuse. Transient compression, stretch or traction (neurapraxia) causes sensory and motor signs lasting days to weeks. Damage to the axon (axonotmesis) without disruption of the nerve framework may cause similar symptoms. The recovery time is delayed and depends upon axon re-growth distally from the site of injury. Laceration or disruption of the entire nerve with complete loss of framework (neurotmesis) is the most severe form of nerve injury and will invariably require surgical intervention. Return of function is dependent upon re-growth of the nerve distal to the injury site. Full return of motor function is variable and may take up to 18 months or longer. Electromyography (EMG) is the most commonly used diagnostic modality to analyze nerve injuries. Electrophysiologic studies, such as electromyography and nerve conduction studies are generally accepted, well-established and widely used for localizing the source of neurological symptoms. These studies should be utilized as an extension of the history and clinical examination and to assess or monitor nerve recovery. Studies should be performed three to four weeks following injury or description of symptoms. Studies performed early may be falsely negative and usually require repeat testing three to four weeks after the original injury. Thus, early testing is not generally recommended. If the symptoms have been present for longer than three to four weeks, studies may be performed immediately after the initial evaluation. Serial studies may be indicated if initial studies are negative and may also be useful for gauging prognosis. Limb temperature should be controlled at 30 to 40 degrees centigrade. A description of six common nerve injuries to the shoulder girdle and their treatment follow.

1. Brachial Plexus Injuries:

a. Description/Definition:

i. The Brachial Plexus is formed by the nerve roots of C5-C8 and T1. These nerve roots exit the cervical spine and pass through the scalene musculature. After leaving the scalene musculature, at the level of the clavicle, they form trunks, division and chords which ultimately form the peripheral nerves of the arm.

b. Occupational Relationship: Direct injury to brachial plexus results in widespread sensory and motor loss. Direct trauma, subluxation to shoulder, clavicular fractures, shoulder depression, or head deviation away from the arm may result in variable brachial plexus lesions. Weight-lifting and carrying heavy back packs have also been associated with plexus injuries. Most injuries involve the upper and/or lower trunks. Upper trunk plexopathies may accompany full-thickness rotator cuff tears. Isolated middle trunk involvement is rare. Infraclavicular brachial plexus injuries have been reported due to hematoma formation secondary to an axillary block. If this occurs, emergency evacuation of the hematoma may be indicated. Symptoms may appear hours-to-days after the Procedure. Severe motor and sensory axonal loss is frequently seen on electrodiagnostic studies. It is important to differentiate injuries to the brachial plexus from the acquired (non work-related) Parsonage-Turner Syndrome or neuralgic amyotrophy occurring without a history of trauma. This idiopathic syndrome begins with severe pain in the shoulder girdle and is accompanied by resistance to passive motion. As the pain decreases, severe, near total weakness of one or more shoulder girdle muscles occurs. Almost total recovery can be expected but occurs over two to three years.

c. Specific Physical Exam Findings may include:

i. Evidence of trauma or deformity;

ii. Identification of sensory loss and demonstration of weakness which relates to the severity and anatomy of the injury to the brachial plexus; and/or

iii. Pain with recreation of the motions related to the mechanism of injury.

iv. Diagnostic Testing Procedures:

(a). EMG may show acute or chronic denervation of specific nerves. Nerve Conduction Studies demonstrating a loss of amplitude of 50 percent compared to

the normal side are considered abnormal. NCVs/EMGs will be repeated at appropriate intervals to assess reinnervation.

(b). If studies do not localize and give sufficient information, then additional information may be obtained from MRI and/or myelography. These studies are employed to differentiate root avulsion from severe brachial plexus injuries. Occasionally MRI may reveal the presence of an unexpected mass lesion consistent with a tumor.

v. Non-operative Treatment Procedures:

(a). In closed injuries, observation is favored. Repeat electrophysiologic studies may be helpful to assess or monitor recovery.

(b). Rehabilitation is based on procedures set forth Non-operative Treatment Procedures. However, utilization of ultrasound, and cold and heat should be discussed with the primary care physician, since these modalities may aggravate nerve injury.

(c). Medications such as analgesics, nonsteroidal anti-inflammatories, anti-depressants and anti-convulsants are indicated and narcotics may be indicated acutely. All medications should be prescribed as found in Thoracic Outlet Syndrome Guidelines.

(d). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

vi. Surgical Indications:

(a). In open injuries, acute exploration may be indicated if nerve discontinuity is visualized. Surgery may be considered post-injury when functional deficits interfere with activities of daily living and/or job duties after active participation in non-operative therapy.

(b). In closed injuries, if functional deficits continue to be documented after three to four months of active patient participation in non-operative therapy, then exploration may be warranted and a surgical consultation should be considered. Patients with progressive weakness or a loss of function post-injury should be referred for surgical consultation immediately.

vii. Operative Procedures.

(a). Exploration and Repair.

viii. Post-operative Treatment.

(a). An individualized rehabilitation program based upon communication between the surgeon and the therapist. Treatment may include the following:

(b). Early therapeutic rehabilitation interventions are recommended to maintain range-of-motion (ROM) and progressive strengthening.

2. Frequency: Suggested frequency pattern is three to five times per week for the first two weeks. Three times per week for the following two weeks, then one to two times per week. The exact frequency per week will depend on the severity and level of the nerve injury.

3. Optimum Duration: Six to eight weeks with progression to home exercise and/or pool therapy.

4. Maximum Duration: Up to 24 sessions. Additional follow-up visits may be justified to reinforce exercise patterns or to reach final functional goals if the therapy to date has demonstrated objective functional gains.

a. Return to work and restrictions after surgery may be made by an experienced primary occupational medicine physician in consultation with the surgeon or by the surgeon.

b. Axillary Nerve:

i. Description/Definition: This nerve is derived from the fifth and sixth cervical roots and passes around the shoulder, supplying motor branches to the teres minor and the three heads of the deltoid. The axillary nerve provides sensation to the top of the shoulder at the level of the deltoid.

5. Occupational Relationship: Direct injury and penetrating wounds to the shoulder and upward pressure on the axilla can cause injury to the axillary nerve. Blunt trauma to the anterolateral shoulder has also been reported. Abnormalities of the nerve can be seen with fractures of the surgical neck of the humerus and dislocation of the shoulder. Axillary nerve injury may also occur from shoulder surgery. Patients complain of reduced abduction of overhead strength and/or numbness in the lateral arm. The quadrilateral space syndrome may cause pain in the axillary nerve region with abduction, external rotation, and extension. The axillary nerve and the posterior circumflex artery are in the space bound by the long head of the triceps, the teres minor, subscapularis, and latissimus dorsi when the arm is abducted. This syndrome is most commonly reported in young males 20 to 40 years of age and has been associated with overhead sports.

6. Specific Physical Exam Findings may include:

a. weakness and atrophy of the deltoid muscle and teres minor;

b. strength is lost in abduction, flexion and extension of the shoulder; and/or

c. sensory loss is reported over the upper arm.

7. Diagnostic Testing Procedures.

a. Plain x-rays.

b. EMG and Nerve Conduction Studies three weeks after the injury and repeated at appropriate intervals to assess for reinnervation. Comparison of EMG and NCV findings with the opposite side is usually necessary to diagnose the degree of injury.

c. MRI may be done to rule out other pathology.

d. To confirm quadrilateral space syndrome, an MRI angiogram may be done to visualize the posterior circumflex artery occlusion in abduction. However, occlusion is present in 80 percent of normals also. This study should only be done after conservative therapy and if surgery is being contemplated.

8. Non-Operative Treatment Procedures:

a. Rehabilitation is based on procedures set forth in Non-operative Treatment Procedures. However, utilization of ultrasound, and cold and heat should be discussed with the primary care physician since these modalities may aggravate the nerve injury. Shoulder range-of-motion should be emphasized. For quadrilateral space syndrome, stretching of the posterior shoulder and teres minor is recommended.

b. Medications such as analgesics, nonsteroidal anti-inflammatory, anti-depressants and anti-convulsants are indicated. Narcotics may be indicated acutely. All medications should be prescribed as described in Thoracic Outlet Syndrome Guidelines.

c. Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

9. Surgical Indications: Surgical procedures are usually not necessary, since most injuries to the axillary nerve are due to stretch and/or traction and recover within three to six months. Even when deltoid weakness persists,

return to full activity can be expected. One may consider surgery when functional deficits interfere with activities of daily living and/or job duties after three to four months of active patient participation in non-operative therapy and with EMG/NCV documentation of ongoing denervation and loss of function. Lesions secondary to direct penetrating trauma or previous surgery may require more immediate intervention. Surgery for quadrilateral space syndrome is not usually necessary as at least 70 percent of patients recover with conservative treatment. Indications may include six months of conservative treatment with persisting functional deficits, a positive arteriogram, and point tenderness at the posterior quadrilateral space. Overall outcomes of surgery cannot be predicted, as only a small case series have been reported.

10. Operative Procedures:

a. Exploration and Repair.

11. Post-Operative Treatment: An individualized rehabilitation program based upon communication between the surgeon and the therapist. Treatment may include the following: Early therapeutic rehabilitation interventions are recommended to maintain range-of-motion ROM) and progressive strengthening.

a. Frequency: Suggested frequency pattern is three to five times per week for the first two weeks. Three times per week for the following two weeks, then one to two times per week. The exact frequency per week will depend on the severity and level of the nerve injury.

b. Optimum Duration: Six to eight weeks with progression to home exercise and/or pool therapy.

c. Maximum Duration: Up to 24 sessions. Additional follow-up visits may be justified to reinforce exercise patterns or to reach final functional goals if the therapy to date has demonstrated objective functional gains.

d. Return to work and restrictions after surgery may be made by an experienced primary occupational medicine physician in consultation with the surgeon or by the surgeon.

e. Long Thoracic Nerve.

12. Description/Definition:

a. The long thoracic nerve is formed by the cervical fifth, sixth, and seventh roots; it crosses the border of the first rib and descends along the posterior surface of the thoracic wall to the serratus anterior.

13. Occupational Relationship:

a. Injury can occur by direct trauma to the posterior triangle of the neck or trauma may be the result of chronically repeated or forceful shoulder depression. Repeated forward, overhead motion of the arms with the head tilted or rotated to the unaffected side, as well as, stretch or compression of the nerve with the arms abducted, can lead to long thoracic nerve dysfunction. Occasionally, severe traction with the shoulder compressed and the head tilted may be associated with long thoracic nerve pathology.

14. Specific Physical Exam Findings may include:

a. dull ache in the region of the shoulder exacerbated by tilting the head away from the effected side and without sensory loss;

b. scapular deformity and/or winging may be described by patient or family; and/or

c. serratus anterior wasting; and

d. scapular winging at the inferior border that may be demonstrated by asking the patient to forward elevate and lean on his arms, such as against a wall and/or the examiner resisting protraction. (Spinal accessory nerve pathology also causes winging when the patient is abducting.)

15. Diagnostic Testing Procedures.

a. Plain x-rays.

b. EMG and Nerve Conduction Studies three weeks after the injury and repeated at appropriate intervals to assess for reinnervation. Comparison of EMG and NCV findings with the opposite side is usually necessary to diagnose the degree of injury. Studies may also exclude more widespread brachial involvement.

c. MRIs or CTs if there is a need to rule out other pathology.

16. Non-Operative Treatment Procedures.

a. Rehabilitation is based on procedures set forth in Non-operative Treatment Procedures. Utilization of ultrasound, cold, and heat should be discussed with the Primary Care Physician since these modalities can aggravate nerve injury. Strengthening of the scapular stabilizers should be stressed.

b. Orthotics may be used to stabilize the scapula but long-term benefit is not established.

c. Medications such as analgesics, nonsteroidal anti-inflammatory, anti-depressants and anti-convulsants are indicated and narcotics may be indicated acutely. All medications should be prescribed as seen in Thoracic Outlet Syndrome Guidelines.

d. Return to work with appropriate restrictions should be considered early in the course of treatment (Refer to Return to Work). Heavy lifting and other activities that might stress the nerve should be avoided.

17. Surgical Indications. Laceration of the nerve and progressive loss of function are indications for prompt surgical intervention. Surgery may be considered when functional deficits interfere with activities of daily living and/or job duties after four to six months of active participation in non-operative therapy. Surgical consultation should occur at three to four months post-injury for these patients. In most cases, function will recover with conservative therapy in 6 to 12 months.

18. Operative Procedures:

a. exploration and repair;

b. muscle transfer;

c. scapular fixation.

19. Post-Operative Treatment: An individualized rehabilitation program based upon communication between the surgeon and the therapist. Treatment may include the following: Early therapeutic rehabilitation interventions are recommended to maintain ROM with progressive strengthening focusing on the scapular stabilizers.

a. Frequency: Suggested frequency pattern is three to five times per week for the first two weeks. Three times per week for the following two weeks, then one to two times per week. The exact frequency per week will depend on the severity and level of the nerve injury.

b. Optimum Duration: Six to eight weeks with progression to home exercise and/or pool therapy.

c. Maximum Duration: Up to 24 sessions. Additional follow-up visits may be justified to reinforce exercise patterns or to reach final functional goals if the therapy to date has demonstrated objective functional gains.

d. Return to work and restrictions after surgery may be made by an experienced primary occupational medicine physician in consultation with the surgeon or by the surgeon.

e. Musculocutaneous Nerve.

D. Description/Definition:The nerve is derived from the fifth and sixth cervical roots. It innervates the coracobrachialis, biceps and brachioradialis muscles and also provides sensation to the lateral aspect of the forearm.

E. Occupational Relationship:Trauma (including surgery) or penetrating wound to the brachial plexus, coracobrachialis, and shoulder often can cause nerve injury. Most commonly, a stretch/traction injury with the arm in abduction and external rotation induces nerve dysfunction. Cases have been reported to be associated with backpack use, pitching, heavy weight-lifting, mal-position during sleep or surgery, and sudden, forceful extension of the elbow. Complaints may include pain from the axilla into the forearm, biceps weakness, or sensation changes to the lateral forearm from the lateral antebrachial cutaneous nerve.

1. Specific Physical Exam Findings may include:

a. weakness and atrophy in the biceps and brachialis; and/or

b. sensory loss over the lateral aspect of the forearm; however, this is not always seen.

2. Diagnostic Testing Procedures.

a. EMG and Nerve Conduction Studies three weeks after the injury and repeated at appropriate intervals to assess for reinnervation. Comparison of EMG and NCV findings with the opposite side is usually necessary to diagnose the degree of injury.

3. Non-operative Treatment Procedures.

a. Rehabilitation is based on procedures set forth in Non-operative Treatment Procedures. Utilization of ultrasound, cold and heat should be discussed with the primary care physician, since these modalities can aggravate nerve injury.

b. Medications such as analgesics, nonsteroidal anti-inflammatory, anti-depressants and anti-convulsants are indicated and narcotics may be indicated acutely. All medications should be prescribed as seen in Thoracic Outlet Syndrome Guidelines.

c. Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

4. Surgical Indications: Laceration of the nerve and progressive loss of function are indications for prompt surgical intervention. Surgery may be considered when functional deficits interfere with activities of daily living and/or job duties after four to six months of active patient participation in non-operative therapy. Surgical consultation should occur at three to four months post-injury for these patients. In most cases, function will recover with conservative therapy in 6 to 12 months.

5. Operative Procedures.

a. Exploration and Repair.

6. Post-operative Treatment: An individualized rehabilitation program based upon communication between the surgeon and the therapist. Treatment may include the following: Early therapeutic rehabilitation interventions are recommended to maintain ROM with progressive strengthening.

a. Frequency: Suggested frequency pattern is three to five times per week for the first two weeks. Three times per week for the following two weeks, then one to two times per week. The exact frequency per week will depend on the severity and level of the nerve injury.

b. Optimum Duration: Six to eight weeks with progression to home exercise and/or pool therapy.

c. Maximum Duration: Up to 24 sessions. Additional follow-up visits may be justified to reinforce exercise patterns or to reach final functional goals if the therapy to date has demonstrated objective functional gains.

d. Return to work and restrictions after surgery may be made by an experienced primary occupational medicine physician in consultation with the surgeon or by the surgeon.

e. Spinal Accessory Nerve:

i. Description/Definition: Spinal Accessory Nerve is the eleventh cranial nerve innervating the ipsilateral sternocleidomastoid and trapezius muscles which are extremely important for scapular control and ultimately shoulder function.

ii. Occupational Relationship: Direct trauma to the posterior neck, forceful compression of the shoulder downward, and/or deviation of the head away from the traumatized shoulder can lead to injury to this nerve such as from a fall or motor vehicle accident. Surgical resection of the posterior neck can disrupt the nerve. Patients complain of inability to fully elevate or abduct above horizontal.

7. Specific Physical Exam Findings may include:

a. pain in the shoulder;

b. asymmetrical neckline;

c. scapular winging with the arms out to the side, abduction, or with external rotation;

d. weakness or paralysis of the trapezius with weakness in forward flexion or abduction above 90 degrees; and/or

e. drooping of the shoulder.

8. diagnostic Testing Procedures:

a. EMG and Nerve Conduction Studies three weeks after the injury and repeated at appropriate intervals to assess for reinnervation. Comparison of EMG and NCV findings with the opposite side is usually necessary to diagnose the degree of injury.

b. Radiographic procedures may be necessary to exclude lesions at the base of the brain or upper cervical spine.

9. Non-operative Treatment Procedures.

a. Rehabilitation is based on procedures set forth in Non-Operative Treatment Procedures. Utilization of ultrasound, cold and heat should be discussed with the Primary Care Physician, since these modalities can aggravate nerve injury. Resistance exercises to strengthen muscles. Braces may be used but probably have no long-term value.

b. Occupational work station will usually need significant modification due to inability to work above 90 degrees flexion or abduction. Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

c. Medications such as analgesics, nonsteroidal anti-inflammatory, anti-depressants and anti-convulsants are indicated and narcotics may be indicated acutely. All

medications should be prescribed as seen in Thoracic Outlet Syndrome Guidelines.

10. Surgical Indications: Laceration of the nerve and progressive loss of function are indications for prompt surgical intervention. Surgery may be considered when functional deficits interfere with activities of daily living and/or job duties after four to six months of active participation in non-operative therapy. Surgical consultation should occur at three to four months post-injury for these patients. In most cases, function will recover with conservative therapy in 6 to 12 months.

11 Operative Procedures.

a. exploration and repair;

b. tendon transfer—trapezius, levator scapular, rhomboids;

c. scapular fixation for cases with heavy work demands and failed previous procedures.

12. Post-operative Treatment: An individualized rehabilitation program based upon communication between the surgeon and the therapist. Treatment may include the following:

a. Early therapeutic rehabilitation interventions are recommended to maintain ROM with progressive strengthening focusing on scapula stabilizers.

i. Frequency: Suggested frequency pattern is three to five times per week for the first two weeks. Three times per week for the following two weeks, then one to two times per week. The exact frequency per week will depend on the severity and level of the nerve injury.

ii. Optimum Duration: Six to eight weeks with progression to home exercise and/or pool therapy.

iii. Maximum Duration: Up to 24 sessions. Additional follow-up visits may be justified to reinforce exercise patterns or to reach final functional goals if the therapy to date has demonstrated objective functional gains.

iv. Return to work and restrictions after surgery may be made by an experienced primary occupational medicine physician in consultation with the surgeon or by the surgeon.

vi. Suprascapular Nerve.

(a). Description/Definition. This nerve is derived from the fifth and sixth cervical root, superior trunk of the brachial plexus and it innervates the supraspinatus and infraspinatus muscles of the rotator cuff.

(b). Occupational Relationship. Supraclavicular trauma, stretch, and friction through the suprascapular notch or against the transverse ligament at the notch, or a fall on an outstretched arms can cause injury to the nerve. Repetitive use of the arm has been shown on occasion to cause traction to the nerve. Damage, may occur secondary to a ganglion cyst which usually causes infraspinatus atrophy. Ganglion cysts may be associated with labral pathology and/or rotator cuff tears. These are most commonly reported in athletes. Up to one third of volley ball players in one study had asymptomatic infraspinatus atrophy secondary to nerve damage. Nerve damage may also occur associated with a full rotator cuff tear. Since the clinical findings are similar for both diagnoses, clinicians should always consider the possibility of nerve damage when atrophy accompanies a rotator cuff tear.

(c). Specific Physical Exam Findings may include:

(i). pain at the shoulder;

(ii). wasting at the supraspinatus and/or infraspinatus muscles with weakness of external rotation and abduction with overhead activity; and/or

(iii). a positive Tinel's eliciting a provocative pain response.

(d). Diagnostic Testing Procedures:

(i). EMG and Nerve Conduction Studies three weeks after the injury and repeated at appropriate intervals to assess for reinnervation. Comparison of EMG and NCV findings with the opposite side is usually necessary to diagnose the degree of injury.

(ii). If one suspects a mass lesion at the suprascapular notch or related labral or cuff pathology then an MRI or sonography may be indicated.

(iii). CT scan with attention to the suprascapular notch may be used to evaluate for boney impingement.

(e). Non-operative Treatment Procedures:

(i). Resolution of symptoms usually occurs within 6 to 12 months of diagnosis with non-operative treatment in the absence of lesions such as a cyst.

(ii). Rehabilitation is based on procedures set forth in Non-operative Treatment Procedures. An emphasis should be placed on posture; maintaining full shoulder motion; strengthening; and stretching the posterior capsule. Utilization of ultrasound, cold and heat should be discussed with the primary care physician, since these modalities can aggravate nerve injury.

(iii). Medications such as analgesics, nonsteroidal anti-inflammatory, anti-depressants, and anti-convulsants are indicated and narcotics may be indicated acutely. All medications should be prescribed as seen in Thoracic Outlet Syndrome Guidelines.

(iv). Return to work with appropriate restrictions should be considered early in the course of treatment (Refer to Return to Work). Heavy lifting or activities that aggravate the condition should be avoided.

13. Surgical Indications: Surgical release is warranted depending upon the presence of a ganglion cyst, results of the electrophysiologic studies, and/or absence of improvement with conservative management. In cases without cysts or other operative diagnoses, non-operative treatment may be tried for three to six months due to the observed recovery rate of cases with no treatment. Difficulty performing functional activities after active patient participation should be the deciding factor. [General Principles]

14. Operative Treatment Procedures.

a. secompression and/or excision of ganglion cyst; and/or labral repair.;

b. surgical release at the suprascapular notch or spinoglenoid region;

15. Post-operative Treatment: An individualized rehabilitation program based upon communication between the surgeon and the therapist using the treatments found in Therapeutic Procedures, Non-operative. Treatment may include the following: Early therapeutic rehabilitation interventions are recommended to maintain ROM with progressive strengthening.

a. Frequency: Suggested frequency pattern is three to five times per week for the first two weeks. Three times

per week for the following two weeks, then one to two times per week. The exact frequency per week will depend on the severity and level of the nerve injury.

b. Optimum Duration: Six to eight weeks with progression to home exercise and/or pool therapy.

c. Maximum Duration: Up to 24 sessions. Additional follow-up visits may be justified to reinforce exercise patterns or to reach final functional goals if the therapy to date has demonstrated objective functional gains.

d. Return to work and restrictions after surgery may be made by an experienced primary occupational medicine physician in consultation with the surgeon or by the surgeon.

F. Bursitis/Rotator Cuff Tendonopathy (Alternate Spelling "Tendinopathy") of the Shoulder

1. Description/Definition.

a. Bursitis: Acute or chronic inflammation of the bursa (a potential fluid filled sac) that may be caused by trauma, chronic overuse, inflammatory arthritis, and acute or chronic infection, and generally presents with localized pain and tenderness of the shoulder.

b. Tendonopathy includes the terms tendonitis, an inflammation of the tendon and tendonosis, non-inflammatory degenerative processes.

c. Rotator cuff tendonopathy may involve one or more of the four musculotendonous structures arising from the scapula and inserting on the lesser or greater tuberosity of the humerus may be involved. These structures include one internal rotator (subscapularis), and two external rotators (infraspinatus and teres minor), and the supraspinatus which assists in abduction.

d. History may include nocturnal pain, pain with over-the-shoulder activities, feeling of shoulder weakness and specific limitations of movement. Prior treatment for presenting complaint(s) and pertinent familial history should be obtained.

2. Occupational Relationship: Onset of symptoms, date, mechanism of onset, and occupational history and current job requirements should be correlated with the intensity, character, duration and frequency of associated pain and discomfort. Tendonopathy may include symptoms of pain and/or achiness that occur after blunt trauma or repetitive use of the shoulder. Bursitis is often a sequela of an occupational strain or tendonopathy in the absence of other mitigating factors.

3. Specific Physical Exam Findings may include:

a. Palpation elicits localized tenderness over the particular bursa or inflamed tendon with loss of motion during activity;

b. Painful arc may be seen between 40 and 120 degrees; and/or

c. Bursitis may be associated with other shoulder injury diagnoses such as impingement, rotator cuff instability, tendonitis, etc.; refer to applicable diagnosis subsections for additional guidelines.

4. Diagnostic Testing Procedures:

a. Plain x-rays include:

5. AP view. Elevation of the humeral head indicates rotator cuff tear;

6. Lateral view in the plane of the scapula or an axillary view determines if there is anterior or posterior dislocation, or the presence of a defect in the humeral head (a Hill-Sachs lesion);

7. Axillary view is also useful to demonstrate arthritis and spurs on the anterior inferior acromion;

8. Outlet view determines if there is a downwardly tipped acromion.

a. Lab Tests. Laboratory tests may be used to rule out systemic illness or disease when proper clinical presentation indicates the necessity for such testing. Testing may include sedimentation rate, rheumatoid profile, complete blood count (CBC) with differential, and serum uric acid level. Routine screening for other medical disorders may be necessary, as well as, bursal aspiration with fluid analysis.

b. The subacromial injection has generally been considered the gold standard for differentiating ROM loss from impingement versus rotator cuff tears. Alleviation from pain may help to confirm the diagnosis. Patients with impingement should recover normal strength after the injection, while those with rotator cuff tears usually do not recover normal strength. However, manually tested elevation strength perceived as normal does not always rule out rotator cuff tear and this may contribute to incorrect diagnoses with this technique. There is good evidence that blinded subacromial blocks are not accurate. Up to a third of blinded injections may involve the cuff, and are likely to cause pain. This may lead to an incorrect diagnosis. One study demonstrated that at least half of the positive responders did so up to 40 minutes after the injection; therefore, a negative response should not be diagnosed until 40 minutes post injection. The inaccuracy of the injection and patient response in some cases may contribute to its inability to completely predict the amount of recovery from subacromial decompression.

c. If there is a concern regarding needle placement, sonography or fluoroscopy may be used.

d. Steroid injections should be used cautiously in diabetic patients. Diabetic patients should be reminded to check their blood glucose level at least daily for two weeks after injections.

9. Non-operative Treatment Procedures:

a. Therapeutic interventions are the mainstay of treatment. They should include ROM, active therapies, and a home exercise program. Passive as well as active therapies may be used for control of pain and swelling. Therapy should progress to strengthening and instruction in a home exercise program targeted to further improve ROM and strength of shoulder girdle musculature. Refer to Therapeutic Procedures, Non-operative.

b. May return to work without overhead activities and lifting with involved arm. An evaluation of the occupational work being performed and the work station may be necessary to institute ergonomic changes or accommodations. Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

c. Medications such as oral nonsteroidal anti-inflammatory, oral steroids and analgesics.

d. Steroid injections may be therapeutic. Injections under significant pressure should be avoided as the needle may be penetrating the tendon and injection into the tendon can cause possible tendon breakdown, tendon degeneration, or rupture. Injections should be minimized for patients under 30 years of age.

i. Time to Produce Effect: One injection.

ii. Maximum: three injections at the same site per year when functional benefits are demonstrated with each injection.

iii. Steroid injections should be used cautiously in diabetic patients. Diabetic patients should be reminded to check their blood glucose level at least daily for two weeks after injections.

e. Other therapies outlined in Therapeutic Procedures, Non-operative, may be employed in individual cases.

10. Operative Procedures: Are not commonly indicated for bursitis or tendonopathy. Refer to other related diagnoses in Specific Diagnosis Testing and Treatment Procedures.

11. Calcifying Tendodnitis

a. Description/Definition:

i. Calcifying tendonitis is characterized by the deposition of hydroxyapatite (calcium phosphate) in any tendon of the rotator cuff. The supraspinatus tendon is affected most frequently. It is a morphologic diagnosis which may be asymptomatic or may produce pain. It may be present in a painful shoulder without being the cause of the pain. Radiographically evident calcifications are present without producing symptoms in some adults (7.5 percent to 20 percent). The calcifying process occurs in two phases: the formative phase, in which calcium deposits coalesce in the tendon matrix, and the resorptive phase, in which the calcium deposits are removed by phagocytic cells. The resorptive phase is thought to be the painful phase of the disorder. The etiology is not known, but trauma is considered unlikely to be causative. Pain may be accompanied by loss of ROM, a painful arc of motion, or by impingement signs. Morphologic classification of calcium deposits is based on the homogeneity and borders of the deposit on plain x-ray. (Gartner and Simons Classifications) Type I is homogenous with well-defined borders. Type II is heterogeneous in structure with sharp outline or homogenous in structure with no defined border. Type III is cloudy and transparent with no well-defined border. Type III frequently resolves without treatment. Generally, they are not associated with rotator cuff tears. The size of the deposit has not been shown to be correlated with severity of symptoms.

b. Occupational Relationship. Symptomatic calcifying tendonitis may occur after repetitive loading of the shoulder with force, such as with shoveling, raking, pushing, pulling, lifting at/or above shoulder level, or after blunt trauma to the shoulder.

c. Specific Physical Exam Findings may include:

i. pain with palpation to the shoulder with active or passive abduction and external rotation of the shoulder (painful arc);

ii. pain with specific activation of the involved muscles; and/or

iii. pain with impingement signs;

iv. severe pain on examination in some cases.

d. Diagnostic Testing Procedures:

i. plain x-ray films including AP lateral, axial, 30 degrees caudally angulated AP, Outlet view.

ii. If shoulder pain is refractory to 4 to 6 weeks of non-operative care and other diagnoses are suspected, adjunctive testing, such as MRI, sonography or arthrography, may be indicated.

e. Non-operative Treatment Procedures

i. Therapeutic rehabilitation interventions are the mainstay of treatment. They should include ROM, active therapies, and a home exercise program. Passive as well as active therapies may be used for pain control, including iontophoresis. Therapy should progress to strengthening and instruction in a home exercise programs targeted to ongoing ROM and strengthening of shoulder girdle musculature. Refer to Therapeutic Procedures, Non-operative for other therapies as well as a description of active and passive therapies.

ii. Medications such as oral nonsteroidal anti-inflammatories, analgesics, and narcotics for significant pain. Refer to Medications.

iii. May return to work without overhead activities and lifting with involved arm. An evaluation of the occupational work station may be necessary to institute ergonomic changes or accommodations. Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

iv. Therapeutic ultrasound (Refer to Passive Therapy) may be used for tendonitis. There is some evidence that ultrasound alleviates symptoms, improves function, and reduces calcium deposits better than sham ultrasound in the short term. The advantage of ultrasound beyond six weeks is not certain.

v. Ultrasound-guided needle lavage and aspiration requires a physician skilled in sonographic techniques and is still considered investigational due to lack of randomized controlled trials. It is less costly and reportedly less painful than extracorporeal shock wave therapy. It requires prior authorization but may be an appropriate therapy in select patients who fail other conservative treatment.

vi. Extracorporeal shock wave therapy has good evidence for improving pain and function with calcifying tendonitis Type I or II when conservative treatment has not resulted in adequate functional improvement (See ESWT). General anesthesia or conscious sedation is not required for this procedure. Patients should be cautioned regarding the potential of avascular necrosis.

vii. Steroid injections may be therapeutic. Injections under significant pressure should be avoided as the needle may be penetrating the tendon and injection into the tendon can cause tendon degeneration, tendon breakdown, or rupture. Injections should be minimized for patients under 30 years of age.

(a). Steroid injections should be used cautiously in diabetic patients. Diabetic patients should be reminded to check their blood glucose level at least daily for two weeks after injections.

(i). Time to Produce Effect: One injection.

(ii). Maximum: Three injections at the same site per year when functional benefits are demonstrated with each injection.

viii. Other therapies outlined in Therapeutic Procedures, Non-operative, may be employed in individual cases.

f. Surgical Indications. When functional deficits interfere with activities of daily living and/or job duties after three to four months of active patient participation in non-operative therapy. The natural history of calcifications

includes resorption over time, with or without therapy. Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities. The patient should agree to comply with the pre- and post-operative treatment plan and home exercise requirements. The patient should understand the length of partial and full disability expected post-operatively.

g. Operative Procedures: Either an arthroscopic or open procedure may be used. Careful lavage to remove all calcium deposits from the surgical field is important. Full recovery may vary from three to six months.

h. Post-operative Treatment. Individualized rehabilitation programs are based upon communication between the surgeon and the therapist using the treatments found in Therapeutic Procedures, Non-operative. Treatment may include the following:

i. Sling, pillow sling, or abduction splint;

ii. Gentle pendulum exercise, passive glenohumeral range-of-motion and posterior scapular stabilizing training can be instituted;

iii. Patients can judiciously return to activities as tolerated per physician recommendations. If there is a significant tendon repair, progression will be delayed;

iv. Progressive resistive exercise program beginning at two months with gradual returning to full activity at 4 to 6 months; all active non-operative procedures listed in Non-operative Treatment Procedures should be considered.

(a). Frequency: Three to five times per week for the first two weeks, three times per week for the following two weeks, then one to two times per week.

(b). Optimum Duration: Six to eight weeks with progression to home exercise and/or pool therapy.

(c). Maximum Duration: 12 weeks. Occasional follow-up visits may be justified to reinforce exercise patterns or to reach final functional goals if the therapy to date has demonstrated objective functional gains.

v. Return to work and restrictions after surgery may be made by an experienced primary occupational medicine physician in consultation with the surgeon or by the surgeon. Depending upon the patient's functional response and their job requirements, return to work with job modifications may be considered as early as one week post-operatively. The employer must be able to fully accommodate restrictions of overhead activities or heavy lifting. Physician/surgeon should be very specific regarding restrictions for overhead activities and heavy lifting. Work restrictions should be evaluated every four to six weeks during post-operative recovery and rehabilitation, with appropriate written communications to both the patient and the employer. Should progress plateau, the provider should re-evaluate the patient's condition and make appropriate adjustments to the treatment plan.

12. Fractures. There are five common types of shoulder fractures; each type will be addressed separately and in the order of most frequent occurrence.

a. Clavicular Fracture:

i. Occupational Relationship: Can result from direct blows or axial loads applied to the upper limb; commonly associated injuries include rib fractures, long-bone fractures of the ipsilateral limb and scapulothoracic dislocations.

ii. Specific Physical Exam Findings may include:

(a). Pain along the clavicle;

(b). Abrasions on the chest wall, clavicle and shoulder;

(c). Deformities in the above regions; and/or

(d). Pain with palpation and motion at the shoulder joint area.

iii. Diagnostic Testing Procedures: Clavicle x-rays. If they do not reveal sufficient information, then a 20 degree caudal-cranial AP view centered over both clavicles can be done.

iv. Non-operative Treatment Procedures:

(a). Most are adequately managed by closed techniques and do not require surgery. After reduction, the arm is immobilized in a sling or figure-8 bandage. Shoulder rehabilitation is begun with pendulum exercises 10 to 14 days after injury. Subsequently, with pain control, the therapy program can be progressed with therapeutic approaches as indicated in Non-operative Treatment Procedures.

(b). Medication, such as analgesics and nonsteroidal anti-inflammatories, would be indicated; narcotics may be indicated acutely for fractures and should be prescribed as indicated in Medications.

(c). All patients with fractures, especially those over 50, should be encouraged to ingest at least 1200 mg of Calcium and 800 IU of Vitamin D per day. There is some evidence that, for women in the older age group (58 to 88) with low hip bone density, greater callus forms for those who adhere to these recommendations than those who do not. Although the clinical implications of this are not known, there is greater non-union in this age group and thus, coverage for these medications during the fracture healing time period is recommended. At this time there is no evidence that bisphosphonates increase acute fracture healing.

(d). All female patients over 65 should be referred for an osteoporosis evaluation. Patients who have been on prednisone at a dose of 5 to 7.5 mg for more than three months should be evaluated for glucocorticoid induced osteoporosis. An osteoporosis evaluation may be considered for males who: are over 70, are physically inactive, have previous fragility fracture, have a BMI less than 20, or have been hypogonadal for five years. Evaluation may also be considered for patients on medications that can cause bone loss, patients who have suffered a fracture due to a low-impact fall or with minimum to no provocation, and women under 65 with one of the following: menopause before 40, current smoker, or body mass index less than 20. Low body weight appears to be the best predictor of osteoporosis in women younger that 65. In one adequate study, all patients aged 50 to 75 referred to an orthopaedic department for treatment of wrist, vertebral, proximal humerus, or hip fractures received bone mass density testing. 97 percent of patients had either osteoporosis (45 percent) or osteopenia (42 percent). Referral is important to prevent future factures in these groups. Long-term care for osteoporosis is not covered under workers compensation even though it may be discovered due to an injury-related acute fracture.

(e). Smoking may affect fracture healing. Patients should be strongly encouraged to stop smoking and provided with appropriate counseling.

(f). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

v. Surgical Indications: Open fractures, vascular or neural injuries requiring repair, bilateral fractures, ipsilateral scapular or glenoid neck fractures, scapulothoracic dislocations, flail chest and non-union (displaced-closed fractures that show no evidence of union after four to six months). A Type II fracture/dislocation at the AC joint where the distal clavicular fragment remains with the acromion and the coracoid, and the large proximal fragment is displaced upwards is another indication for surgery. Completely displaced midclavicular fractures may be an indication for surgical repair. There is some evidence that plate fixation of completely displaced fractures involving the middle third of the clavicle leads to slightly better shoulder function than immobilization without surgical fixation and shorter healing time. Conservatively treated completely displaced fractures heal with mild decreases in strength and good patient satisfaction in 70 percent or more of cases. However, initial surgical repair may be considered for patients who desire excellent shoulder function for sport or job activities and/or those with approximately two cm or greater shortening of the clavicle. Because smokers have a higher risk of non-union and post-operative costs, it is recommended that insurers cover a smoking cessation program peri-operatively.

vi. Operative Procedures: Repair of fracture or associated distal clavicular resection using plates and screws or an intramedullary device.

vii. Post-operative Treatment: An individualized rehabilitation program based upon communication between the surgeon and the therapist. This program would begin with two to three weeks of rest with a shoulder immobilizer while encouraging isometric deltoid strengthening. Pendulum exercises with progression to assisted forward flexion and external rotation would follow. Strengthening exercises should be started at 10 to 12 weeks as indicated in Non-operative Treatment Procedures.

viii. Bone-Growth Stimulators

(a). Electrical: Preclinical and experimental literature has shown a stimulatory effect of externally applied electrical fields on the proliferation and calcification of osteoblasts and periosteal cells. Ensuing clinical literature on electrical stimulation of bone fractures has principally focused on the spine and lower extremity. Several techniques have been developed to deliver an electrical stimulus to a fracture or osteotomy site. Nonsurgical techniques include Capacitive Coupling (CC), which places skin electrodes on opposite sides of the bone being treated. Pulsed Electromagnetic Field (PEMF) uses a current-carrying coil which induces a secondary electrical field in bone. High-quality literature of electrical bone growth stimulation are lacking for shoulder injuries. Literature is conflicting in the use of electrical stimulation in other regions of the body. Due to a lack of supporting scientific evidence, it requires prior authorization and may be only considered when conventional surgical management has failed.

(b). Low-intensity Pulsed Ultrasound: There is some evidence that low-intensity pulsed ultrasound, applied by the patient at home and administered as initial treatment of the fracture, reduces the time required for cortical bridging in certain fractures of bones outside the shoulder joint. Shoulder fractures were not included in this literature. Non-union and delayed unions were not included in these clinical trials. Possible indications for Low-Intensity Pulsed Ultrasound are non-unions or fractures that are expected to require longer healing time. Prior authorization is required.

b. Proximal Humeral Fractures: Fractures of the humeral head have been classically described using Neer criteria; however, literature has shown a low level of observer agreement. These fractures are commonly referred to as one, two, three or four part fractures based on the number of fracture fragments. Displaced fractures of the greater tuberosity and impacted angulated fractures of the humeral head also have specific associated problems.

i. Occupational Relationship: May be caused by a fall onto an abducted arm; high-energy (velocity or crush) trauma with an abducted or non-abducted arm. Associated injuries are common, such as glenohumeral dislocation; stretch injuries to the axillary, musculocutaneous, and radial nerves; and axillary artery injuries with high-energy accident.

ii. Specific Physical Exam Findings may include:

(a). pain in the upper arm;

(b). swelling and bruising in the upper arm, shoulder and chest wall;

(c). abrasions about the shoulder; and/or

(d). pain with any attempted passive or active shoulder motion.

iii. Diagnostic Testing Procedures:

(a). X-ray trauma series (three views) are needed; AP view, axillary view and a lateral view in the plane of the scapula. The latter two views are needed to determine if there is a glenohumeral dislocation. When an axillary view cannot be obtained, a CT should be done to rule out posterior dislocation.

(b). Vascular studies are obtained emergently if the radial and brachial pulses are absent.

(c). Classification can be by the Neer Method, however, agreement between observers using this method is poor. There are four fragments: the humeral shaft, humeral head, greater tuberosity, and the lesser tuberosity. The fragments are not usually considered fragments unless they are separated by 1 cm or are angulated 45 degrees or more.

iv. Non-operative Treatment Procedures

(a). Non-displaced and minimally displaced fractures are generally treated conservatively with broad arm sling or body swath. There is some evidence that simple non-displaced proximal humeral fractures recover normal function more quickly when physical therapy is started one week after the fracture than when it is started three weeks after the fracture. Immobilization without physical therapy for more than one week is not recommended.

(b). Anterior or posterior dislocation associated with minimally displaced fractures can usually be reduced by closed means, but a general anesthetic is needed. These are usually not performed in the emergency room in order to avoid displacement of the fracture.

(c). Medication, such as analgesics and nonsteroidal anti-inflammatories, would be indicated; narcotics may be indicated acutely for fracture and should be prescribed as indicated in Medications.

(d). Immobilization may be provided with a sling, to support the elbow, or with an abduction immobilizer if a non-impacted greater tuberosity fragment is present. Immobilization is usually continued for four to ix weeks; however, the time will vary according to the type of fracture and surgeon's discretion.

(e). Shoulder rehabilitation is begun with pendulum exercises 0 to 14 days after injury. Light, functional exercises may be added at two to four weeks post-injury. Subsequently, with pain control, the therapy program can be progressed with therapeutic approaches as described in Non-operative Treatment Procedures. Home exercises are essential for recovery.

(i). Time to Produce Effect: Six sessions.

(ii). Optimum Duration: Nine sessions.

(iii). Maximum Duration: 12 to 24 sessions.

(f). Use of the injured arm at work is determined by the orthopaedist. The patient may, however, return to work without use of the injured arm soon after the injury. Refer to Return to Work.

(g). Also refer to osteoporosis in this Clavicular Fracture.

(h). Smoking may affect fracture healing. Patients should be strongly encouraged to stop smoking and provided with appropriate counseling.

v. Surgical Indications:

(a). Greater tuberosity fractures with 5mm of displacement usually require surgical fixation. However, rehabilitation may start as early as two to three days post-operatively.

(b). Two-part fractures are repaired according to the surgeon's preference. Internal fixation may be necessary to prevent varus or valgus angulation of the humerus; however, it is unclear whether this technique is more successful than more conservative treatment particularly in patients over 70. Percutaneous techniques and closed reduction have both been used.

(c). Three and four-part fractures frequently require operative treatment. Internal fixation is commonly used. Hemiarthroplasty may be used in the elderly population or for severely comminuted fractures. Use of this technique in the younger active patients frequently leads to the need for revision surgery and/or increased wear of the glenoid cavity. For four-part fractures with a fractured greater tuberosity, reverse arthroplasties have also been described, however; they should rarely be used since the long-term success of this prosthesis is currently unknown. This procedure is described under Section G. Therapeutic Procedures, Operative Shoulder Replacement (arthroplasty).

(i). Because smokers have a higher risk of non-union and post-operative costs, it is recommended that carriers cover a smoking cessation program peri-operatively.

vi. Operative Procedures: Percutaneous or internal fixation of the fracture or arthroplasty.

vii. Post-operative Treatment

(a). An individualized rehabilitation program based upon communication between the surgeon and the therapist using the treatment found in Section F.

(b). Schanz pins will require removal, frequently between Two to six weeks.

(c). One-time Extracorporeal Shock Wave Therapy (ESWT) has been purported to increase healing in non-union fractures of long bones. None have been tested in prospective controlled studies. They are all considered experimental and are not recommended at this time.

(d). Bone-Growth Stimulators. (Refer to Clavicular Fractures.)

(e). Hyperbaric oxygen therapy – there is no evidence to support long-term benefit of hyperbaric oxygen therapy for non-union upper extremity fractures. It is not recommended.

(f). Return to work and restrictions after surgery may be made by an experienced primary occupational medicine physician in consultation with the surgeon or by the surgeon.

c. Humeral Shaft Fractures:

i. Occupational Relationship: A direct blow can fracture the humeral shaft at the junction of its middle and distal thirds. Twisting injuries to the arm will cause a spiral humeral shaft fracture. High energy (velocity or crush) will cause a comminuted humeral shaft fracture.

ii. Specific Physical Exam Findings may include:

(a). deformity of the arm;

(b). bruising and swelling; and/or

(c). possible sensory and/or motor dysfunction of the radial nerve.

iii. Diagnostic Testing Procedures:

(a). plain x-rays including AP view and lateral of the entire humeral shaft.

(b). vascular studies if the radial pulse is absent.

(c). compartment pressure measurements if the surrounding muscles are swollen, tense and painful and particularly if the fracture resulted from a crush injury.

iv. Non-operative Treatment Procedures:

(a). Most isolated humeral shaft fractures can be managed non-operatively.

(b). Medication, such as analgesics and nonsteroidal anti-inflammatories, would be indicated. Narcotics may be indicated acutely for fracture and should be prescribed as indicated in Section F.6, Medications.

(c). A coaptation splint may be used.

(d). At two to three weeks after injury, a humeral fracture orthosis may be used to allow for full elbow motion.

(e). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(f). Other therapies outlined in Therapeutic Procedures, Non-operative, may be employed in individual cases.

(g). Refer to comments related to osteoporosis in Clavicular Fracture.

(h). Smoking may affect fracture healing. Patients should be strongly encouraged to stop smoking and provided with appropriate counseling.

v. Surgical Indications:Indications for operative care would include:

(a). open fracture;

(b). associated forearm or elbow fracture (i.e., the floating elbow injury);

(c). burned upper extremity;

(d). associated paraplegia;

(e). multiple injuries (polytrauma);

(f). A radial nerve palsy which presented after closed reduction;

(g). pathologic fracture related to an occupational injury; and/or

(h). inability to perform basic activities of daily living while following conservative care.

(i). because smokers have a higher risk of non-union and post-operative costs, it is recommended that carriers cover a smoking cessation program peri-operatively.

vi. Operative Procedures

(a). Accepted methods of internal fixation of the fracture include:

(i). A broad plate and screws; and/or

(ii). Intramedullary rodding with or without cross-locking screws may be used but is associated with increased shoulder pain;

(b). Human Bone Morphogenetic Protein (RhBMP). Use of this material for surgical repair of shoulder fractures requires prior authorization. Refer to Operative Procedures, for further details.

vii. Post-operative Treatment:An individualized rehabilitation program based upon communication between the surgeon and the therapist using the treatments found in Therapeutic Procedures, Non-operative. Treatment may include the following:

(a). Following rigid internal fixation, therapy may be started to obtain passive and later active shoulder motion using appropriate therapeutic approaches as indicated in Section F, Non-operative Treatment Procedures. Active elbow and wrist motion may be started immediately. Early therapeutic rehabilitation interventions are recommended to maintain range-of-motion (ROM) and progressive strengthening.

(i). Frequency: Three to five times per week for the first two weeks, three times per week for the following two weeks, then to two times per week.

(ii). Optimum Duration: Six to eight weeks with progression to home exercise and/or pool therapy.

(iii). Maximum Duration: 12 weeks. Additional follow-up visits may be justified to reinforce exercise patterns or to reach final functional goals if the therapy to date has demonstrated objective functional gains or if a nerve injury accompanies the fracture.

(b). Return to work and restrictions after surgery may be made by an experienced primary occupational medicine physician in consultation with the surgeon or by the surgeon.

(c). Bone Growth Stimulation. (Refer to Clavicular Fractures.)

d. Scapular Fractures:

i. Occupational Relationship. These are the least common of the fractures about the shoulder and include acromial, glenoid, glenoid neck and scapular body fractures. With the exception of anterior glenoid lip fractures caused by an anterior shoulder dislocation, all other scapular fractures are due to a high-energy injury.

ii. Specific Physical Findings may include:

(a). pain about the shoulder and thorax;

(b). bruising and abrasions;

(c). possibility of associated humeral or rib fractures; and/or

(d). vascular problems (pulse evaluation and Doppler examination).

iii. Diagnostic Testing Procedures:

(a). Trauma x-ray series - AP view, axillary view, and a lateral view in the plane of the scapula.

(b). Arteriography if a vascular injury is suspected.

(c). Electromyographic exam if nerve injuries are noted.

iv. Non-operative Treatment:

(a). Non-displaced acromial, coracoid, glenoid, glenoid neck and scapular body fractures may all be treated with the use of a shoulder immobilizer.

(b). Medication, such as analgesics and nonsteroidal anti-inflammatories, would be indicated. Narcotics may be indicated acutely for fracture and should be prescribed as indicated in Medications.

(c). Pendulum exercises may be started within the first week.

(d). Progress to assisted range-of-motion exercises at three to four weeks using appropriate therapeutic procedures as indicated in Section F, Non-operative Treatment Procedures.

(e). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(f). Refer to comments related to osteoporosis in Clavicular Fracture.

(g). Smoking may affect fracture healing. Patients should be strongly encouraged to stop smoking and provided with appropriate counseling.

v. Surgical Indications

(a). displaced acromial fractures.

(b). displaced glenoid fractures.

(c). displaced scapular body fractures in some circumstances.

(d). displaced fractures of the scapular neck and the ipsilateral clavicle.

(e). because smokers have a higher risk of non-union and post-operative costs, it is recommended that carriers cover a smoking cessation program peri-operatively.

vi. Operative Treatment

(a). displaced acromial fractures are treated with internal fixation.

(b). displaced glenoid fractures greater than 5 mm should be fixed internally. Fractures with less displacement may be treated surgically according to the surgeon's discretion. Two and three dimensional CT scans may be useful in planning the surgical approach.

(c). displaced scapular body fractures require internal fixation if the lateral or medial borders are displaced to such a degree as to interfere with scapulothoracic motion.

(d). displaced fractures of the scapular neck and the ipsilateral clavicle require internal fixation of the clavicle to reduce the scapular neck fracture.

vii. Post-operative Treatment: An individualized rehabilitation program based upon communication between the surgeon and the therapist using the appropriate therapeutic procedures as indicated in Section F, Non-

operative Treatment Procedures. Treatment may include the following:

(a). A shoulder immobilizer is utilized. Pendulum exercises initially begin at one week, and deltoid isometric exercises are started early at four to six weeks, active ROM is usually commenced.

(b). Early therapeutic rehabilitation interventions are recommended to maintain ROM with progressive strengthening.

(i). Frequency: Three to five times per week for the first two weeks, three times per week for the following two weeks, then one to two times per week.

(ii). Optimum Duration: 8 to 10 weeks with progression to home exercise and/or pool therapy.

(iii). Maximum Duration: 12 to 14 weeks. Occasional follow-up visits may be justified to reinforce exercise patterns or to reach final functional goals if the therapy to date has demonstrated objective functional gains.

(c). Return to work and restrictions after surgery may be made by an experienced primary occupational medicine physician in consultation with the surgeon or by the surgeon.

e. Sternoclavicular Dislocation/Fracture

i. Occupational Relationship: Sudden trauma to the shoulder/anterior chest wall. Anterior dislocations of the sternoclavicular joint usually do not require active treatment; however, symptomatic posterior dislocations will require reduction.

ii. Specific Physical Findings may include:

(a). Dysphagia and shortness of breath which requires emergency reduction.

(b). Pain at the sternoclavicular area;

(c). Abrasions on the chest wall, clavicle and shoulder;

(d). Deformities in the above regions; and/or

(e). Pain with palpation and motion at the sternoclavicular joint area.

iii. Diagnostic Testing Procedures:

(a). Plain x-rays of the sternoclavicular joint are routinely done. When indicated, comparative views of the contralateral limb may be necessary.

(b). X-rays of other shoulder areas and chest may be done if clinically indicated.

(c). CT scan for classification of pathology.

(d). Vascular studies should be considered if the history and clinical examination indicate extensive injury.

iv. Non-operative Treatment Procedures:

(a). Symptomatic posterior dislocations should be reduced in the operating room under general anesthesia.

(b). Immobilize with a sling for three to four weeks. Subsequently, further rehabilitation may be utilized using procedures set forth in Non-operative Treatment Procedures.

(c). Medications, such as analgesics and nonsteroidal anti-inflammatories, would be indicated. Narcotics may be indicated acutely for fracture and should be prescribed as indicated in Medications.

(d). Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(e). Refer to comments related to osteoporosis in Clavicular fracture.

(f). Smoking may affect fracture healing. Patients should be strongly encouraged to stop smoking and provided with appropriate counseling.

v. Surgical Indications:

(a). failure of closed reduction.

(b). because smokers have a higher risk of non-union and post-operative costs, it is recommended that carriers cover a smoking cessation program peri-operatively.

vi. Operative Procedures

(a). reduction with soft tissue reconstruction is preferred;

(b). internal fixation - significant complications can occur with use of pins due to migration into other tissues.

vii. Post-operative Treatment: An individualized rehabilitation program based upon communication between the surgeon and the therapist. This program would begin with four to six weeks of rest with a shoulder immobilizer, followed by therapeutic rehabilitation interventions.

(a). Early therapeutic rehabilitation interventions are recommended to maintain ROM with progressive strengthening.

(i). Frequency: Three to five times per week for the first two weeks, three times per week for the following two weeks, then one to two times per week.

(ii). Optimum Duration: Six to eight weeks with progression to home exercise and/or pool therapy.

(iii). Maximum Duration: 12 weeks. Occasional follow-up visits may be justified to reinforce exercise patterns or to reach final functional goals if the therapy to date has demonstrated objective functional gains.

(b). Return to work and restrictions after surgery may be made by an experienced primary occupational medicine physician in consultation with the surgeon or by the surgeon.

13. Impingement Syndrome

a. Description/Definition: A collection of symptoms, not a pathologic diagnosis. The symptoms result from the encroachment of the acromion, coracoacromial ligament, coracoid process, and/or the AC joint of the rotator cuff mechanism that passes beneath them as the shoulder is moved. The cuff mechanism is intimately related to the coracoacromial arch. Separated only by the thin lubricating surfaces of the bursa, compression and friction can be minimized by several factors, such as:

i. shape of the coracoacromial arch that allows passage of the subjacent rotator cuff;

ii. normal undersurface of the AC joint;

iii. normal bursa;

iv. normal capsular laxity; and

v. coordinated scapulothoracic function.

b. The impingement syndrome may be associated with AC joint arthritis and both partial and full thickness rotator cuff tears, as well as, adhesive capsulitis/frozen shoulder. Normal function of the rotator cuff mechanism and biceps tendon assist to diminish impingement syndrome.

i. History may include

(a). delayed presentation (since the syndrome is usually not an acute problem). Patients will access care if their symptoms have not resolved with rest, time and "trying to work it out";

(b). complaints of functional losses due to pain, stiffness, weakness and catching when the arm is flexed and internally rotated; and

(c). sleep complaints are common and pain is often felt down the lateral aspect of the upper arm near the deltoid insertion or over the anterior proximal humerus.

(d). occupational Relationship: Repetitive overuse of the upper extremity, often seen with constant overhead motion.

c. specific Physical Exam Findings may include: As with most shoulder diagnoses, the examiner should not rely upon one set of physical exam findings alone due to the lack of specificity and sensitivity of most tests and common overlap of diagnoses. Physical examination findings may include the following:

i. Range-of-motion is limited particularly in internal rotation and in cross-body adduction, which may reflect posterior capsular tightness. Forward flexion and elevation may also be limited.

ii. Passive motion through the 60 to 90 degrees arc of flexion may be accompanied by pain and crepitus. This is accentuated as the shoulder is moved in-and-out of internal rotation.

iii. Active elevation of the shoulder is usually more uncomfortable than passive elevation.

iv. Pain on maximum active forward flexion is frequently seen with impingement syndrome, but is not specific for diagnosis.

v. Strength testing may reveal weakness of flexion and external rotation in the scapular plane. This weakness may be the result of disuse, tendon damage, or poor scapulothoracic mechanics.

vi. Pain on resisted abduction or external rotation may also indicate that the integrity of the rotator cuff tendons may be compromised, causing alteration of shoulder mechanics.

vii. Weakness of the posterior scapular stabilizers causing alteration of shoulder mechanics can also contribute to impingement syndrome.

viii. If inspection of the shoulder reveals deltoid and rotator cuff atrophy other diagnoses should be suspected such as cervical radiculopathy, axillary nerve pathology, or massive rotator cuff tears.

(a). Impingement syndromes commonly co-exist with other shoulder abnormalities such as rotator cuff tears, AC joint arthritis, biceps tendon ruptures, calcifying tendonitis, bursitis, labral tears, and in older patients, glenohumeral instability. This combination of pathology further complicates diagnostic decisions based mainly on clinical findings. Physicians use a combination of test results with history and other findings to create a differential diagnosis.

(b). Commonly used clinical tests include the following:

(i). Hawkins;
(ii). Neer;
(iii). Horizontal adduction;
(iv). Drop arm test;
(v). Yergason's;
(vi). Speed test.

(c). Diagnostic Testing Procedures

(i). Plain x-rays include:

[a]. AP view is useful to evaluate for arthritis and elevation of the humeral head which are not typically present in impingement syndrome.

[b]. Lateral view in the plane of the scapula or an axillary view can help to determine aspects of instability which can give symptoms similar to impingement syndrome.

[c]. Axillary view is also useful to demonstrate glenohumeral arthritis and spurs on the anterior inferior acromion.

[d]. Outlet view determines if there is a downward curved acromion. A downward curved acromion does not necessarily establish the diagnosis of impingement syndrome and is not a sole indication for operative treatment.

(ii). Adjunctive testing, sonography or MRI, may be considered when shoulder pain is refractory to four to ix weeks of non-operative conservative treatment and the diagnosis is not readily identified by a good history and clinical examination. (Refer to Follow-up Diagnostic Procedures.)

(iii). The subacromial injection has generally been considered the gold standard for differentiating ROM loss from impingement versus rotator cuff tears. Alleviation from pain may help to confirm the diagnosis. Patients with impingement should recover normal strength after the injection, while those with rotator cuff tears usually do not recover normal strength. However, manually tested elevation strength perceived as normal does not always rule out rotator cuff tear and this may contribute to incorrect diagnoses with this technique. There is good evidence that blinded subacromial blocks are not accurate. Up to a third of blinded injections may involve the cuff, and are likely to cause pain. This may lead to an incorrect diagnosis. One study demonstrated that at least half of the positive responders did so up to 40 minutes after the injection. Therefore, a negative response should not be diagnosed until 40 minutes post injection. The inaccuracy of the injection and patient response in some cases may contribute to its inability to completely predict the amount of recovery from subacromial decompression.

(iv). If there is a concern regarding needle placement, sonography or fluoroscopy may be used.

(v). Steroid injections should be used cautiously in diabetic patients. Diabetic patients should be reminded to check their blood glucose level at least daily for two weeks after injections.

(d). Non-operative Treatment Procedures

(i). An aggressive attempt should be made to define the contributing factors which are driving the syndrome, such as shoulder stiffness, humeral head depressor weakness (rotator cuff fiber failure), posterior capsular tightness and subacromial crowding, AC joint arthritis, muscle imbalance, and postural dysfunction.

(ii). Benefits may be achieved through therapeutic interventions. They should include ROM, active therapies, and a home exercise program. Passive as well as active therapies may be used for control of pain and swelling. Therapy should progress to strengthening and an independent home exercise program targeted to further improve ROM and strength of the shoulder girdle

musculature. Refer to Therapeutic Procedures, Non-operative.

(iii). There is some evidence that manual therapy at a frequency of three times per week for four weeks, increases function and decreases pain.

(iv). Patients may return to work without overhead activities and lifting with involved arm. An evaluation of the jobsite may be necessary to institute ergonomic changes or accommodations. Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

(v). Medications, such as nonsteroidal anti-inflammatories and analgesics, should be prescribed. Refer to Medications.

(vi). Subacromial space injection may be therapeutic. Injections under significant pressure should be avoided as the needle may be penetrating the tendon and injection into the tendon can cause tendon degeneration, tendon breakdown, or rupture. Injections should be minimized for patients under 30 years of age.

[a]. Time to Produce Effect: One Injection.

[b]. Maximum: Three injections at the same site per year when functional benefits are demonstrated with each injection. Steroid injections should be used cautiously in diabetic patients. Diabetic patients should be reminded to check their blood glucose level at least daily for two weeks post injections.

(vii). Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

(e). Surgical Indications

(i). When functional deficits interfere with activities of daily living and/or job duties after three to six months of active patient participation in non-operative therapy, surgery may restore functional anatomy and reduce the potential for repeated impingement. Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities and the patient should agree to comply with the pre- and post-operative treatment plan including home exercise. The provider should be especially careful to make sure the patient understands the amount of post-operative therapy required and the length of partial and full disability expected post-operatively.

(f). Operative Procedures

(i). Procedures might include partial coracoacromial ligament release, and an acromioplasty, as well as, repair of associated pathology. An acromioplasty is not always necessary as an adjunct to rotator cuff repair. There is some evidence that patients with a full-thickness rotator cuff tear and Type II acromions do not show appreciable benefit from subacromial decompression.

(ii). Coplaning of the clavicle involves the removal of spurs from its inferior surface with the purpose of increasing the space available for movement of the supraspinatus tendon. It is an acceptable procedure. Studies are conflicting regarding possible pain sequelae at the acromioclavicular joint as a consequence of the procedure. In cases with extensive rotator cuff repair, preservation of the coraco–acromial ligament is recommended to maintain joint stability.

(g). Post-operative Treatment

(i). An individualized rehabilitation program based upon communication between the surgeon and the therapist using the treatments found in Therapeutic Procedures, Non-operative. Treatment may include the following:

(ii). sling, pillow sling, or abduction splint;

(iii). gentle pendulum exercise, passive glenohumeral range-of-motion, and posterior scapular stabilizing training can be instituted;

(iv). patients can judiciously return to activities as tolerated per physician recommendations. If there is a significant tendon repair, progression will be delayed;

(v). Progressive resistive exercise from six to eight weeks with gradual returning to full activity at four to six months.

(vi). Return to work and restrictions after surgery may be made by an experienced primary occupational medicine physician in consultation with the surgeon or by the surgeon. Depending upon the patient's functional response and their job requirements, return to work with job modifications may be considered as early as one week post-operatively, depending on job requirements. The employer must be able to fully accommodate restrictions of overhead activities or heavy lifting. Work restrictions should be evaluated every four to six weeks during post-operative recovery and rehabilitation with appropriate written communications to both the patient and the employer. Should progress plateau, the provider should re-evaluate the patient's condition and make appropriate adjustments to the treatment plan.

14. Rotator Cuff Tear

a. Description/Definition: Partial or full-thickness tears of the rotator cuff tendons, most often the supraspinatus, can be caused by vascular, traumatic or degenerative factors or a combination. Further tear classification includes: a small tear is less than 1cm; medium tear is 1 to 3cm; large tear is 3 to 5cm; and massive tear is greater than 5cm, usually with retraction. Partial thickness cuff tears usually occur in age groups older than 30. Full-thickness tears can occur in younger age groups. Patient usually complains of pain along anterior, lateral shoulder or posterior glenohumeral joint.

b. Occupational Relationship: May be caused by sudden trauma to the shoulder such as breaking a fall using an overhead railing or an out-stretched arm; or chronic overuse with repetitive overhead motion or heavy lifting; or moderate lifting in de-conditioned workers.

c. Specific Physical Exam Findings may include

i. partial Thickness Tear

(a). There may be pain at the end of range-of-motion (ROM) when full passive ROM for abduction, elevation, external rotation and internal rotation are obtainable;

(b). Occasionally, there is a restriction of passive motion in one or more planes;

(c). Active ROM will be limited and painful for abduction and external rotation, as well as internal rotation and forward flexion;

(d). A painful arc may be present with active elevation;

(e). Pain will be positive for resisted tests (abduction, flexion, external rotation, internal rotation, abduction/internal rotation at 90 degrees, and abduction/external rotation at 45 degrees); and/or

(f). There may be positive impingement signs, refer to Impingement Syndrome.

ii. Full-Thickness Tear

(a). Passive and resisted findings are similar to those for partial thickness tears with greater weakness of abduction and external rotation;

(b). Active elevation may be severely limited with substitution of scapular rotation;

(c). Occasionally strength remains well preserved.

(d). Rotator cuff tears commonly co-exist with other shoulder abnormalities such as impingement, AC joint arthritis, bicep tendon ruptures, calcifying tendonitis, and older patients with glenohumeral instability, bursitis, and labral tears. This combination of pathology further complicates diagnostic decisions based mainly on the clinical findings. Full-thickness tears are usually readily apparent from the drop arm test or weakness with elevation. For other diagnoses, physicians should use a combination of test results with history and other findings to create a differential diagnosis. The following tests may be used:

(i). hawkins;
(ii). drop arm;
(iii). lift off;
(iv). subscapularis strength test;
(v). empty can test;
(vi). external rotation lag test.

(e). Neurological lesions can occur with rotator cuff tears or may be missed as isolated lesions. When muscle atrophy and weakness are present, the physician should consider neurologic lesions in the differential diagnoses.

d. Diagnostic Testing Procedures

i. AP view is useful to evaluate for arthritis and elevation of the humeral head. Superior migration of the humeral head is indicative of an extensive, and possibly irreparable, rotator cuff tear.

ii. Lateral view in the plane of the scapula or an axillary view can help to determine aspects of instability which can give symptoms similar to impingement syndrome.

iii. The axillary view is also useful to demonstrate glenohumeral arthritis and spurs on the anterior inferior acromion.

iv. Outlet view determines if there is a downward curved acromion. A downward curved acromion does not necessarily establish the diagnosis of impingement syndrome and is not a sole indication for operative treatment.

(a). Cases with the presence of significant weakness on elevation or rotation, a palpated defect at the greater tuberosity or a traumatic history should have early MRI. Adjunctive testing such as sonography or MRI should be considered for other shoulder cases refractory to four to six weeks of non-operative conservative treatment. Sonography may be better at detecting partial thickness tears but is operator dependent. The sonogram is very specific for rotator cuff tears but is not sensitive.

(b). Rotator cuff tears, both full-thickness and partial, appear to occur commonly in asymptomatic individuals. Sonographic diagnostic criteria for rotator cuff tear may be met in approximately 39 percent of asymptomatic persons, and MRI criteria for rotator cuff tear may occur in approximately 26 percent of asymptomatic persons. There also appears to be a linear trend with age, such that more than half of asymptomatic individuals over the age of 60 may demonstrate imaging changes consistent with rotator cuff tear, while a small minority of patients younger than 40 demonstrate these changes. Correlation of radiological and clinical findings is an important part of patient management.

e. Non-operative Treatment Procedures

i. Medications, such as nonsteroidal anti-inflammatories and analgesics, would be indicated. Acute rotator cuff tear may indicate the need for limited narcotics use.

ii. Relative rest initially and procedures outlined in Non-Operative Treatment Procedures. Therapeutic rehabilitation interventions may include ROM and use a home exercise program and passive modalities for pain control. Therapy should progress to strengthening and independent home exercise programs targeted to ongoing ROM and strengthening of shoulder girdle musculature.

iii. Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

iv. Other therapies outlined in Therapeutic Procedures, Non-operative, may be employed in individual cases.

f. Surgical Indications

i. Goals of surgical intervention are to restore functional anatomy by re-establishing continuity of the rotator cuff, addressing associated pathology and reducing the potential for repeated impingement.

ii. Surgery may be indicated when functional deficits interfere with activities of daily living and/or job duties after 6 to 12 weeks of active patient participation in non-operative therapy.

iii. If no increase in function for a partial tear is observed after 6 to 12 weeks, a surgical consultation is indicated. For full-thickness tears it is thought that early surgical intervention produces better surgical outcome due to healthier tissues and often less limitation of movement prior to and after surgery. Patients may need pre-operative therapy to increase ROM.

iv. Full- thickness tears in individuals less than 60 should generally be repaired. Surgery for partial thickness tears has variable results and debridement should be performed early in younger active patients. Many patients with partial tears and good ROM and strength recover well without surgery. In patients over 65 the decision to repair a full rotator cuff tear depends on the length of time since the injury, the amount of muscle or tendon that has retracted, the level of fatty infiltration and the quality of the tendon. Procedures for these patients may include biceps tendon repair and shaving of the humeral tuberosity. For patients with lack of active elevation above 90 degrees, arthroscopic biceps tenotomy and tenodesis may be effective in returning some elevation. Recurrence rate may be up to 50 percent in older patients with multiple tendon full-thickness tears.

Pseudo paralysis or severe rotator cuff arthropathy are contraindications to the procedure.

v. Literature suggests that the presence of three of the following factors may decrease the likelihood of a successful repair: decreased passive ROM, superior migration of the humeral head, presence of atrophy, and/or external rotation/abduction weakness strength. Presence of these conditions is not necessarily contraindications to surgery, however, the patient should be made aware that the outcome may be less predictable.

vi. Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities and the patient should agree to comply with the pre- and post-operative treatment plan and home exercise requirements. The patient should understand the length of partial and full disability expected post-operatively.

vii. Smoking may affect soft tissue healing through tissue hypoxia. Patients should be strongly encouraged to stop smoking and provided with appropriate counseling.

g. Operative Procedures:

i. Options would include arthroscopic or open debridement and/or repair. In some cases, partial coracoacromial ligament release, and/or anterior acromioplasty.

ii. An acromioplasty is not always necessary as an adjunct to rotator cuff repair. There is some evidence that patients with a full-thickness rotator cuff tear and Type II acromions do not show appreciable benefit from subacromial decompression.

iii. Coplaning of the clavicle involves the removal of spurs from its inferior surface with the purpose of increasing the space available for movement of the supraspinatus tendon. It is an acceptable procedure. Studies are conflicting concerning the consequences of the procedure for the stability of the acromioclavicular joint.

iv. Distal clavicular resection is not recommended for patients without AC joint pain.

v. In cases with extensive rotator cuff tear, preservation of the coracoacromial ligament is recommended to prevent instability.

vi. Arthroscopic laser treatment is not recommended due to lack of evidence regarding outcomes.

h. Post-operative Treatment: Individualized rehabilitation program based upon communication between the surgeon and the therapist. Treatment may include the following:

i. Sling, pillow sling, or abduction splint. Sling protection for a period of two to eight weeks is usually recommended after rotator cuff repair;

ii. Gentle pendulum exercise, passive glenohumeral range-of-motion in flexion and external rotation to prevent adhesions and maintain mobilization;

iii. Isometrics and activity of daily living skills usually being six weeks post-operatively.

iv. Active assisted range-of-motion exercises in supine with progression to sitting;

v. Light resistive exercise may begin at 6 to 12 weeks, depending on quality of tissue and surgeon's discretion;

vi. Pool exercise initially under therapists or surgeon's direction then progressed to independent pool program;

vii. Progression to a home exercise program is essential;

viii. Gradual resistive exercise from 3 to 12 months, with gradual return to full activity at 6 to 12 months;

ix. Time frames for therapy (excluding pool therapy).

(a). Optimum: 24 to 36 sessions.

(b). Maximum: 48 sessions. If functional gains are being achieved additional visits may be authorized for the patient to achieve their functional goal.

x. Continuous passive motion is not generally recommended. It may be used if the patient has no home assistance to regularly perform the passive movements required in the first six weeks and/or access to therapy is limited.

xi. Should progress plateau, the provider should re-evaluate the patient's condition and make appropriate adjustments to the treatment plan. Refer to Therapeutic Procedures-Non-Operative for other therapies that may be employed in individual cases.

xii. Return to work and restrictions after surgery may be made by an experienced primary occupational medicine physician in consultation with the surgeon or by the surgeon. Work restrictions should be evaluated every four to six weeks during post-operative recovery and rehabilitation with appropriate written communications to both the patient and employer. Return to full-duty too early in the course of tendon recovery increases the likelihood of recurrent, symptomatic tears. Animal models estimate that the infraspinatus tendon regains only 30 percent of strength at six weeks, 50 percent at three months, and 80 percent at six months. Therefore, return to any significant lifting early in the course of recovery may result in failure of the surgery and/or recurrent tears.

15. Shoulder Instability/Glenohumeral Instability

a. Description/Definition: Subluxation (partial dislocation), or dislocation of the glenohumeral joint in either an anterior, interior, posterior or a combination of positions.

i. History may include:

(a). a slipping sensation in the arm;

(b). severe pain with inability to move the arm;

(c). abduction and external rotation producing a feeling that the shoulder might "come out"; or

(d). feeling of shoulder weakness.

b. Occupational Relationship: Instability may be caused by any of the following:

i. a direct traumatic blow to the shoulder;

ii. a fall on an outstretched arm;

iii. performing repetitive forceful overhead activities similar to pitching baseball;

iv. a significant traction injury to the arm.

v. In cases of subluxation symptoms may be exacerbated or provoked by work and initially alleviated with a period of rest. Symptoms may also be exacerbated by other activities that are not necessarily work related (e.g., driving a car or sports).

c. Specific Physical Exam Findings may include

i. Anterior dislocations may exhibit loss of normal shoulder contour; fullness in the axilla and pain over the shoulder with any motion. The patient may hold the extremity in a static position;

ii. Posterior dislocations usually occur with a direct fall on the shoulder or outstretched arm resulting in posteriorly directed forces to the humeral head. Seizures or electrocution may also cause posterior dislocations. Patients present with inability to externally rotate the shoulder;

iii. Neurologic examination may reveal findings consistent with axillary nerve injuries, musculocutaneous nerve injuries, generalized brachioplexopathies or other entrapment neuropathies;

iv. Abduction and external rotation positioning classically produces apprehension in those who have anterior instability. This finding may be present with other diagnoses. If apprehension is reproduced and then relieved with positive posterior pressure after a positive first maneuver, this is considered a positive relocation test. As with all shoulder diagnoses, a combination of physical findings and history should guide the provider in determining the final diagnoses. Direct posterior stress may produce pain and apprehension in those with posterior instability;

v. The contralateral joint should always be examined. Patients who have laxity in multiple positions, who have contralateral joint laxity or who have increased external rotation (90 degrees or more) with the arm at the side are not likely to be surgical candidates and can be treated conservatively.

vi. Other clinical findings (described in the Initial Diagnostic Procedures Section C):

(a). sulcus sign;

(b). inferior instability;

(c). posterior instability;

(d). apprehension, also known as crank, fulcrum or feagin;

(e). relocation;

(f). load and shift or anterior and posterior drawer.

d. Diagnostic Testing Procedures

i. Plain x-rays to rule out bony deficit on the glenoid, including AP, axillary view, lateral in the plane of the scapula and possibly the West Point view. Axillary view to identify larger Hill-Sachs lesion of humeral head.

ii. More difficult diagnostic cases with subtle history and physical findings suggesting instability, rotator cuff or labral tear, may require a MRI or a CT arthrogram. This imaging may be useful to evaluate for labral detachment and capsular stress injury or laxity after four to eight weeks of active patient involvement in therapy.

iii. Suspected rotator cuff tear cases may require diagnostic arthroscopy.

e. Non-Operative Treatment Procedures: In subacute and/or chronic instabilities, age of onset of instability is an important part of the history. Older patients are less likely to have recurrent dislocations unless they have associated large rotator cuff tears. Therefore, the rotator cuff tear protocol should be followed if there is a suspicion of this pathology. Associated axillary nerve injuries are more common in older patients. Patients less than 30 years of age, especially males actively participating in sports, tend to have a higher recurrence rate, up to 75 percent in some series. Surgery should be considered for these patients after the first dislocation. Avoid any aggressive treatment in patients with history of voluntary subluxation or dislocation. These patients may need a psychiatric evaluation. Patient may not return to work with overhead activity or lifting with involved arm until cleared by physician for heavier activities.

i. First-time dislocation

(a). Immobilization. There is no evidence that immobilization beyond splinting for comfort initially affords any additional treatment advantage thus, it is not routinely required. Literature using MRI has shown that the Bankart lesion is separated from the bone in internal rotation and apposed to the bone in external rotation. There is some evidence that immobilization for three weeks with the shoulder in adduction and approximately 10 degrees of external rotation reduces the risk of recurrent dislocation. Decisions concerning external rotation splinting versus other options will depend on surgeon and patient preferences.

(b). Consider surgical intervention for young patients active in sports, or older patients with significant rotator cuff tears. If additional pathology is present consult appropriate diagnostic categories.

(c). Medications such as analgesics and anti-inflammatories may be helpful. (Refer to medication discussions in Medications.

(d). Other therapeutic procedures may include instruction in therapeutic exercise and proper work techniques, evaluation of occupational work station and passive modalities for pain control. (Refer to Therapeutic Procedures-Non operative, for specific time parameters.)

(e). Additional treatment may include, depending on level of improvement, manual therapy techniques, work conditioning and other treatment found in section F.

(f). Patient may not return to work with overhead activity or lifting with involved arm until cleared by physician for heavier activities. Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

ii. Acute or chronic dislocations: with a fracture contributing to instability;

(a). Practitioner should immobilize dislocations if in an acceptable position. Consultation should be obtained as surgical repair may be necessary.

(b). Return-to-work will be directly related to the time it takes the fracture to heal.

iii. Subacute and/or chronic instability:

(a). Chronic dislocations should first be treated similarly to acute dislocation. If continuing treatment is unsuccessful, with findings of instability, operative repair should be considered.

f. Surgical Indications

i. Identify causative agent for the instability (i.e., labral detachment, bony lesion, large rotator cuff tear, subscapularis tendon rupture, or multi-directional instability). There is strong evidence that initial operative repair in young active patients results in fewer recurrent dislocations, thus, operative repair should be considered for these patients. Those with Hill Sachs lesions, bony Bankart injuries, or significant glenoid bone loss have a worse prognosis for recurrences.

ii. Fractures not amenable to immobilization may also need operative management after the first dislocation.

Even with open repairs some decrease in function should be expected. Loss of external rotation is common. In some cases the loss of motion may have an adverse effect on post-operative function. The desire for surgery should carefully balance the desire to prevent recurrent dislocations and the need for ROM.

iii. Older patients with documented large rotator cuff tears should also be considered for operative repair after first time dislocations. Repair of the rotator cuff tear alone or in combination with stabilization should be considered. Refer to the rotator cuff tear section.

iv. In general, older patients without the above lesions will suffer few recurrences, and therefore, are treated conservatively. Operative repair may be considered only after recurrent dislocations when functional deficits interfere with activities of daily living and/or job duties and active patient participation in non-operative therapy has occurred. Patients with multi-directional laxity and/or laxity in the contralateral shoulder are usually not good candidates for operative repair.

g. Operative Procedures:

i. Bankart lesion repair; or

ii. Capsular tightening. There is no evidence of benefit from thermal capsulorrhaphy and it is not recommended;

iii. Bony block transfer;

h. Post-operative Treatment:

i. An individualized rehabilitation program based upon communication between the surgeon and the therapist. Depending upon the type of surgery, the patient will be immobilized for three to six weeks.

ii. As soon as it is safe to proceed without damaging the repair, begin therapeutic exercise. Pool therapy may be beneficial. Refer to Therapeutic Procedures, Non-operative for other therapies.)

iii. During this period of time, the patient could resume working when the surgeon has cleared the patient for specific activities and appropriate modifications can be made in the workplace. Return to work and restrictions after surgery may be made by an experienced primary occupational medicine physician in consultation with the surgeon or by the surgeon. Full ROM, lifting and pushing are prohibited usually for at least three months. Overhead work may be restricted up to six months.

iv. MMI can be expected three months after non-operative treatment and 6 to 12 months after operative treatment. Further job assessment and adjusted work restrictions may be needed prior to the patients return to full-duty.

16. Superior Labrum Anterior and Posterior (Slap) Lesions

a. Description/Definition: Lesions of the superior aspect of the glenoid labrum that extend anteriorly and posteriorly in relation to the biceps tendon insertion. There are several different types of SLAP lesions described.

i. Type I is a fraying of the superior labral edge without detachment of the labrum from the glenoid rim.

ii. Type II is a detachment of the biceps anchor from the glenoid. Three distinct Type II lesions have been described as anterior only, posterior only, or combined anterior and posterior.

iii. Type III is a bucket handle tear in the superior labrum only with biceps tendon and remainder of the superior labrum having stable attachment.

iv. Type IV is a bucket handle tear as in Type III, but with extension of the tear in to the biceps tendon. Additional types of lesions have been described that include extensions of the above-described lesions or extensions of Bankart lesions.

v. History may include:

(a). Symptoms with overhead throwing motions;

(b). Dislocation, subluxation, or subjective sense of instability;

(c). Poorly localized shoulder pain that is exacerbated by overhead activities;

(d). Catching, locking, popping or snapping;

(e). Subtle instability.

b. Occupational Relationship: Common mechanisms of injury that are thought to contribute to SLAP lesions include: compression injury such as fall on an outstretched arm with the shoulder in forward flexion and abduction or direct blow to the glenohumeral joint; traction injury such as repetitive overhead throwing, attempting to break a fall from a height, and sudden pull when losing hold of a heavy object; driver of an automobile who is rear ended; repetitive overhead motions with force such as pitching; or a fall on adducted arm with upward force directed on elbow. In some cases no mechanism of injury can be identified.

c. Specific Physical Exam Findings: The physical examination is often nonspecific secondary to other associated intra-articular abnormalities. No one test or combination of tests has been shown to have an acceptable sensitivity and specificity or positive predictive values for diagnosing SLAP lesion. Sensitivity and specificity are relatively low for individual tests and combinations. Overall physical examination tests for SLAP lesions may be used to strengthen a diagnosis of SLAP lesion, but the decision to proceed to operative management should not be based on physical examination alone. Refer to Initial Diagnostic Procedures for specific descriptions of these signs and tests.

i. Speed Test.

ii. Yergason's Test.

iii. Active Compression (O'Brien) Test.

iv. Jobe Relocation Test.

v. Crank Test.

vi. Anterior Apprehension Maneuver.

vii. Tenderness at the bicipital groove.

viii. Anterior Slide (Kibler) Test.

ix. Compression Rotation Test.

x. Pain Provocation Test.

xi. Biceps Load Test II.

d. Diagnostic Testing Procedures:

i. Radiographs are usually normal in isolated SLAP lesions. However, they can be useful in identifying other sources of abnormalities.

ii. Magnetic resonance imaging with arthrogram has the highest reported accuracy for both diagnosis and classification of SLAP lesions; however, it may be difficult to differentiate SLAP lesions, especially Type II lesions, from normal anatomic variants and from asymptomatic age related changes.

iii. Arthroscopic evaluation is the most definitive diagnostic test.

e. Non-operative Treatment Procedures: Most SLAP lesions are associated with other pathology such as rotator cuff tears, Bankart lesions, joint instability, biceps tendon tears, and supraspinatus tears. The provider should refer to the treatment protocols for these conditions and follow both the surgical and non surgical recommendations. For suspected isolated SLAP lesions, non invasive care, consider the following.

i. Medications such as analgesics and anti-inflammatories may be helpful. (Refer to medication discussions are in Medications.)

ii. Therapeutic procedures may include instruction in therapeutic exercise and proper work techniques, evaluation of occupational work station.

iii. Benefits may be achieved through therapeutic rehabilitation and rehabilitation interventions. They should include range-of-motion (ROM), active therapies, and a home exercise program. Passive as well as active therapies may be used for control of pain and swelling. Therapy should progress to strengthening and an independent home exercise program targeted to further improve ROM and strength of the shoulder girdle musculature. (Refer to Therapeutic Procedures, Non-operative.)

iv. Subacromial bursal and/or glenohumeral steroid injections may decrease inflammation and allow the therapist to progress with functional exercise and ROM.

(a). Time to Produce Effect: One injection.

(b). Maximum Duration: Three injections in one year at least four to eight weeks apart.

(c). Steroid injections should be used cautiously in diabetic patients. Diabetic patients should be reminded to check their blood glucose levels at least daily for two weeks after injections.

v. Return to work with appropriate restrictions should be considered early in the course of treatment. Refer to Return to Work.

vi. Other therapies in Therapeutic Procedures, Non-operative may be employed in individual cases.

f. Surgical Indications: There is a significant amount of normal anatomic variation of the superior glenoid labrum and origin of the long head of the biceps tendon. Differentiation between normal variation and pathology is imperative.

i. The physician should identify other shoulder pathology if any exists and follow the appropriate surgical indications. If a SLAP lesion is suspected, an arthroscopic exam should be performed in conjunction with the primary surgical procedure and an appropriate repair performed if necessary. See Specific Diagnosis Testing, & Treatment related sections. Or;

ii. When no additional pathology is identified and there is an inadequate response to at least three months of non-operative management with active patient participation as evidenced by continued pain with functional limitations and/or instability significantly affecting activities of daily living or work duties;

iii. Prior to surgical intervention, the patient and treating physician should identify functional operative goals and the likelihood of achieving improved ability to perform activities of daily living or work activities and the patient should agree to comply with the pre- and post-operative treatment plan and home exercise requirements. The patient should understand the length of partial and full disability expected post-operatively. The patient should also understand that non-operative treatment is an acceptable option and that a potential complication of the surgery is shoulder stiffness with pain and possibly decreased function.

g. Operative Procedures: Operative treatment of SLAP lesions depends on the type of lesion present and whether any other intra-articular abnormalities are present. The following are generally accepted protocols for surgical intervention; however, due to current lack of evidence, operative treatment is not limited to these.

i. TypeI: Debridement is reasonable but not required.

ii. TypeII: Repair via suture anchors or biceps tenotomy are reasonable options.

iii. TypeIII: Debridement or excision of the bucket handle component alone or repair via suture anchors or biceps tenotomy/tenodesis are reasonable options.

iv. TypeIV: Debridement and/or biceps tenotomy or tenodesis are reasonable options.

h. Post-Operative Treatment: Post-operative rehabilitation programs should be individualized and dependent upon whether any other intra-articular abnormalities exist and were operatively treated. There is a paucity of information on rehabilitation of isolated SLAP lesions. Common post-operative care involves wearing a sling, without active shoulder motion for 4 to 6 weeks. Elbow, wrist, and hand range-of-motion (ROM) exercises may be used at this time. The sling is removed at 4 to 6 weeks and active ROM is usually begun with restrictions directed by the surgeon. It is reasonable to restrict external rotation and abduction up to six months post-operative. Return to work and restrictions after surgery may be made by an experienced primary occupational medicine physician in consultation with the surgeon or by the surgeon.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1828 (June 2011).

§2325. Therapeutic Procedures—Non-Operative

A. Treating providers, as well as employers and insurers are highly encouraged to reference the General Guideline Principles. Before initiation of any therapeutic procedure, the authorized treating provider, employer, and insurer must consider these important issues in the care of the injured worker.

B. First, patients undergoing therapeutic procedure(s) should be released or returned to modified or restricted duty during their rehabilitation at the earliest appropriate time. Refer to "Return-to-Work" in this section for detailed information.

C. Second, cessation and/or review of treatment modalities should be undertaken when no further significant subjective or objective improvement in the patient's condition is noted. If patients are not responding within the recommended duration periods, alternative treatment interventions, further diagnostic studies or consultations should be pursued.

D. Third, providers should provide and document education to the patient. No treatment plan is complete without addressing issues of individual and/or group patient

education as a means of facilitating self-management of symptoms.

E. Lastly, formal psychological or psychosocial evaluation should be performed on patients not making expected progress within 6 to 12 weeks following injury and whose subjective symptoms do not correlate with objective signs and tests.

F. In cases where a patient is unable to attend an outpatient center, skilled home therapy may be necessary. Skilled home therapy may include active and passive therapeutic procedures as well as other modalities to assist in alleviating pain, swelling, and abnormal muscle tone. Skilled home therapy is usually of short duration and continues until the patient is able to tolerate coming to an outpatient center.

1. Acupuncture is an accepted and widely used procedure for the relief of pain and inflammation, and there is some scientific evidence to support its use. The exact mode of action is only partially understood. Western medicine literature suggests that acupuncture stimulates the nervous system at the level of the brain, promotes deep relaxation, and affects the release of neurotransmitters. Acupuncture is commonly used as an alternative or in addition to traditional Western pharmaceuticals. While it is commonly used when pain medication is reduced or not tolerated, it may be used as an adjunct to physical rehabilitation and/or surgical intervention to hasten the return to functional activity. Acupuncture should be performed by licensed practitioners.

a. Acupuncture is the insertion and removal of filiform needles to stimulate acupoints (acupuncture points). Needles may be inserted, manipulated, and retained for a period of time. Acupuncture can be used to reduce pain, reduce inflammation, increase blood flow, increase range of motion, decrease the side effect of medication-induced nausea, promote relaxation in an anxious patient, and reduce muscle spasm.

i. Indications include joint pain, joint stiffness, soft tissue pain and inflammation, paresthesia, post-surgical pain relief, muscle spasm, and scar tissue pain.

b. Acupuncture with Electrical Stimulation: is the use of electrical current (micro-amperage or milli-amperage) on the needles at the acupuncture site. It is used to increase effectiveness of the needles by continuous stimulation of the acupoint. Physiological effects (depending on location and settings) can include endorphin release for pain relief, reduction of inflammation, increased blood circulation, analgesia through interruption of pain stimulus, and muscle relaxation. It is indicated to treat chronic pain conditions, radiating pain along a nerve pathway, muscle spasm, inflammation, scar tissue pain, and pain located in multiple sites.

c. Total Time Frames for Acupuncture and Acupuncture with Electrical Stimulation: Time frames are not meant to be applied to each of the above sections separately. The time frames are to be applied to all acupuncture treatments regardless of the type or combination of therapies being provided.

i. Time to Produce Effect: three to ix treatments.
ii. Frequency: one to three times per week.
iii. Optimum Duration: one to two months.
iv. Maximum Duration: 14 treatments.

(a). Any of the above acupuncture treatments may extend longer if objective functional gains can be documented or when symptomatic benefits facilitate progression in the patient's treatment program. Treatment beyond 14 treatments must be documented with respect to need and ability to facilitate positive symptomatic or functional gains. Such care should be re-evaluated and documented with each series of treatments.

d. Other Acupuncture Modalities: Acupuncture treatment is based on individual patient needs and therefore treatment may include a combination of procedures to enhance treatment effect. Other procedures may include the use of heat, soft tissue manipulation/massage, and exercise. Refer to Active Therapy (Therapeutic Exercise) and Passive Therapy sections (Massage and Superficial Heat and Cold Therapy) for a description of these adjunctive acupuncture modalities and time frames.

2. Biofeedback is a form of behavioral medicine that helps patients learn self-awareness and self-regulation skills for the purpose of gaining greater control of their physiology, such as muscle activity, brain waves, and measures of autonomic nervous system activity. Electronic instrumentation is used to monitor the targeted physiology and then displayed or fed back to the patient visually, auditorily, or tactilely, with coaching by a biofeedback specialist. Biofeedback is provided by clinicians certified in biofeedback and/or who have documented specialized education, advanced training, or direct or supervised experience qualifying them to provide the specialized treatment needed (e.g., surface EMG, EEG, or other).

a. Treatment is individualized to the patient's work-related diagnosis and needs. Home practice of skills is required for mastery and may be facilitated by the use of home training tapes. The ultimate goal in biofeedback treatment is normalizing the physiology to the pre-injury status to the extent possible and involves transfer of learned skills to the workplace and daily life. Candidates for biofeedback therapy or training must be motivated to learn and practice biofeedback and self-regulation techniques.

b. Indications for biofeedback include individuals who are suffering from musculoskeletal injury in which muscle dysfunction or other physiological indicators of excessive or prolonged stress response affects and/or delays recovery. Other applications include training to improve self-management of emotional stress/pain responses such as anxiety, depression, anger, sleep disturbance, and other central and autonomic nervous system imbalances. Biofeedback is often utilized along with other treatment modalities.

i. Time to Produce Effect: three to four sessions.
ii. Frequency: One to two times per week.
iii. Optimum Duration: Five to six sessions.
iv. Maximum Duration: 10 to 12 sessions. Treatment beyond 12 sessions must be documented with respect to need, expectation, and ability to facilitate positive symptomatic or functional gains.

3. Extracorporeal Shock Wave Therapy (ESWT) is used to increase function and decrease pain in patients with specified types of calcifying tendonitis who have failed conservative therapy. It is not a first line therapy. ESWT uses acoustic impulses with duration in microseconds focused on the target tissue. The mechanism of action is not

known, but is not likely to be simply the mechanical disintegration of the calcium deposit. High-energy application of ESWT may be painful, and rare complications such as osteonecrosis of the humeral head have been reported. Dosage is established according to patient tolerance. Higher dosages are generally associated with better functional results. There is good evidence that ESWT may improve pain and function in radiographically or sonographically defined Type I or Type II calcium deposits when conservative treatment has failed to result in adequate functional improvement, but optimal dosing has not been defined. In the absence of a documented calcium deposit, there is no evidence that ESWT is effective and its use in this setting is not recommended. Neither anesthesia nor conscious sedation is required nor is it recommended for this procedure. There is no evidence that results with fluoroscopic guidance or with computer-assisted navigation are superior to results obtained by palpation. These are not recommended.

a. Indications—patients with calcifying tendonitis who have not achieved functional goals after two to three months of active therapy. The calcium deposits must be Type I, homogenous calcification with well-defined borders or Type II, heterogeneous with sharp border or homogenous with no defined border.

i. Time to Produce Effect: Three days.

ii. Frequency: Every four to seven days.

iii. Optimum Duration: Two sessions. Progress can be documented by functional reports and/or x-ray or sonographic decrease in calcium.

iv. Maximum Duration: Four sessions.

4. Injections-Therapeutic

a. Description. Therapeutic injection procedures are generally accepted, well-established procedures that may play a significant role in the treatment of patients with upper extremity pain or pathology. Therapeutic injections involve the delivery of anesthetic and/or anti-inflammatory medications to the painful structure. Therapeutic injections have many potential benefits. Ideally, a therapeutic injection will: reduce inflammation in a specific target area; relieve secondary muscle spasm; allow a break from pain; and support therapy directed to functional recovery. Diagnostic and therapeutic injections should be used early and selectively to establish a diagnosis and support rehabilitation. If injections are overused or used outside the context of a monitored rehabilitation program, they may be of significantly less value.

b. Indications. Diagnostic injections are procedures which may be used to identify pain generators or pathology. For additional specific clinical indications, see Specific Diagnosis, Testing and Treatment Procedures.

c. Contraindications - General contraindications include local or systemic infection, bleeding disorders, allergy to medications used and patient refusal. Specific contraindications may apply to individual injections.

i. Shoulder Joint Injections: are generally accepted, well-established procedures that can be performed as analgesic or anti-inflammatory procedures. Common shoulder joint injections include anterior and posterior glenohumeral and acromioclavicular.

(a). Time to Produce Effect: Immediate with local anesthesia, or within 3 days if no anesthesia.

(b). Optimum Duration: Usually One or two injections are adequate.

(c). Maximum Duration: Not more than three to four times annually.

(d). Steroid injections should be used cautiously in diabetic patients. Diabetic patients should be reminded to check their blood glucose level at least daily for two weeks post injections.

ii. Subacromial Injections There is good evidence that blinded subacromial blocks are not accurate. Up to a third of blinded injections may involve the cuff and are likely to cause pain. This may lead to an incorrect diagnosis when the injection is being used diagnostically. (Refer to Diagnostic injections) If there is a concern regarding needle placement, sonography or fluoroscopy may be used.

iii. Soft Tissue Injections: include bursa and tendon insertions. Injections under significant pressure should be avoided as the needle may be penetrating the tendon. Injection into the tendon can cause tendon degeneration, tendon breakdown, or rupture. Injections should be minimized for patients under 30 years of age. Steroid injections should be used cautiously in diabetic patients. Diabetic patients should be reminded to check their blood glucose level at least daily for two weeks post injections. The risk of tendon rupture should be discussed with the patient and the need for restricted duty emphasized.

(a). Frequency: Usually one or two injections are adequate.

(b). Time to Produce Effect: Immediate with local anesthesia, or within three days if no anesthesia.

(c). Optimum/Maximum Duration: Three steroid injections at the same site per year.

iv. Trigger Point Injections: although generally accepted, are not routinely used in the shoulder. However, it is not unusual to find shoulder girdle myofascial trigger points associated with shoulder pathology which may require injections.

(a). Description. Trigger point treatment can consist of dry needling or injection of local anesthetic with or without corticosteroid into highly localized, extremely sensitive bands of skeletal muscle fibers that produce local and referred pain when activated. Medication is injected in a four-quadrant manner in the area of maximum tenderness. Injection efficacy can be enhanced if injections are immediately followed by myofascial therapeutic interventions, such as vapo-coolant spray and stretch, ischemic pressure massage (myotherapy), specific soft tissue mobilization and physical modalities. There is conflicting evidence regarding the benefit of trigger point injections. A truly blinded study comparing dry needle treatment of trigger points is not feasible. There is no evidence that injection of medications improves the results of trigger-point injections. Needling alone may account for some of the therapeutic response.

(i). There is no indication for conscious sedation for patients receiving trigger point injections. The patient must be alert to help identify the site of the injection.

(b). Indications. Trigger point injections may be used to relieve myofascial pain and facilitate active therapy and stretching of the affected areas. They are to be used as an adjunctive treatment in combination with other treatment modalities such as functional restoration programs. Trigger

point injections should be utilized primarily for the purpose of facilitating functional progress. Patients should continue with a therapeutic exercise program as tolerated throughout the time period they are undergoing intensive myofascial interventions. Myofascial pain is often associated with other underlying structural problems and any abnormalities need to be ruled out prior to injection.

(i). Trigger point injections are indicated in those patients where well circumscribed trigger points have been consistently observed, demonstrating a local twitch response, characteristic radiation of pain pattern and local autonomic reaction, such as persistent hyperemia following palpation. Generally, these injections are not necessary unless consistently observed trigger points are not responding to specific, noninvasive, myofascial interventions within approximately a 6-week time frame.

(ii). Complications. Potential but rare complications of trigger point injections include infection, pneumothorax, anaphylaxis, neurapraxia, and neuropathy. If corticosteroids are injected in addition to local anesthetic, there is a risk of local developing myopathy. Severe pain on injection suggests the possibility of an intraneural injection, and the needle should be immediately repositioned.

[a]. Time to Produce Effect: Local anesthetic 30 minutes; no anesthesia 24 to 48 hours.

[b]. Frequency: Weekly, suggest no more than four injection sites per session per week to avoid significant post-injection soreness.

[c]. Optimum Duration: Four Weeks.

[d]. Maximum Duration: Eight weeks. Occasional patients may require two to four repetitions of trigger point injection series over a one to two year period.

v. Prolotherapy: (also known as Sclerotherapy/Regenerative Injection Therapy) consists of peri- or intra-ligamentous injections of hypertonic dextrose with or without phenol with the goal of inducing an inflammatory response that will recruit cytokine growth factors involved in the proliferation of connective tissue. Advocates of prolotherapy propose that these injections will alleviate complaints related to joint laxity by promoting the growth of connective tissue and stabilizing the involved joint.

(a). Laboratory studies may lend some biological plausibility to claims of connective tissue growth, but high quality published clinical studies are lacking. The dependence of the therapeutic effect on the inflammatory response is poorly defined, raising concerns about the use of conventional anti-inflammatory drugs when proliferant injections are given. The evidence in support of prolotherapy is insufficient and therefore, its use is not recommended in upper extremity injuries.

vi. Viscosupplementation/Intracapsular Acid Salts: involves the injection of hyaluronic acid and its derivatives into the glenohumeral joint space. Hyaluronic acid is secreted into the joint space by the healthy synovium and has functions of lubrication and cartilage protection. Its use in the shoulder is not supported by scientific evidence at this time.

5. Jobsite Alteration. Early evaluation and training of body mechanics are essential for every injured worker. Risk factors to be addressed include repetitive overhead work, lifting and/or tool use. In some cases, this requires a jobsite evaluation. Some evidence supports alteration of the work site in the early treatment of shoulder injuries. There is no single factor or combination of factors that is proven to prevent or ameliorate shoulder pain, but a combination of ergonomic and psychosocial factors are generally considered to be important. Physical factors that may be considered include use of force, repetitive overhead work, and awkward overhead positions requiring use of force, upper extremity vibration, and contact pressure on the nerve. Psychosocial factors to be considered include pacing, degree of control over job duties, perception of job stress, and supervisory support. The job analysis and modification should include input from the employee, employer, and ergonomist or other professional familiar with work place evaluation. The employee must be observed performing all job functions in order for the jobsite analysis to be valid. Periodic follow-up is recommended to evaluate effectiveness of the intervention and need for additional ergonomic changes.

a. Ergonomic Changes may be made to modify the hazards identified. In addition, workers should be counseled to vary tasks throughout the day whenever possible. OSHA suggests that workers' who perform overhead repetitive tasks with or without force, take 15 to 30 second breaks every 10 to 20 minutes, or 5-minute breaks every hour. Mini-breaks should include stretching exercises.

b. Interventions should consider engineering controls (e.g., mechanizing the task, changing the tool used, or adjusting the jobsite), or administrative controls (e.g., adjusting the time an individual performs the task).

6. Medications for the treatment of upper extremity injuries is appropriate to control acute pain and inflammation. Use of medications will vary widely due to the spectrum of injuries from simple strains to complicated fractures. All drugs should be used according to patient needs. A thorough medication history, including use of alternative and over the counter medications, should be performed at the time of the initial visit and updated periodically. Treatment for pain control is initially accomplished with acetaminophen and/or NSAIDs. The patient should be educated regarding the interaction with prescription and over-the-counter medications as well as the contents of over-the-counter herbal products.

a. Nonsteroidal anti-inflammatory drugs (NSAIDs) and acetaminophen are useful in the treatment of injuries associated with degenerative joint disease and/or inflammation. These same medications can be used for pain control.

b. Topical agents may be beneficial for pain management in some patients with upper extremity injuries. This includes topical capsaicin, nonsteroidal, as well as, topical iontphoretics/phonophoretics, such as steroid creams and lidocaine.

c. The following are listed in alphabetical order.

i. Acetaminophen is an effective analgesic with antipyretic but not anti-inflammatory activity. Acetaminophen is generally well tolerated, causes little or no gastrointestinal irritation and is not associated with ulcer formation. Acetaminophen has been associated with liver toxicity in overdose situations or in chronic alcohol use. Patients may not realize that many over-the-counter preparations may contain acetaminophen. The total daily dose of acetaminophen is recommended not to exceed 2250

mg per 24 hour period, from all sources, including narcotic-acetaminophen combination preparations.

(a). Optimum Duration: 7 to 10 days.

(b). Maximum Duration: Chronic use as indicated on a case-by-case basis. Use of this substance long-term for three days per week or greater may be associated with rebound pain upon cessation.

ii. Minor Tranquilizer/Muscle Relaxants are appropriate for muscle spasm, mild pain and sleep disorders. When prescribing these agents, physicians must seriously consider side effects of drowsiness or dizziness and the fact that benzodiazepines may be habit-forming.

(a). Optimum Duration: Up to one week.

(b). Maximum Duration: Four weeks.

iii. Narcotics should be primarily reserved for the treatment of severe upper extremity pain. There are circumstances where prolonged use of narcotics is justified based upon specific diagnosis and in pre- and post–operative patients. In these and other cases, it should be documented and justified. In mild-to-moderate cases of upper extremity pain, narcotic medication should be used cautiously on a case-by-case basis. Adverse effects include respiratory depression, the development of physical and psychological dependence, and impaired alertness.

(a). Narcotic medications should be prescribed with strict time, quantity, and duration guidelines, and with definitive cessation parameters. Pain is subjective in nature and should be evaluated using a pain scale and assessment of function to rate effectiveness of the narcotic prescribed. Any use beyond the maximum should be documented and justified based on the diagnosis and/or invasive procedures.

(i). Optimum Duration: Up to 10 days.

(ii). Maximum Duration: Two weeks for most non-operative cases. Use beyond two weeks is acceptable in appropriate cases. Refer to Chronic Pain Guidelines which provides a detailed discussion regarding medication use in chronic pain management.

iv.. Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) are useful for pain and inflammation. In mild cases, they may be the only drugs required for analgesia. There are several classes of NSAIDs, and the response of the individual injured worker to a specific medication is unpredictable. For this reason, a range of NSAIDs may be tried in each case with the most effective preparation being continued. Patients should be closely monitored for adverse reactions. The US Food and Drug Administration advises that many NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infarction, and stroke, which can be fatal. Naproxen sodium does not appear to be associated with increased risk of vascular events. Administration of proton pump inhibitors, Histamine 2 Blockers, or prostaglandin analog misoprostol along with these NSAIDs may reduce the risk of duodenal and gastric ulceration but do not impact possible cardiovascular complications. Due to the cross-reactivity between aspirin and NSAIDs, NSAIDs should not be used in aspirin-sensitive patients, and should be used with caution in all asthma patients. NSAIDs are associated with abnormal renal function, including renal failure, as well as, abnormal liver function. Certain NSAIDs may have interactions with various other medications. Individuals may have adverse events not listed above. Intervals for metabolic screening are dependent upon the patient's age, general health status and should be within parameters listed for each specific medication. Complete Blood Count (CBC) and liver and renal function should be monitored at least every six months in patients on chronic NSAIDs and initially when indicated.

(a). Non-selective Nonsteroidal Anti-Inflammatory Drugs:

(i). Includes NSAIDs, and acetylsalicylic acid (aspirin). Serious GI toxicity, such as bleeding, perforation, and ulceration can occur at any time, with or without warning symptoms in patients treated with traditional NSAIDs. Physicians should inform patients about the signs and/or symptoms of serious gastrointestinal toxicity and what steps to take if they occur. Anaphylactoid reactions may occur in patients taking NSAIDs. NSAIDs may interfere with platelet function. Fluid retention and edema have been observed in some patients taking NSAIDs.

[a]. Optimal Duration: One week.

[b]. Maximum Duration: One year. Use of these substances long-term (Three days per week or greater) is associated with rebound pain upon cessation.

(b). Selective Cyclo-oxygenase-2 (COX-2) Inhibitors:

(i). COX-2 inhibitors are more recent NSAIDs and differ in adverse side effect profiles from the traditional NSAIDs. The major advantages of selective COX-2 inhibitors over traditional NSAIDs are that they have less gastrointestinal toxicity and no platelet effects. COX-2 inhibitors can worsen renal function in patients with renal insufficiency, thus renal function may need monitoring.

(ii). COX-2 inhibitors should not be first-line for low risk patients who will be using an NSAID short term but are indicated in select patients for whom traditional NSAIDs are not tolerated. Serious upper GI adverse events can occur even in asymptomatic patients. Patients at high risk for GI bleed include those who use alcohol, smoke, are older than 65, take corticosteroids or anti-coagulants, or have a longer duration of therapy. Celecoxib is contraindicated in sulfonamide allergic patients.

[a]. Optimal Duration: 7 to 10 days.

[b]. Maximum Duration: Chronic use is appropriate in individual cases. Use of these substances long-term (three days per week or greater) is associated with rebound pain upon cessation.

v. Oral Steroids: have limited use but are accepted in cases requiring potent anti-inflammatory drug effect in carefully selected patients. A one-week regime of steroids may be considered in the treatment of patients who have arthritic flare-ups with significant inflammation of the joint. The physician must be fully aware of potential contraindications for the use of all steroids such as avascular necrosis, hypertension, diabetes, glaucoma, peptic ulcer disease, etc., which should be discussed with the patient.

(a). Optimal Duration: Three to seven days.

(b). Maximum Duration: Seven days.

vi. Psychotropic/Anti-anxiety/Hypnotic Agents: may be useful for treatment of mild and chronic pain, dysesthesia, sleep disorders, and depression. Antidepressant medications, such as tricyclics and Selective Serotonin Reuptake inhibitors (SSRIs) and Selective serotonin norephrine reuptake inhibitors (SSNRIs), are useful for affective disorder and chronic pain management. Tricyclic

antidepressant agents, in low dose, are useful for chronic pain but have more frequent side effects.

(a). Anti-anxiety medications are best used for short-term treatment (i.e., less than six months). Accompanying sleep disorders are best treated with sedating antidepressants prior to bedtime. Frequently, combinations of the above agents are useful. As a general rule, physicians should access the patient's prior history of substance abuse or depression prior to prescribing any of these agents.

(b). Due to the habit-forming potential of the benzodiazepines and other drugs found in this class, they are not routinely recommended. Refer to the Chronic Pain Guidelines which give a detailed discussion regarding medication use in chronic pain management.

(i). Optimum Duration: One to six months.

(ii). Maximum Duration: 6 to 12 months, with monitoring.

vii.. Tramadol is useful in relief of upper extremity pain and has been shown to provide pain relief equivalent to that of commonly prescribed NSAIDs. Tramadol is an atypical opioid with norepinephrine and serotonin reuptake inhibition. It is not considered a controlled substance in the U.S. Although tramadol may cause impaired alertness it is generally well tolerated, does not cause gastrointestinal ulceration, or exacerbate hypertension or congestive heart failure. Tramadol should be used cautiously in patients who have a history of seizures or who are taking medication that may lower the seizure threshold, such as MAO inhibiters, SSRIs, and tricyclic antidepressants. This medication has physically addictive properties and withdrawal may follow abrupt discontinuation and is not recommended for patients with prior opioid addiction.

(a). Optimum Duration: Three to seven days.

(b). Maximum Duration: Two weeks. Use beyond two weeks is acceptable in appropriate cases.

viii. Topical Drug Delivery. Creams and patches may be an alternative treatment of localized musculoskeletal disorders. It is necessary that all topical agents be used with strict instructions for application as well as maximum number of applications per day to obtain the desired benefit and avoid potential toxicity. As with all medications, patient selection must be rigorous to select those patients with the highest probability of compliance.

(a). Topical Salicylates and Nonsalicylates have been shown to be effective in relieving pain in acute and chronic musculoskeletal conditions. Topical salicylate and nonsalicylates achieve tissue levels that are potentially therapeutic, at least with regard to COX inhibition. Other than local skin reactions, the side effects of therapy are minimal, although not nonexistent, and the usual contraindications to use of these compounds needs to be considered. Local skin reactions are rare and systemic effects were even less common. Their use in patients receiving warfarin therapy may result in alterations in bleeding time. Overall, the low level of systemic absorption can be advantageous; allowing the topical use of these medications when systemic administration is relatively contraindicated such as is the case in patients with hypertension, cardiac failure, or renal insufficiency.

(b). There is no evidence that topical agents are more effective than oral medications. Therefore, they should not generally be used unless the patient has an intolerance to anti-inflammatories.

(i). Optimum Duration: One week.

(ii). Maximum Duration: Two weeks per episode.

(c). Capsaicin is another medication option for topical drug use in upper extremity injury. Capsaicin offers a safe and effective alternative to systemic NSAID therapy. Although it is quite safe, effective use of capsaicin is limited by the local stinging or burning sensation that typically dissipates with regular use, usually after the first 7 to 10 days of treatment. Patients should be advised to apply the cream on the affected area with a plastic glove or cotton applicator and to avoid inadvertent contact with eyes and mucous membranes.

(i). Optimum Duration: One week.

(ii). Maximum Duration: Two weeks per episode.

(d). Other Agents. Other topical agents, including prescription drugs (i.e., lidocaine), prescription compound agents, and prescribed over-the-counter medications (i.e., blue ice), may be useful for pain and inflammation. These drugs should be used according to patient needs.

(i). Optimum Duration: Varies with drug or compound.

(ii). Maximum Duration: Varies with drug or compound.

(e). Iontophoretic Agents: Refer to Iontophoresis under Passive Therapy of this section.

7. Occupational Rehabilitation Programs

a. Non-Interdisciplinary. These generally accepted programs are work-related, outcome-focused, individualized treatment programs. Objectives of the program include, but are not limited to, improvement of cardiopulmonary and neuromusculoskeletal functions (strength, endurance, movement, flexibility, stability, and motor control functions), patient education, and symptom relief. The goal is for patients to gain full or optimal function and return to work. The service may include the time-limited use of passive modalities with progression to achieve treatment and/or simulated/real work. These programs are frequently necessary for patients who must return to physically demanding job duties or whose injury requires prolonged rehabilitation and therapy spanning several months.

i. Work Conditioning. These programs are usually initiated once reconditioning has been completed, but may be offered at any time throughout the recovery phase. It should be initiated when imminent return of a patient to modified or full duty is not an option, but the prognosis for returning the patient to work at completion of the program is at least fair to good.

(a). Length of visit: One to two hours per day.

(b). Frequency: Two to five visits per week.

(c). Optimum Duration: Two to five weeks.

(d). Maximum Duration: Six weeks. Participation in a program beyond six weeks must be documented with respect to need and the ability to facilitate positive symptomatic or functional gains.

ii. Work Simulation. Work Simulation is a program where an individual completes specific work-related tasks for a particular job and return to work. Use of this program is appropriate when modified duty can only be

partially accommodated in the work place, when modified duty in the work place is unavailable, or when the patient requires more structured supervision. The need for work place simulation should be based upon the results of a Functional Capacity Evaluation and/or Jobsite Analysis.

(a). Length of visit: Two to six hours per day.

(b). Frequency: Two to five visits per week.

(c). Optimum Duration: Two to four weeks.

(d). Maximum Duration. Six weeks. Participation in a program beyond six weeks must be documented with respect to need and the ability to facilitate positive symptomatic or functional gains.

b. Interdisciplinary. These generally accepted programs are characterized by a variety of disciplines that participate in the assessment, planning, and/or implementation of an injured workers program with the goal for patients to gain full or optimal function and return to work. There should be close interaction and integration among the disciplines to ensure that all members of the team interact to achieve team goals. These programs are for patients with greater levels of perceived disability, dysfunction, de-conditioning and psychological involvement. For patients with chronic pain, refer to the OWCA's Chronic Pain Disorder Medical Treatment Guidelines.

i Work Hardening. Work Hardening is an interdisciplinary program addressing a patient's employability and return to work. It includes a progressive increase in the number of hours per day that a patient completes work simulation tasks until the patient can tolerate a full workday. This is accomplished by addressing the medical, psychological, behavioral, physical, functional, and vocational components of employability and return-to-work.

ii. This can include a highly structured program involving a team approach or can involve any of the components thereof. The interdisciplinary team should, at a minimum, be comprised of a qualified medical director who is board certified with documented training in occupational rehabilitation; team physicians having experience in occupational rehabilitation, occupational therapist; physical therapist; case manager; and psychologist. As appropriate, the team may also include: chiropractor, RN, or vocational specialist or Certified Biofeedback Therapist.

(a). Length of visit: Up to eight hours/day.

(b). Frequency: Two to five visits per week.

(c). Optimum Duration: Two to four weeks.

(d). Maximum Duration. Six weeks. Participation in a program beyond six weeks must be documented with respect to need and the ability to facilitate positive symptomatic or functional gains.

8. Orthotics and Prosthetics

a. Fabrication/Modification of Orthotics facilitate better motion response, stabilize a joint with insufficient muscle or proprioceptive/reflex competencies, to protect subacute conditions as needed during movement, and correct biomechanical problems. For specific types of orthotics/prosthetics, refer to Specific Diagnosis, Testing and Treatment Procedures.

i. Time to Produce Effect: One to three sessions (includes wearing schedule evaluation).

ii. Frequency: One to two times per week.

iii. Optimum/Maximum Duration: Four sessions of evaluation, casting, fitting, and re-evaluation.

b. Orthotic/Prosthetic Training is the skilled instruction (preferably by qualified providers) in the proper use of orthotic devices and/or prosthetic limbs including stump preparation, donning and doffing limbs, instruction in wearing schedule and orthotic/prosthetic maintenance training. Training can include activities of daily living and self-care techniques.

i. Time to Produce Effect: Two to six sessions.

ii. Frequency: Three times per week.

iii. Optimum/Maximum Duration: Two to four months.

c. Splints or adaptive equipment design, fabrication and/or modification indications include the need to control neurological and orthopedic injuries for reduced stress during functional activities and modify tasks through instruction in the use of a device or physical modification of a device, which reduces stress on the injury. Equipment should improve safety and reduce risk of re-injury. This includes high and low technology assistive options such as workplace modifications, computer interface or seating, and self-care aids.

i. Time to Produce Effect: Immediate.

ii. Frequency: One to three sessions or as indicated to establish independent use.

iii. Optimum/Maximum Duration: One to three sessions.

9. Patient Education. No treatment plan is complete without addressing issues of individual and/or group patient education as a means of prolonging the beneficial effects of treatment, as well as facilitating self-management of symptoms and injury prevention. The patient should be encouraged to take an active role in the establishment of functional outcome goals. They should be educated on their specific injury, assessment findings, and plan of treatment. Instruction on proper body mechanics and posture, positions to avoid, self-care for exacerbation of symptoms, and home exercise should also be addressed.

a. Time to Produce Effect: Varies with individual patient.

b. Frequency: Should occur at each visit.

10. Personality/Psychosocial/Psychiatric/Psychological Intervention. Psychosocial treatment is generally accepted widely used and well-established intervention. This group of therapeutic and diagnostic modalities includes, but is not limited to, individual counseling, group therapy, stress management, psychosocial crises intervention, hypnosis and meditation. Any evaluation or diagnostic workup should clarify and distinguish between pre-existing versus aggravated versus purely causative psychological conditions. Psychosocial intervention is recommended as an important component in the total management program that should be implemented as soon as the problem is identified. This can be used alone or in conjunction with other treatment modalities. Providers treating patients with chronic pain should refer to the OWCA's Chronic Pain Disorder Medical Treatment Guidelines.

a. Time to Produce Effect: Two to four weeks.

b. Frequency: One to three times weekly for the first four weeks (excluding hospitalization, if required),

decreasing to one to two times per week for the second month. Thereafter, two to four times monthly.

c. Optimum Duration: Six weeks to three months.

d. Maximum Duration. 3 to 12 months. Counseling is not intended to delay but to enhance functional recovery. For select patients, longer supervised treatment may be required, and if further counseling beyond 3 months is indicated, extensive documentation addressing which pertinent issues are pre-existing versus aggravated versus causative, as well as projecting a realistic functional prognosis, should be provided by the authorized treating provider every 4 to 6 weeks during treatment.

11. Restriction of Activities varies according to the specific diagnosis and the severity of the condition. Job modification/modified duty are frequently required to avoid exacerbation of the injured shoulder. Complete work cessation should be avoided, if possible, since it often further aggravates the pain presentation. Modified return-to-work is almost always more efficacious and rarely contraindicated in the vast majority of injured workers with upper extremity injuries.

12. Return-to-work. Early return-to-work should be a prime goal in treating occupational injuries given the poor return-to-work prognosis for an injured worker who has been out of work for more than six months. It is imperative that the patient be educated regarding the benefits of return-to-work, work restrictions, and follow-up if problems arise. When attempting to return a patient to work after a specific injury, clear objective restrictions of activity level should be made. An accurate job description with detailed physical duty restrictions is often necessary to assist the physician in making return-to-work recommendations. This may require a jobsite evaluation.

a. Employers should be prepared to offer transitional work. This may consist of temporary work in a less demanding position, return to the regular job with restrictions, or gradual return to the regular job. Company policies which encourage return-to-work with positive communication are most likely to have decreased worker disability.

b. Return-to-work is defined as any work or duty that the patient is able to perform safely. It may not be the patient's regular work. Due to the large spectrum of injuries of varying severity and varying physical demands in the work place, it is not possible to make specific return-to-work guidelines for each injury. Therefore, the OWCA recommends the following:

i. Establishment of a Return-to-Work Status. Ascertaining a return-to-work status is part of medical care, should be included in the treatment and rehabilitation plan, and addressed at every visit. A description of daily activity limitations is part of any treatment plan and should be the basis for restriction of work activities. In most non-surgical cases the patient should be able to return to work in some capacity or in an alternate position consistent with medical treatment within several days unless there are extenuating circumstances. Injuries requiring more than two weeks off work should be thoroughly documented. Refer to Specific Diagnoses in Post-operative Return to Work Subsections.

ii. Establishment of Activity Level Restrictions. Communication is essential between the patient, employer and provider to determine appropriate restrictions and return-to-work dates. It is the responsibility of the physician to provide clear, concise restrictions, and it is the employer's responsibility to determine if temporary duties can be provided within the restrictions. For shoulder injuries, the following should be addressed when describing the patient's activity level:

(a). Activities such as overhead motion, lifting, abduction;

(b). Static shoulder positions with regard to duration and frequency;

(c). Use of adaptive devices or equipment for proper ergonomics and to enhance capacities;

(d). Maximum lifting limits with reference to the frequency of the lifting and/or the object height level; and

(e). Maximum limits for pushing, pulling, with limits on bending and twisting at the waist as necessary.

iii. Compliance with Activity Restrictions. In some cases, compliance with restriction of activity levels may require a complete jobsite evaluation, a functional capacity evaluation (FCE), or other special testing. Refer to "Special Tests" of this section.

13. Therapy-Active

a. The following active therapies are widely used and accepted methods of care for a variety of work-related injuries. They are based on the philosophy that therapeutic exercise and/or activity are beneficial for restoring flexibility, strength, endurance, function, range of motion, and can alleviate discomfort. Active therapy requires an internal effort by the individual to complete a specific exercise or task. This form of therapy requires supervision from a therapist or medical provider such as verbal, visual and/or tactile instruction(s). At times, the provider may help stabilize the patient or guide the movement pattern but the energy required to complete the task is predominately executed by the patient.

b. Patients should be instructed to continue active therapies at home as an extension of the treatment process in order to maintain improvement levels. Follow-up visits to reinforce and monitor progress and proper technique are recommended. Home exercise can include exercise with or without mechanical assistance or resistance and functional activities with assistive devices. Frequency times and duration of treatment apply only to diagnoses not previously covered in Section E.

i. Activities of Daily Living (ADL) are well-established interventions which involve instruction, active-assisted training, and/or adaptation of activities or equipment to improve a person's capacity in normal daily activities such as self-care, work re-integration training, homemaking, and driving.

(a). Time to Produce Effect: Four to five treatments.

(b). Frequency: Three to five times per week.

(c). Optimum Duration: Four to six weeks.

(d). Maximum Duration: Six weeks.

ii. Aquatic Therapy is a well-accepted treatment which consists of the therapeutic use of aquatic immersion for therapeutic exercise to promote ROM, flexibility, strengthening, core stabilization, endurance, body mechanics, and pain management. Aquatic therapy includes the implementation of active therapeutic procedures in a swimming or therapeutic pool. The water provides a

buoyancy force that lessens the amount of force gravity applies to the body. The decreased gravity effect allows the patient to have a mechanical advantage and more likely to have a successful trial of therapeutic exercise. Literature has shown that the muscle recruitment for aquatic therapy versus similar non–aquatic motions is significantly less. Because there is always a risk of recurrent or additional damage to the muscle tendon unit after a surgical repair, aquatic therapy may be preferred by surgeons to gain early return of ROM. In some cases the patient will be able to do the exercises unsupervised after the initial supervised session. Parks and recreation contacts may be used to locate less expensive facilities for patients. Indications include:

(a). Postoperative therapy as ordered by the surgeon;

(b). Intolerance for active land-based or full-weight bearing therapeutic procedures;

(c). Symptoms that are exacerbated in a dry environment; and/or

(d). Willingness to follow through with the therapy on a regular basis.

iii. The pool should be large enough to allow full extremity ROM and fully erect posture. Aquatic vests, belts, snorkels, and other devices may be used to provide stability, balance, buoyancy, and resistance.

(a). Time to Produce Effect: Four to five treatments.

(b). Frequency: Three to five times per week.

(c). Optimum Duration: Four to six weeks.

(d). Maximum Duration: Eight weeks.

iv. A self-directed program is recommended after the supervised aquatics program has been established, or, alternatively a transition to a self-directed dry environment exercise program.

v. Functional Activities are well-established interventions which involve the use of therapeutic activity to enhance mobility, body mechanics, employability, coordination, balance, and sensory motor integration.

(a). Time to Produce Effect: Four to five treatments.

(b). Frequency: Three to five times per week.

(c). Optimum Duration: Four to six weeks.

(d). Maximum Duration: Six weeks.

vi. Functional Electrical Stimulation is an accepted treatment in which the application of electrical current to elicit involuntary or assisted contractions of atrophied and/or impaired muscles. Indications include muscle atrophy, weakness, and sluggish muscle contraction secondary to pain, injury, neuromuscular dysfunction or peripheral nerve lesion. Indications also may include an individual who is precluded from active therapy.

(a). Time to Produce Effect: Two to six treatments.

(b). Frequency: Three times per week.

(c). Optimum Duration: Eight weeks.

(d). Maximum Duration: Eight weeks. If functional gains are documented by a therapist, a home unit may be provided.

vii. Neuromuscular Re-education is a generally accepted treatment. It is the skilled application of exercise with manual, mechanical, or electrical facilitation to enhance strength; movement patterns; neuromuscular response; proprioception; kinesthetic sense; coordination; education of movement, balance and posture. Indications include the need to promote neuromuscular responses through carefully timed proprioceptive stimuli, to elicit and improve motor activity in patterns similar to normal neurologically developed sequences, and to improve neuromotor response with independent control.

(a). Time to Produce Effect: Two to six treatments.

(b). Frequency: Three times per week.

(c). Optimum Duration: Four to eight weeks.

(d). Maximum Duration: Eight weeks.

viii. Therapeutic Exercise is a generally well-accepted treatment. Therapeutic exercise, with or without mechanical assistance or resistance, may include isoinertial, isotonic, isometric and isokinetic types of exercises. The exact type of program and length of therapy should be determined by the treating physician with the physical or occupational therapist. Refer to Specific Diagnosis, Testing and Treatment Procedures regarding specific diagnoses for details. In most cases, the therapist instructs the patient in a supervised clinic and home program to increase motion and subsequently increase strength. Usually, isometrics are performed initially, progressing to isotonic exercises as tolerated.

(a). Time to Produce Effect: Two to six treatments.

(b). Frequency: Two to three times per week.

(c). Optimum Duration: 16 to 24 sessions.

(d). Maximum Duration. 36 sessions. Additional visits may be necessary in cases of re-injury, interrupted continuity of care, exacerbation of symptoms, and in those patients with co-morbidities. Functional gains including increased ROM must be demonstrated to justify continuing treatment.

14. Therapy-Passive. Most of the following passive therapies and modalities are generally accepted methods of care for a variety of work-related injuries. Passive therapy includes those treatment modalities that do not require energy expenditure on the part of the patient. They are principally effective during the early phases of treatment and are directed at controlling symptoms such as pain, inflammation and swelling and to improve the rate of healing soft tissue injuries. They should be used adjunctively with active therapies to help control swelling, pain, and inflammation during the rehabilitation process. They may be used intermittently as a therapist deems appropriate or regularly if there are specific goals with objectively measured functional improvements during treatment.

a. On occasion, specific diagnoses and post-surgical conditions may warrant durations of treatment beyond those listed as "maximum." Factors such as exacerbation of symptoms, re-injury, interrupted continuity of care, and comorbidities may also extend durations of care. Specific goals with objectively measured functional improvement during treatment must be cited to justify extended durations of care. It is recommended that, if no functional gain is observed after the number of treatments under "time to produce effect" have been completed, alternative treatment interventions, further diagnostic studies, or further consultations should be pursued.

b. The following passive therapies and modalities are listed in alphabetical order.

i. Continuous Passive Movement (CPM): Refer to Rotator Cuff Tear.

ii. Electrical Stimulation (Unattended is an accepted treatment. Unattended electrical stimulation once applied, requires minimal on-site supervision by the physician or non-physician provider. Indications include pain, inflammation, muscle spasm, atrophy, decreased circulation, and the need for osteogenic stimulation.

(a). Time to Produce Effect: Two to four treatments.

(b). Frequency. Varies. Depending upon indication, between two to three times per day to one time a week. Provide home unit if frequent use.

(c). Optimum Duration: One to three months.

(d). Maximum Duration: Three months.

iii. Hyperbaric Oxygen Therapy. There is no evidence to support long-term benefit of hyperbaric oxygen therapy for non-union upper extremity fractures. It is not recommended.

iv. Immobilization: Time is dependent upon type of injury.

(a). Time to Produce Effect: One day.

(b). Frequency: Once.

(c). Optimum Duration: One week.

(d). Maximum Duration: 12 weeks.

(e). The arm may be immobilized in a sling for 1 to 12 weeks post-injury, depending upon the age of the patient and diagnosis. The patient is instructed in isometric exercises while in the sling for the internal and external rotators and the deltoid.

v. Iontophoresis is an accepted treatment which consists of the transfer of medication, including, but not limited to, steroidal anti-inflammatory and anesthetics, through the use of electrical stimulation. Indications include pain (Lidocaine), inflammation (hydrocortisone, salicylate), edema (mecholyl, hyaluronidase, salicylate), ischemia (magnesium, mecholyl, iodine), muscle spasm (magnesium, calcium), calcifying deposits (acetate), scars, and keloids (chlorine, iodine, acetate).

(a). Time to Produce Effect: One to four treatments.

(b). Frequency: 3 times per week with at least 48 hours between treatments.

(c). Optimum Duration: 8 to 10 treatments.

(d). Maximum Duration: 10 treatments.

vi. Manipulation is a generally accepted, well-established and widely used therapeutic intervention for shoulder injuries. Manipulative treatment (not therapy) is defined as the therapeutic application of manually guided forces by an operator to improve physiologic function and/or support homeostasis that has been altered by the injury or occupational disease, and has associated clinical significance.

(a). High velocity, low amplitude (HVLA) technique, chiropractic manipulation, osteopathic manipulation, muscle energy techniques, counter strain, and non-force techniques are all types of manipulative treatment. This may be applied by osteopathic physicians (D.O.), chiropractors (D.C.), properly trained physical therapists (P.T.), properly trained occupational therapists (O.T.), or properly trained medical physicians. Under these different types of manipulation exist many subsets of different techniques that can be described as direct- a forceful engagement of a restrictive/pathologic barrier, indirect- a gentle/non-forceful disengagement of a restrictive/pathologic barrier, the patient actively assists in the treatment and the patient relaxing, allowing the practitioner to move the body tissues. When the proper diagnosis is made and coupled with the appropriate technique, manipulation has no contraindications and can be applied to all tissues of the body. Pre-treatment assessment should be performed as part of each manipulative treatment visit to ensure that the correct diagnosis and correct treatment is employed.

(i). Time to Produce Effect for all types of manipulative treatment: One to six treatments.

(ii). Frequency: Up to three times per week for the first three weeks as indicated by the severity of involvement and the desired effect.

(iii). Optimum Duration: 10 treatments.

(iv). Maximum Duration. 12 treatments. Additional visits may be necessary in cases of re-injury, interrupted continuity of care, exacerbation of symptoms, and in those patients with co-morbidities. Functional gains including increased ROM must be demonstrated to justify continuing treatment.

vii. Manual Electrical Stimulation is used for peripheral nerve injuries or pain reduction that requires continuous application, supervision, or involves extensive teaching. Indications include muscle spasm (including TENS), atrophy, decreased circulation, osteogenic stimulation, inflammation, and the need to facilitate muscle hypertrophy, muscle strengthening, muscle responsiveness in Spinal Cord Injury/Brain Injury (SCI/BI), and peripheral neuropathies.

(a). Time to Produce Effect: Variable, depending upon use.

(b). Frequency: Three to seven times per week.

(c). Optimum Duration: Eight weeks.

(d). Maximum Duration: Two months.

viii. Massage—Manual or Mechanical. Massage is manipulation of soft tissue with broad ranging relaxation and circulatory benefits. This may include stimulation of acupuncture points and acupuncture channels (acupressure), application of suction cups and techniques that include pressing, lifting, rubbing, pinching of soft tissues by, or with, the practitioner's hands. Indications include edema (peripheral or hard and non-pliable edema), muscle spasm, adhesions, the need to improve peripheral circulation and ROM, or to increase muscle relaxation and flexibility prior to exercise. In cases with edema, deep vein thrombosis should be ruled out prior to treatment.

(a). Time to Produce Effect: Immediate.

(b). Frequency: One to two times per week.

(c). Optimum Duration: Six weeks.

(d). Maximum Duration: Two months.

ix. Mobilization (Joint) is a generally well-accepted treatment. Mobilization is passive movement which may include passive ROM performed in such a manner (particularly in relation to the speed of the movement) that it is, at all times, within the ability of the patient to prevent the movement if they so choose. It may include skilled manual

joint tissue stretching. Indications include the need to improve joint play, improve intracapsular arthrokinematics, or reduce pain associated with tissue impingement/maltraction.

(a). Time to Produce Effect: Six to nine treatments.

(b). Frequency: Three times per week.

(c). Optimum Duration: Six weeks.

(d). Maximum Duration: Two months.

x. Mobilization (Soft Tissue) is a generally well-accepted treatment. Mobilization of soft tissue is the skilled application of muscle energy, strain/counter strain, myofascial release, manual trigger point release and manual therapy techniques designed to improve or normalize movement patterns through the reduction of soft tissue pain and restrictions. These can be interactive with the patient participating or can be with the patient relaxing and letting the practitioner move the body tissues. Indications include muscle spasm around a joint, trigger points, adhesions, and neural compression. Mobilization should be accompanied by active therapy.

(a). Time to Produce Effect: Two to three weeks.

(b). Frequency: Two to three times per week.

(c). Optimum Duration: Four to six weeks.

(d). Maximum Duration: Six weeks.

xi. Superficial Heat and Cold Therapy is a generally accepted treatment. Superficial heat and cold therapies are thermal agents applied in various manners that lower or raise the body tissue temperature for the reduction of pain, inflammation, and/or effusion resulting from injury or induced by exercise. It may be used acutely with compression and elevation. Indications include acute pain, edema and hemorrhage, need to increase pain threshold, reduce muscle spasm and promote stretching/flexibility. Includes portable cryotherapy units, and application of heat just above the surface of the skin at acupuncture points.

(a). Time to Produce Effect: Immediate.

(b). Frequency: Two to five times per week.

(c). Optimum Duration: Three weeks as primary, or up to two months if used intermittently as an adjunct to other therapeutic procedures.

(d). Maximum Duration: Two months.

xii. Transcutaneous Electrical Nerve Stimulation (TENS) is a generally accepted treatment. TENS should include at least one instructional session for proper application and use. Indications include muscle spasm, atrophy, and decreased circulation and pain control. Minimal TENS unit parameters should include pulse rate, pulse width and amplitude modulation. Consistent, measurable functional improvement must be documented prior to the purchase of a home unit.

(a). Time to Produce Effect: Immediate.

(b). Frequency: Variable.

(c). Optimum Duration: Three sessions.

(d). Maximum Duration: Three sessions. If beneficial, provide with home unit or purchase if effective.

xiii.. Ultrasound (including Phonophoresis) is an accepted treatment. Ultrasound includes ultrasound with electrical stimulation and phonophoresis. Ultrasound uses sonic generators to deliver acoustic energy for therapeutic thermal and/or non-thermal soft tissue effects. Indications include scar tissue, adhesions, collagen fiber and muscle spasm, and the need to extend muscle tissue or accelerate the soft tissue healing.

(a). Ultrasound with electrical stimulation is concurrent delivery of electrical energy that involves a dispersive electrode placement. Indications include muscle spasm, scar tissue, and pain modulation and muscle facilitation.

(b). Phonophoresis is the transfer of medication to the target tissue to control inflammation and pain through the use of sonic generators. These topical medications include, but are not limited to, steroidal anti-inflammatory and anesthetics.

(i). Time to Produce Effect: 6 to 15 treatments.

(ii). Frequency: Three times per week.

(iii). Optimum Duration: Four to eight weeks.

(iv). Maximum Duration: Two months.

15. Vocational Rehabilitation is a generally accepted intervention. Initiation of vocational rehabilitation requires adequate evaluation of patients for quantification of highest functional level, motivation and achievement of maximum medical improvement. Vocational rehabilitation may be as simple as returning to the original job or as complicated as being retrained for a new occupation.

a. It may also be beneficial for full vocational rehabilitation to be started before MMI if it is evident that the injured worker will be unable to return to his/her previous occupation. A positive goal and direction may aid the patient in decreasing stress and depression, and promote optimum rehabilitation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1850 (June 2011).

§2327. Therapeutic Procedures—Operative

A. All operative interventions must be based upon positive correlation of clinical findings, clinical course and diagnostic tests. A comprehensive assimilation of these factors must lead to a specific diagnosis with positive identification of pathologic condition(s). It is imperative to rule out non-physiologic modifiers of pain presentation or non-operative conditions mimicking operative conditions (e.g., peripheral neuropathy, myofascial pain, scleratogenous or sympathetically mediated pain syndromes, psychological), prior to consideration of elective surgical intervention.

B. In addition, operative treatment is indicated when the natural history of surgically treated lesions is better than the natural history for non-operatively treated lesions. All patients being considered for surgical intervention should first undergo a comprehensive neuro-musculoskeletal examination to identify mechanical pain generators that may respond to non-surgical techniques or may be refractory to surgical intervention.

C. Structured rehabilitation interventions should be strongly considered post-operative in any patient not making expected functional progress within three weeks post-operative.

D. Post-operative therapy will frequently require a repeat of the therapy provided pre-operatively. Refer to Therapeutic Procedures, Non-operative, and consider the first post-

operative visit as visit number one, for the time frame parameters provided.

E. Return-to-work restrictions should be specific according to the recommendation in Therapeutic Procedures—Non-Operative.

1. Shoulder Replacement (Arthroplasty)

a. Description/Definition. Prosthetic replacement of the articulating surfaces of the shoulder joint. There are three types of procedures commonly performed. The total shoulder component in which the glenoid and humeral head are replaced anatomically. The hemiarthroplasty which involves replacement of the humeral head only. The reverse arthroplasty where the head of the humerus is replaced by a prosthesis forming a socket and the glenoid is replaced with a ball prosthesis.

b. Occupational Relationship. Usually from post-traumatic arthritis, or from trauma resulting in severe humeral head fractures.

c. Specific Physical Exam Findings. Stiff, painful shoulder with limited function.

d. Diagnostic Testing Procedures: Radiographs or CTs demonstrating humeral head fracture. CTs or diagnostic arthroscopy to explore the status of rotator cuff and associated muscles and tendons, the presence of arthritis or subluxation, or superior migration of the humeral head. For revision procedures, a non-MRI arthrography or sonogram may be important to better visualize associated pathology.

e. Surgical Indications. The decision of whether a patient receives a total arthroplasty or a hemiarthroplasty depends on the surgeon's discretion. Factors to consider are the presence of glenoid erosions, humeral head subluxation and rotator cuff strength. There is good evidence that total arthroplasties compared to hemi-arthroplasties results in improved function in primary osteoarthritis of the shoulder, and relief of pain two years post-operatively. Longer-term results are unknown.

i. Hemiarthroplasty may utilize a long stem humeral head replacement or a resurfacing device. It may also be performed for humeral head fractures. It has been used for severe arthritis unresponsive to other treatments; however, there is some evidence that total shoulder arthroplasty may yield a better functional outcome. In younger active patients the eventual wear on the glenoid cartilage may cause decreased function over time. Total arthroplasty may therefore be preferred in many cases. Partial humeral head prosthesis may be useful in some cases. Cementless surface humeral head replacement may be indicated in young patients with glenohumeral arthritis and retained glenoid cartilage.

ii. Total shoulder arthroplasty is usually performed in cases of severe arthritis when all reasonable conservative measures have been exhausted without sufficient return to activities of daily living. Arthroscopic surgery may be considered in selected patients with a milder degree of arthritis. Arthroscopic SLAP repair is usually not recommended in cases of severe arthritis. The rotator cuff should generally be intact or repairable.

iii. Reverse arthroplasty is generally considered a salvage procedure for patients over 70 with severe osteoarthritis, massive rotator cuff tears and pseudo paralysis with integrity of the deltoid. Complications rates may be in the vicinity of 10 percent of patients within the first year following surgery. The long-term success of the prosthesis is not known at this time.

iv. Reverse prosthesis may also be the treatment for failed hemiarthroplasty with extensive cuff tears and/or instability. Most literature confirms that the complication rate is higher and the success rate lower when reverse arthroplasty is performed on a previously operated joint, however, many patients demonstrate good improvement with elevation, but not necessarily rotation. Bone loss may increase the complication rate.

v. Procedural complications may include humeral head subluxation or dislocation, humeral and/or glenoid loosening, rotator cuff tear, fractures, stiffness, painful glenoid erosion, transient nerve palsies, heterotopic ossification, bone loss, and component mal-positioning.

vi. Revision surgery may be performed by an orthopedic surgeon in cases with chronic pain and stiffness, painful glenoid erosion, or difficulty with activities of daily living. Prior authorization is required and a second opinion by a surgeon with special expertise in shoulder surgery should usually be performed. In the case of a total failure of the prosthesis, arthrodesis is the salvage procedure.

f. Operative Treatment: Prosthetic replacement of the articular surfaces of the shoulder.

g. Post-operative Treatment:

i. Individualized rehabilitation program based on communication between the surgeon and the therapist. Timing of passive motion and active rehabilitation is dependent on the type of procedures performed.

(a). Pool exercise initially under therapists or surgeon's direction then progressed to independent pool program.

(b). Progression to a home exercise is essential. Therapy should continue for at least 10 weeks with transition to home exercises at the beginning of each new phase of therapy.

(c). Gradual resistive exercise from 3 to 12 months, with gradual return to full activity at 6 to 12 months.

(i). Time frames for therapy (excluding pool therapy).

(ii). Optimum: 12 to 24 sessions.

(iii). Maximum: 36 sessions. If functional gains are being achieved additional visits may be authorized for the patient to achieve their functional goal.

ii. Reverse arthroplasty patients may have a more rapid rehabilitation in some cases. Per the recommendation of the surgeon the following therapies may take place: Sling use for the first three weeks, ADLs at three to six weeks, and then gentle strengthening.

iii. Should progress plateau the provider should reevaluate the patient's condition and make appropriate adjustments to the treatment plan. Other therapies may be employed in individual cases.

iv. Gradual return to full activity can occur between 6 to 12 months, depending on the procedure.

v. Return to work and restrictions after surgery may be made by an experienced primary occupational medicine physician in consultation with the surgeon or by the surgeon.

2. Oats Procedure Osteoarticular allograft transplantation is a procedure which places a plug of cadaveric bone tissue into a chondral defect at the articular

surface of an injured bone. Its use has been described in case reports in the treatment of recurrent shoulder instability when large humeral head defects (Hill-Sachs lesions) are thought to be responsible for repeated episodes of subluxation. At this time, there is limited information concerning its effectiveness and appropriate application. For this reason, it requires prior authorization as an isolated procedure with a second opinion by a surgeon with special expertise in shoulder surgery. The procedure may be used for isolated chondral/bony deficits involving the humeral head, including avascular necrosis. Partial humeral head prosthesis may be useful in some cases. (Refer to Hemi-arthroplasty)

3. Arthrodesis

a. Description/Definition:

i. Fusion of the shoulder. Used as a salvage procedure.

b. Occupational Relationship:

i. Secondary to severe trauma and failure of other procedures.

c. Specific Physical Exam Findings:

i. Shoulder function is minimal and is usually associated with severe rotator cuff pathology.

d. Diagnostic Testing Procedures:

i. See Specific Diagnostic sections.

e. Surgical Indications:

i. Inability to perform activities of daily living, failed previous procedures.

f. Operative Treatment:

i. Fusion.

g. Post-operative Treatment. An individualized rehabilitation program based upon communication between the surgeon and the therapist. Therapy may begin 6 weeks to 3 months depending on recovery. Occupational therapy is critical to improve function in activities of daily living. Assistive devices may be necessary.

i. Time frames for therapy (excluding pool therapy).

ii. Optimum: 12 to 24 sessions.

iii. Maximum: 36 sessions. If functional gains are being achieved additional visits may be authorized for the patient to achieve their functional goal.

4. Manipulation Under Anesthesia (Refer to Adhesive Capsulitis/Frozen Shoulder Disorder)

5. Hardware Removal

a. Description/Definition:

i. Surgical removal of internal or external fixation device, commonly related to fracture repairs.

b. Occupational Relationship:

i. Following healing of a post-traumatic injury that required fixation or reconstruction using instrumentation.

c. Specific Physical Exam Findings:

i. Local pain to palpation, swelling, erythema.

d. Diagnostic Testing Procedures:

i. Radiographs, tomography, CT scan, MRI.

e. Non-operative Treatment:

i. Active and/or passive therapy for local modalities, activity modification. Nonsteroidal Anti-Inflammatory Drugs (NSAIDs).

f. Surgical Indications:

i. Persistent local pain, irritation around hardware.

g. Operative Treatment:

i. Removal of instrumentation may be accompanied by scar release/resection, capsular release, and/or manipulation. Some instrumentation may be removed in the course of standard treatment without local irritation.

h. Post-operative Treatment:

i. Include an individualized rehabilitation program based upon communication between the surgeon and the therapist.

ii. Early rehabilitation interventions are recommended to maintain range-of-motion and progressive strengthening.

(a). Frequency – Three to five times per week for the first two weeks, three times per week for the following two weeks, then one to two times per week.

(b). Optimum Duration for six to eight weeks with progression to home exercise and or pool therapy.

(c). Maximum Duration – 12 weeks. Occasional follow-up visits may be justified to reinforce exercise patterns, or to reach final functional goals if the therapy to date has demonstrated objective functional gains.

(d). Return to work and restrictions after surgery may be made by an experienced primary occupational medicine physician in consultation with the surgeon or by the surgeon.

5. Human Bone Morphogenetic Protein (RhBMP) is a member of a family of proteins which are involved in the growth, remodeling, and regeneration of bone tissue. It has become available as a recombinant biomaterial with osteo-inductive potential for application in long bone fracture non-union and other situations in which the promotion of bone formation is desired. In the treatment of non-union of fractures of the humerus and clavicle, no controlled clinical trials have been conducted as of this date, though small case series have resulted in union of some fractures. Ectopic ossification into adjacent muscle has been reported to restrict motion in periarticular fractures. Due to lack of information on the incidence of complications and overall success rate, its use requires prior authorization. It should be used principally for non-union of fractures that have not healed with conventional surgical management or peri-prosthetic fractures.

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1860 (June 2011).

§2328. LWC-WC 1009. Disputed Claim for Medical Treatment

Mail to:
OWCA—Medical Services
ATTN: Medical Director
P.O. Box 94040
Baton Rouge, LA 70804

1. Social Security No. __-__-__
2. Date of Injury/Illness __-__-__
3. Parts of Body Injury_____
4. Date of Birth __-__-__
5. Date of This Request __-__-__
6. Claim Number _____

DISPUTED CLAIM FOR MEDICAL TREATMENT

NOTE: THIS REQUEST WILL NOT BE HONORED UNLESS THE INSURER HAS ISSUED A DENIAL FOR THE MEDICAL SERVICES IN DISPUTE AS PER R.S. 23:1203.1 J.

GENERAL INFORMATION
Claimant files this dispute with the Office of Workers' Compensation – Medical Services Director. This office must be notified immediately in writing of changes in address. An employee may be represented by an attorney, but it is not required.

7. This request is submitted by
___ Employee ___ Employer __ Insurer ___ Health Care Provider ___ Other ___

A. Copies of all relevant medical records must be included with this request.

B. A copy of the denial letter issued by the insurance carrier must be attached to this request.

EMPLOYEE
8. Name _____
Street or Box _____
City _____
State _____ Zip _____
Phone (____) _____

EMPLOYEE'S ATTORNEY
9. Name _____
Street or Box _____
City _____
State _____
Phone (____) _____
Fax (____) _____

EMPLOYER

10. Name _____
Street or Box _____
City _____
State _____ Zip _____
Phone (____) _____
Fax (____) _____

INSURER/ADMINISTRATOR
(circle one)
11. Name _____
Street or Box _____
City _____
State _____
Phone (____) _____
Fax (____) _____

EMPLOYER/INSURER'S ATTORNEY
12. Name _____
Street or Box _____
City _____
State _____ Zip _____
Phone (____) _____
Fax (____) _____

TREATING/REQUESTING PHYSICIAN
13. Name _____
Street or Box _____
City _____
State _____
Phone (____) _____
Fax (____) _____

LWC-WC 1009
11/2010

14. PLEASE PROVIDE A SUMMARY OF THE DETAILS REGARDING THE ISSUE AT DISPUTE:
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

You may attach a letter or petition with additional information with this disputed claim.
The information given above is true and correct to the best of my knowledge and belief.

_____ _____
SIGNATURE OF REQUESTING PARTY DATE

LWC-WC 1009
11/2010

AUTHORITY NOTE: Promulgated in accordance with R.S. 23:1203.1.

HISTORICAL NOTE: Promulgated by the Louisiana Workforce Commission, Office of Workers Compensation Administration, LR 37:1862 (June 2011).

Curt Eysink
Executive Director

1106#028

Notices of Intent

NOTICE OF INTENT

Board of Elementary and Secondary Education

Bulletin 111—The Louisiana School, District, and State Accountability System (LAC 28:LXXXIII.2401 and 2403)

In accordance with R.S. 49:950 et seq., the Administrative Procedure Act, notice is hereby given that the Board of Elementary and Secondary Education approved for advertisement revisions to *Bulletin 111—The Louisiana School, District, and State Accountability System*: §2401. Eligibility for Transfer to the Recovery School District and §2403. Transfer of Schools out of the Recovery School District. Proposed changes in Bulletin 111, Chapter 24, provide detail for governing the transfer of schools that have been under the jurisdiction of the Recovery School District for five years. The process will begin this fall with those schools meeting the Performance requirement earning the right to return to their former Louisiana Education Authority or those schools that remain in Academically Unacceptable Schools status being eligible for takeover via a Request for Application competition. Act 478 of the 1997 Regular Legislative Session called for the development of an Accountability System for the purpose of implementing fundamental changes in classroom teaching by helping schools and communities focus on improved student achievement. The state's accountability system is an evolving system with different components that are required to change in response to state and federal laws and regulations.

Title 28
EDUCATION
Part LXXXIII. Bulletin 111—The Louisiana School, District, and State Accountability System
Chapter 24. Recovery School District

§2401. Eligibility for Transfer to the Recovery School District

A. The Louisiana legislature established the recovery school district with the passage of R.S. 17:1990. A school is eligible for the recovery school district under any of the following conditions.

1. The LEA fails to submit a reconstitution plan for a school in AUS 4 to BESE for approval.
2. A school's reconstitution plan is submitted to BESE but is deemed to be unacceptable.
3. A school and/or the LEA fails to comply with the terms of a BESE approved reconstitution plan.
4. A school is labeled Academically Unacceptable for four consecutive years.

B. The recovery school district under R.S. 17:10.5 and 10.7 shall retain jurisdiction of any school transferred to it for a period of not less than five school years not including the school year in which the transfer occurred if the transfer occurred during a school year.

1. No later than October 1 each year, the recovery school district shall make a report to the state Board of Elementary and Secondary Education.

a. The report shall include at a minimum each of the following elements:

i. the status of each school transferred;
ii. the nature of its faculty and administration;
iii. the demographics and size of its student body;
iv. its organizational and management structure;
v. whether there has been improvement in student academic performance and, if so, how much and, if not, why not.

2. No later than January 1 prior to the expiration of the five-year period, the state Board of Elementary and Secondary Education shall take action on the recommendations of the recovery school district concerning the transfer of schools.

AUTHORITY NOTE: Promulgated in accordance with R.S. 17:10.1.

HISTORICAL NOTE: Promulgated by the Board of Elementary and Secondary Education, LR 32:1028 (June 2006), amended LR 33:2599 (December 2007), LR 34:431 (March 2008), LR 35:640 (April 2009), LR 37:

§2403. Transfer of Schools out of the Recovery School District

A. This policy provides the mechanism for transferring of eligible schools from the jurisdiction of the recovery school district (RSD) while ensuring that the school's autonomy and flexibility is retained to allow continued substantial improvement and high standards of accountability. An eligible school may elect to transfer from the RSD and return to its former local educational authority (LEA) or an alternative governing authority (AGA), if authorized by law. If a school chooses not to transfer to its LEA, it will automatically remain within the RSD for an additional five year period.

B. No school shall be eligible for transfer from the jurisdiction of the recovery school district until the conclusion of the 2011-2012 school year. No school shall be transferred from the RSD without the approval of the Louisiana Board of Elementary and Secondary School (BESE).

C. A non-failing school is eligible for transfer from the jurisdiction of the recovery school district provided it meets all of the following:

1. The school has been under the jurisdiction of the recovery school district for a minimum of five years as either a direct-run RSD school or a Type-5 charter school.
2. The school meets the performance requirement as defined by having established two consecutive years of a school performance score (SPS) that is at least 80 or if the academically unacceptable school (AUS) bar is raised above 75, then at least 5 points above the AUS bar as established by BESE pursuant to the statewide school and district accountability system.

3. The school elects to transfer from the RSD and has notified BESE no later than December 1 of the year preceding the effective date of the proposed transfer.

a. Type 5 Charter School. The charter school's governing authority, in accordance with its by-laws, shall notify BESE in writing of its desire to transfer from the jurisdiction of the RSD.

b. Direct-Run RSD School. The superintendent of the RSD, in consultation with the parents of students attending the school, and the school's staff, shall make a recommendation to BESE seeking transfer from the jurisdiction of the RSD.

4. No later than January 1 of the school year preceding the effective date of the proposed transfer, BESE shall make a determination whether or not to transfer the school and the mechanism of such transfer.

5. The former local educational authority or the alternative governing authority (collectively referred to as recipient authority) has agreed to accept jurisdiction of the transferring school.

6. The following parties must agree to transfer no later than April 1 of the school year preceding the effective date of such transfer:

a. the governing authority of a charter school, if a charter school; or

b. the superintendent of the RSD, if a direct-run RSD school; and

c. BESE; and

d. the recipient authority.

D. A direct-run RSD school that is deemed a failing school may be eligible for transfer from the jurisdiction of the recovery school district provided it meets all of the following.

1. The school has been under the jurisdiction of the recovery school district for a minimum of five years.

2. The school is labeled as in AUS status as defined by the statewide school and district accountability system during its fifth year, or any subsequent year the school remains within the RSD.

3. The school is not undergoing a charter conversion or phase-out, as defined in Subsection I below.

4. The recipient authority has agreed to accept the school and has developed a proposal for the school's turnaround.

5. BESE has approved the recipient authority's turnaround proposal for the school.

6. The following parties have agreed to such transfer from the RSD:

a. the superintendent of the RSD; and

b. BESE; and

c. the recipient authority.

E. Type 5 Charter Schools. The transfer of a Type 5 charter school from the RSD shall become effective on July 1 of the year following BESE's approval of such transfer.

1. The charter school must negotiate a new charter agreement with the recipient authority to become either a Type 3 or Type 4 charter school. A copy of the signed negotiated charter agreement must be provided to BESE no later than Apri1 1 preceding the effective date of the proposed transfer. The new charter agreement must:

a. be effective on the date of transfer (July 1);

b. be consistent with all state and federal laws governing charter school authorization; and

c. contain academic performance standards and other requirements for extension and renewal that are equal to or greater than Type 5 charter school performance standards as enumerated in BESE Bulletin 126.

2. Transfer to a Type 3 Charter School. If the charter school elects to become a Type 3 charter school, the non-profit charter organization shall apply to the recipient authority to operate the school. The charter contract agreement must conform to all the laws and requirements governing Type 3 charter schools.

3. Transfer to a Type 4 Charter School. If the charter school elects to become a Type 4 charter school, the recipient authority must apply to BESE to operate the charter school, with the approval from the charter operator. The charter contract agreement must conform to all the laws and requirements governing Type 4 charter schools.

F. Direct-Run RSD Schools. A direct-run RSD school may transfer directly to the Recipient Authority as a direct-run school, or may transfer as a Type 3 or Type 4 charter school.

1. Transfer to a Charter School. A non-failing direct-run RSD school may elect to transfer to the recipient authority as either a Type 3 or a Type 4 charter school. Such transfer to the recipient authority shall be made in the same manner as described in Paragraph E.1 above.

2. Transfer as a Direct-Run School. A direct-run RSD school may elect to become a direct-run school under the recipient authority, in which case the recipient authority shall enter into a memorandum of understanding (MOU) with BESE. The MOU shall be effective for a maximum of three years, and shall provide, at a minimum, the following.

a. Non-Failing Direct-Run RSD Schools

i. Preserve the Existing School Autonomy. The transferring school shall retain its existing level of autonomy over such elements, including but not limited to, its educational program and curricula, its staffing, and its budget decisions.

ii. Continued Performance. The recipient authority shall be required to maintain school performance equal to or greater than that achieved by the RSD. Should the transferring school become AUS during the term of the MOU, the school shall be immediately returned to the jurisdiction of the RSD.

iii. School Budget. The transferring school shall maintain its school-level budget at a level at least equal to that school-level budget it maintained while in the RSD, adjusted for current enrollment, the MFP and/or federal, local and/or other sources of revenue.

iv. Recourse. Violation of the MOU may result in the school being returned to the RSD.

b. Failing Direct-Run RSD Schools

i. Turnaround Plan. The MOU shall identify key benchmarks and milestones demonstrating the turnaround strategy being executed and successfully improving student academic outcomes.

G. The RSD has the responsibility to maintain high educational standards for all direct-run schools and charter schools under its jurisdiction.

H. Type 5 Charter School Accountability. The renewal of a charter agreement for any Type 5 charter school that is labeled AUS in its fifth year of operation shall be governed by provisions found in Bulletin 126. If not renewed, the charter school will either revert to the direct control of the RSD, be closed, or may be transferred to another non-profit charter organization.

I. Direct-Run RSD Schools. Any direct-run RSD school that is labeled AUS in its fifth year of operation within the RSD shall be subject to one of the following.

1. Phase-Out. The school will be closed according to a timeline and its students will be transferred to other high performing schools.

2. Charter Conversion. The school may be converted to the control of a charter school that has a proven ability to implement a school turnaround model and will operate as a Type 5 charter school.

3. Transfer to a Recipient Authority. The school may be transferred to a recipient authority, which has the proven ability to implement a school turnaround plan.

4. Remain within the RSD. The school may remain within the RSD for an additional five-year period. The school performance will be reviewed on an annual basis and, if the school remains in AUS, a charter operator or recipient authority may submit a proposal to BESE for operation of the school.

AUTHORITY NOTE: Promulgated in accordance with R.S. 17:10.1.

HISTORICAL NOTE: Promulgated by the Board of Elementary and Secondary Education, LR 37:

Family Impact Statement

In accordance with Section 953 and 974 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a Family Impact Statement on the Rule proposed for adoption, repeal or amendment. All Family Impact Statements shall be kept on file in the state board office which has adopted, amended, or repealed a Rule in accordance with the applicable provisions of the law relating to public records.

1. Will the proposed Rule affect the stability of the family? No.

2. Will the proposed Rule affect the authority and rights of parents regarding the education and supervision of their children? No.

3. Will the proposed Rule affect the functioning of the family? No.

4. Will the proposed Rule affect family earnings and family budget? No.

5. Will the proposed Rule affect the behavior and personal responsibility of children? No.

6. Is the family or a local government able to perform the function as contained in the proposed Rule? No.

Public Comments

Interested persons may submit written comments via the U.S. Mail until 4:30 p.m., July 20, 2011, to Nina A. Ford, State Board of Elementary and Secondary Education, P.O. Box 94064, Capitol Station, Baton Rouge, LA 70804-9064.

Catherine R. Pozniak
Executive Director

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES
RULE TITLE: Bulletin 111—The Louisiana School, District, and State Accountability System

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

Proposed changes in Bulletin 111, Chapter 24 provide detail for governing the transfer of schools that have been under the jurisdiction of the Recovery School District for 5 years. The process will begin this fall with those schools meeting the Performance requirement earning the right to return to their former Louisiana Education Authority or those schools that remain in Academically Unacceptable Schools status being eligible for takeover via a Request for Application competition.

The proposed rule changes will result in no cost or savings to state or local governmental units.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

There will be no effect on revenue collections of state or local governmental units.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS (Summary)

There will be no estimated costs and/or economic benefits to directly affected persons or non-governmental groups.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

There will be no effect on competition and employment.

Beth Scioneaux
Deputy Superintendent
1106#041

H. Gordon Monk
Legislative Fiscal Officer
Legislative Fiscal Office

NOTICE OF INTENT

Board of Elementary and Secondary Education

Bulletin 741—Louisiana Handbook for School Administrators—Red Tape Reduction Waiver and Local Empowerment Program (LAC 28:CXV.344)

In accordance with R.S. 49:950 et seq., the Administrative Procedure Act, notice is hereby given that the Board of Elementary and Secondary Education approved for advertisement revisions to *Bulletin 741—Louisiana Handbook for School Administrators:* §344. Red Tape Reduction Waiver and Local Empowerment Program. The addition of Section 344 provides for BESE to waive state policy and law as requested by districts who feel such laws and policies inhibit their ability to significantly improve teacher effectiveness and student academic achievement. Districts can request relief from any policy by demonstrating that alternative procedures and rules they will adopt to meet targets for increased teacher effectiveness and student achievement will be successful. A district's ability to maintain the waiver depends on whether it meets such performance targets. This revision was required by Act 749 of the 2010 Regular Legislative Session.

Title 28
EDUCATION
Part CXV. Bulletin 741—Louisiana Handbook for School Administrators
Chapter 3. Operation and Administration
§344. Red Tape Reduction Waiver and Local Empowerment Program

A. General Provisions

1. Purpose

a. The purpose of this policy is to provide schools and school districts with the ability to seek waivers from rules and regulations that may hinder academic progress and replace those policies with protocols designed to improve teaching effectiveness and student academic achievement.

2. Waivers

a. A waiver allows a public school to be exempt from one or more provisions of Title 17 of the Louisiana Revised Statutes of 1950, or any rules, regulations or policies of the Louisiana Board of Elementary and Secondary Education (BESE) that are applicable to public schools, school officers or school employees. A waiver may be granted to exempt a school from laws, rules, and/or policies that affect such activities as, but are not limited to, instructional time, curriculum, funding, personnel, student-to-personnel ratios, and student support.

b. Waivers from the following shall not be granted pursuant to this Chapter:

i. provisions governing school nutrition programs (R.S. 17:191 et seq.);

ii. providing free transportation to any student attending a public school (R.S. 17:158);

iii. providing alternative educational programs for any student suspended or expelled from school (R.S. 17:416.2);

iv evaluation of teachers or administrators pursuant to R.S. 17:3902;

v. the exemptions authorized for Charter Schools pursuant to R.S. 17:3996; or

vi. any limitations or restrictions on outsourcing food, clerical, custodial or paraprofessional services.

B. Request for Waivers

1. Governing Authority

a. For purposes of this Chapter, "governing authority" means the governing authority of any public elementary or secondary school, including any local or parish school board or a charter school board.

b. The governing authority may request a waiver from any statute, rule, regulation or BESE policy, as permitted by law, for any school, or any combination of schools, or all schools under its jurisdiction provided that the such waiver shall be designed to improve the quality of instruction and student academic achievement.

C. Waiver Procedure

1. The governing authority shall submit a written request for a waiver to BESE. The governing authority may use a waiver request form designed by the department. Alternatively, a written request from the governing authority shall be considered valid provided it contains all the requisite information. The waiver request shall contain the following information:

a. identification of the specific laws, rules, regulations and/or policies from which a waiver is being sought;

b. identification of the school or schools for which the waiver will cover;

c. description of the policies and procedures that will be instituted as a substitute for the waived provisions;

d. description of how the proposed waiver will:

i. increase the quality of instruction for students;

ii. improve the academic achievement of students; and

iii. improve teaching effectiveness within the school for which the waiver is sought;

e. description of the specific, measurable educational goals, growth targets, performance targets and the methods to be used to measure progress in meeting the goals for each year. The educational goals should be, at a minimum, measured using state-administered, standardized assessment data. For purposes of this Chapter, "growth targets" shall mean the number of School Performance School (SPS) points, as established by the statewide School and District Accountability System, required and determined annually for the school to make sufficient progress toward the statewide school performance goal:

i. all schools receiving a waiver must meet their growth targets annually. Failure to meet its growth target may result in a termination of the waiver upon review by BESE;

ii. a school is deemed to have met its growth target if the school achieves its yearly growth target for each year for which the school received a waiver (e.g., if a school receives a waiver for four years, that school is deemed to have met its growth targets if it meets its yearly growth target in each year of the four year waiver period);

2. the governing authority shall certify that a majority of classroom teachers employed at the school or schools affected by the waiver voted in favor of the requested waiver.

D. Teacher Voting Procedure

1. A majority of the classroom teachers employed in the school or schools seeking the waiver must vote in favor of the proposed waiver request.

2. Voting by the classroom teachers shall be by secret ballot and shall be conducted as follows.

a. Teachers shall be given no less than five business days notice of the waiver request prior to the date of the vote. Notice shall include a copy of the waiver request and the date(s) of the vote. Notice shall be considered sufficient when it is distributed in a manner reasonably designed to provide each teacher a copy of the proposed waiver. Acceptable means of notice include, but are not limited to, placing a copy of such notice in each teacher's mail box, by posting it on the wall of a common area such as a teacher's resource room or in the school office, or sending the notice via email.

b. Voting may be conducted through on-line voting, provided that such on-line voting takes place only on the designated date(s) for said vote.

c. The vote shall be tallied by the school principal or his designee and a teacher representative employed at the

school seeking the waiver. A majority of votes shall determine the outcome of the waiver request.

3. The Department of Education may provide an optional sample ballot that may be used in the voting process.

E. Low-Performing Schools

1. For purposes of this Chapter, a low-performing school shall be a school that is defined as in Academically Unacceptable School (AUS) status as determined by BESE.

2. A low-performing school may be granted a waiver provided it meets the terms and conditions, as determined by BESE that are aimed at improving:

a. teacher effectiveness pursuant to R.S. 17:3881 et seq.;

b. the quality of instruction; and

c. student academic achievement.

3. The governing authority of a low-performing school that is granted a waiver shall:

a. ensure the improvement of the school's teachers in accordance with R.S. 17:3881, et seq.;

b. ensure the improvement of quality of instruction and student achievement by implementing one of the following intervention options:

i. turnaround: put in place new leadership and a majority of new staff, new governance, and improved instructional programs, and provide the school with sufficient operational flexibility such as the ability to select staff, control its budget as approved by the school's governing authority, and increase learning time;

ii. restart: convert the school to a charter school. However, every teacher employed in such school prior to its conversation to a charter school, who has been determined to be effective in accordance with the provisions of Part II of Chapter 39 of Title 17 of the Louisiana Revised Statutes of 1950, shall be given the option to remain at the school or to be reassigned by the governing authority to another school under its jurisdiction;

iii. school closure: close the school and place its students in a high- performing school within the district;

iv. transformation: hire new school leadership and implement a suite of best practices including comprehensive instructional management reform and measures of effective teaching. A waiver shall not be granted to a district that proposes to utilize this option for more than 50 percent of its low-performing schools covered by the waiver;

c. a district that has implemented one or more of the interventions described above for its low-performing schools in the two academic years immediately preceding the waiver application is not eligible to receive a waiver unless both of the following apply:

i. the school has met its statewide accountability growth target or surpassed the statewide growth average, calculated by examining whether the school's growth exceeded the average statewide growth for that year, for each year during such period of implementation; and

ii. the district agrees to implement any remaining conditions of school intervention by the beginning of the following school year;

d. a school implementing any of the intervention options described in Subparagraph 3.b, above, shall not be subject to transfer to the Recovery School District for the duration of the waiver period;

e. upon expiration of the waiver, a school's status shall be determined by identifying the school's previous AUS status and identifying whether the school's current School Performance Score (SPS) surpasses the AUS bar as determined by BESE. If the school's score is not above AUS, the school shall advance one year in AUS (e.g., if a school enters into a waiver as an AUS 2 school and upon expiration of the waiver the school does not earn a SPS above AUS status, then the school shall be labeled as AUS 3);

f. in the event the school has neither met its growth targets, as described in Subparagraph C.1.e above, nor surpassed an acceptable level of academic performance as determined by BESE, and BESE terminates its waiver in accordance with Subsection G below, the school shall be either:

i. governed under a Memorandum of Understanding (MOU) between the governing authority of the school and the RSD, which shall govern the operation of the school; or

ii. based on the recommendation of the State Superintendent, transferred directly to the jurisdiction of the Recovery School District;

g. a school that entered into an MOU with the RSD prior to the receipt of a waiver, and which upon the expiration of the MOU or termination of the waiver, has not met its growth targets, shall be transferred to the jurisdiction of the RSD.

4. RSD Accountability

a. A school that has been under the jurisdiction of the RSD that has not met its growth targets at the expiration of the waiver period shall:

i. if the school is a direct-run RSD school, be converted to a charter school; or

ii. if the school is a charter school, the RSD will recommend to BESE that the charter school's charter authority be terminated. The RSD may enter into a contract with another chartering organization for the operation of the school; or

iii. the school shall be closed and its students will be transferred to a higher-performing school within the jurisdiction of the RSD.

F. Grant, Denial or Extension of Waiver

1. Only BESE has the authority to grant waivers. A waiver may be approved as requested or may be subject to modifications as determined by BESE. The Department shall make a recommendation to BESE on each waiver request, and such recommendation shall identify any special modifications that may be required. A waiver shall be effective for a period of up to four years unless terminated earlier upon a determination by BESE. A school may seek termination of a waiver upon application to BESE; however, in the case of a low-performing school, nothing shall preclude BESE from taking any action permitted by law to impose conditions upon said school to ensure that performance expectations are met.

2. Upon approval by BESE, the terms and conditions shall be in writing and shall be signed by the Superintendent and the governing authority. BESE will authorize an electronic signature of the waiver agreement.

3. Upon a request by the governing authority, and a recommendation by the Department, BESE may extend the

waiver period upon a determination that the waiver has been effective in enabling the school to carry out the activities for which the waiver was granted and upon a demonstration that the waiver has contributed to the improved quality of instruction and student academic achievement.

4. A waiver extension shall not prevent a school otherwise eligible from being subject to transfer to the Recovery School District.

G. Termination of Waivers

1. If BESE determines that the performance of the school has been insufficient to justify a continuation of a waiver, or if the waiver is no longer necessary to achieve its original intent, BESE may terminate a waiver, either in full or with respect to individual schools.

2. BESE shall terminate a waiver granted to a low-performing school if the school fails to implement the requirements of R.S. 17:4044 within two school years from the issuance of the waiver.

3. BESE may terminate a waiver granted to a low-performing school if the school has not met its statewide accountability growth targets within two years of the granting of the waiver or has not met other requirements or benchmarks.

H. Reporting Requirements

1. The governing authority of a school that receives a waiver shall provide reports on an annual basis to BESE which shall provide information on the effectiveness of the waiver or waivers granted. Such annual report shall be submitted to the Department of Education, Superintendent's Office, no later than December 1 of each year and shall include, but not be limited to, a description of whether or not policies implemented to replace the procedures waived are:

a. increasing the quality of instruction to students;

b. improving the academic achievement of the students; and

c. improving teacher effectiveness.

AUTHORITY NOTE: Promulgated in accordance with R.S. 17:7, R.S. 17:4031-4039.

HISTORICAL NOTE: Promulgated by the Board of Elementary and Secondary Education, LR 37:

Family Impact Statement

In accordance with Section 953 and 974 of Title 49 of the Louisiana Revised Statutes, there is hereby submitted a Family Impact Statement on the rule proposed for adoption, repeal or amendment. All Family Impact Statements shall be kept on file in the State Board Office which has adopted, amended, or repealed a rule in accordance with the applicable provisions of the law relating to public records.

1. Will the proposed rule affect the stability of the family? No.

2. Will the proposed rule affect the authority and rights of parents regarding the education and supervision of their children? No.

3. Will the proposed rule affect the functioning of the family? No.

4. Will the proposed rule affect family earnings and family budget? No.

5. Will the proposed rule affect the behavior and personal responsibility of children? No.

6. Is the family or a local government able to perform the function as contained in the proposed rule? Yes.

Public Comments

Interested persons may submit written comments via the U.S. Mail until 4:30 p.m., July 20, 2011, to Nina A. Ford, State Board of Elementary and Secondary Education, P.O. Box 94064, Capitol Station, Baton Rouge, LA 70804-9064.

Catherine R. Pozniak
Executive Director

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES
RULE TITLE: Bulletin 741—Louisiana Handbook for School Administrators—Red Tape Reduction Waiver and Local Empowerment Program

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

This addition of Section 344 to *Bulletin 741: Louisiana Handbook for School Administrators* provides for BESE to waive state policy and law as requested by districts who demonstrate that alternative procedures and rules they will adopt to meet targets for increased teacher effectiveness and student achievement will be successful. These changes will not result in an increase in costs or savings to state or local governmental units.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

There will be no effect on revenue collections of state or local governmental units.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS (Summary)

There will be no costs or economic benefits to directly affected persons or non-governmental groups.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

If districts choose to seek waivers from state laws and policies that limit competition and performance-based employment procedures, districts can implement alternative policies that ensure performance and competition are the primary drivers of school and district personnel decisions.

Beth Scioneaux	H. Gordon Monk
Deputy Superintendent	Legislative Fiscal Officer
1106#040	Legislative Fiscal Office

NOTICE OF INTENT

Board of Elementary and Secondary Education

Bulletin 741 (Nonpublic)—Louisiana Handbook for Nonpublic School Administrators
(LAC 28:LXXIX.2109, 2331, and 2335)

In accordance with R.S. 49:950 et seq., the Administrative Procedure Act, notice is hereby given that the Board of Elementary and Secondary Education approved for advertisement revisions to *Bulletin 741 (Nonpublic)—Louisiana Handbook for Nonpublic School Administrators:* §2109. High School Graduation Requirements, §2331. Social Studies, and §2335. Course Credit for Religious Studies. These policy revisions add the courses History of Religion and World Religions to the Religious Studies Program of Study for nonpublic schools.

The revisions were recommended by the study group required by HR 204 of the 2010 Regular Legislative Session.

Title 28
EDUCATION
Part LXXIX. Bulletin 741 (Nonpublic)—Louisiana Handbook for Nonpublic School Administrators
Chapter 21. Curriculum and Instruction
Subchapter C. Secondary Schools
§2109. High School Graduation Requirements

A. - E.3. …

4. Social Studies—four units, shall be:

a. one unit of civics or AP American government, or 1/2 unit of civics or AP American Government and 1/2 unit of free enterprise;

b. one unit of American history;

c. one unit from the following:

i. world history;
ii. world geography;
iii. western civilization; or
iv. AP European history;

d. one unit from the following:

i. world history;
ii. world geography;
iii. western civilization;
iv. AP European history;
v. law studies;
vi. psychology;
vii. sociology;
viii. African American studies; or
ix. a course from the religious studies program of study (§2335).

E.5. - F.7. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 17:6 (A)(10), (11), (15); R.S. 17:7(6); R.S. 17:10; R.S. 17:22(6); R.S. 17:391.1-391.10; R.S. 17:411.

HISTORICAL NOTE: Promulgated by the Board of Elementary and Secondary Education, LR 29:2351 (November 2003), amended LR 30:2776 (December 2004), LR 31:3081 (December 2005), LR 34:2099 (October 2008), LR 36:2849 (December 2010), LR 37:

Chapter 23. High School Program of Studies
§2331. Social Studies

A. - C. …

D. One unit of religious studies (§2335) may be used as the fourth social studies course required for the Louisiana Core 4 curriculum.

AUTHORITY NOTE: Promulgated in accordance with R.S. 17:6 (A)(10), (11), (15); R.S. 17:7(6); R.S. 17:10; R.S. 17:22(6); R.S. 17:391.1-391.10; R.S. 17:411.

HISTORICAL NOTE: Promulgated by the Board of Elementary and Secondary Education, LR 29:2356 (November 2003), amended LR 31:3088 (December 2005), LR 34:2102 (October 2008), LR 37:

§2335. Course Credit for Religious Studies

A. A maximum of four units in religion shall be granted to students transferring from state-approved private and sectarian high schools who have completed such course work. Those credits shall be accepted in meeting the requirements for high school graduation.

Course Title	Units
Religious Studies I	1
Religious Studies II	1
Religious Studies III	1
Religious Studies IV	1
World Religions	1
History of Religion	1

AUTHORITY NOTE: Promulgated in accordance with R.S. 17:6 (A)(10), (11), (15); R.S. 17:7(6); R.S. 17:10; R.S. 17:22(6); R.S. 17:391.1-391.10; R.S. 17:411.

HISTORICAL NOTE: Promulgated by the Board of Elementary and Secondary Education, LR 29:2356 (November 2003), amended LR 31:3088 (December 2005), LR 37:

Family Impact Statement

1. Will the proposed Rule affect the stability of the family? No.
2. Will the proposed Rule affect the authority and rights of parents regarding the education and supervision of their children? No.
3. Will the proposed Rule affect the functioning of the family? No.
4. Will the proposed Rule affect family earnings and family budget? No.
5. Will the proposed Rule affect the behavior and personal responsibility of children? No.
6. Is the family or a local government able to perform the function as contained in the proposed Rule? Yes.

Public Comments

Interested persons may submit written comments via the U.S. Mail until 4:30 p.m., July 20, 2011 to Nina A. Ford, State Board of Elementary and Secondary Education, P.O. Box 94064, Capitol Station, Baton Rouge, LA 70804-9064.

Catherine R. Pozniak
Executive Director

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES
RULE TITLE: Bulletin 741 (Nonpublic)—Louisiana Handbook for Nonpublic School Administrators

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

These policy revisions to Sections 2109, 2331, and 2335 in *Bulletin 741: Louisiana Handbook for Nonpublic School Administrators* add the courses History of Religion and World Religions to the Religious Studies Program of Study for nonpublic schools. These revisions were recommended by the Study Group required by HR 204 of the 2010 Regular Legislative Session. These changes will not result in an increase in costs or savings to state or local governmental units.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

There will be no effect on revenue collections of state or local governmental units.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS (Summary)

There will be no costs or economic benefits to directly affected persons or non-governmental groups.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

There will be no effect on competition and employment.

Beth Scioneaux	H. Gordon Monk
Deputy Superintendent	Legislative Fiscal Officer
1106#039	Legislative Fiscal Office

NOTICE OF INTENT

Student Financial Assistance Commission
Office of Student Financial Assistance

LASFAC Committees (LAC 28:V.107 and 109)

The Louisiana Student Financial Assistance Commission (LASFAC) announces its intention to amend the Rules and Regulations of the Louisiana Student Financial Assistance Commission (R.S. 17:3021-3025, R.S. 3041.10-3041.15, R.S. 17:3042.1, R.S. 17:3048.1, R.S. 17:3048.5 and R.S. 17:3048.6).

This rulemaking amends the commission's bylaws to include a public comment period at all meetings; to provide for the order of business; to delete the current standing committees, except the executive committee; and to provide additional duties and responsibilities to the executive committee. (SFAC11130NI)

Title 28
EDUCATION
Part V. Student Financial Assistance—Higher Education Loan Program
Chapter 1. Student Financial Assistance Commission Bylaws

§107. Order of Business

A. …

B. Order of Business. The order of business of regular meetings of the commission shall be as follows, unless the rules are suspended by a simple majority vote of the quorum present:

1. call to order;
2. roll call;
3. introductions and announcements;
4. corrections and approval of minutes of preceding regular meetings and of all special meetings held subsequent thereto;
5. public comment;
6. program updates and special reports;
7. old business, including reports and recommendations of standing and special committees;
8. new business; and
9. adjournment.

C. Reference to Committees

1. In cases where the commission determines that it is feasible and desirable, it may refer any subject or measure to the executive committee or to a special committee.

2. The committee to which a matter is referred should submit to the commission its recommendations in writing, together with any resolutions necessary to facilitate such recommendations.

D. Meetings

1. Meetings shall be conducted in accordance with state law governing public bodies.

2. It is the policy of the commission for all meetings to be open to all who wish to attend and that the public shall be granted an opportunity to comment.

3. The commission may enter into an executive session only upon two-thirds majority vote of the quorum present and only for one of the reasons specified in the Louisiana Open Meetings Law.

4. Prior to each regular meeting of the commission, the executive director, with approval of the chairman, shall prepare and forward to each member of the commission a tentative agenda for the meeting at least five working days prior to such regular meeting.

5. Upon request of three members of the commission made prior to the fifth day before the next commission meeting that a particular item be included, the chairman shall place the subject or subjects upon the agenda.

6. The commission may add any item to its agenda during a meeting upon a simple majority vote of the quorum present.

7. Each resolution shall be reduced to writing and presented to the commission before it is acted upon.

8. All official actions of the commission shall require a simple majority vote of the quorum present at the meeting.

E. - F. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 17:3021.

HISTORICAL NOTE: Promulgated by the Student Financial Assistance Commission, Office of Student Financial Assistance, LR 22:810 (September 1996), repromulgated LR 24:1264 (July 1998), amended LR 37:

§109. Committees

A. In addition to the executive committee established in these bylaws, the commission may establish standing committees by the vote of a simple majority of the membership of the commission.

B - E. …

F. Executive Committee

1. The executive committee shall consist of seven members. The chairman and vice chairman of the commission shall serve in those capacities on the executive committee. The remaining persons, for a total of seven members, shall be appointed by the chairman of the commission from the other members of the commission.

2. The executive committee shall:

a. meet for and conduct the business of the commission in all instances that the public has been given notice of a meeting of the commission and the commission does not have a quorum at that meeting. In such cases, the actions of the committee shall have the same force and effect as if a quorum of the commission had taken the action;

b. consider such matters as shall be referred to it by the commission and shall execute such orders and resolutions as shall be assigned to it at any meeting of the commission;

c. in the event that an emergency requiring immediate commission action shall arise between commission meetings, meet in emergency session to take such action as may be necessary and appropriate. The executive committee shall report the actions it takes in emergency session to the commission for ratification at the commission's next meeting.

3. All official actions of the executive committee shall require a majority vote of the quorum present at the meeting.

4. The executive committee may enter into an executive session only upon two-thirds majority vote of the quorum present and only for one of the reasons specified in the Louisiana Open Meetings Law.

G. Special Committees

1. As the necessity therefor arises, the chairman may, with the concurrence of the commission, create special (ad hoc) committees with such functions, powers and authority as may be delegated.

2. The chairman may appoint special committees for special assignments for limited periods of existence not to exceed the completion of the assigned task.

AUTHORITY NOTE: Promulgated in accordance with R.S. 17:3021.

HISTORICAL NOTE: Promulgated by the Student Financial Assistance Commission, Office of Student Financial Assistance, LR 22:811 (September 1996), repromulgated LR 24:1264 (July 1998), amended LR 26:484 (March 2000), LR 27:35 (January 2001), LR 32:391 (March 2006), amended LR 37:

Family Impact Statement

The proposed Rule has no known impact on family formation, stability, or autonomy, as described in R.S. 49:972.

Small Business Statement

The proposed Rule will have no adverse impact on small businesses as described in R.S. 49:965.2 et seq.

Public Comments

Interested persons may submit written comments on the proposed changes (SFAC11130NI) until 4:30 p.m., July 11, 2011, to Melanie Amrhein, Executive Director, Office of Student Financial Assistance, P.O. Box 91202, Baton Rouge, LA 70821-9202.

George Badge Eldredge
General Counsel

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES
RULE TITLE: LASFAC Committees

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

The proposed rule changes the operating procedures of the Louisiana Student Financial Assistance Commission found in the Commission's bylaws and does not change the Commission's composition. There are no implementation costs or savings to state or local governmental units due to the proposed changes.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

Revenue collections of state and local governments will not be affected by the proposed changes.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS (Summary)

There are no estimated effects on economic benefits to directly affected persons or non-governmental groups resulting from these measures.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

There are no anticipated effects on competition and employment resulting from these measures.

George Badge Eldredge
General Counsel
1106#008

Evan Brasseaux
Staff Director
Legislative Fiscal Office

NOTICE OF INTENT

Student Financial Assistance Commission
Office of Student Financial Assistance

TOPS Equivalent Courses (LAC 28:IV.703)

The Louisiana Student Financial Assistance Commission (LASFAC) announces its intention to amend its Scholarship/Grant rules (R.S. 17:3021-3025, R.S. 3041.10-3041.15, R.S. 17:3042.1, R.S. 17:3048.1, R.S. 17:3048.5 and R.S. 17:3048.6).

This rulemaking adds anatomy and physiology as an equivalent (substitute) course to the TOPS core curriculum advanced science courses effective for students graduating during the 2010-2011 high school academic year and thereafter. The Board of Elementary and Secondary Education and the Board of Regents have recommended this change. (SG11132NI).

Title 28
EDUCATION
Part IV. Student Financial Assistance—Higher Education Scholarship and Grant Programs
Chapter 7. Taylor Opportunity Program for Students (TOPS) Opportunity, Performance, and Honors Awards
§703. Establishing Eligibility

A. - A.5.a.ii.(b). ….

(c). For students graduating in academic year (high school) 2009-2010, for purposes of satisfying the requirements of §703.A.5.a.i above, or §803.A.6.a, the following courses shall be considered equivalent to the identified core courses and may be substituted to satisfy corresponding core courses.

Core Curriculum Course	Equivalent (Substitute) Course
Physical Science	Integrated Science
Algebra I	Algebra I, Parts 1 and 2, Integrated Mathematics I, Applied Algebra I
Applied Algebra IA and IB	Applied Mathematics I and II
Algebra I, Algebra II and Geometry	Integrated Mathematics I, II and III
Algebra II	Integrated Mathematics II
Geometry	Integrated Mathematics III, Applied Geometry
Geometry, Trigonometry, Calculus, or Comparable Advanced Mathematics	Pre-Calculus, Algebra III, Probability and Statistics, Discrete Mathematics, Applied Mathematics III*, Advanced Math – Pre-Calculus**, Advanced Math – Functions and Statistics***

Core Curriculum Course	Equivalent (Substitute) Course
Chemistry	Chemistry Com
Fine Arts Survey	Speech III and Speech IV (both units)
Western Civilization	European History
Civics	AP American Government
*Applied Mathematics III was formerly referred to as Applied Geometry **Advanced Math—Pre-Calculus was formerly referred to as Advanced Mathematics II ***Advanced Math—Functions and Statistics was formerly referred to as Advanced Mathematics II	

(d). For students graduating in academic year (high school) 2010-2011 and after, for purposes of satisfying the requirements of §703.A.5.a.i above, or §803.A.6.a, the following courses shall be considered equivalent to the identified core courses and may be substituted to satisfy corresponding core courses.

Core Curriculum Course	Equivalent (Substitute) Course
Physical Science	Integrated Science
Algebra I	Algebra I, Parts 1 and 2, Integrated Mathematics I, Applied Algebra I
Applied Algebra IA and IB	Applied Mathematics I and II
Algebra I, Algebra II and Geometry	Integrated Mathematics I, II and III
Algebra II	Integrated Mathematics II
Geometry	Integrated Mathematics III, Applied Geometry
Geometry, Trigonometry, Calculus, or Comparable Advanced Mathematics	Pre-Calculus, Algebra III, Probability and Statistics, Discrete Mathematics, Applied Mathematics III*, Advanced Math – Pre-Calculus**, Advanced Math – Functions and Statistics***
Chemistry	Chemistry Com
Earth Science, Environmental Science, Physical Science, Biology II, Chemistry II, Physics, Physics II, or Physics for Technology or Agriscience I and II (both for 1 unit;	Anatomy and Physiology
Fine Arts Survey	Speech III and Speech IV (both units)
Western Civilization	European History
Civics	AP American Government
*Applied Mathematics III was formerly referred to as Applied Geometry **Advanced Math—Pre-Calculus was formerly referred to as Advanced Mathematics II ***Advanced Math—Functions and Statistics was formerly referred to as Advanced Mathematics II	

A.5.a.iii - J.4.b.ii. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 17:3021-3025, R.S. 17:3042.1 and R.S. 17:3048.1.

HISTORICAL NOTE: Promulgated by the Student Financial Assistance Commission, Office of Student Financial Assistance, LR 22:338 (May 1996), repromulgated LR 24:636 (April 1998), amended LR 24:1902 (October 1998), LR 24:2237 (December 1998), LR 25:257 (February 1999), LR 25:655 (April 1999), LR 25:1794 (October 1999), LR 26:64, 67 (January 2000), LR 26:689 (April 2000), LR 26:1262 (June 2000), LR 26:1602 (August 2000), LR 26:1996, 1999, 2001 (September 2000), LR 26:2268 (October 2000), LR 26:2753 (December 2000), LR 27:36 (January 2001), LR 27:702 (May 2001), LR 27:1219, 1219 (August 2001), repromulgated LR 27:1850 (November 2001), amended LR 28:772 (April 2002), LR 28:2330, 2332 (November 2002), LR 29:125 (February 2003), LR 29:2372 (November 2003), LR 30:1162 (June 2004), LR 30:1471 (July 2004), LR 30:2019 (September 2004), LR 31:37 (January 2005), LR 31:2213 (September 2005), LR 31:3112 (December 2005), LR 32:2239 (December 2006), LR 33:435 (March 2007), LR 33:2357 (November 2007), LR 33:2612 (December 2007), LR 34:1389 (July 2008), LR 35:228 (February 2009), LR 36:312 (February 2010), LR 36:490 (March 2010), LR 36:2269 (October 2010), LR 36:2855 (December 2010), LR 37:

Family Impact Statement

The proposed Rule has no known impact on family formation, stability, or autonomy, as described in R.S. 49:972.

Small Business Statement

The proposed Rule will have no adverse impact on small businesses as described in R.S. 49:965.2 et seq.

Public Comments

Interested persons may submit written comments on the proposed changes (SG11132NI) until 4:30 p.m., July 11, 2011, to Melanie Amrhein, Executive Director, Office of Student Financial Assistance, P.O. Box 91202, Baton Rouge, LA 70821-9202.

George Badge Eldredge
General Counsel

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES
RULE TITLE: TOPS Equivalent Courses

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

In accordance with the requirements of R.S. 17:3048.1.C(2)(e) and with the concurrence of BESE and Regents, the proposed rule change modifies the Scholarship and Grant Program rules to add anatomy and physiology as an equivalent (substitute) course to the TOPS core curriculum advanced science courses effective for students graduating during the 2010-2011 high school academic year and thereafter. There are no estimated implementation costs or savings to state or local governmental units.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

Revenue collections of state and local governments will not be affected by the proposed changes.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS (Summary)

There are no estimated effects on economic benefits to directly affected persons or non-governmental groups resulting from these measures.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

There are no anticipated effects on competition and employment resulting from these measures.

George Badge Eldredge General Counsel 1106#006	Evan Brasseaux Staff Director Legislative Fiscal Office

NOTICE OF INTENT

Tuition Trust Authority
Office of Student Financial Assistance

LATTA Committees (LAC 28:VII.107 and 109)

The Louisiana Tuition Trust Authority announces its intention to amend its Bylaws (LSA-R.S. 17:3091 et seq.).

This rulemaking amends the Authority's Bylaws to include a public comment period at all meetings; to provide

for the order of business; to delete the current standing committees, except the executive committee; and to provide additional duties and responsibilities to the executive committee. (ST11131NI)

Title 28
EDUCATION
Part VII. Tuition Trust Authority

Chapter 1. Bylaws

§107. Order of Business

A. …

B. Order of Business. The order of business of regular meetings of the authority shall be as follows, unless the rules are suspended by a simple majority of the quorum present:

1. call to order;
2. roll call;
3. introductions and announcements;
4. corrections and approval of minutes of preceding regular meetings and of all special meetings held subsequently thereto;
5. public comment;
6. program updates and special reports;
7. old business, including reports and recommendations of standing and special committees;
8. new business; and
9. adjournment.

C. Reference to Committees

1. In cases where the authority determines it is feasible and desirable, it may refer any subject or measure to the executive committee or to a special committee.

2. The committee to which a matter is referred should submit to the authority its recommendations in writing, together with any resolutions necessary to facilitate such recommendations.

D. Meetings

1. Meetings shall be conducted in accordance with state law governing public bodies.

2. It is the policy of the authority for all meetings to be open to all who wish to attend and that the public shall be granted an opportunity to comment.

3. The authority may enter into an executive session only upon two-thirds majority vote of the quorum present and only for one of the exceptions specified in the Louisiana Open Meetings Law.

4. Prior to each regular meeting of the authority, the executive director, with approval of the chairman, shall prepare and forward to each member of the authority a tentative agenda for the meeting at least five working days prior to such regular meeting.

5. Upon request of three members of the authority made prior to the fifth day before the authority's next meeting that a particular item be included, the chairman shall place the subject or subjects upon the agenda.

6. The authority may add any item to its agenda upon a simple majority vote of the quorum present.

7. Each proposal and/or resolution shall be reduced to writing and presented to the authority before it is acted upon.

8. All official actions of the authority shall require a simple majority vote of the quorum present at the meeting.

E. - F.4. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 17:3093 et seq.

HISTORICAL NOTE: Promulgated by the Tuition Trust Authority, Office of Student Financial Assistance, LR 23:1654 (December 1997), amended LR 37:

§109. Committees

A. In addition to the executive committee established in these bylaws, the authority may establish standing committees by simple vote of a majority of the membership of the authority.

B. - E. …

F. Executive Committee

1. The executive committee shall consist of seven members.

2. The chairman and vice-chairman of the authority shall serve in those capacities on the executive committee.

3. The remaining members, for a total of seven members, shall be appointed by the chairman of the authority from the other members of the authority.

4. The executive committee shall:

a. meet for and conduct the business of the authority in all instances that the public has been given notice of a meeting of the authority and the authority does not have a quorum at that meeting. In such cases, the actions of the authority shall have the same force and effect as if a quorum of the authority had taken the action;

b. consider such matters as shall be referred to it by the authority and shall execute such orders and resolutions as shall be assigned to it at any meeting of the authority;

c. in the event that an emergency requiring immediate authority action shall arise between authority meetings, meet in emergency session to take such action as may be necessary and appropriate. The executive committee shall report the actions it takes in emergency session to the authority for ratification at the authority's next meeting.

5. All official actions of the executive committee shall require a majority vote of the quorum present at the meeting.

6. The executive committee may enter into an executive session only upon two-thirds majority vote of the quorum present and only for one of the reasons specified in the Louisiana Open Meetings Law.

G. Special Committees

1. As the necessity therefor arises, the chairman may, with the concurrence of the authority, create special (ad hoc) committees with such functions, powers and authority as may be delegated.

2. The chairman may appoint special committees for special assignments for limited periods of existence not to exceed the completion of the assigned task.

AUTHORITY NOTE: Promulgated in accordance with R.S. 17:3091et seq.

HISTORICAL NOTE: Promulgated by the Tuition Trust Authority, Office of Student Financial Assistance, LR 23:1655 (December 1997), amended LR 27:190 (February 2001), LR 27:1221 (August 2001), LR 30:785 (April 2004), LR 32:392 (March 2006), LR 37:

Family Impact Statement

The proposed Rule has no known impact on family formation, stability, or autonomy, as described in R.S. 49:972.

Small Business Statement

The proposed Rule will have no adverse impact on small businesses as described in R.S. 49:965.2 et seq.

Public Comments

Interested persons may submit written comments on the proposed changes (ST1131NI) until 4:30 p.m., July 11, 2011, to Melanie Amrhein, Executive Director, Office of Student Financial Assistance, P.O. Box 91202, Baton Rouge, LA 70821-9202.

George Badge Eldredge
General Counsel

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES
RULE TITLE: LATTA Committees

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

The proposed rule changes the operating procedures of the Louisiana Tuition Trust Authority found in the Authority's bylaws and does not change the Authority's composition. There are no implementation costs or savings to state or local governmental units due to the proposed changes.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

Revenue collections of state and local governments will not be affected by the proposed changes.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS (Summary)

There are no estimated effects on economic benefits to directly affected persons or non-governmental groups resulting from these measures.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

There are no anticipated effects on competition and employment resulting from these measures.

George Badge Eldredge	Evan Brasseaux
General Counsel	Staff Director
1106#009	Legislative Fiscal Office

NOTICE OF INTENT

Department of Health and Hospitals
Board of Chiropractic Examiners

Specialty Advertising, Unethical Conduct, Code of Ethics
(LAC 46:XXVII.320, 501, and 502)

Notice is hereby given that the Board of Chiropractic Examiners, in accordance with the Administrative Procedure Act, R.S. 49:950 et seq., and relative to its authority to adopt, amend or repeal rules provided by R.S. 37:2804, proposes revisions to Chapter 3 and Chapter 5 of LAC 46:XXVII. The board proposes to amend 46:XXVII.320, Specialty Advertising, to recognize an exception for the chiropractic physician, who does not meet certain requirements, to seek approval from the board to advertise a specialty when possessing special knowledge, skills or training. The board proposes to amend LAC 46:XXVII.501, Unethical Conduct, to include a code of ethics as a basis for a determination that a chiropractic physician's behavior is unethical. The board proposes to adopt LAC 46:XXVII.502, Code of Ethics, to set forth applicable ethical duties for chiropractic physicians.

Title 46
PROFESSIONAL AND OCCUPATIONAL STANDARDS
Part XXVII. Chiropractors

Chapter 3. Professional Conduct

§320. Specialty Advertising

A. - C. ...

D. Only those licensees holding the final certification in postgraduate training and certification programs may hold themselves out to the public as possessing special knowledge, skills or training. A licensee who utilizes any advertisement, which states that a licensee has special training or skills or is certified in a specialty that does not comply with Subparagraphs D.1.a-d, is engaged in deceptive and misleading advertising practices, unless an exception to D.1.a-d has been approved by the board, which would allow the licensee to hold themselves out to the public as possessing special knowledge, skills or training or certified in a specialty.

1. - 1.d. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:2801 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Chiropractic Examiners, LR 35:954 (May 2009), amended LR 37:

Chapter 5. Due Process Procedures for Ethics Violations

Subchapter A. Applicability

§501. Unethical Conduct

A. Unethical conduct shall be determined on the basis of the provisions of the rules and regulations of the Board of Chiropractic Examiners, ethical standards of chiropractors, and other provisions included in the Code of Ethics and R.S. 37:2801-2807, specifically, if a chiropractor:

1. - 3. ...

4. has used any fraud or deception in applying for a license, in renewing a license, or in taking an examination provided for in the act; or

5. - 8. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:2816.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Board of Chiropractic Examiners, LR 10:327 (April 1984), amended LR 13:344 (June 1987), LR 35:955 (May 2009), LR 37:

§502. Code of Ethics

A. Preamble. This code of ethics sets forth principles for the ethical practice of chiropractic. All chiropractic physicians are responsible for maintaining and promoting an ethical practice and otherwise complying with the terms of this code of ethics. To this end, the chiropractic physician shall act in the best interest of the patient. This code of ethics shall be binding on all chiropractic physicians.

B. Duty to Report. It shall be the duty of every licensee to notify the board of any violation of law or board rules.

1. Reporting of certain judgments to the board.

a. The following must be reported to the board within 30 days:

i. if a judgment is entered against a licensee in any court;

ii.. a settlement is reached on a claim involving malpractice exceeding $50,000;

iii. a licensee is convicted of a felony or a crime involving dishonesty, theft, violence, habitual use of drugs or alcohol, or sexual misconduct;

iv. the licensee may satisfy the provision of this subsection if he/she provides the board with a copy of the judgment or settlement.

C. Prohibition Against Sexual Contact, Impropriety and Misconduct

1. The physician and patient relationship is of a fiduciary nature in which the patient entrusts his/her welfare to the physician, and reflects the physician's respect for the patient. That boundary, once crossed, severely impacts the patient's wellbeing on an individual basis and causes distrust to other professional relationships in general. Sexual misconduct is a harmful example of a boundary violation, occurring in multiple contexts and involving a wide range of behaviors. The physician and patient relationship requires the doctor of chiropractic to exercise the utmost care that he or she will do nothing to exploit the trust and dependency of the patient.

2. Definitions

Sexual Contact—may include, but is not limited to the following:

i. genital to genital contact;

ii. oral to genital contact;

iii. anal to genital contact;

iv. kissing;

v. touching breasts, genitals, or other body parts without clinical justification;

vi. encouraging patient to masturbate in presence of chiropractor;

vii. chiropractor masturbating in the presence of a patient;

viii. offering clinical services in exchange for sexual favors.

Sexual Impropriety—may include, but is not limited to, sexually suggestive behavior, gestures, expressions, statements, and it may include failing to respect a patient's privacy such as in the following examples:

i. failing to employ disrobing or draping practices with respect to the patient's privacy;

ii. examination or touching a patient's genital region without donning gloves and having another professional staff present during the examination;

iii. inappropriate comments to a patient about the patient's body, sexual orientation, or potential sexual performance during the examination;

iv. soliciting a date or romantic relationship;

v. performing an intimate examination without clinical justification;

vi. requesting personal information from the patient which is not clinically necessary.

Sexual-Misconduct—includes sexual impropriety towards a patient, sexual contact towards a patient, sexual harassment in the workplace, facilitating a hostile work environment, sexual conduct between supervisors and subordinates, and commission of sexual assault and other sexual crimes.

3. A patient's or staff's consent to, initiation of or participation in sexual behavior or involvement with a licensee does not change the nature of the conduct nor lift the prohibition.

4. This rule shall not apply between a chiropractor and their spouse.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:2804.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Board of Chiropractic Examiners, LR 37:

Family Impact Statement

1. What effect will this Rule have on the stability of the family? The proposed Rule will not affect the stability of the family.

2. What effect will this have on the authority and rights of person regarding the education and supervision of their children? The proposed Rule will not affect the authority or rights of persons regarding the education and supervision of their children

3. What effect will this have on the functioning of the family? This Rule will not affect the functioning of the family.

4. What effect will this have on family earnings and family budget? This Rule will not affect the family earnings or family budget.

5. What effect will this have on the behavior and personal responsibility of children? This Rule will not affect the behavior or personal responsibility of children.

6. Is the family or local government able to perform the function as contained in this proposed Rule? No. The action proposed is strictly a board enforcement function.

Public Comments

Interested persons may submit written comments to Patricia Oliver, Board of Chiropractic Examiners, 8621 Summa Avenue, Baton Rouge, LA 70809. All comments must be submitted by 4:30 p.m., on July 20, 2011.

Patricia Oliver
Executive Director

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES
RULE TITLE: Specialty Advertising, Unethical Conduct, Code of Ethics

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

There will be no costs or savings to state or local governmental units resulting from these rule changes other than the costs associated with promulgation of the rule in FY 11, which will be approximately $1000. The board proposes to amend 46:XXVII.320, Specialty Advertising, to recognize an exception for the qualifying chiropractic physician, to seek approval from the board to advertise a specialty when possessing special knowledge, skills or training. The board proposes to amend LAC 46:XXVII.501, Unethical Conduct, to include a code of ethics as a basis for a determination that a chiropractic physician's behavior is unethical. The board proposes to adopt LAC 46:XXVII.502, code of ethics, to set forth applicable ethical duties for chiropractic physicians. The actions proposed are strictly part of the board enforcement function.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

There will be no effect on revenue collections of state or local governmental units as a result of this proposed action.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS (Summary)

The proposed changes to the Specialty Advertising rule will increase the marketability of certain chiropractic physicians. There are no costs to directly affected persons, and the economic benefits to directly affected persons or non-governmental groups is unknown.

There are no costs and/or economic benefits directly affecting persons or non-governmental groups, associated with the proposed amendment to the Unethical Conduct rule and proposed adoption of a code of ethics rule.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed specialty advertising rule change will have no effect on competition and employment. Notably, it will allow another avenue for increased marketability of certain chiropractic physicians that possess knowledge, skills and training in a specialty they wish to advertise.

The proposed rule change to "Unethical Conduct" and the adoption of a code of ethics should not effect competition and employment, unless a licensee is engaging in inappropriate conduct with a patient or employee, which would subject him/her to discipline by the board.

Patricia A. Oliver
Executive Director
1106#014

H. Gordon Monk
Legislative Fiscal Officer
Legislative Fiscal Office

NOTICE OF INTENT

Department of Health and Hospitals
Board of Nursing

Alternative to Disciplinary Proceedings
(LAC 46:XLVII.3419)

The Louisiana State Board of Nursing proposes to amend LAC 46:XLVII. §3419. Disciplinary Proceedings: Alternative to Disciplinary Proceedings" in accordance with 37:918, R.S. 37:919 and R.S. 37:920 and in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950, et seq.

In April 2010, The National Council of State Boards of Nursing (NCSBN) Substance Use Disorder Guidelines Forum presented findings from the committee review and began to provide recommendations for alternative and disciplinary programs. The model guidelines established by the NCSBN committee were presented in the April 2011 Journal of Nursing Regulation. The Louisiana State Board of Nursing (LSBN) Recovering Nurse Program (RNP) is very congruent with the guidelines established by NCSBN except there was not an exclusion criterion for substituting a patient's medication in order to divert the narcotic. This is extremely serious and can result in untreated pain and significant patient harm. Although rarely reported to the RNP staff, participants should be ineligible for alternative to disciplinary entry when engaging in behavior which has such a high potential to cause patient harm and therefore an addendum to the LSBN rules is necessary to align with the NCSBN recommendations.

Title 46
PROFESSIONAL AND OCCUPATIONAL STANDARDS
Part XLVII. Nurses: Practical Nurses and Registered Nurses
Subpart 2. Registered Nurses
Chapter 34. Disciplinary Proceedings; Alternative to Disciplinary Proceedings
§3419. Alternative to Disciplinary Proceedings

A. - D.3.h. …

i. no related nursing problems involving death or significant harm to patient. No substitution of narcotic medications destined for patients for the purpose of diversion;

j. agrees to comply with all RNP specifications and signs program agreement including statement of admission of chemical dependency or other impairment.

E. - F.1. …

a. sign RNP agreement for 3-5 years for substance use disorders. Agreements to rule out substance dependence or medical, mental or physical agreements may be of shorter duration depending on treatment team recommendations;

b. refrain from the practice of nursing until approved by RNP;

c. complete and submit to the board a comprehensive inpatient evaluation and treatment as recommended from a board recognized treatment facility. Admission shall be within 10 days unless approved by RNP or board's professional staff;

d. submit to the board a "Fitness for Employment" release form completed by a board approved addictionologist prior to approval by RNP to return to work;

e. be granted confidentiality and no disciplinary action will be taken against the license.

2. At first relapse/non-compliance for nurses in the program confidentially, the following steps will be taken.

a. Refrain from the practice of nursing until approved by RNP.

b. Complete a relapse evaluation as directed by RNP staff. Must follow all treatment recommendations. Admission shall be within 10 days unless approved by RNP.

c. Sign RNP agreement for length of time to be determined by treatment team.

d. Submit to the board a Fitness for Employment release form completed by a board approved addictionologist prior to approval by RNP to return to work.

F.3. - H. …

I. Costs of Alternative to Disciplinary Proceedings. The participant agrees to submit payment of $250 per year as an administrative fee.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:918.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Nursing, LR 24:1293 (July 1998), amended LR 27:728 (May 2001), LR 31:1586 (July 2005), LR 35:1535 (August 2009), LR 36:1244 (June 2010), LR 37:

Family Impact Statement

In compliance with R.S. 49:953 and 974, the following Family Impact Statement of the proposed amendments to

rules is provided. There should be no adverse effect on the stability of the family; the authority and rights of parents regarding the education and supervision of their children; or the ability of the family or a local government to perform the function as contained in the proposed Rule amendments.

Public Comments

Interested persons may submit written comments on the proposed Rule until 5 p.m., July 11, 2011 to Barbara L. Morvant, Executive Director, 17373 Perkins Road, Baton Rouge, LA, 70810.

Barbara L. Morvant, MN, RN
Executive Director

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES
RULE TITLE: Alternative to Disciplinary Proceedings

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

With this rule change to LAC 46:XLVII section 3419, a new administrative fee of $250 will be charged to confidential participants of the Recovering Nurse Program (RNP), and the RNP will be extended from 3 years to 3-5 years depending on the Louisiana State Board of Nursing's (LSBN) evaluation and recommendation. Current participants will not be affected by the rule change and will not have to pay any additional fees or extend their participation in the RNP. There will be approximately 160 additional participants in the program by FY 16 as a result of the two-year extension of the RNP. Current staff will absorb the workload associated with monitoring these additional participants; as such, the board does not anticipate any additional costs as a result of the program extension. The annual costs of the confidential side of the RNP are estimated to be $272,750 in FY 12, $272,930 in FY 13, and $273,117 in FY 14. Implementation costs associated with publishing the rule change in the Register are anticipated to be approximately $300.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

Historically, the confidential side of the RNP has been fully funded by the license renewal fees generated by the LSBN. In an effort to shift a portion of the monitoring costs from license fees, and free a like amount from this revenue source for other costs of the board, this rule change has been proposed to add an annual confidential monitoring Administrative Fee of $250 per participant beginning in FY 12. The remaining costs of the program will continue to be funded by the annual licensure fees.

This $250 annual fee is to be paid in a lump sum at the end of each Program year. This amounts to approximately $20 per month per participant. The additional revenue collected as a result of this fee will assist in compensating for the administrative costs associated with confidentially monitoring individuals in the RNP, including the review and analysis of employer, group facilitator, therapist, and drug screen reports by professional staff as well as scanning, linking, and filing of all reports, letters, and documents. The new administrative fee will not be implemented until FY 12, and therefore, will have no impact in FY 11. The revenue collections from the proposed fee in FY 12 are estimated to be $20,000 ($250 x 80 participants), $40,500 in FY 13 ($250 x 162 participants), and $61,500 in FY 14 ($250 x 246 participants).

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS (Summary)

All Registered Nurses entering the Recovering Nurse Program with confidential status will be required to pay an additional $250 annually to pay for the administrative costs of monitoring confidential participants.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

There is no foreseen impact on competition and employment in the public and private sectors.

Barbara L. Morvant
Executive Director
1106#043

H. Gordon Monk
Legislative Fiscal Officer
Legislative Fiscal Office

NOTICE OF INTENT

Department of Health and Hospitals
Board of Nursing

Paperless Licensing Revisions
(LAC 46:XLVII.3323, 3329, 3333, 3339, and 4507)

The Louisiana State Board of Nursing proposes Paperless License revisions to Chapter 33, Subchapter C., Sections 3323. Registration and Registered Nurse Licensure; 3329. Temporary Permits; 3333. Renewal of License; 3339. Verification of Licensure; 3341. Fees for Registration and Licensure; and 4507. Licensure as Advanced Practice Registered Nurse; in accordance with R.S. 37:918, 37:919 and 37:920 and in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950, et seq.

In September 2010, the Louisiana State Board of Nursing motioned for LSBN to move to paperless license. In order for paperless licensure to be accomplished, rulemaking revisions are being recommended to provide consistency in all sections pertaining to paperless licenses.

Title 46
PROFESSIONAL AND OCCUPATIONAL STANDARDS
Part XLVII. Nurses: Practical Nurses and Registered Nurses
Subpart 2. Registered Nurses
Chapter 33. General
Subchapter C. Registration and Registered Nurse Licensure
§3323. Registration and Licensure

A. Registration in Louisiana is mandatory for practicing as a registered nurse.

B. Registration and licensure as a registered nurse shall be issued only to an applicant who qualifies by examination or endorsement in accordance with R.S. 37:920. All applicants shall meet the same standards.

C. The board shall issue a certificate of registration, carrying a permanent registration number, designating the date of issuance, the authorization to practice as a registered nurse in Louisiana, to all applicants who qualify for initial licensure.

D. The executive director, or a designee of the board, shall record the registration of the permanent records of the board and shall issue a license to practice, valid from the date of issuance until January 31. For individuals registered between January 1 and January 31, the board shall issue a license to practice, valid from the date of issuance until January 31 of the next year.

E. An individual may provide educational and/or consultative services in accordance with R.S. 37:929(9) for a period of not more than 30 days in a calendar year, without applying for a Louisiana registered nurse license.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:918 and R.S. 37:920.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, LR 7:77 (March 1981), amended by the Department of Health and Hospitals, Board of Nursing, LR 23:962 (August 1997), LR 24:1293 (July 1998), LR 37:

§3329. Temporary Permits

A. In accordance with R.S. 37:920, the Board of Nursing may issue the following temporary permits to practice as a registered nurse.

A.1. - A.3.c. …

4. The working permit expires upon the R.N. applicant's receipt of the results of the first examination after graduation, or at the end of three months if the examination has not been taken.

B. - D.6. …

E. Any individual who is issued a temporary permit pursuant to Subsection D of this Section shall:

E.1. - F. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:918, 920 and 921.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Board of Nursing, LR 7:78 (March 1981), amended by the Department of Health and Hospitals, Board of Nursing, LR 23:961 (August 1997), LR 24:1293(July 1998), LR 28:2513 (December 2002), LR 33:460 (March 2007), LR 37:

§3333. Renewal of License

A. Every person holding a license to practice as a registered nurse, and an advanced practice registered nurse, and intending to practice during the ensuing year, shall renew his or her license annually prior to the expiration of his or her license. The board shall furnish an application for renewal of a license to every person who holds a current license. The licensee shall complete the renewal application before January 1. Upon completion of the application and submission of the renewal fee as required under §3341, the board shall verify the accuracy of the application and issue to the licensee a license of renewal for the current year beginning February 1 and expiring January 31. Incomplete applications will be returned. Applications submitted after December 31 will be considered late and subject to the fee as required under §3341 for late renewals. Failure to renew a license prior to expiration subjects the individual to forfeiture of the right to practice. An individual shall notify the board of:

1. change of address. Notify the office of the board in writing or electronically within 30 days if a change of address has occurred;

2. ...

B. Requirements for renewal of license include:

1. completion of application form, including statistical information;

2. payment of fee;

3. evidence of meeting the requirements of §3335, effective January 1, 1993;

4. provide any/all information, documents, records, reports, evidence and/or items as requested by the board/board staff within 60 days from the date of the letter of request/notification sent by board staff, or else the RN/APRN license shall be subject to immediate invalidation with change of status to inactive license and practice as a registered nurse and/or advanced practice registered nurse will no longer be legal.

C. An inactive or lapsed license may be reinstated by submitting a completed application, paying the required fee, and meeting all other relevant requirements, provided there is no evidence of violation of R.S. 37:911 et seq., §3331, or other administrative rules, or no allegations of acts or omissions which constitute grounds for disciplinary action as defined in R.S. 37:921 or §3405. Any person practicing as a registered nurse or advance practice registered nurse during the time one's license is inactive or has lapsed is considered an illegal practitioner and is subject to the penalties provided for violation of this Part and will not be reinstated until the disciplinary action is resolved.

D.1.A retired status license may be issued to any individual who is no longer engaged in the practice of nursing, provided said individual:

a. completes an application provided by the board prior to the expiration of the active license; and

b. pays the required one-time fee as specified under §3341.

2. A licensee in retired status will continue to receive *The Examiner* and other official communications and continue to be listed in the official roster of registered nurses in Louisiana.

3. After placed in retired status, no further renewal notices will be sent.

4. Repealed

5. - 8. …

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Board of Nursing, LR 7:78 (March 1981), amended by the Department of Health and Hospitals, Board of Nursing, LR 16:1061 (December 1990), LR 23:962 (August 1997), LR 23:963 (August 1997), repromulgated LR 24:1293 (July 1998), amended LR 26:1443 (July 2000), LR 32:247 (February 2006), LR 35:1536 (August 2009), LR 37:

§3339. Verification of Licensure

A. Verification of a registered nurse or advanced practice registered nurse license only requires the correct spelling of the name of the licensee.

B. Before employing a person as a registered nurse and/or advanced practice registered nurse, current licensure must be verified by primary source verification through the board. Failure to do so may result in aiding and abetting an unlicensed person to practice nursing in violation of the law.

C. Annually, on or before January 31, current licensure of registered nurses and advanced practice registered nurses should be verified by directors of nursing or supervisors. Documentation of on-line verification is necessary to ascertain that the year is current.

AUTHORITY NOTE: Promulgated in accordance with R.S.37:918 and R.S. 37:920.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Board of Nursing, LR 7:77 (March 1981), amended by the Department of Health and Hospitals, Board of Nursing, LR 24:1293 (July 1998), LR 32:2255 (December 2006), LR 37:

§3341. Fees for Registration and Licensure

A. Not withstanding any provisions of this Chapter, the board shall collect in advance fees for licensure and administrative services as follows.

1. Licensure

a. - q. …

r.- s. Repealed.

A.2. - C. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:918 and R.S. 37:927.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:918 and R.S. 37:927.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, LR 8:417 (August 1982), amended by the Department of Health and Hospitals, Board of Nursing, LR 14:533 (August 1988), LR 22:981 (October 1996), repromulgated LR 24:1293 (July 1998), amended LR 26:84 (January 2000), LR 30:2829 (December 2004), LR:31:2027 (August 2005), LR 36:1246 (June 2010), LR 37:

Chapter 45. Advanced Practice Registered Nurses

§4507. Licensure as Advanced Practice Registered Nurse

A. - B.3.c.i. …

ii. notify the employer of the results.

B.4. - F.2.g. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:918.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Board of Nursing, LR 22:281 (April 1996), amended LR 27:724 (May 2001), LR 29:580 (April 2003), LR 31:1340 (June 2005), LR 31:2015 (August 2005), LR 32:247 (February 2006), LR 37:

Family Impact Statement

In compliance with R.S. 49:953 and 974, the following Family Impact Statement of the proposed amendments to rules is provided. There should be no adverse effect on the stability of the family; the authority and rights of parents regarding the education and supervision of their children; or the ability of the family or a local government to perform the function as contained in the proposed rule amendments.

Public Comments

Interested persons may submit written comments on the proposed rules until 5 p.m., July 11, 2011 to Barbara L. Morvant, Executive Director, 17373 Perkins Road, Baton Rouge, LA, 70810.

Barbara L. Morvant, MN, RN
Executive Director

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES
RULE TITLE: Paperless Licensing Revisions

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

Initial implementation costs for FY 11 will be approximately $300 to publish the rule change in the Register. In FY 12, savings are anticipated to be approximately $29,660 due to reduced printing and mailing costs associated with renewal licenses ($27,524) and temporary permits ($2,136). The savings in FY 12 will be mitigated by the one-time costs associated with an additional mailing to all licensees (postage & printing) prior to the renewal period to inform licensees of the switch to paperless licensure ($31,191). As such, the net impact of the rule change on the board in FY 12 is estimated to be a $1,531 cost ($31,191 cost - $29,660 savings = $1,531 cost). Savings in subsequent years are estimated to increase approximately 2% based on historical trends in the number of new licensees. Therefore, savings in FY 13 are estimated to be $30,254 and $30,860 in FY 14.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

The rule change to LAC 46:XLVII.33 section 4507 eliminates paper licensure and allows for the Louisiana State Board of Nursing (LSBN) to renew licenses for its members online. The LSBN will lose an average of $7,700 annually in duplicate license fees by going paperless ($10 X 770 duplicate requests).

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS (Summary)

Licensees will no longer have to pay $10 for duplicate license fees since proof of licensure will now be online. Licensees will continue to be charged the regular renewal fee for licenses ($80) and temporary permits ($50).

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule will have no effect on competition and employment.

Barbara L. Morvant	H. Gordon Monk
Executive Director	Legislative Fiscal Officer
1106#042	Legislative Fiscal Officer

NOTICE OF INTENT

Department of Health and Hospitals
Bureau of Health Services Financing

Federally Qualified Health Centers—Diabetes Self-Management Training
(LAC 50:XI.Chapters 103-105 and 10701)

The Department of Health and Hospitals, Bureau of Health Services Financing proposes to amend LAC 50:XI.Chapters 103-105 and §10701 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This proposed Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq.

Act 11 of the 2010 Regular Session of the Louisiana Legislature authorized the Department of Health and Hospitals, through its primary and preventive care activity, to provide reimbursement to providers for rendering services that will educate and encourage Medicaid enrollees to obtain appropriate preventive and primary care in order to improve their overall health and quality of life. In keeping with the intent of Act 11, the Department of Health and Hospitals, Bureau of Health Services Financing promulgated an Emergency Rule which amended the provisions governing federally qualified health centers (FQHCs) to provide Medicaid reimbursement for diabetes self-management training (DSMT) services (*Louisiana Register*, Volume 37, Number 2). It is anticipated that this new service will promote improved patient self-management skills which will reduce diabetes-related complications that adversely affect quality of life, and subsequently reduce Medicaid costs associated with the care of recipients diagnosed with diabetes-related illnesses. The February 20, 2011 Emergency Rule also reorganized the existing provisions governing provider participation and services in a more clear and concise manner in the *Louisiana Administrative Code*. The

department amended the February 20, 2011 Emergency Rule to clarify the provisions governing service limits (*Louisiana Register*, Volume 37, Number 6). This proposed Rule is being promulgated to continue the provisions of the February 20, 2011 and the June 20, 2011 Emergency Rules.

Title 50

PUBLIC HEALTH—MEDICAL ASSISTANCE

Part XI. Clinic Services

Subpart 13. Federally-Qualified Health Centers

Chapter 103. Services

§10301. Scope of Services

[Formerly 10501]

A. Medicaid reimbursement is limited to medically necessary services that are covered by the Medicaid State Plan and would be covered if furnished by a physician. The following services shall be covered:

1. services furnished by a physician within the scope of practice of his profession under Louisiana law;

2. services furnished by a:

a. physician assistant;

b. nurse practitioner;

c. nurse midwife;

d. clinical social worker;

e. clinical psychologist; or

f. dentist;

3. services and supplies that are furnished as an incident to professional services furnished by all eligible professionals;

4. other ambulatory services; and

5. diabetes self-management training (DSMT) services.

B. Effective February 20, 2011, the department shall provide coverage of diabetes self-management training services rendered to Medicaid recipients diagnosed with diabetes.

1. The services shall be comprised of one hour of individual instruction and nine hours of group instruction on diabetes self-management.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 30:2328 (October 2004), repromulgated LR 30:2488 (November 2004), amended LR 32:1902 (October 2006), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§10303. Service Limits

[Formerly 10503]

A. Federally qualified health center visits (encounters) are limited to 12 visits per year for medically necessary services rendered to Medicaid recipients who are 21 years of age or older. Visits for Medicaid recipients who are under 21 years of age and for prenatal postpartum care are excluded from the service limitation.

B. Recipients of DSMT services shall receive up to 10 hours of services during the first 12-month period beginning with the initial training date.

1. After the first 12-month period has ended, recipients shall only be eligible for two hours of individual instruction on diabetes self-management per calendar year.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1902 (October 2006), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:2280 (October 2010), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Chapter 105. Provider Participation

§10501. Provider Enrollment

[Formerly 10301]

A. In order to enroll and participate in the Medicaid Program, an FQHC must submit a completed provider enrollment packet that includes a copy of the HRSA grant approving its FQHC status.

B. The effective date of a FQHC's enrollment to participate in the Medicaid Program shall not be prior to the date of receipt of the completed enrollment packet.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 30:2328 (October 2004), repromulgated LR 30:2487 (November 2004), amended LR 32:1901 (October 2006), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§10503. Standards for Participation

[Formerly 10303]

A. Federally qualified health centers must comply with the applicable licensure, accreditation and program participation standards for all services rendered. If a FQHC wishes to initiate participation, it shall be responsible for meeting all of the enrollment criteria of the program. The FQHC provider shall:

1. maintain an acceptable fiscal record keeping system that readily distinguishes one type of service from another type of service that may be provided;

2. retain all records necessary to fully disclose the extent of services provided to recipients for five years from the date of service and furnish such records, and any payments claimed for providing such services, to the Medicaid Program upon request; and

3. abide by and adhere to all federal and state regulations and policy manuals.

B. If a FQHC receives approval for a satellite site, the satellite site must enter into a separate provider agreement and obtain its own Medicaid provider number.

C. In order to receive Medicaid reimbursement for DSMT services, a FQHC must have a DSMT program that meets the quality standards of one of the following accreditation organizations:

1. the American Diabetes Association;

2. the American Association of Diabetes Educators; or

3. the Indian Health Service.

D. All DSMT programs must adhere to the national standards for diabetes self-management education.

1. Each member of the instructional team must:

a. be a certified diabetes educator (CDE) certified by the National Certification Board for Diabetes Educators; or

b. have recent didactic and experiential preparation in education and diabetes management.

2. At a minimum, the instructional team must consist of one the following professionals who is a CDE:

a. a registered dietician;
b. a registered nurse; or
c. a pharmacist.

3. All members of the instructional team must obtain the nationally recommended annual continuing education hours for diabetes management.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1902 (October 2006), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:2280 (October 2010), amended LR 37:

Chapter 107. Reimbursement Methodology

§10701. Prospective Payment System

A. - B.2.NOTE. …

3. Effective for dates of service on or after February 20, 2011, the Medicaid Program shall include coverage for diabetes self-management training services rendered by qualified health care professionals in the FQHC encounter rate.

a. Separate encounters for DSMT services are not permitted and the delivery of DSMT services alone does not constitute an encounter visit.

C. - F. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1902 (October 2006), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Implementation of the provisions of this Rule may be contingent upon the approval of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), if it is determined that submission to CMS for review and approval is required.

Family Impact Statement

In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature, the impact of this proposed Rule on the family has been considered. It is anticipated that this proposed Rule will have a positive impact on family functioning, stability and autonomy as described in R.S. 49:972, by increasing access to diabetes self-management training which is anticipated to improve the health outcomes of Medicaid recipients diagnosed with diabetes.

Public Comments

Interested persons may submit written comments to Don Gregory, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. He is responsible for responding to inquiries regarding this proposed Rule.

Public Hearing

A public hearing on this proposed Rule is scheduled for Wednesday, July 27, 2011 at 9:30 a.m. in Room 118, Bienville Building, 628 North Fourth Street, Baton Rouge, LA. At that time all interested persons will be afforded an opportunity to submit data, views or arguments either orally or in writing. The deadline for receipt of all written comments is 4:30 p.m. on the next business day following the public hearing.

Bruce D. Greenstein
Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES
RULE TITLE: Federally Qualified Health Centers—Diabetes Self-Management Training

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

It is anticipated that the implementation of this proposed rule will result in estimated state general fund programmatic costs of $1,815 for FY 10-11 $6,207 for FY 11-12 and $6,302 for FY 12-13. However, the cost is expected to be offset by an indeterminable amount from the anticipated savings realized from a corresponding reduction in expenditures for services related to diabetes treatment. It is anticipated that $902 ($451 SGF and $451 FED) will be expended in FY 10-11 for the state's administrative expense for promulgation of this proposed rule and the final rule. The numbers reflected above are based on a blended Federal Medical Assistance Percentage (FMAP) rate of 69.34 percent in FY 11-12. The enhanced rate of 69.78 percent for the last nine months of FY 12 is the federal rate for disaster-recovery FMAP adjustment states.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

It is anticipated that the implementation of this proposed rule will increase federal revenue collections by approximately $4,492 for FY 10-11 $14,037 for FY 11-12 and $14,550 for FY 12-13. It is anticipated that $451 will be expended in FY 10-11 for the federal administrative expenses for promulgation of this proposed rule and the final rule. The numbers reflected above are based on a blended Federal Medical Assistance Percentage (FMAP) rate of 69.34 percent in FY 11-12. The enhanced rate of 69.78 percent for the last nine months of FY 12 is the federal rate for disaster-recovery FMAP adjustment states.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS (Summary)

This proposed rule, which continues the provisions of the February 20, 2011 and June 20, 2011 emergency rules, amends the provisions governing federally qualified health centers (FQHCs) to provide Medicaid reimbursement for diabetes self-management training (approximately 100 recipients), and reorganizes the existing provisions governing provider participation and services in a more clear and concise manner in the Louisiana Administrative Code. It is anticipated that implementation of this proposed rule will increase programmatic expenditures in the Medicaid Program by approximately $5,405 for FY 10-11, $20,244 for FY 11-12 and $20,852 for FY 12-13.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

It is anticipated that the implementation of this proposed rule will not have an effect on competition and employment.

Don Gregory	H. Gordon Monk
Medicaid Director	Legislative Fiscal Officer
1106#066	Legislative Fiscal Office

NOTICE OF INTENT

Department of Health and Hospitals
Bureau of Health Services Financing
and
Office of Aging and Adult Services

Home and Community-Based Services Waivers
Adult Day Health Care (LAC 50:XXI.2103, 2107, 2301, 2501, 2503, 2701, 2901-2905, and 2915)

The Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services proposes to amend LAC 50:XXI.2103, §2107, §2301, §2501, §2503, §2701, §2901-2905, and §2915 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This proposed Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq.

The Department of Health and Hospitals, Office of Aging and Adult Services amended the provisions governing the adult day health care (ADHC) waiver to redefine and clarify the provisions of the waiver relative to the target population, the request for services registry, the comprehensive plan of care, and support coordination services (*Louisiana Register,* Volume 34, Number 10). The October 20, 2008 Rule also amended the provisions governing the reimbursement methodology to reduce the comprehensive ADHC rate paid to providers as a result of adding support coordination as a separate service since these services were traditionally reimbursed as part of the comprehensive ADHC rate. These provisions were repromulgated by the department in December 2008 to correct an error of omission in the publication (*Louisiana Register,* Volume 34, Number 12). The department promulgated an Emergency Rule which amended the Rule governing the ADHC Waiver to revise the provisions governing: 1) the program description; 2) the allocation of waiver opportunities; and 3) the provision of services and discharge criteria (*Louisiana Register*, Volume 37, Number 1). The Department amended the provisions of the January 1, 2011 Emergency Rule to revise the reimbursement methodology governing the ADHC Waiver to implement a quarter hour pay rate and a provider specific transportation component, and reduced the direct care floor (*Louisiana Register,* Volume 37, Number 6). This proposed Rule is being promulgated to continue the provisions of the January 1, 2011 and the June 20, 2011 Emergency Rules.

Title 50
PUBLIC HEALTH—MEDICAL ASSISTANCE
Part XXI. Home and Community-Based Services Waivers
Subpart 3. Adult Day Health Care
Chapter 21. General Provisions
§2103. Program Description

A. An Adult Day Health Care Waiver Program expands the array of services available to individuals with functional impairments, and helps to bridge the gap between independence and institutional care by allowing them to remain in their own homes and communities. This program provides direct care for individuals who have physical, mental or functional impairments. ADHC waiver participants must attend a minimum of 36 days per calendar quarter, absent extenuating circumstances. Exceptions for extenuating circumstances must be approved by the assigned support coordinator based upon guidance provided by OAAS.

B. - C.6. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 30:2034 (September 2004), amended by the Department of Health and Hospitals, Office of Aging and Adult Services, LR 34:2161 (October 2008), repromulgated LR 34:2566 (December 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 37:

§2107. Programmatic Allocation of Waiver Opportunities

A. …

B. Adult day health care waiver opportunities shall be offered to individuals on the registry according to priority groups. The following groups shall have priority for ADHC waiver opportunities in the order listed:

1. individuals with substantiated cases of abuse or neglect with Adult Protective Services (APS) or Elderly Protective Services (EPS) and who, absent ADHC waiver services, would require institutional placement to prevent further abuse and neglect;

a. - c. Repealed.

2. individuals who have been discharged after a hospitalization within the past 30 days that involved a stay of at least one night;

3. individuals presently residing in nursing facilities for 90 or more continuous days; and

4. all other eligible individuals on the Request for Services Registry (RFSR), by date of first request for services.

C. If an applicant is determined to be ineligible for any reason, the next individual on the registry is notified and the process continues until an individual is determined eligible. An ADHC waiver opportunity is assigned to an individual when eligibility is established and the individual is certified.

D. Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and pursuant to Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Aging and Adult Services, LR 34:2162 (October 2008), repromulgated LR 34:2566 (December 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 37:

Chapter 23. Services
§2301. Covered Services

A. …

1. Adult Day Health Care. ADHC services are a planned, diverse daily program of individual services and group activities structured to enhance the recipient's physical functioning and to provide mental stimulation. Services are furnished on a regularly scheduled basis, not to exceed 10 hours a day, 50 hours a week. An adult day health care center shall, at a minimum, furnish the following services:

a. - j. …

NOTE: Repealed.

2. Support Coordination. These services assist participants in gaining access to necessary waiver and other

State Plan services, as well as medical, social, educational and other services, regardless of the funding source for these services. Support coordinators shall be responsible for ongoing monitoring of the provision of services included in the recipient's approved plan of care (POC). This is a mandatory service.

A.3. - B. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 30:2036 (September 2004), amended by the Department of Health and Hospitals, Office of Aging and Adult Services, LR 34:2162 (October 2008), repromulgated LR 34:2566 (December 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 37:

Chapter 25. Admission and Discharge Criteria

§2501. Admission Criteria

A. Admission to the ADHC Waiver Program shall be determined in accordance with the following criteria:

1. - 3. …

4. reasonable assurance that the health and welfare of the individual can be maintained in the community with the provision of ADHC Waiver services.

B. Failure of the individual to cooperate in the eligibility determination process or to meet any of the criteria in this Section will result in denial of admission to the ADHC Waiver.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 30:2040 (September 2004), amended by the Department Of Hospitals, Office of Aging and Adult Services, LR 34:2163 (October 2008), repromulgated LR 34:2568 (December 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 37:

§2503. Denial and Discharge Criteria

A. Admission shall be denied or the recipient shall be discharged from the ADHC Waiver Program if any of the following conditions are determined.

1. - 7. …

8. The participant fails to attend the ADHC center for a minimum of 36 days per calendar quarter.

9. The individual fails to maintain a safe home environment.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and pursuant to Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Aging and Adult Services, LR 34:2163 (October 2008), repromulgated LR 34:2568 (December 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 37:

Chapter 27. Provider Participation

§2701. General Provisions

A. - B. …

C. ADHC providers shall ensure that all non-licensed direct care staff meet the minimum mandatory qualifications and requirements for direct service workers as required by R.S. 40:2179 - 2179.1.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 30:2041 (September 2004), amended by the Department of Health and Hospitals, Office for Aging and Adult Services, LR 34:2164 (October 2008), repromulgated LR 34:2568 (December 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 37:

Chapter 29. Reimbursement

§2901. General Provisions

A. Development. Adult day health care providers shall be reimbursed a per quarter hour rate for services provided under a prospective payment system (PPS). The system shall be designed in a manner that recognizes and reflects the cost of direct care services provided. The reimbursement methodology is designed to improve the quality of care for all adult day health care waiver recipients by ensuring that direct care services are provided at an acceptable level while fairly reimbursing the providers.

B. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 30:2041 (September 2004), amended by the Department of Health and Hospitals, Office of the Secretary, Office of Aging and Adult Services, LR 32:2257 (December 2006), LR 34:2164 (October 2008), repromulgated LR 34:2569 (December 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 37:

§2903. Cost Reporting

A. Cost Centers Components

1. - 3.e. …

4. Property. This component reimburses for depreciation, interest on capital assets, lease expenses, property taxes and other expenses related to capital assets, excluding property cost related to patient transportation.

5. Transportation. This component reimburses for in-house and contractual driver salaries and related benefits, non-emergency medical transportation, vehicle maintenance and supply expense, and automotive expenses related to ADHC patient transportation.

B. - L.2. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Aging and Adult Services, LR 34:2164 (October 2008), repromulgated LR 34:2569 (December 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 37:

§2905. Cost Categories Included in the Cost Report

A. - B.19. …

C. Administrative and Operating Costs (AOC)

1. - 5. …

6. Salaries, Other Administrative—gross salaries of other administrative personnel including bookkeepers, receptionists, administrative assistants and other office and clerical personnel.

7. Salaries, Owner or Owner/Administrator—gross salaries of all owners of the center that are paid through the center.

8. Payroll Taxes—cost of employer's portion of Federal Insurance Contribution Act (FICA), Federal Unemployment Tax Act (FUTA), State Unemployment Tax Act (SUTA), and Medicare tax for administrative and operating employees.

9. Group Insurance, AOC—cost of employer's contribution to employee health, life, accident and disability insurance for administrative and operating employees.

10. Pensions, AOC—cost of employer's contribution to employee pensions for administration and operating employees.

11. Uniform Allowance, AOC—employer's cost of uniform allowance and/or uniforms for administration and operating employees.

12. Worker's Compensation, AOC—cost of worker's compensation insurance for administration and operating employees.

13. Contract, Housekeeping—cost of housekeeping services and personnel hired through contract that are not employees of the center.

14. Contract, Laundry—cost of laundry services and personnel hired through contract that are not employees of the center.

15. Contract, Maintenance—cost of maintenance services and persons hired through contract that are not employees of the center.

16. Consultant Fees, Dietician—fees paid to consulting registered dieticians.

17. Accounting Fees—fees incurred for the preparation of the cost report, audits of financial records, bookkeeping, tax return preparation of the adult day health care center and other related services excluding personal tax planning and personal tax return preparation.

18. Amortization Expense, Non-Capital—costs incurred for legal and other expenses when organizing a corporation must be amortized over a period of 60 months. Amortization of costs attributable to the negotiation or settlement of the sale or purchase of any capital asset on or after July 18, 1984, whether by acquisition or merger, for which any payment has previously been made are nonallowable costs. If allowable cost is reported on this line, an amortization schedule must be submitted with the cost report.

19. Bank Service Charges—fees paid to banks for service charges, excluding penalties and insufficient funds charges.

20. Dietary Supplies—costs of consumable items such as soap, detergent, napkins, paper cups, straws, etc., used in the dietary department.

21. Dues—dues to one organization are allowable.

22. Educational Seminars and Training—the registration cost for attending educational seminars and training by employees of the center and costs incurred in the provision of in-house training for center staff, excluding owners or administrative personnel.

23. Housekeeping Supplies—cost of consumable housekeeping items including waxes, cleaners, soap, brooms and lavatory supplies.

24. Insurance, Professional Liability and Other—includes the costs of insuring the center against injury and malpractice claims.

25. Interest Expense, Non-Capital and Vehicles—interest paid on short term borrowing for center operations.

26. Laundry Supplies—cost of consumable goods used in the laundry including soap, detergent, starch and bleach.

27. Legal Fees—only actual and reasonable attorney fees incurred for non-litigation legal services related to patient care are allowed.

28. Linen Supplies—cost of sheets, blankets, pillows, gowns, under-pads and diapers (reusable and disposable).

29. Miscellaneous—costs incurred in providing center services that cannot be assigned to any other line item on the cost report. Examples of miscellaneous expense are small equipment purchases, all employees' physicals and shots, nominal gifts to all employees, such as a turkey or ham at Christmas, allowable advertising, and flowers purchased for the enjoyment of the clients. Items reported on this line must be specifically identified.

30. Management Fees and Home Office Costs—the cost of purchased management services or home office costs incurred that are allocable to the provider. Costs included that are for related management/home office costs must also be reported on a separate cost report that includes an allocation schedule.

31. Office Supplies and Subscriptions—cost of consumable goods used in the business office such as:

a. pencils, paper and computer supplies;

b. cost of printing forms and stationery including, but not limited to, nursing and medical forms, accounting and census forms, charge tickets, center letterhead and billing forms;

c. cost of subscribing to newspapers, magazines and periodicals.

32. Postage—cost of postage, including stamps, metered postage, freight charges and courier services.

33. Repairs and Maintenance—supplies and services, including electricians, plumbers, extended service agreements, etc., used to repair and maintain the center building, furniture and equipment except vehicles. This includes computer software maintenance.

34. Taxes and Licenses—the cost of taxes and licenses paid that are not included on any other line on Form 6. This includes tags for vehicles, licenses for center staff (including nurse aide re-certifications) and buildings.

35. Telephone and Communications—cost of telephone services, wats lines and fax services.

36. Travel—cost of travel (airfare, lodging, meals, etc.) by the administrator and other authorized personnel to attend professional and continuing educational seminars and meetings or to conduct center business. Commuting expenses and travel allowances are not allowable.

37. Utilities—cost of water, sewer, gas, electric, cable TV and garbage collection services.

38. Allocated Costs, Hospital Based—costs that have been allocated through the step-down process from a hospital as administrative and operating costs.

39. Total Administrative and Operating Costs.

D. Property and Equipment

1. - 7. …

8. Allocated Costs, Hospital Based—costs that have been allocated through the step-down process from a hospital or state institution as property costs when those costs include allocated overhead.

9. Total Property and Equipment.

E. Transportation Costs

1. Salaries, Drivers—gross salaries of personnel involved in transporting clients to and from the center.

2. Non-Emergency Medical Transportation—the cost of purchased non-emergency medical transportation services including, but not limited to:

a. payments to employees for use of personal vehicle;

b. ambulance companies; and

c. other transportation companies for transporting patients of the center.

3. Vehicle Expenses—vehicle maintenance and supplies, including gas and oil.

4. Lease, Automotive—cost of leases for vehicles used for patient care. A mileage log must be maintained. If a leased vehicle is used for both patient care and personal purposes, cost must be allocated based on the mileage log.

5. Total Transportation Costs.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Aging and Adult Services, LR 34:2166 (October 2008), repromulgated LR 34:2571 (December 2008), amended by the Department of Health and Hospitals, Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 37:

§2915. Provider Reimbursement

A. Cost Determination Definitions

* * *

Base Rate Components—the base rate is the summation of the following:

a. direct care;

b. care related costs;

c. administrative and operating costs;

d. property costs; and

e. transportation costs.

* * *

B. Rate Determination

1. - 5. …

6. Allowable quarter hours are used to calculate the per quarter hour costs for each of the rate components. Allowable quarter hours are calculated using the following criteria:

a. a maximum daily reimbursement limit of 10 hours per participant day;

b. reimbursement will be for full quarter hour (15 minute) increments only; and

c. the quarter hour data used in rate setting shall be from the database of hours provided by the department.

7. Formulae. Each median cost component shall be calculated as follows.

a. Direct Care Cost Component. Direct care allowable quarter hour costs from all acceptable full year cost reports, except those for which an audit disclaimer has been issued, shall be arrayed from lowest to highest. The cost at the midpoint of the array shall be the median cost. Should there be an even number of arrayed cost, an average of the two midpoint centers shall be the median cost. The median cost shall be trended forward by dividing the value of the Consumer Price Index-Medical Services (South Region) Index for December of the year preceding the base rate year by the value of the index for the December of the year preceding the cost report year. The direct care rate component shall be set at 115 percent of the inflated median.

i.-ii. Repealed.

b. Care Related Cost Component. Care related allowable quarter hour costs from all acceptable full year cost reports, except those for which an audit disclaimer has been issued, shall be arrayed from lowest to highest. The cost of the center at the midpoint of the array shall be the median cost. Should there be an even number of arrayed cost, an average of the two midpoint centers shall be the median cost. The median cost shall be trended forward by the value of the Consumer Price Index-All Items (South Region) Index for December of the year preceding the base rate year by the value of the index for the December of the year preceding the cost report year. The care related rate component shall be set at 105 percent of the inflated median.

c. Administrative and Operating Cost Component. Administrative and operating allowable quarter hour cost from all acceptable full year cost reports, except those for which an audit disclaimer has been issued, shall be arrayed from lowest to highest. The cost of the midpoint of the array shall be the median cost. Should there be an even number of arrayed cost, an average of the two midpoint centers shall be the median cost. The median cost shall be trended forward by dividing the value of the CPI-All Items (South Region) Index for December of the year preceding the base rate year by the value of the index for the December of the year preceding the cost report year. The administrative and operating rate component shall be set at 105 percent of the inflated median.

d. Property Cost Component. The property allowable quarter hour costs from all acceptable full year cost reports, except those for which an audit disclaimer has been issued, shall be arrayed from lowest to highest. The cost at the midpoint of the array shall be the median cost. Should there be an even number of arrayed cost, an average of the two midpoint centers shall be the median cost. This will be the rate component. Inflation will not be added to property costs.

e. Transportation Cost Component. The transportation allowable quarter hour costs from all acceptable full year cost reports, except those for which an audit disclaimer has been issued, will be calculated on a provider by provider basis. Should a provider not have filed an acceptable full year cost report, the provider's transportation cost will be reimbursed as follows:

i. New provider, as described in §2915.E.1, will be reimbursed in an amount equal to the statewide allowable quarter hour median transportation costs.

(a). In order to calculate the statewide allowable quarter hour median transportation costs, all acceptable full year cost reports, except those for which an audit disclaimer has been issued, shall be arrayed from lowest to highest. The cost at the midpoint of the array shall be the median cost. Should there be an even number of arrayed cost, an average of the two midpoint centers shall be the median cost. This will be the rate component. Inflation will not be added to transportation costs.

ii. Providers that gave gone through a change of ownership (CHOW), as described in §2915.E.2, will be reimbursed for transportation costs based upon the previous owner's specific allowable quarter hour transportation costs

for the period of time between the effective date of the CHOW and the first succeeding base year in which the new owner could possibly file an allowable 12-month cost report. Thereafter, the new owner's data will be used to determine the provider's rate following the procedures specified in this Rule.

iii. Providers that have been issued an audit disclaimer, or have a non-filer status, as described in §2915.E.3, will be reimbursed for transportation costs at a rate equal to the lowest allowable quarter hour transportation cost in the state as of the most recent audited and/or desk reviewed rate database.

8. Budgetary Constraint Rate Adjustment. Effective July 1, 2011, the allowable quarter hour rate components for direct care, care related, administrative and operating, property, and transportation shall be reduced by 10.8563 percent.

9. Interim Adjustments to Rates. If an unanticipated change in conditions occurs that affects the cost of at least 50 percent of the enrolled ADHC providers by an average of five percent or more, the rate may be changed. The department will determine whether or not the rates should be changed when requested to do so by 25 percent or more of the enrolled providers, or an organization representing at least 25 percent of the enrolled providers. The burden of proof as to the extent and cost effect of the unanticipated change will rest with the entities requesting the change. The department may initiate a rate change without a request to do so. Changes to the rates may be temporary adjustments or base rate adjustments as described below.

a. Temporary Adjustments. Temporary adjustments do not affect the base rate used to calculate new rates.

i. Changes Reflected in the Economic Indices. Temporary adjustments may be made when changes which will eventually be reflected in the economic indices, such as a change in the minimum wage, a change in FICA or a utility rate change, occur after the end of the period covered by the indices, i.e., after the December preceding the rate calculation. Temporary adjustments are effective only until the next annual base rate calculation.

ii. Lump Sum Adjustments. Lump sum adjustments may be made when the event causing the adjustment requires a substantial financial outlay, such as a change in certification standards mandating additional equipment or furnishings. Such adjustments shall be subject to the bureau's review and approval of costs prior to reimbursement.

b. Base Rate Adjustment. A base rate adjustment will result in a new base rate component value that will be used to calculate the new rate for the next fiscal year. A base rate adjustment may be made when the event causing the adjustment is not one that would be reflected in the indices.

10. Provider Specific Adjustment. When services required by these provisions are not made available to the recipient by the provider, the department may adjust the prospective payment rate of that specific provider by an amount that is proportional to the cost of providing the service. This adjustment to the rate will be retroactive to the date that is determined by the department that the provider last provided the service and shall remain in effect until the department validates, and accepts in writing, an affidavit that the provider is then providing the service and will continue to provide that service.

C. Cost Settlement. The direct care cost component shall be subject to cost settlement. The direct care floor shall be equal to 70 percent of the median direct care rate component trended forward for direct care services (plus 70 percent of any direct care incentive added to the rate). The Medicaid Program will recover the difference between the direct care floor and the actual direct care amount expended. If a provider receives an audit disclaimer, the cost settlement for that year will be based on the difference between the direct care floor and the lowest direct care per diem of all facilities in the most recent audited and/or desk reviewed database trended forward to the rate period related to the disclaimer.

D. Support Coordination Services Reimbursement. Support coordination services previously provided by ADHC providers and included in the rate, including the minimum data set home care (MDS/HC), the social assessment, the nursing assessment, the CPOC and home visits will no longer be the responsibility of the ADHC provider. Support coordination services shall be provided as a separate service covered in the ADHC waiver. As a result of the change in responsibilities, the rate paid to ADHC providers shall be adjusted accordingly.

1. - 2. Repealed.

E. New Facilities, Changes of Ownership of Existing Facilities, and Existing Facilities with Disclaimer or Non-Filer Status

1. New facilities are those entities whose beds have not previously been certified to participate, or otherwise have participated, in the Medicaid program. New facilities will be reimbursed in accordance with this Rule and receiving the direct care, care related, administrative and operating, property rate components as determined in §2915.B.1-7. These new facilities will also receive the state-wide average transportation rate component, as calculated in §2915.B.7.e.i.(a), effective the preceding July 1.

2. A change of ownership exists if the beds of the new owner have previously been certified to participate, or otherwise have participated, in the Medicaid program under the previous owner's provider agreement. Rates paid to facilities that have undergone a change in ownership will be based upon the rate paid to the previous owner for all rate components. Thereafter, the new owner's data will be used to determine the facility's rate following the procedures in this rule.

3. Existing providers that have been issued an audit disclaimer, or are a provider who has failed to file a complete cost report in accordance with §2903, will be reimbursed based upon the statewide allowable quarter hour median costs for the direct care, care related, administrative and operating, and property rate components as determined in §2915.B.1-7. The transportation component will be reimbursed as described in §2915.B.7.e.iii.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Aging and Adult Services, LR 34:2170 (October 2008), repromulgated LR 34:2575 (December 2008), amended by the Department of Health and Hospitals,

Bureau of Health Services Financing and the Office of Aging and Adult Services, LR 37:

Implementation of the provisions of this Rule may be contingent upon the approval of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), if it is determined that submission to CMS for review and approval is required.

Family Impact Statement

In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature, the impact of this proposed Rule on the family has been considered. It is anticipated that this proposed Rule will have no impact on family functioning, stability and autonomy as described in R.S. 49:972.

Public Comments

Interested persons may submit written comments to Don Gregory, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. He is responsible for responding to inquiries regarding this proposed Rule.

Public Hearing

A public hearing on this proposed Rule is scheduled for Wednesday, July 27, 2011 at 9:30 a.m. in Room 118, Bienville Building, 628 North Fourth Street, Baton Rouge, LA. At that time all interested persons will be afforded an opportunity to submit data, views or arguments either orally or in writing. The deadline for receipt of all written comments is 4:30 p.m. on the next business day following the public hearing.

Bruce D. Greenstein
Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES
RULE TITLE: Home and Community-Based Services Waivers, Adult Day Health Care

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

It is anticipated that implementation of this proposed rule will have no programmatic fiscal impact to the state other than the cost of promulgation for FY 10-11. It is anticipated that $2,296 ($1,148 SGF and $1,148 FED) will be expended in FY 10-11 for the state's administrative expense for promulgation of this proposed rule and the final rule.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

It is anticipated that the implementation of this proposed rule will not affect revenue collections other than the federal share of the promulgation costs for FY 10-11. It is anticipated that $1,148 will be collected in FY 10-11 for the federal share of the expense for promulgation of this proposed rule and the final rule.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS (Summary)

This proposed rule, which continues the provisions of the January 1, 2011 and June 20, 2011 emergency rules, amends the provisions governing the Adult Day Health Care (ADHC) Waiver to revise the provisions governing: 1) the program description; 2) the allocation of waiver opportunities; 3) services and discharge criteria; and 4)the reimbursement methodology and direct care floor. The reduction in the direct care floor will be cost neutral to the Medicaid Program as it does not increase payments to providers; however, it does provide economic benefits to ADHC providers as the amount they are required to spend on direct care costs will be reduced by an indeterminable amount in FY 10-11, FY 11-12 and FY 12-13.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

This rule has no known effect on competition and employment.

Don Gregory
Medicaid Director
1106#068

H. Gordon Monk
Legislative Fiscal Officer
Legislative Fiscal Office

NOTICE OF INTENT

Department of Health and Hospitals
Bureau of Health Services Financing

Home and Community-Based Service Providers
Minimum Licensing Standards
(LAC 48:I.Chapter 50)

The Department of Health and Hospitals, Bureau of Health Services Financing proposes to adopt LAC 48:I.Chapter 50 in the Medical Assistance Program as authorized by R.S. 36:254 and R.S. 40:2120.2. This proposed Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq.

Act 839 of the 2008 Regular Session of the Louisiana Legislature directed the Department of Health and Hospitals to adopt provisions governing the minimum licensing standards for home and community-based services (HCBS) providers and gave the department the authority to issue a single license to all providers of home and community-based services rather than a separate license for each provider type. Providers of the following services will be licensed under the comprehensive licensing standards: Adult Day Care, Family Support, Personal Care Attendant (PCA), Respite Care, Substitute Family Care, Supervised Independent Living (SIL) and Supported Employment. In compliance with the directives of Act 839, the department promulgated a Notice of Intent which proposed to revise and combine the existing licensing standards for providers of Adult Day Care services, Family Support services, Personal Care services, Respite Care services, and Supervised Independent Living services, and to adopt minimum licensing standards for providers of Substitute Family Care and Supported Employment services in order to establish comprehensive HCBS provider licensing standards and a single HCBS license (*Louisiana Register,* Volume 36, Number 6). A public hearing was held on July 28, 2010. As a result of the comments received, the department promulgated an Emergency Rule which revised and republished the provisions of the June 20, 2010 Notice of Intent (*Louisiana Register,* Volume 37, Number 6). This proposed Rule is being promulgated to continue the provisions of the July 1, 2011 Emergency Rule.

Title 48
PUBLIC HEALTH—GENERAL
Part 1. General Administration
Subpart 3. Licensing and Certification
Chapter 50. Home and Community-Based Services Providers Licensing Standards
Subchapter A. General Provisions
§5001. Introduction

A. Pursuant to R.S. 40:2120.2, the Department of Health and Hospitals hereby establishes the minimum licensing standards for home and community-based services (HCBS) providers. These licensing provisions contain the core requirements for HCBS providers as well as the module-specific requirements, depending upon the services rendered by the HCBS provider. These regulations are separate and apart from Medicaid Standards of Participation or any other requirements established by the Medicaid Program for reimbursement purposes.

B. Any person or entity applying for an HCBS provider license or who is operating as a provider of home and community-based services shall meet all of the core licensing requirements contained in this Chapter, as well as the module-specific requirements, unless otherwise specifically noted within these provisions.

C. Providers of the following services shall be licensed under the HCBS license:

1. Adult Day Care (ADC);
2. Family Support;
3. Personal Care Attendant (PCA);
4. Respite;
5. Substitute Family Care (SFC);
6. Supervised Independent Living (SIL), including the Shared Living Conversion services in a waiver home; and
7. Supported Employment.

D. The following entities shall be exempt from the licensure requirements for HCBS providers:

1. any person, agency, institution, society, corporation, or group that solely:
   a. prepares and delivers meals;
   b. provides sitter services; or
   c. provides housekeeping services;
2. any person, agency, institution, society, corporation, or group that provides gratuitous home and community-based services;
3. any individual licensed practical nurse (LPN) or registered nurse (RN) who has a current Louisiana license in good standing;
4. staffing agencies that supply contract workers to a health care provider licensed by the department; and
5. any person who is employed as part of a departmentally authorized self-direction program;
   a. For purposes of these provisions, a self-direction program shall be defined as a service delivery option based upon the principle of self-determination. The program enables participants and/or their authorized representative(s) to become the employer of the people they choose to hire to provide supports to them.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5003. Definitions

Accredited—the process of review and acceptance by an accreditation body such as the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), the Commission on Accreditation of Rehabilitation Facilities (CARF) or Council on Accreditation (COA).

Activities of Daily Living—the functions or tasks which are performed either independently or with supervision that assist an individual to live in a community setting, or that provide assistance for mobility (i.e., bathing, dressing, eating, grooming, walking, transferring and toileting).

Adult Day Care Services—structured and comprehensive services provided in a group setting that are designed to meet the individual needs of adults with functional impairments. This program provides a variety of health, social and related support services in a protective setting for a portion of a 24-hour day.

Client—an individual who is receiving services from a home and community-based service provider.

Department—the Louisiana Department of Health and Hospitals (DHH) or any of its sections, bureaus, offices or its contracted designee.

DHH Region—the geographical administrative regions designated by the Department of Health and Hospitals.

Developmental Disability—a severe, chronic condition as defined in the Developmental Disabilities Law of 2005, R.S. 28:451.l-455.2.

Family Support Services—advocacy services, family counseling, including genetic counseling, family subsidy programs, parent-to-parent outreach, legal assistance, income maintenance, parent training, homemaker services, minor home renovations, marriage and family education, and other related programs.

Health Standards Section—the licensing and certification section of the Department of Health and Hospitals.

Home and Community-Based Service Provider—an agency, institution, society, corporation, person(s) or any other group licensed by the department to provide one or more home and community-based services as defined in R.S. 40:2120.1 or these licensing provisions.

Incident—a death, serious illness, allegation of abuse, neglect or exploitation or an event involving law enforcement or behavioral event which causes serious injury to the client or others.

Individual Service Plan—a service plan developed for each client that is based on a comprehensive assessment which identifies the individual's strengths and needs in order to establish goals and objectives so that outcomes to service delivery can be measured.

Instrumental Activities of Daily Living—the functions or tasks that are not necessary for fundamental functioning but assist an individual to be able to live in a community setting. These are activities such as light house-keeping, food preparation and storage, grocery shopping, laundry, reminders to take medication, scheduling medical appointments, arranging transportation to medical appointments and accompanying the client to medical appointments.

Personal Care Attendant Services—services required for a person with a disability to become physically independent to

maintain physical function or to remain in, or return to, the community.

Respite Care—an intermittent service designed to provide temporary relief to unpaid, informal caregivers of the elderly and/or people with disabilities.

Service Area—the DHH administrative region in which the provider's geographic business location is located and for which the license is issued.

Substitute Family Care Caregiver—a single or dual parent family living in a home setting which has been certified through a home study assessment as adequate and appropriate to provide care to the client by the SFC provider. At least one family member will be designated as a principal SFC caregiver.

Substitute Family Care Services—provide 24-hour personal care, supportive services and supervision to adults who meet the criteria for having a developmental disability.

Supervised Independent Living via a Shared Living Conversion model—a home and community-based shared living model for up to six persons, chosen by clients of the Residential Options Waiver (ROW), or any successor waiver, as their living option.

Supervised Independent Living Services—necessary training, social skills and medical services to enable a person who has mental illness or a developmental disability, and who is living in congregate, individual homes or individual apartments, to live as independently as possible in the community.

Supported Employment—a system of supports for people with disabilities in regards to ongoing employment in integrated settings. Supported employment can provide assistance in a variety of areas including:

1. job development;
2. job coaches;
3. job retention;
4. transportation;
5. assistive technology;
6. specialized job training; and
7. individually tailored supervision.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5005. Licensure Requirements

A. All HCBS providers shall be licensed by the Department of Health and Hospitals. It shall be unlawful to operate as a home and community-based service provider without a license issued by the department. DHH is the only licensing authority for HCBS providers in Louisiana.

B. An HCBS license shall:

1. be issued only to the person or entity named in the license application;
2. be valid only for the HCBS provider to which it is issued and only for the specific geographic address of that provider;
3. designate which home and community-based services the provider can provide;
4. enable the provider to render delineated home and community-based services within a DHH region;
5. be valid for one year from the date of issuance, unless revoked, suspended, modified or terminated prior to that date, or unless a provisional license is issued;
6. expire on the last day of the twelfth month after the date of issuance, unless timely renewed by the HCBS provider;
7. not be subject to sale, assignment, donation or other transfer, whether voluntary or involuntary; and
8. be posted in a conspicuous place on the licensed premises at all times.

C. An HCBS provider shall provide only those home and community-based services or modules specified on its license and only to clients residing in the provider's designated service area, DHH Region or at the provider's licensed location.

D. An HCBS provider may apply for a waiver from the Health Standards Section (HSS) to provide services to a client residing outside of the provider's designated service area or DHH Region only under the following condition:

1. A waiver may be granted by the department if there is no other HCBS provider in the client's service area or DHH Region that is licensed and that has the capacity to provide the required services to the client, or for other good cause shown by the HCBS provider and client.
2. The provider must submit a written waiver request to HSS prior to providing services to the client residing outside of the designated service area or DHH Region.
3. The written waiver request shall be specific to one client and shall include the reasons for which the waiver is requested.

E. In order for the HCBS provider to be considered operational and retain licensed status, the provider shall meet the following conditions.

1. Each HCBS provider shall have a business location which shall not be located in an occupied personal residence and shall conform to the provisions of §5027 of this Chapter.
   a. The business location shall be part of the licensed location of the HCBS provider and shall be in the DHH Region for which the license is issued.
   b. The business location shall have at least one employee on duty at the business location during stated hours of operation.
   c. An HCBS provider which provides ADC services or out of home (center-based) respite care services may have the business location at the ADC building or center-based respite building.
2. Adult day care facilities shall have clearly defined days and hours of operation posted. The ADC must be open at least five hours on days of operation. Center-based respite facilities shall have the capacity to provide 24 hour services. All other HCBS providers shall render services at all times to clients receiving services in the home, according to the individual service plan (ISP).
3. There shall be adequate direct care staff and professional services staff employed and available to be assigned to provide services to persons in their homes as per the plan of care and for persons receiving ADC services and center-based respite services, during the provider's or facility's hours of operation.
4. Each HCBS provider shall have a published telephone number which is available and accessible 24 hours a day, seven days a week, including holidays.

F. The licensed HCBS provider shall abide by and adhere to any state law, rule, policy, procedure, manual or memorandum pertaining to HCBS providers.

G. A separately licensed HCBS provider shall not use a name which is substantially the same as the name of another HCBS provider licensed by the department. An HCBS provider shall not use a name which is likely to mislead the client or family into believing it is owned, endorsed or operated by the State of Louisiana.

H. Upon promulgation of the final Rule governing these provisions, existing providers of the following home and community-based services shall be required to apply for an HCBS provider license at the time of renewal of their current license(s):

1. Adult Day Care;
2. Family Support;
3. Personal Care Attendant;
4. Respite;
5. Supervised Independent Living; and
6. Supported Employment.

I. If an existing provider currently has multiple licenses, such as PCA, Respite and SIL, the provider shall be required to apply for an HCBS provider license at the time the first such license is due for renewal. The HCBS provider license shall include all modules for which the provider is currently licensed, and will replace all of the separate licenses.

J. If applicable, each HCBS provider shall obtain facility need review approval prior to licensing.

1. An existing licensed PCA, Respite or SIL provider who is applying for an HCBS provider license at the time of license renewal shall not be required to apply for facility need review approval. However, if an existing licensed provider, who is not currently providing PCA, Respite or SIL services wants to begin providing these services, the provider shall be required to apply for facility need review approval for each of the requested services.

EXAMPLE: A currently licensed PCA provider with no Respite license is now applying for his HCBS provider license and wants to add the respite module. The PCA provider shall be required to apply for facility need review approval for the respite module.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5007. Initial Licensure Application Process

A. An initial application for licensing as an HCBS provider shall be obtained from the department. A completed initial license application packet for an HCBS provider shall be submitted to and approved by the department prior to an applicant providing HCBS services.

B. The initial licensing application packet shall include:

1. a completed HCBS licensure application and the non-refundable licensing fee as established by statute;
2. a copy of the approval letter of the architectural facility plans for the adult day care module and the center-based respite module from the Office of the State Fire Marshal and any other office/entity designated by the department to review and approve the facility's architectural plans;
3. a copy of the on-site inspection report with approval for occupancy by the Office of the State Fire Marshal, if applicable;
4. a copy of the health inspection report with approval of occupancy from the Office of Public Health for the adult day care module and the center-based respite module;
5. a copy of a statewide criminal background check, including sex offender registry status, on all owners and administrators;
6. proof of financial viability, comprised of the following:
   a. a line of credit issued from a federally insured, licensed lending institution in the amount of at least $50,000;
   b. general and professional liability insurance of at least $300,000; and
   c. worker's compensation insurance;
7. a completed disclosure of ownership and control information form;
8. the days and hours of operation;
9. an organizational chart and names, including position titles, of key administrative personnel and governing body; and
10. any other documentation or information required by the department for licensure.

C. Any person convicted of one of the following felonies is prohibited from being the owner or the administrator of an HCBS provider agency. For purposes of these provisions, the licensing application shall be rejected by the department for any felony conviction relating to:

1. the violence, abuse, or negligence of a person;
2. the misappropriation of property belonging to another person;
3. cruelty, exploitation or the sexual battery of the infirmed;
4. a drug offense;
5. crimes of a sexual nature;
6. a firearm or deadly weapon;
7. Medicare or Medicaid fraud; or
8. fraud or misappropriation of federal or state funds.

D. If the initial licensing packet is incomplete, the applicant shall be notified of the missing information and shall have 90 days from receipt of the notification to submit the additional requested information.

1. If the additional requested information is not submitted to the department within 90 days, the application shall be closed.
2. If an initial licensing application is closed, an applicant who is still interested in becoming an HCBS provider must submit a new initial licensing packet with a new initial licensing fee to start the initial licensing process, subject to any facility need review approval.

E. Applicants for HCBS licensure shall be required to attend a mandatory training class when a completed initial licensing application packet has been received by the department.

F. Upon completion of the mandatory training class and written notification of satisfactory class completion from the department, an HCBS applicant shall be required to admit one client and contact the HSS field office to schedule an initial licensing survey.

1. Prior to scheduling the initial survey, applicants must be:
   a. fully operational;
   b. in compliance with all licensing standards; and
   c. providing care to only one client at the time of the initial survey.

2. If the applicant has not admitted one client or called the field office to schedule a survey within 30 days of receipt of the written notification from the department, the application will be closed. If an applicant is still interested in becoming an HCBS provider, a new initial licensing packet with a new initial licensing fee must be submitted to the department to start the initial licensing process, subject to any facility need review approval.

G. Applicants must be in compliance with all appropriate federal, state, departmental or local statutes, laws, ordinances, rules, regulations and fees before the HCBS provider will be issued an initial license to operate.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5009. Initial Licensing Surveys

A. Prior to the initial license being issued, an initial on-site licensing survey shall be conducted to ensure compliance with the licensing laws and standards.

B. In the event that the initial licensing survey finds that the HCBS provider is compliant with all licensing laws, regulations and other required statutes, laws, ordinances, rules, regulations, and fees, the department shall issue a full license to the provider. The license shall be valid until the expiration date shown on the license, unless the license is modified, revoked, suspended or terminated.

C. In the event that the initial licensing survey finds that the HCBS provider is noncompliant with any licensing laws or regulations, or any other required rules or regulations that present a potential threat to the health, safety, or welfare of the clients, the department shall deny the initial license.

D. In the event that the initial licensing survey finds that the HCBS provider is noncompliant with any licensing laws or regulations, or any other required rules or regulations, but the department in its sole discretion determines that the noncompliance does not present a threat to the health, safety or welfare of the clients, the department may issue a provisional initial license for a period not to exceed six months. The provider shall submit a plan of correction to the department for approval, and the provider shall be required to correct all such noncompliance or deficiencies prior to the expiration of the provisional license.

1. If all such noncompliance or deficiencies are corrected on the follow-up survey, a full license will be issued.

2. If all such noncompliance or deficiencies are not corrected on the follow-up survey, or new deficiencies affecting the health, safety or welfare of a client are cited, the provisional license will expire and the provider shall be required to begin the initial licensing process again by submitting a new initial license application packet and the appropriate licensing fee.

E. The initial licensing survey of an HCBS provider shall be an announced survey. Follow-up surveys to the initial licensing surveys are unannounced surveys.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5011. Types of Licenses and Expiration Dates

A. The department shall have the authority to issue the following types of licenses:

1. Full Initial License. The department shall issue a full license to the HCBS provider when the initial licensing survey finds that the provider is compliant with all licensing laws and regulations, and is compliant with all other required statutes, laws, ordinances, rules, regulations, and fees. The license shall be valid until the expiration date shown on the license, unless the license is modified, revoked, suspended, or terminated.

2. Provisional Initial License. The department may issue a provisional initial license to the HCBS provider when the initial licensing survey finds that the HCBS provider is noncompliant with any licensing laws or regulations or any other required statutes, laws, ordinances, rules, regulations or fees, but the department determines that the noncompliance does not present a threat to the health, safety or welfare of the clients.

3. Full Renewal License. The department may issue a full renewal license to an existing licensed HCBS provider who is in substantial compliance with all applicable federal, state, departmental, and local statutes, laws, ordinances, rules, regulations and fees. The license shall be valid until the expiration date shown on the license, unless the license is modified, revoked, suspended, or terminated.

B. The department, in its sole discretion, may issue a provisional license to an existing licensed HCBS provider for a period not to exceed six months, for any of the following reasons:

1. the existing HCBS provider has more than five deficient practices or deficiencies cited during any one survey;

2. the existing HCBS provider has more than three validated complaints in a 12 month period:

a. A validated complaint is a complaint received by the Health Standards Section and found to be substantiated;

3. the existing HCBS provider has been issued a deficiency that involved placing a client at risk for serious harm or death;

4. the existing HCBS provider has failed to correct deficient practices within 60 days of being cited for such deficient practices or at the time of a follow-up survey; or

5. the existing HCBS provider is not in substantial compliance with all applicable federal, state, departmental and local statutes, laws, ordinances, rules regulations and fees at the time of renewal of the license.

C. When the department issues a provisional license to an existing licensed HCBS provider, the provider shall submit a plan of correction to DHH for approval, and the provider shall be required to correct all such noncompliance or deficiencies prior to the expiration of the provisional license. The department shall conduct a follow-up survey, either on-site or by desk review, of the HCBS provider prior to the expiration of the provisional license.

1. If the follow-up survey determines that the HCBS provider has corrected the deficient practices and has maintained compliance during the period of the provisional license, the department may issue a full license for the remainder of the year until the anniversary date of the HCBS license.

2. If the follow-up survey determines that all non-compliance or deficiencies have not been corrected, or if new deficiencies that are a threat to the health, safety or welfare of a client are cited on the follow-up survey, the

provisional license shall expire and the provider shall be required to begin the initial licensing process again by submitting a new initial license application packet and fee, subject to any facility need review approval.

3. The department shall issue written notice to the provider of the results of the follow-up survey.

D. If an existing licensed HCBS provider has been issued a notice of license revocation, suspension or termination, and the provider's license is due for annual renewal, the department shall deny the license renewal application and shall not issue a renewal license.

1. If a timely administrative appeal has been filed by the provider regarding the license revocation, suspension, or termination, the administrative appeal shall be suspensive, and the provider shall be allowed to continue to operate and provide services until such time as the administrative tribunal or department issues a decision on the license revocation, suspension, or termination.

2. If the secretary of the department determines that the violations of the HCBS provider pose an imminent or immediate threat to the health, welfare, or safety of a client, the imposition of such action may be immediate and may be enforced during the pendency of the administrative appeal. If the secretary of the department makes such a determination, the HCBS provider will be notified in writing.

3. The denial of the license renewal application does not affect in any manner the license revocation, suspension, or termination.

E. The renewal of a license does not in any manner affect any sanction, civil monetary penalty or other action imposed by the department against the provider.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5013. Changes in Licensee Information or Personnel

A. An HCBS license shall be valid only for the person or entity named in the license application and only for the specific geographic address listed on the license application.

B. Any change regarding the HCBS provider's entity name, "doing business as" name, mailing address, telephone number or any combination thereof, shall be reported in writing to the department within two days of the change.

C. Any change regarding the HCBS provider's key administrative personnel shall be reported in writing to the department within 10 days of the change.

1. Key administrative personnel include the:
   a. administrator;
   b. director of nursing, if applicable; and
   c. medical director, if applicable.

2. The HCBS provider's notice to the department shall include the individual's:
   a. name;
   b. address;
   c. hire date; and
   d. qualifications.

D. A change of ownership (CHOW) of the HCBS provider shall be reported in writing to the department within five days of the change. The license of an HCBS provider is not transferable or assignable and cannot be sold. The new owner shall submit the legal CHOW document, all documents required for a new license and the applicable licensing fee. Once all application requirements are completed and approved by the department, a new license shall be issued to the new owner.

1. An HCBS provider that is under license revocation may not undergo a CHOW.

2. If the CHOW results in a change of geographic address, an on-site survey may be required prior to issuance of the new license.

E. If the HCBS provider changes its name without a change in ownership, the HCBS provider shall report such change to the department in writing five days prior to the change. The change in the HCBS provider name requires a change in the HCBS provider license. Payment of the applicable fee is required to re-issue the license.

F. Any request for a duplicate license shall be accompanied by the applicable fee.

G. If the HCBS provider changes the physical address of its geographic location without a change in ownership, the HCBS provider shall report such change to DHH in writing at least five days prior to the change. Because the license of an HCBS provider is valid only for the geographic location of that provider, and is not transferrable or assignable, the provider shall submit a new licensing application.

1. An on-site survey may be required prior to the issuance of the new license.

2. The change in the HCBS provider's physical address results in a new anniversary date and the full licensing fee must be paid.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5015. Renewal of License

A. The HCBS provider shall submit a completed license renewal application packet to the department at least 30 days prior to the expiration of the current license. The license renewal application packet shall include:

1. the license renewal application;
2. the days and hours of operation;
3. a current State Fire Marshal report, if applicable;
4. a current Office of Public Health inspection report for the adult day care module and the center-based respite module;
5. the non-refundable license renewal fee;
6. any other documentation required by the department; and
7. proof of financial viability, comprised of the following:
   a. a line of credit issued from a federally insured, licensed lending institution in the amount of at least $50,000;
   b. general and professional liability insurance of at least $300,000; and
   c. worker's compensation insurance.

B. The department may perform an on-site survey and inspection upon annual renewal of a license.

C. Failure to submit a completed license renewal application packet prior to the expiration of the current license will result in the voluntary non-renewal of the HCBS license.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5016. Deemed Status through Accreditation

A. An HCBS provider may request deemed status from the department. The department may accept accreditation in lieu of a routine on-site resurvey provided that:

1. the accreditation is obtained through an organization approved by the Department;

2. all services provided under the HCBS license must be accredited; and

3. the provider forwards the accrediting body's findings to the Health Standards Section within 30 days of its accreditation.

B. The accreditation will be accepted as evidence of satisfactory compliance with all provisions of these requirements.

C. The following set of circumstances can cause the state agency to perform a full licensing survey on an accredited HCBS provider:

1. any valid complaints in the preceding 12-month period;

2. addition of services;

3. a change of ownership in the preceding 12-month period;

4. issuance of a provisions license in the preceding 12-month period;

5. serious violations of licensing standards or professional standards of practice that were identified in the preceding 12-month period; or

6. reports of inappropriate treatment or service resulting in death or serious injury.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5017. Survey Activities

A. The department, or its designee, may conduct periodic licensing surveys and other surveys as deemed necessary to ensure compliance with all laws, rules and regulations governing HCBS providers and to ensure client health, safety and welfare. These surveys may be conducted on-site or by administrative review and shall be unannounced.

B. The department shall also conduct complaint surveys. The complaint surveys shall be conducted in accordance with R.S. 40:2009.13 et seq.

C. The department may require an acceptable plan of correction from a provider for any survey where deficiencies have been cited, regardless of whether the department takes other action against the facility for the deficiencies cited in the survey. The acceptable plan of correction shall be approved by the department.

D. A follow-up survey may be conducted for any survey where deficiencies have been cited to ensure correction of the deficient practices.

E. The department may issue appropriate sanctions for noncompliance, deficiencies and violations of law, rules and regulations. Sanctions include, but are not limited to:

1. civil monetary penalties;

2. directed plans of correction; and

3. license revocation.

F. DHH surveyors and staff shall be:

1. given access to all areas of the provider agency, as necessary, and all relevant files during any survey; and

2. allowed to interview any provider staff, client or other persons as necessary or required to conduct the survey.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5019. Statement of Deficiencies

A. The following statements of deficiencies issued by the department to the HCBS provider shall be posted in a conspicuous place on the licensed premises:

1. the most recent annual survey statement of deficiencies; and

2. any subsequent complaint survey statement of deficiencies.

B. Any statement of deficiencies issued by the department to an HCBS provider shall be available for disclosure to the public 30 days after the provider submits an acceptable plan of correction to the deficiencies or 90 days after the statement of deficiencies is issued to the provider, whichever occurs first.

C. Unless otherwise provided in statute or in these licensing provisions, a provider shall have the right to an informal reconsideration of any deficiencies cited as a result of a survey or investigation.

1. Correction of the violation, noncompliance or deficiency shall not be the basis for the reconsideration.

2. The informal reconsideration of the deficiencies shall be requested in writing within 10 days of receipt of the statement of deficiencies, unless otherwise provided in these standards.

3. The request for informal reconsideration of the deficiencies shall be made to the department's Health Standards Section and will be considered timely if received by HSS within 10 days of the provider's receipt of the statement deficiencies.

4. If a timely request for an informal reconsideration is received, the department shall schedule and conduct the informal reconsideration.

5. The provider shall be notified in writing of the results of the informal reconsideration.

6. Except as provided for complaint surveys pursuant to R.S. 40:2009.13 et seq., and as provided in these licensing provisions for license denials, revocations and non-renewals, the decision of the informal reconsideration team shall be the final administrative decision regarding the deficiencies.

a. There is no administrative appeal right of such deficiencies.

7. Pursuant to R.S. 40:2009.13 et seq., for complaint surveys in which the Health Standards Section determines that the complaint involves issues that have resulted in or are likely to result in serious harm or death, as defined in the statute, the determination of the informal reconsideration may be appealed administratively to the Division of Administrative Law or its successor. The hearing before the Division of Administrative Law, or its successor, is limited only to whether the investigation or complaint survey was conducted properly or improperly. The Division of Administrative Law shall not delete or remove deficiencies as a result of such hearing.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5021. Denial of License, Revocation of License, Denial of License Renewal

A. The department may deny an application for an initial license or a license renewal, or may revoke a license in accordance with the provisions of the Administrative Procedure Act. These actions may be taken against the entire license or certain modules of the license.

B. Denial of an Initial License

1. The department shall deny an initial license in the event that the initial licensing survey finds that the HCBS provider is noncompliant with any licensing laws or regulations, or any other required statutes or regulations that present a potential threat to the health, safety or welfare of the clients.

2. The department shall deny an initial license for any of the reasons a license may be revoked or non-renewed pursuant to these licensing provisions.

3. If the department denies an initial license, the applicant for an HCBS provider license shall discharge the client receiving services.

C. Voluntary Non-Renewal of a License. If a provider fails to timely renew its license, the license expires on its face and is considered voluntarily surrendered. There are no appeal rights for such surrender or non-renewal of the license, as this is a voluntary action on the part of the provider.

D. Revocation of License or Denial of License Renewal. An HCBS provider license may be revoked or denied renewal for any of the following reasons, including but not limited to:

1. failure to be in substantial compliance with the HCBS licensing laws, rules and regulations;

2. failure to be in substantial compliance with other required statutes, laws, ordinances, rules or regulations;

3. failure to comply with the terms and provisions of a settlement agreement or education letter;

4. failure to uphold client rights whereby deficient practices result in harm, injury or death of a client;

5. failure to protect a client from a harmful act of an employee or other client including, but not limited to:

a. mental or physical abuse, neglect, exploitation or extortion;

b. any action posing a threat to a client's health and safety;

c. coercion;

d. threat or intimidation;

e. harassment; or

f. criminal activity;

6. failure to notify the proper authorities, as required by federal or state law or regulations, of all suspected cases of the acts outlined in §5021.D.5;

7. knowingly making a false statement in any of the following areas, including but not limited to:

a. application for initial license or renewal of license;

b. data forms;

c. clinical records, client records or provider records;

d. matters under investigation by the department or the Office of the Attorney General; or

e. information submitted for reimbursement from any payment source;

8. knowingly making a false statement or providing false, forged or altered information or documentation to DHH employees or to law enforcement agencies;

9. the use of false, fraudulent or misleading advertising; or

10. an owner, officer, member, manager, administrator, director or person designated to manage or supervise client care has pled guilty or nolo contendere to a felony, or has been convicted of a felony, as documented by a certified copy of the record of the court;

a. For purposes of these provisions, conviction of a felony involves any felony conviction relating to:

i. the violence, abuse, or negligence of a person;

ii. the misappropriation of property belonging to another person;

iii. cruelty, exploitation or the sexual battery of the infirmed;

iv. a drug offense;

v. crimes of a sexual nature;

vi. a firearm or deadly weapon;

vii. Medicare or Medicaid fraud; or

viii. fraud or misappropriation of federal or state funds;

11. failure to comply with all reporting requirements in a timely manner, as required by the department;

12. failure to allow or refusal to allow the department to conduct an investigation or survey or to interview provider staff or clients;

13. interference with the survey process, including but not limited to, harassment, intimidation, or threats against the survey staff;

14. failure to allow or refusal to allow access to provider, facility or client records by authorized departmental personnel;

15. bribery, harassment, intimidation or solicitation of any client designed to cause that client to use or retain the services of any particular HCBS provider;

16. cessation of business or non-operational status;

17. failure to repay an identified overpayment to the department or failure to enter into a payment agreement to repay such overpayment; or

18. failure to timely pay outstanding fees, fines, sanctions or other debts owed to the department.

E. In the event an HCBS provider license is revoked, renewal is denied (other than for cessation of business or non-operational status) or the license is surrendered in lieu of an adverse action, any owner, board member, director or administrator, and any other person named on the license application of such HCBS provider is prohibited from owning, managing, directing or operating another HCBS agency for a period of two years from the date of the final disposition of the revocation, denial action or surrender.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5023. Notice and Appeal of License Denial, License Revocation and License Non-Renewal

A. Notice of a license denial, license revocation or license non-renewal (i.e. denial of license renewal) shall be given to the provider in writing.

B. The HCBS provider has a right to an informal reconsideration of the license denial, license revocation or license non-renewal. There is no right to an informal reconsideration of a voluntary non-renewal or surrender of a license by the provider.

1. The HCBS provider shall request the informal reconsideration within 15 days of the receipt of the notice of the license denial, license revocation or license non-renewal. The request for informal reconsideration shall be in writing and shall be forwarded to the department's Health Standards Section. The request for informal reconsideration shall be considered timely if received by the Health Standards Section within 15 days from the provider's receipt of the notice.

2. The request for informal reconsideration shall include any documentation that demonstrates that the determination was made in error.

3. If a timely request for an informal reconsideration is received by HSS, an informal reconsideration shall be scheduled and the provider will receive written notification of the date of the informal reconsideration.

4. The provider shall have the right to appear in person at the informal reconsideration and may be represented by counsel.

5. Correction of a violation or deficiency which is the basis for the license denial, revocation or non-renewal shall not be a basis for reconsideration.

6. The informal reconsideration process is not in lieu of the administrative appeals process.

7. The provider will be notified in writing of the results of the informal reconsideration.

C. The HCBS provider has a right to an administrative appeal of the license denial, license revocation or license non-renewal. There is no right to an administrative appeal of a voluntary non-renewal or surrender of a license by the provider.

1. The HCBS provider shall request the administrative appeal within 30 days of the receipt of the results of the informal reconsideration.

a. The HCBS provider may forego its rights to an informal reconsideration, and if so, shall request the administrative appeal within 30 days of the receipt of the notice of the license denial, revocation or non-renewal.

2. The request for administrative appeal shall be in writing and shall be submitted to the Division of Administrative Law or its successor. The request shall include any documentation that demonstrates that the determination was made in error and shall include the basis and specific reasons for the appeal.

3. If a timely request for an administrative appeal is received by the Division of Administrative Law, or its successor, the administrative appeal of the license revocation or license non-renewal shall be suspensive, and the provider shall be allowed to continue to operate and provide services until such time as the department issues a final administrative decision.

a. If the secretary of the department determines that the violations of the provider pose an imminent or immediate threat to the health, welfare or safety of a client, the imposition of the license revocation or license non-renewal may be immediate and may be enforced during the pendency of the administrative appeal. If the secretary of the department makes such a determination, the provider will be notified in writing.

4. Correction of a violation or a deficiency which is the basis for the denial, revocation or non-renewal shall not be a basis for an administrative appeal.

D. If an existing licensed HCBS provider has been issued a notice of license revocation, and the provider's license is due for annual renewal, the department shall deny the license renewal application. The denial of the license renewal application does not affect, in any manner, the license revocation.

E. If a timely administrative appeal has been filed by the provider on a license denial, license non-renewal or license revocation, the Division of Administrative Law, or its successor, shall conduct the hearing within 90 days of the docketing of the administrative appeal. One extension, not to exceed 90 days, may be granted by the Division of Administrative Law, or its successor, if good cause is shown.

1. If the final agency decision is to reverse the license denial, license non-renewal or license revocation, the provider's license will be re-instated or granted upon the payment of any licensing fees, outstanding sanctions or other fees due to the department.

2. If the final agency decision is to affirm the license non-renewal or license revocation, the provider shall discharge any and all clients receiving services according to the provisions of this Chapter.

a. Within 10 days of the final agency decision, the provider must notify HSS, in writing, of the secure and confidential location where the client records will be stored.

F. There is no right to an informal reconsideration or an administrative appeal of the issuance of a provisional initial license to a new HCBS provider, or the issuance of a provisional license to an existing HCBS provider. A provider who has been issued a provisional license is licensed and operational for the term of the provisional license. The issuance of a provisional license is not considered to be a denial of license, renewal or revocation.

G. A provider with a provisional initial license or an existing provider with a provisional license that expires due to noncompliance or deficiencies cited at the follow-up survey, shall have the right to an informal reconsideration and the right to an administrative appeal, as to the deficiencies.

1. The correction of a violation, noncompliance or deficiency after the follow-up survey shall not be the basis for the informal reconsideration or for the administrative appeal.

2. The informal reconsideration and the administrative appeal are limited to whether the deficiencies were properly cited at the follow-up survey.

3. The provider shall request the informal reconsideration in writing, which shall be received by the Health Standards Section within five days of receipt of the notice of the results of the follow-up survey from the department.

4. The provider shall request the administrative appeal within 15 days of receipt of the notice of the results of the follow-up survey from the department. The request for administrative appeal shall be in writing and shall be submitted to the Division of Administrative Law or its successor.

5. A provider with a provisional initial license or an existing provider with a provisional license that expires under the provisions of this Chapter shall cease providing services and discharge clients unless the Division of Administrative Law, or its successor, issues a stay of the expiration.

a. The stay may be granted by the Division of Administrative Law, or its successor, upon application by the provider at the time the administrative appeal is filed and only after a contradictory hearing and only upon a showing that there is no potential harm to the clients being served by the provider.

6. If a timely administrative appeal has been filed by a provider with a provisional initial license that has expired, or by an existing provider whose provisional license has expired under the provisions of this Chapter, the Division of Administrative Law, or its successor, shall conduct the hearing within 90 days of the docketing of the administrative appeal. One extension, not to exceed 90 days, may be granted by the Division of Administrative Law, or its successor, if good cause is shown.

a. If the final agency decision is to remove all deficiencies, the provider's license will be re-instated upon the payment of any outstanding sanctions and licensing or other fees due to the department.

b. If the final agency decision is to uphold the deficiencies and affirm the expiration of the provisional license, the provider shall discharge any and all clients receiving services.

i. Within 10 days of the final agency decision, the provider must notify HSS in writing of the secure and confidential location where the client records will be stored.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5025. Inactivation of License due to a Declared Disaster or Emergency

A. An HCBS provider licensed in a parish which is the subject of an executive order or proclamation of emergency or disaster issued in accordance with R.S. 29:724 or R.S. 29:766, may seek to inactivate its license for a period not to exceed one year, provided that the following conditions are met:

1. the licensed provider shall submit written notification to the Health Standards Section within 60 days of the date of the executive order or proclamation of emergency or disaster that:

a. the HCBS provider has experienced an interruption in the provisions of services as a result of events that are the subject of such executive order or proclamation of emergency or disaster issued in accordance with R.S. 29:724 or R.S. 29:766;

b. the licensed HCBS provider intends to resume operation as an HCBS provider in the same service area;

c. includes an attestation that the emergency or disaster is the sole casual factor in the interruption of the provision of services;

d. includes an attestation that all clients have been properly discharged or transferred to another provider; and

e. provides a list of each client and where that client is discharged or transferred to;

2. the licensed HCBS provider resumes operating as a HCBS provider in the same service area within one year of the issuance of an executive order or proclamation of emergency or disaster in accordance with R.S. 29:724 or R.S. 29:766;

3. the licensed HCBS provider continues to pay all fees and cost due and owed to the department including, but not limited to, annual licensing fees and outstanding civil monetary penalties; and

4. the licensed HCBS provider continues to submit required documentation and information to the department.

B. Upon receiving a completed written request to inactivate a HCBS provider license, the department shall issue a notice of inactivation of license to the HCBS provider.

C. Upon completion of repairs, renovations, rebuilding or replacement, an HCBS provider which has received a notice of inactivation of its license from the department shall be allowed to reinstate its license upon the following conditions being met.

1. The HCBS provider shall submit a written license reinstatement request to the licensing agency of the department 60 days prior to the anticipated date of reopening.

a. The license reinstatement request shall inform the department of the anticipated date of opening, and shall request scheduling of a licensing survey.

b. The license reinstatement request shall include a completed licensing application with appropriate licensing fees.

2. The provider resumes operating as an HCBS provider in the same service area within one year.

D. Upon receiving a completed written request to reinstate an HCBS provider license, the department shall conduct a licensing survey. If the HCBS provider meets the requirements for licensure and the requirements under this Section, the department shall issue a notice of reinstatement of the HCBS provider license.

1. The licensed capacity of the reinstated license shall not exceed the licensed capacity of the HCBS provider at the time of the request to inactivate the license.

E. No change of ownership in the HCBS provider shall occur until such HCBS provider has completed repairs, renovations, rebuilding or replacement construction, and has resumed operations as an HCBS provider.

F. The provisions of this Section shall not apply to an HCBS provider which has voluntarily surrendered its license and ceased operation.

G. Failure to comply with any of the provisions of this Section shall be deemed a voluntary surrender of the HCBS provider license and any applicable facility need review approval for licensure.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Subchapter B. Administration and Organization

§5027. Governing Body

A. An HCBS provider shall have an identifiable governing body with responsibility for and authority over the policies and activities of the program/agency.

1. A provider shall have documents identifying all members of the governing body, their addresses, their terms

of membership, officers of the governing body and terms of office of any officers.

2. The governing body shall be comprised of three or more persons and shall hold formal meetings at least twice a year.

3. There shall be written minutes of all formal meetings of the governing body and by-laws specifying frequency of meetings and quorum requirements.

B. The governing body of an HCBS provider shall:

1. ensure the provider's continual compliance and conformity with all relevant federal, state, local and municipal laws and regulations;

2. ensure that the provider is adequately funded and fiscally sound;

3. review and approve the provider's annual budget;

4. designate a person to act as administrator and delegate sufficient authority to this person to manage the provider agency;

5. formulate and annually review, in consultation with the administrator, written policies concerning the provider's philosophy, goals, current services, personnel practices, job descriptions and fiscal management;

6. annually evaluate the administrator's performance;

7. have the authority to dismiss the administrator;

8. meet with designated representatives of the department whenever required to do so;

9. inform the department, or its designee, prior to initiating any substantial changes in the services provided by the provider; and

10. ensure statewide criminal background checks on all unlicensed persons.

C. An HCBS provider shall maintain an administrative file that includes:

1. documents identifying the governing body;

2. a list of members and officers of the governing body, along with their addresses and terms of membership;

3. minutes of formal meetings and by-laws of the governing body, if applicable;

4. documentation of the provider's authority to operate under state law;

5. an organizational chart of the provider which clearly delineates the line of authority;

6. all leases, contracts and purchases-of-service agreements to which the provider is a party;

7. insurance policies;

8. annual budgets and audit reports; and

9. a master list of all the community resources used by the provider.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORY NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5029. Policy and Procedures

A. An HCBS provider shall provide supervision and services that:

1. conform to the department's rules and regulations;

2. meet the needs of the clients as identified and addressed in the ISP;

3. provide for the full protection of clients' rights; and

4. promote the social, physical and mental well-being of clients;

B. An HCBS provider shall make any required information or records, and any information reasonably related to assessment of compliance with these requirements, available to the department.

C. An HCBS provider shall allow designated representatives of the department, in performance of their mandated duties, to:

1. inspect all aspects of an HCBS provider's operations which directly or indirectly impact clients; and

2. conduct interviews with any staff member or client of the provider.

D. An HCBS provider shall, upon request by the department, make available the legal ownership documents.

E. The HCBS provider shall have written policies and procedures approved by the owner or governing body, which must be implemented and followed, that address at a minimum the following:

1. confidentiality and confidentiality agreements;

2. security of files;

3. publicity and marketing, including the prohibition of illegal or coercive inducement, solicitation and kickbacks;

4. personnel;

5. client rights;

6. grievance procedures;

7. client funds;

8. emergency preparedness;

9. abuse and neglect;

10. incidents and accidents, including medical emergencies;

11. universal precautions;

12. documentation; and

13. admission and discharge procedures.

F. An HCBS provider shall have written personnel policies, which must be implemented and followed, that include:

1. a plan for recruitment, screening, orientation, ongoing training, development, supervision and performance evaluation of staff members;

2. written job descriptions for each staff position, including volunteers;

3. policies that shall, at a minimum, be consistent with Office of Public Health guidelines to indicate whether, when, and how staff have a health assessment;

4. an employee grievance procedure;

5. abuse reporting procedures that require all employees to report any incidents of abuse or mistreatment, whether that abuse or mistreatment is done by another staff member, a family member, a client or any other person; and

6. a written policy to prevent discrimination.

G. An HCBS provider shall maintain, in force at all times, the requirements for financial viability under this rule.

H. The provider shall have written policies and procedures for behavior management which:

1. prohibits:

a. corporeal punishment;

b. chemical restraints;

c. psychological and verbal abuse;

d. seclusion;

e. forced exercise;

f. physical and mechanical restraints;

f. any cruel, severe, unusual, degrading or unnecessary punishment; and

g. any procedure which denies:

i. food;

ii. drink;

iii. visits with family; or

iv. use of restroom facilities;

2. ensure that non-intrusive positive approaches to address the meaning/origins of behaviors are used prior to the development of a restrictive plan; and

3. cover any behavioral emergency and provide documentation of the event in an incident report format.

I. An HCBS provider shall comply with all federal and state laws, rules and regulations in the development and implementation of its policies and procedures.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORY NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5031. Business Location

A. All HCBS providers shall have a business location in the DHH Region for which the license is issued. The business location shall be a part of the physical geographic licensed location and shall be where the provider:

1. maintains staff to perform administrative functions;

2. maintains the provider's personnel records;

3. maintains the provider's client service records; and

4. holds itself out to the public as being a location for receipt of client referrals.

B. The business location shall have a separate entrance and exit from any other entity, business or trade, and shall have appropriate signage indicating the legal or trade name and address of the health care provider. The HCBS provider shall operate independently from any other business or entity, and shall not operate office space with any other business or entity.

1. The HCBS provider may share common areas with another business or entity. Common areas include foyers, kitchens, conference rooms, hallways, stairs, elevators or escalators when used to provide access to the provider's separate entrance.

2. Records or other confidential information shall not be stored in areas deemed to be common areas.

C. The business location shall:

1. be commercial office space or, if located in a residential area, be zoned for appropriate commercial use and shall be used solely for the operation of the business;

a. the business location may not be located in an occupied personal residence;

2. have approval from the Louisiana Office of the State Fire Marshal;

3. have a published telephone number which is available and accessible 24 hours a day, seven days a week, including holidays;

4. have a business fax number that is operational 24 hours a day, seven days a week;

5. have internet access and a working e-mail address;

a. the e-mail address shall be provided to the department;

6. have hours of operation posted in a location outside of the business that is easily visible to persons receiving services and the general public; and

7. have space for storage of client records in an area that is secure and does not breach confidentiality of personal health information.

D. Branch Offices and Satellites of HCBS Providers

1. An HCBS provider who currently provides in-home services such as PCA, respite or SIL services may apply to the department for approval to operate a branch office to provide those same services. The branch office falls under the license of the parent agency and shall be located in the same DHH Region as the parent agency.

2. An HCBS provider who currently provides ADC services or provides center-based respite services may apply to the department for approval to operate a satellite location to provide additional ADC services or center-based respite services at that satellite location. The satellite location falls under the license of the parent agency and shall be located in the same DHH Region as the parent agency.

3. No branch office or satellite location may be opened without written approval from the department. In order for a branch office or satellite location to be approved, the parent agency must have full licensure for at least one year. Branch office approvals and satellite location approvals will be renewed at the time of renewal of the parent agency's license, if the parent agency meets the requirements for licensure.

4. A branch office or a satellite location shall not be approved if any of the following conditions exist:

a. the parent agency was cited with more than five deficiencies on its last annual survey or on a complaint survey within the last 12 months;

b. the parent agency was cited with a deficiency resulting in immediate jeopardy or actual harm to a client on its last annual survey or on a complaint survey within the last 12 months;

c. the parent agency has a provisional license;

d. the parent agency is under license revocation;

e. the parent agency is undergoing a change of ownership; or

f. adverse action, including license revocation, denial or suspension, has been taken against the license of other agencies operated by the owner of the parent agency.

5. The branch office or satellite location shall be held out to the public as a branch, division, or satellite of the parent agency so that the public will be aware of the identity of the agency operating the branch or satellite.

a. Reference to the name of the parent agency shall be contained in any written documents, signs or other promotional materials relating to the branch or satellite.

6. Original personnel files shall not be maintained at the branch office or satellite location.

7. A branch office or a satellite location is subject to survey, including complaint surveys, by the department at any time to determine compliance with minimum licensing standards.

8. A branch office or a satellite location shall:

a. serve as part of the geographic service area approved for the parent agency;

b. retain all original clinical records for its clients. Duplicate records need not be maintained at the parent agency, but shall be made available to state surveyors during any survey upon request within a reasonable amount of time;

c. maintain a statement of personnel policies on-site for staff usage;

d. post and maintain regular office hours; and

e. staff the branch office or satellite location during regular office hours.

9. Each branch office shall be assessed a fee of $200, assessed at the time the license application is made for the branch and once a year thereafter for renewal of the branch license. This fee is non-refundable and is in addition to any other fees that may be assessed according to the laws, rules, regulations and standards.

10. Each satellite location shall be assessed a fee of $250, assessed at the time the license application is made for the satellite location and once a year thereafter for renewal of the satellite location license. This fee is non-refundable and is in addition to any other fees that may be assessed according to the laws, rules, regulations and standards.

11. The department at its sole discretion, and taking into consideration resources of the department, may approve branch offices for HCBS providers rending in-home services.

12. The department at its sole discretion, and taking into consideration resources of the department, may approve satellite locations for HCBS providers rendering center-based respite or adult day care services.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Subchapter C. Admission, Transfer and Discharge Criteria

§5033. Admissions

A. An HCBS provider shall have written admissions policies and criteria which shall include the following:

1. intake policy and procedures;
2. admission criteria and procedures;
3. admission criteria and procedures for minors;
4. policy regarding the determination of legal status, according to appropriate state laws, before admission;
5. the age of the populations served;
6. the services provided by the provider's program(s); and
7. criteria for discharge.

B. The written description of admissions policies and criteria shall be provided to the department upon request, and made available to the client and his/her legal representative.

C. An HCBS provider shall ensure that the client, the legal representative, where appropriate, or other persons are provided an opportunity to participate in the admission process and decisions.

1. Proper consents shall be obtained before admission.

2. Where such involvement of the client is not possible or not desirable, the reasons for their exclusion shall be recorded.

D. An HCBS provider shall not refuse admission to any client on the grounds of race, national origin, ethnicity or disability.

E. An HCBS provider shall meet the needs of each client admitted to his/her program as identified and addressed in the client's ISP.

F. When refusing admission to a client, a provider shall provide a written statement as to the reason for the refusal. This shall be provided to designated representatives of the department upon request.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5035. Voluntary Transfers and Discharges

A. A client has the right to choose a provider. This right includes the right to be discharged from his current provider, be transferred to another provider and to discontinue services altogether.

B. Upon notice by the client or authorized representative that the client has selected another provider or has decided to discontinue services, the HCBS provider shall have the responsibility of planning for a client's voluntary transfer or discharge.

C. The transfer or discharge responsibilities of the HCBS provider shall include:

1. holding a transfer or discharge planning conference with the client, family, support coordinator, legal representative and advocate, if such are known, in order to facilitate a smooth transfer or discharge, unless the client declines such a meeting;

2. providing a current individual service plan (ISP). Upon written request and authorization by the client or authorized representative, a copy of the current ISP shall be provided to the client or receiving provider; and

3. preparing a written discharge summary. The discharge summary shall include, at a minimum, a summary on the health, developmental issues, behavioral issues, social issues, and nutritional status of the client. Upon written request and authorization by the client or authorized representative, a copy of the discharge summary shall be disclosed to the client or receiving provider.

D. The written discharge summary shall be completed within five working days of the notice by the client or authorized representative that the client has selected another provider or has decided to discontinue services.

1. The provider's preparation of the discharge summary shall not impede or impair the client's right to be transferred or discharged immediately if the client so chooses.

E. The provider shall not coerce the client to stay with the provider agency or interfere in any way with the client's decision to transfer. Failure to cooperate with the client's decision to transfer to another provider will result in adverse action by the department.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5037. Involuntary Transfers and Discharges

A. An HCBS provider shall not transfer or discharge the client from the provider except under the following circumstances. These situations will be considered involuntary transfers or discharges.

1. The client's health has improved sufficiently so that the client no longer needs the services rendered by the provider.

2. The safety or health of a client(s) or provider staff is endangered.

3. The client has failed to pay any outstanding amounts for services for which he is liable within 15 days after receipt of written notice from the provider.

4. The provider ceases to operate.

5. The client moves from the geographical region serviced by the HCBS provider.

6. The client or family refuses to cooperate or interferes with attaining the objectives of the HCBS provider.

7. The HCBS provider closes a particular module so that certain services are no longer provided.

B. When the provider proposes to involuntarily transfer or discharge a client, compliance with the provisions of this Section shall be fully documented in the client's records.

C. An HCBS provider shall provide a written notice of the involuntary transfer or discharge to the client, a family member of the client, if known, and to the authorized representative, if known, at least 30 days prior to the transfer or discharge.

1. The written notice shall be sent via certified mail, return receipt requested.

2. When the safety or health of clients or provider staff is endangered, written notice shall be given as soon as practicable before the transfer or discharge.

3. When the client has failed to pay any outstanding amounts for services for which he is liable, written notice may be given immediately. Payment is due within 15 days of receipt of written notice from the provider that an amount is due and owing.

4. The notice of involuntary discharge or transfer shall be in writing and in a language and manner that the client understands.

5. A copy of the notice of involuntary discharge or transfer shall be placed in the client's clinical record.

D. The written notice of involuntary transfer or discharge shall include:

1. a reason for the transfer or discharge;

2. the effective date of the transfer or discharge;

3. an explanation of a client's right to personal and/or third party representation at all stages of the transfer or discharge process;

4. contact information for the Advocacy Center;

a. the contact information shall include the addresses and telephone numbers for the Advocacy Center locations in Shreveport, Lafayette, and New Orleans;

5. names of provider personnel available to assist the client and family in decision making and transfer arrangements;

6. the date, time and place for the discharge planning conference;

7. a statement regarding the client's appeal rights;

8. the name of the director, current address and telephone number of the Division of Administrative Law or its successor; and

9. a statement regarding the client's right to remain with the provider and not be transferred or discharged if an appeal is timely filed.

E. Appeal Rights for Involuntary Transfers or Discharges

1. If a timely appeal is filed by the client or authorized representative disputing the involuntary discharge, the provider shall not transfer or discharge the client pursuant to the provisions of this Section.

NOTE: The provider's failure to comply with these requirements may result in revocation of a provider's license.

2. If nonpayment is the basis of the involuntary transfer or discharge, the client shall have the right to pay the balance owed to the provider up to the date of the transfer or discharge and is then entitled to remain with the agency if outstanding balances are paid.

3. If a client files a timely appeal request, the Division of Administrative Law, or its successor, shall hold an appeal hearing at the agency or by telephone, if agreed upon by the appellant, within 30 days from the date the appeal is filed with the Division of Administrative Law or its successor.

a. If the basis of the involuntary discharge is due to endangerment of the health or safety of the staff or individuals, the provider may make a written request to the Division of Administrative Law, or its successor, to hold a pre-hearing conference.

i. If a pre-hearing conference request is received by the Division of Administrative Law, or its successor, the pre-hearing conference shall be held within 10 days of receipt of the written request from the provider.

4. The Division of Administrative Law, or its successor, shall issue a decision within 30 days from the date of the appeal hearing.

5. The burden of proof is on the provider to show, by a preponderance of the evidence, that the transfer or discharge of the client is justified pursuant to the provisions of the minimum licensing standards.

F. Client's Right to Remain with the Provider Pending the Appeal Process

1. If a client is given 30 days written notice of the involuntary transfer or discharge and the client or authorized representative files a timely appeal, the client may remain with the provider and not be transferred or discharged until the Division of Administrative Law, or its successor, renders a decision on the appeal.

2. If a client is given less than 30 days written notice and files a timely appeal of an involuntary transfer/discharge based on the health and safety of individuals or provider staff being endangered, the client may remain with the provider and not be transferred or discharged until one of the following occurs:

a. the Division of Administrative Law, or its successor, holds a pre-hearing conference regarding the safety or health of the staff or individuals; or

b. the Division of Administrative Law, or its successor, renders a decision on the appeal.

3. If a client is given less than 30 days written notice and files a timely appeal of an involuntary transfer/discharge based on the client's failure to pay any outstanding amounts for services within the allotted time, the provider may discharge or transfer the client.

4. If a client is given less than 30 days written notice and files a timely appeal of an involuntary transfer/discharge based on the client moving outside of the provider's geographic service area, the client may remain with the provider and not be transferred or discharged until the Division of Administrative Law, or its successor, renders a decision on the appeal.

G. The transfer or discharge responsibilities of the HCBS provider shall include:

1. holding a transfer or discharge planning conference with the client, family, support coordinator, legal

representative and advocate, if such are known, in order to facilitate a smooth transfer or discharge;

2. development of discharge options that will provide reasonable assurance that the client will be transferred or discharged to a setting that can be expected to meet his/her needs;

3. preparing an updated ISP; and

4. preparing a written discharge summary. The discharge summary shall include, at a minimum, a summary of the health, developmental issues, behavioral issues, social issues and nutritional status of the client. Upon written request and authorization by the client or authorized representative, a copy of the discharge summary and/or updated ISP shall be disclosed to the client or receiving provider.

H. The agency shall provide all services required prior to discharge that are contained in the final update of the individual service plan and in the transfer or discharge plan.

1. The provider shall not be required to provide services if the discharge is due to the client moving out of the provider's geographical region. An HCBS provider is prohibited from providing services outside of its geographical region without the Department's approval.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Subchapter D. Service Delivery

§5039. General Provisions

A. The HCBS provider shall ensure that the client receives the necessary care and services to attain or maintain the highest practicable physical, mental and psychosocial well-being of the client, in accordance with the comprehensive assessment and individual service plan.

B. All services provided to the client shall be provided in accordance with an individual service plan.

C. Assessment of Needs

1. Prior to any service being rendered, an HCBS provider shall conduct an assessment of the client's needs. The assessment shall include, at a minimum:

a. risk assessment, including:

i. life safety (i.e. the ability to access emergency services, basic safety practices and evaluation of the living unit);

ii. home environment;

iii. environmental risk; and

iv. medical risk;

b. medical assessments, including:

i. diagnosis;

ii. medications, including methods of administration; and

iii. current services and treatment regimen;

c. activities of daily living;

d. instrumental activities of daily living including money management, if applicable;

e. communication skills;

f. social skills; and

g. psychosocial skills including behavioral needs.

2. Each assessment shall be conducted by a licensed professional or a team of licensed professionals who are qualified and appropriate to conduct the assessment, and shall determine the necessary supports and services which shall be addressed in the ISP. If medical issues are identified in the assessment, a licensed physician or licensed registered nurse (RN) shall perform a medical assessment to determine necessary supports and services which shall be addressed in the ISP.

3. The assessment shall be conducted prior to admission and at least annually thereafter. The assessment may be conducted more often as the client's needs change.

4. An HCBS comprehensive assessment performed for a client in accordance with policies and procedures established by Medicaid or by a DHH program office for reimbursement purposes can substitute for the assessment required under these provisions.

D. Service Agreement

1. An HCBS provider shall ensure that a written service agreement is completed prior to admission of a client. A copy of the agreement, signed by all parties involved, shall be maintained in the client's record and shall be made available upon request by the department, the client and the legal representative, where appropriate.

2. The service agreement shall include:

a. a delineation of the respective roles and responsibilities of the provider;

b. specification of all of the services to be rendered by the provider;

c. the provider's expectations concerning the client; and

d. specification of the financial arrangements, including any fees to be paid by the client.

3. An HCBS plan of care or agreement to provide services signed by the provider or client in accordance with policies and procedures established by Medicaid or by a DHH program office for reimbursement purposes can substitute for the agreement required under these provisions.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5041. Individual Service Plan

A. Upon admission, an individual service plan shall be developed for each client based upon a comprehensive assessment.

B. The client shall participate in the planning process. If the client is unable to participate in all or part of the planning, the provider shall document the parts or times and reasons why the client did not participate.

C. The agency shall document that they consulted with the client or legal representative regarding who should be involved in the planning process.

D. The agency shall document who attends the planning meeting.

E. The provider shall ensure that the ISP and any subsequent revisions are explained to the client receiving services and, where appropriate, the legal representative, in language that is understandable to them.

F. The ISP shall include the following components:

1. the findings of the comprehensive assessment;

2. a statement of goals to be achieved or worked towards for the person receiving services and their family or legal representative;

3. daily activities and specialized services that will be provided directly or arranged for;

4. target dates for completion or re-evaluation of the stated goals; and

5. identification of all persons responsible for implementing or coordinating implementation of the plan.

G. The provider shall ensure that all agency staff working directly with the person receiving services are appropriately informed of and trained on the ISP.

H. A comprehensive plan of care or ISP prepared in accordance with policies and procedures established by Medicaid or by a DHH program office for reimbursement purposes may be substituted for the individual service plan.

I. Each client's ISP shall be reviewed, revised, updated and amended annually, and more often as necessary, to reflect changes in the client's needs, services and personal outcomes.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5043. Contract Services

A. A provider may enter into contracts or other agreements with other companies or individuals to provide services to a client. The provider is still responsible for the management of the client's care and for all services provided to the client by the contractor or its personnel.

B. When services are provided through contract, a written contract must be established. The contract shall include all of the following items:

1. designation of the services that are being arranged for by contract;

2. specification of the period of time that the contract is to be in effect;

3. a statement that the services provided to the client are in accordance with the individual service plan;

4. a statement that the services are being provided within the scope and limitations set forth in the individual service plan and may not be altered in type, scope or duration by the contractor;

5. assurance that the contractor meets the same requirements as those for the provider's staff, such as staff qualifications, functions, evaluations, orientation and in-service training;

a. the provider shall be responsible for assuring the contractor's compliance with all personnel and agency policies required for HCBS providers during the contractual period;

6. assurance that the contractor completes the clinical record in the same timely manner as required by the staff of the provider;

7. payment of fees and terms; and

8. assurance that reporting requirements are met.

C. The provider and contractor shall document review of their contract on an annual basis.

D. The provider shall coordinate services with contract personnel to assure continuity of client care.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5045. Transportation

A. An HCBS provider shall arrange for or provide transportation necessary for implementing the client's service plan.

B. Any vehicle owned by the agency or its employees used to transport clients shall be:

1. properly licensed and inspected in accordance with state law;

2. maintained in a safe condition;

3. operated at a temperature that does not compromise the health, safety or needs of the client; and

4. operated in conformity with all of the applicable motor vehicle laws.

C. The provider shall have documentation of liability insurance coverage for any vehicle owned by the agency or its employees and used to transport clients. The personal liability insurance of a provider's employee shall not be substituted for the required coverage.

D. Any staff member of the provider, or other person acting on behalf of the provider, who is operating a vehicle owned by the agency or its employees for the purpose of transporting clients shall be properly licensed to operate that class of vehicle in accordance with state law.

E. The provider shall have documentation of successful completion of a safe driving course for each employee who transports clients.

1. Employees shall successfully complete a safe driving course within 90 days of hiring, every three years thereafter, and within 90 days of the provider's discovery of any moving violation.

F. Upon hire, the provider shall conduct a driving history record of each employee, and annually thereafter.

G. The provider shall not allow the number of persons in any vehicle used to transport clients to exceed the number of available seats with seatbelts in the vehicle.

H. The provider shall ascertain the nature of any need or problem of a client which might cause difficulties during transportation. This information shall be communicated to agency staff who will transport clients.

I. The following additional arrangements are required for transporting non-ambulatory clients and those who cannot otherwise be transferred to and from the vehicle.

1. A ramp device to permit entry and exit of a client from the vehicle shall be provided for vehicles.

a. A mechanical lift may be utilized, provided that a ramp is also available in case of emergency, unless the mechanical lift has a manual override.

2. Wheelchairs used in transit shall be securely fastened inside the vehicle utilizing approved wheelchair fasteners.

3. The arrangement of the wheelchairs shall not impede access to the exit door of the vehicle.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Subchapter E. Client Protections

§5049. Client Rights

A. Unless adjudicated by a court of competent jurisdiction, clients served by HCBS providers shall have the same rights, benefits and privileges guaranteed by the constitution and the laws of the United States and Louisiana.

B. There shall be written policies and procedures that protect the client's welfare, including the means by which the protections will be implemented and enforced.

C. Each HCBS provider's written policies and procedures, at a minimum, shall ensure the client's right to:

1. human dignity;

2. impartial access to treatment regardless of race, religion, sex, ethnicity, age or disability;

3. cultural access as evidenced by:

a. interpretive services;

b. translated materials;

c. the use of native language when possible; and

d. staff trained in cultural awareness;

4. have sign language interpretation, allow for the use of service animals and/or mechanical aids and devices that assist those persons in achieving maximum service benefits when the person has special needs;

5. privacy;

6. confidentiality;

7. access his/her records upon the client's written consent for release of information;

8. a complete explanation of the nature of services and procedures to be received, including:

a. risks;

b. benefits; and

c. available alternative services;

9. actively participate in services, including:

a. assessment/reassessment;

b. service plan development; and

c. discharge;

10. refuse specific services or participate in any activity that is against their will and for which they have not given consent;

11. obtain copies of the provider's complaint or grievance procedures;

12. file a complaint or grievance without retribution, retaliation or discharge;

13. be informed of the financial aspect of services;

14. be informed of the need for parental or guardian consent for treatment of services, if appropriate;

15. personally manage financial affairs, unless legally determined otherwise;

16. give informed written consent prior to being involved in research projects;

17. refuse to participate in any research project without compromising access to services;

18. be free from mental, emotional and physical abuse and neglect;

19. be free from chemical or physical restraints;

20. receive services that are delivered in a professional manner and are respectful of the client's wishes concerning their home environment;

21. receive services in the least intrusive manner appropriate to their needs;

22. contact any advocacy resources as needed, especially during grievance procedures; and

23. discontinue services with one provider and freely choose the services of another provider.

D. An HCBS provider shall assist in obtaining an independent advocate:

1. if the client's rights or desires may be in jeopardy;

2. if the client is in conflict with the provider; or

3. upon any request of the client.

E. The client has the right to select an independent advocate, which may be:

1. a legal assistance corporation;

2. a state advocacy and protection agency;

3. a trusted church or family member; or

4. any other competent key person not affiliated in any way with the licensed provider.

F. The client, client's family and legal guardian, if one is known, shall be informed of their rights, both verbally and in writing in a language they are able to understand.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5051. Grievances

A. The agency shall establish and follow a written grievance procedure to be used to formally resolve complaints by clients, their family member(s) or a legal representative regarding provision of services. The written grievance procedure shall be provided to the client.

1. The notice of grievance procedure shall include the names of organizations that provide free legal assistance.

B. The client, family member or legal representative shall be entitled to initiate a grievance at any time.

C. The agency shall annually explain the grievance procedure to the client, family member(s) or a legal representative, utilizing the most appropriate strategy for ensuring an understanding of what the grievance process entails.

1. The agency shall provide the grievance procedure in writing and grievance forms shall be made available.

D. The administrator of the agency, or his/her designee, shall investigate all grievances and shall make all reasonable attempts to address the grievance.

E. The administrator of the agency, or his/her designee, shall issue a written report and/or decision within five business days of receipt of the grievance to the:

1. client;

2. client's advocate;

3. authorized representative; and

4. the person making the grievance.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Subchapter F. Provider Responsibilities

§5053. General Provisions

A. HCBS providers shall have qualified staff sufficient in number to meet the needs of each client as specified in the ISP and to respond in emergency situations.

B. Additional staff shall be employed as necessary to ensure proper care of clients and adequate provision of services.

C. Staff shall have sufficient communication and language skills to enable them to perform their duties and interact effectively with clients and other staff persons.

D. All client calls to the provider's published telephone number shall be returned within an appropriate amount of time not to exceed 24 hours. Each client shall be informed of the provider's published telephone number, in writing, as well as through any other method of communication most readily understood by the client according to the following schedule:

1. upon admission to the HCBS provider agency;

2. at least once per year after admission; and

3. when the provider's published telephone number changes.

E. HCBS providers shall establish policies and procedures relative to the reporting of abuse and neglect of clients, pursuant to the provisions of R.S. 15:1504-1505, R.S. 40:2009.20 and any subsequently enacted laws. Providers shall ensure that staff complies with these regulations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORY NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5055. Core Staffing Requirements

A. Administrative Staff. The following administrative staff is required for all HCBS providers:

1. a qualified administrator at each licensed geographic location who shall meet the qualifications as established in these provisions; and

2. other administrative staff as necessary to properly safeguard the health, safety and welfare of the clients receiving services.

B. Administrator Qualifications

1. The administrator shall be a resident of the state of Louisiana and shall have the following educational qualifications and experience:

a. a master's degree in a human services field including, but not limited to:

i. nursing, hospital or nursing facility administration;

ii. physical therapy;

iii. social work;

iv. psychology;

v. gerontology;

vi. rehabilitation counseling; or

vii. health care administration; plus

viii. a minimum of three years of verifiable work experience with persons with disabilities or the elderly, with one year of the three years being at the administrative level; or

b. a bachelor's degree in a human services field including, but not limited to:

i. nursing, hospital or nursing facility administration;

ii. physical therapy;

iii. social work;

iv. psychology

v. gerontology;

vi. rehabilitation counseling; or

vii. health care administration; plus

viii. a minimum of four years verifiable work experience with persons with disabilities or the elderly, with two years of the four years being at the administrative level;

c. be a registered nurse with a minimum of seven years of verifiable work experience with persons with disabilities or the elderly, with three years of the seven years being at the administrative level; or

d. have a Juris Doctorate or a Master's or PhD in business management, provided there is a full-time individual on staff in a managerial position who has a human service degree.

2. Any person convicted of a felony as defined in these provisions is prohibited from serving as the administrator of an HCBS provider agency.

C. Administrator Responsibilities. The administrator shall:

1. be a full time employee of the HCBS provider and shall not be a contract employee;

2. be available in person or by telecommunication at all times for all aspects of agency operation;

3. designate in writing an individual who meets the qualifications for an administrator to assume the authority and control of the agency if the administrator is unavailable;

4. direct the operations of the agency;

5. be responsible for compliance with all regulations, laws, policies and procedures applicable to home and community-based service providers;

6. employ qualified individuals and ensure adequate staff education and evaluations;

7. ensure the accuracy of public information and materials;

8. act as liaison between staff, contract personnel and the governing body;

9. implement an ongoing, accurate and effective budgeting and accounting system;

10. ensure that all staff receive proper orientation and training on policies and procedures, client care and services and documentation, as required by law or as necessary to fulfill each staff person's responsibilities;

11. assure that services are delivered according to the client's individual service plan; and

12. not serve as administrator for more than one licensed HCBS provider.

D. Professional Services Staff

1. The provider shall employ, contract with or assure access to all necessary professional staff to meet the needs of each client as identified and addressed in the client's ISP. The professional staff shall include, but not be limited to:

a. licensed practical nurses;

b. registered nurses;

c. speech therapists;

d. physical therapists;

e. occupational therapists;

f. social workers; and

g. psychologists.

2. Professional staff employed or contracted by the provider shall hold a current, valid license issued by the appropriate licensing board and shall comply with continuing education requirements of the appropriate board.

3. The provider shall maintain proof of annual verification of current license of all professional staff.

4. All professional services furnished or provided shall be provided in accordance with acceptable professional practice standards, according to the scope of practice requirements for each licensed discipline.

E. Direct Care Staff

1. The provider shall be staffed with direct care staff to properly safeguard the health, safety and welfare of clients.

2. The provider shall employ direct care staff to ensure the provision of home and community-based services as required by the ISP.

3. The HCBS provider shall have back-up staff available on a 24-hour basis to ensure that services to the

client are uninterrupted in the event that the primary direct care staff for the client is unable to report to work.

F. Direct Care Staff Qualifications

1. All providers who receive state or federal funds, and compensate their direct service workers with such funds, shall ensure that all non-licensed direct care staff meet the minimum mandatory qualifications and requirements for direct service workers as required by R.S. 40:2179-40:2179.1 or a subsequently amended statute and any rules published pursuant to those statutes.

2. All direct care staff shall have the ability to read, write and carry out directions competently as assigned.

a. The training must address areas of weakness, as determined by the worker's performance reviews, and may address the special needs of clients.

3. All direct care staff shall be trained in recognizing and responding to the medical emergencies of clients.

G. Direct Care Staff Responsibilities. The direct care staff shall:

1. provide personal care services to the client, per the ISP;

2. provide the direct care services to the client at the time and place assigned;

3. report and communicate changes in a client's condition to a supervisor immediately upon discovery of the change;

4. report and communicate a client's request for services or change in services to a supervisor on the date of such request;

5. follow emergency medical training while attending the client;

6. subsequently report any medical emergencies to the supervisor, the provider or others, pursuant to the provider policies and procedures;

7. report any suspected abuse, neglect or exploitation of clients to a supervisor on the date of discovery, and as required by law;

8. be trained on daily documentation such as progress notes and progress reports; and

9. be responsible for daily documentation of services provided and status of clients to be reported on progress notes and/or progress reports.

H. Volunteers/Student Interns

1. A provider utilizing volunteers or student interns on a regular basis shall have a written plan for using such resources. This plan shall be given to all volunteers and interns. The plan shall indicate that all volunteers and interns shall:

a. be directly supervised by a paid staff member;

b. be oriented and trained in the philosophy, policy and procedures of the provider, confidentiality requirements and the needs of clients; and

c. have documentation of three reference checks.

2. Volunteer/student interns shall be a supplement to staff employed by the provider but shall not provide direct care services to clients.

I. Direct Care Staff Supervisor. The HCBS provider shall designate and assign a direct care staff supervisor to monitor and supervise the direct care staff.

1. The supervisor shall be selected based upon the needs of the client outlined in the ISP.

2. A provider may have more than one direct care staff supervisor.

3. Staff in supervisor positions shall have annual training in supervisory and management techniques.

J. Direct Care Supervision

1. A direct care staff supervisor shall make an onsite supervisor visit of each direct care staff not to exceed 90 days between visits. Supervisory visits should occur more frequently:

a. if dictated by the ISP;

b. as needed to address worker performance;

c. to address a client's change in status; or

d. to assure services are provided in accordance with the ISP.

2. The supervisory visit shall be unannounced and utilized to evaluate the direct care staff's ability to perform assigned duties, determine whether services are being provided in accordance with the ISP and whether goals are being met.

3. Documentation of supervision shall include:

a. the worker/client relationship;

b. services provided;

c. observations of the worker performing assigned duties;

d. instructions and comments given to the worker during the onsite visit;

e. verification that the worker is actually reporting to the work site according to the frequency specified in the ISP; and

f. client satisfaction with service delivery.

4. An annual performance evaluation for each direct care staff person shall be documented in his/her personnel record.

K. Direct Care Staff Training

1. The provider shall ensure that each direct care staff satisfactorily completes a minimum of 16 hours of training upon hire and before providing direct care and services to clients. Such training shall include the following topics and shall be documented in each employee's personnel record:

a. the provider's policies and procedures;

b. emergency and safety procedures;

c. recognizing and responding to medical emergencies that require an immediate call to 911;

d. client's rights;

e. detecting and reporting suspected abuse and neglect, utilizing the department's approved training curriculum;

f. reporting critical incidents;

g. universal precautions;

h. documentation;

i. implementing service plans;

j. confidentiality;

k. detecting signs of illness or dysfunction that warrant medical or nursing intervention;

l. basic skills required to meet the health needs and problems of the client; and

m. the management of aggressive behavior, including acceptable and prohibited responses.

2. The provider shall ensure that each direct care staff satisfactorily completes a basic first aid course within 45 days of hire.

L. Competency Evaluation

1. A competency evaluation must be developed and conducted to ensure that each direct care staff, at a minimum, is able to demonstrate competencies in the training areas in §5055.K.

2. Written or oral examinations shall be provided.

3. The examination shall reflect the content and emphasis of the training curriculum components in §5055.K and shall be developed in accordance with accepted educational principles.

4. A substitute examination, including an oral component, will be developed for those direct care staff with limited literacy skills. This examination shall contain all of the content that is included in the written examination and shall also include a written reading comprehension component that will determine competency to read job-related information.

M. Continuing Education

1. Annually thereafter, the provider shall ensure that each direct care staff person satisfactorily completes a minimum of 16 hours of continuing training in order to ensure continuing competence. Orientation and normal supervision shall not be considered for meeting this requirement. This training shall address the special needs of clients and may address areas of employee weakness as determined by the direct care staff's performance reviews.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5057. Client Records

A. Client records shall be maintained in the HCBS provider's office. Current progress notes shall be maintained at the home. The provider shall have a written record for each client which shall include:

1. other identifying data including:
   a. name;
   b. date of birth;
   c. address;
   d. telephone number;
   e. social security number; and
   f. legal status;

2. a copy of the client's ISP or Medicaid comprehensive plan of care, as well as any modifications or updates to the service plan;

3. the client's history including, where applicable:
   a. family data;
   b. next of kin;
   c. educational background;
   d. employment record;
   e. prior medical history; and
   f. prior service history;

4. the service agreement or comprehensive plan of care;

5. written authorization signed by the client or, where appropriate, the legally responsible person for emergency care;

6. written authorization signed by the client or, where appropriate, the legally responsible person for managing the client's money, if applicable;

7. a full and complete separate accounting of each client's personal funds which includes a written record of all of the financial transactions involving the personal funds of the client deposited with the provider;
   a. the client (or his legal representative) shall be afforded reasonable access to such record;
   b. the financial records shall be available through quarterly statements;
   c. the provider shall safeguard and account for any such funds;

8. required assessment(s) and additional assessments that the provider may have received or is privy to;

9. the names, addresses and telephone numbers of the client's physician(s) and dentist;

10. written progress notes or equivalent documentation and reports of the services delivered for each client for each visit. The written progress notes shall include, at a minimum:
   a. the date and time of the visit and services;
   b. the services delivered;
   c. who delivered or performed the services;
   d. observed changes in the physical and mental condition(s) of the client, if applicable; and
   e. doctor appointments scheduled or attended that day;

11. health and medical records of the client, including:
   a. a medical history, including allergies;
   b. a description of any serious or life threatening medical condition(s);
   c. a description of any medical treatment or medication necessary for the treatment of any medical condition; and
   d. physician delegation form for the administration of medication or treatment, if applicable; and

12. a copy of any advance directive that has been provided to the HCBS provider, or any physician orders relating to end of life care and services.

B. HCBS providers shall maintain client records for a period of five years.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5059. Client Funds and Assets

A. The HCBS provider shall develop and implement written policies and procedures to protect client funds.

B. If the provider manages a client's personal funds, the provider must furnish a written statement which includes the client's rights regarding personal funds, a list of the services offered and charges, if any, to the client and/or his/her legal or responsible representative.

C. If a client chooses to entrust funds with the provider, the provider shall obtain written authorization from the client and/or his/her legal or responsible representative for the safekeeping and management of the funds.

D. The provider shall:

1. provide each client with an account statement on a quarterly basis with a receipt listing the amount of money the provider is holding in trust for the client;

2. maintain a current balance sheet containing all financial transactions to include the signatures of staff and the client for each transaction;

3. provide a list or account statement regarding personal funds upon request of the client;

4. maintain a copy of each quarterly account statement in the client's record;

5. keep funds received from the client for management in a separate account and maintain receipts from all purchases with each receipt being signed by the client and the staff assisting the client with the purchase, or by the staff assisting the client with the purchase and an independent staff when the client is not capable of verifying the purchase; and

6. not commingle the clients' funds with the provider's operating account.

E. A client with a personal fund account managed by the HCBS provider may sign an account agreement acknowledging that any funds deposited into the personal account, by the client or on his/her behalf, are jointly owned by the client and his legal representative or next of kin. The account agreement shall state that:

1. the funds in the account shall be jointly owned with the right of survivorship;

2. the funds in the account shall be used by the client or on behalf of the client;

3. the client or the joint owner may deposit funds into the account; and

4. the client or joint owner may endorse any check, draft or other instrument to the order of any joint owner, for deposit into the account.

F. If the provider is managing funds for a client and he/she is discharged, any remaining funds shall be refunded to the client or his/her legal or responsible representative within five business days of notification of discharge.

G. Distribution of Funds upon the Death of a Client

1. Unless otherwise provided by state law, upon the death of a client, the provider shall provide the executor or administrator of the client's estate or the client's responsible representative with a complete account statement of the client's funds and personal property being held by the provider.

2. If a valid account agreement has been executed by the client, the provider shall transfer the funds in the client's personal fund account to the joint owner within 30 days of the client's death. This provision only applies to personal fund accounts not in excess of $2,000.

3. If a valid account agreement has not been executed, the provider shall comply with the federal and state laws and regulations regarding the disbursement of funds in the account and the properties of the deceased. The provider shall comply with R.S. 9:151–181, the Louisiana Uniform Unclaimed Property Act, and the procedures of the Louisiana Department of the Treasury regarding the handling of a deceased client's funds that remain unclaimed.

H. A termination date of the account and the reason for termination shall be recorded on the client's participation file. A notation shall read, "to close account." The endorsed cancelled check with check number noted on the ledger sheet shall serve as sufficient receipt and documentation.

I. Burial or Insurance Policies

1. Upon discharge of a client, the provider shall immediately remit any burial policies or insurance policies to the client or his/her legal or responsible representative.

2. Upon the death of a client, the provider shall act upon any burial or insurance policies of the client accordingly.

J. The provisions of this section shall have no effect on federal or state tax obligations or liabilities of the deceased client's estate. If there are other laws or regulations which conflict with these provisions, those laws or regulations will govern over and supersede the conflicting provisions.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5061. Quality Enhancement Plan

A. An HCBS provider shall have a quality enhancement (QE) plan which puts systems in place to effectively identify issues for which quality monitoring, remediation and improvement activities are necessary. The QE plan includes plans of action to correct identified issues including monitoring the effect of implemented changes and making needed revisions to the action plan.

B. The QE plan shall include:

1. a process for obtaining input annually from the client/guardian/authorized representatives and family members ,as applicable. This process shall include, but not be limited to:

a. satisfaction surveys done by mail or telephone;

b. focus groups; and

c. other processes for receiving input regarding the quality of services received;

2. a 10 percent sample review of client case records and/or site visits on a quarterly bases to assure that:

a. individual service plans are up to date;

b. records are complete and current; and

c. supervisory visits are current and documented;

3. a process for identifying on a quarterly basis the risk factors that affect or may affect the health, safety and/or welfare of individuals being supported which includes, but is not limited to:

a. review and resolution of complaints;

b. review and resolution of incidents; and

c. Office of Protective Services' investigations of abuse, neglect and exploitation;

4. a process to review and resolve individual client issues that are identified; and

5. a process to review and develop action plans to resolve all system wide issues identified as a result of the processes above.

C. The QE program outcomes shall be reported to the administrator for action, as necessary, for any identified systemic problems.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5063. Emergency Preparedness

A. A disaster or emergency may be a local, community-wide, regional or statewide event. Disasters or emergencies may include, but are not limited to:

1. tornados;
2. fires;
3. floods;
4. hurricanes;
5. power outages;
6. chemical spills;
7. biohazards;

8. train wrecks; or
9. declared health crisis.

B. Providers shall ensure that each client has an individual plan for dealing with emergencies and disasters and shall assist clients in identifying the specific resources available through family, friends, the neighborhood and the community.

C. Continuity of Operations. The provider shall have an emergency preparedness plan to maintain continuity of the agency's operations in preparation for, during and after an emergency or disaster. The plan shall be designed to manage the consequences of all hazards, declared disasters or other emergencies that disrupt the provider's ability to render care and treatment, or threatens the lives or safety of the clients.

D. The provider shall follow and execute its emergency preparedness plan in the event of the occurrence of a declared disaster or other emergency. The plan shall include, at a minimum:

1. provisions for the delivery of essential services to each client as identified in the individualized emergency plan for each client, whether the client is in a shelter or other location;

2. provisions for the management of staff, including provisions for adequate, qualified staff as well as for distribution and assignment of responsibilities and functions;

3. provisions for back-up staff;

4. the method that the provider will utilize in notifying the client's family or caregiver if the client is evacuated to another location either by the provider or with the assistance or knowledge of the provider. This notification shall include:

a. the date and approximate time that the facility or client is evacuating;

b. the place or location to which the client(s) is evacuating which includes the name, address and telephone number; and

c. a telephone number that the family or responsible representative may call for information regarding the provider's evacuation;

5. provisions for ensuring that supplies, medications, clothing and a copy of the service plan are sent with the client, if the client is evacuated; and

6. the procedure or methods that will be used to ensure that identification accompanies the individual. The identification shall include the following information:

a. current and active diagnosis;

b. medication, including dosage and times administered;

c. allergies;

d. special dietary needs or restrictions; and

e. next of kin, including contact information.

E. If the state, parish or local Office of Homeland Security and Emergency Preparedness (OHSEP) orders a mandatory evacuation of the parish or the area in which the agency is serving, the agency shall ensure that all clients are evacuated according to the client's individual plan and the agency's emergency preparedness plan.

1. The provider shall not abandon a client during a disaster or emergency. The provider shall not evacuate a client to a shelter without ensuring staff and supplies remain with the client at the shelter, in accordance with the client's service plan.

F. Emergency Plan Review and Summary. The provider shall review and update its emergency preparedness plan, as well as each client's emergency plan at least annually.

G. The provider shall cooperate with the department and with the local or parish OHSEP in the event of an emergency or disaster and shall provide information as requested.

H. The provider shall monitor weather warnings and watches as well as evacuation order from local and state emergency preparedness officials.

I. All agency employees shall be trained in emergency or disaster preparedness. Training shall include orientation, ongoing training and participation in planned drills for all personnel.

J. Upon request by the department, the HCBSP shall submit a copy of its emergency preparedness plan and a written summary attesting how the plan was followed and executed. The summary shall contain, at a minimum:

1. pertinent plan provisions and how the plan was followed and executed;

2. plan provisions that were not followed;

3. reasons and mitigating circumstances for failure to follow and execute certain plan provisions;

4. contingency arrangements made for those plan provisions not followed; and

5. a list of all injuries and deaths of clients that occurred during execution of the plan, evacuation or temporary relocation including the date, time, causes and circumstances of the injuries and deaths.

K. Inactivation of License due to a Declared Disaster or Emergency.

1. An HCBS provider licensed in a parish which is the subject of an executive order or proclamation of emergency or disaster, as issued in accordance with R.S. 29:724 or R.S. 29:766 may seek to inactivate its license for a period not to exceed one year, provided that the following conditions are met:

a. the licensed provider shall submit written notification to the Health Standards Section within 60 days of the date of the executive order or proclamation of emergency or disaster that:

i. the HCBS provider has experienced an interruption in the provisions of services as a result of events that are the subject of such executive order or proclamation of emergency or disaster issued in accordance with R.S. 29:724 or R.S. 29:766;

ii. the licensed HCBS provider intends to resume operation as an HCBS provider in the same service area;

iii. includes an attestation that the emergency or disaster is the sole casual factor in the interruption of the provision of services;

iv. includes an attestation that all clients have been properly discharged or transferred to another provider; and

v. provides a list of each client and where that client is discharged or transferred to;

b. the licensed HCBS provider resumes operating as a HCBS provider in the same service area within one year of the issuance of an executive order or proclamation of emergency or disaster in accordance with R.S. 29:724 or R.S. 29:766;

c. the licensed HCBS provider continues to pay all fees and cost due and owed to the department including, but

not limited to, annual licensing fees and outstanding civil monetary penalties; and

d. the licensed HCBS provider continues to submit required documentation and information to the department.

2. Upon receiving a completed written request to inactivate a HCBS provider license, the department shall issue a notice of inactivation of license to the HCBS provider.

3. Upon completion of repairs, renovations, rebuilding or replacement, an HCBS provider which has received a notice of inactivation of its license from the department shall be allowed to reinstate its license upon the following conditions being met.

a. The HCBS provider shall submit a written license reinstatement request to the licensing agency of the department 60 days prior to the anticipated date of reopening.

b. The license reinstatement request shall inform the department of the anticipated date of opening, and shall request scheduling of a licensing survey.

c. The license reinstatement request shall include a completed licensing application with appropriate licensing fees.

d. The provider resumes operating as an HCBS provider in the same service area within one year.

4. Upon receiving a completed written request to reinstate an HCBS provider license, the department shall conduct a licensing survey. If the HCBS provider meets the requirements for licensure and the requirements under this Section, the department shall issue a notice of reinstatement of the HCBS provider license.

a. The licensed capacity of the reinstated license shall not exceed the licensed capacity of the HCBS provider at the time of the request to inactivate the license.

5. No change of ownership in the HCBS provider shall occur until such HCBS provider has completed repairs, renovations, rebuilding or replacement construction, and has resumed operations as an HCBS provider.

6. The provisions of this Section shall not apply to an HCBS provider which has voluntarily surrendered its license and ceased operation.

7. Failure to comply with any of the provisions of this Section shall be deemed a voluntary surrender of the HCBS provider license and any applicable facility need review approval for licensure.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Subchapter G. Adult Day Care Module

§5071. General Provisions

A. Providers applying for the Adult Day Care module under the HCBS license shall meet the core licensing requirements as well as the module specific requirements of this Section.

B. Adult Day Care is designed to meet the individual needs of functionally impaired adults. This is a structured and comprehensive group program which provides a variety of health, social, and related support services in a protective setting for a portion of the 24-hour day.

C. An ADC program shall provide services for 10 or more functionally impaired adults who are not related to the owner or operator of the HCBS provider.

1. For the purposes of this Section, "*functionally impaired adult*" shall be defined as individuals 17 years of age or older who are physically, mentally or socially impaired to a degree that requires supervision.

D. The following two programs shall be provided under the ADC Module:

1. Day Habilitation Services

a. Day habilitation services include assistance with acquisition, retention or improvement in self-help, socialization, and adaptive skills that take place in a non-residential setting separate from the recipient's private residence or other residential living arrangement. Day habilitation services provide activities and environments designed to foster the acquisition of skills, appropriate behavior, greater independence and personal choice.

b. Services are furnished to a client who is 17 years of age or older and has a developmental disability, or who is a functionally impaired adult, on a regularly scheduled basis during normal daytime working hours for one or more days per week, or as specified in the recipient's service plan.

c. Day habilitation services focus on enabling the recipient to attain or maintain his or her maximum functional level, and shall be coordinated with any physical, occupational, or speech therapies in the service plan. These services may also serve to reinforce skills or lessons taught in other settings.

2. Prevocational/Employment-Related Services

a. Prevocational/employment-related services prepare a recipient for paid or unpaid employment. Services include teaching such concepts as compliance, attendance, task completion, problem solving and safety. Services are not job-task oriented, but are aimed at a generalized result. These services are reflected in the recipient's service plan and are directed to habilitative (e.g. attention span, motor skills) rather than explicit employment objectives.

b. Prevocational services are provided to clients who are not expected to join the general work force or participate in a transitional sheltered workshop within one year of service initiation.

c. This service is not available to clients eligible to receive services under a program funded under the Rehabilitation Act of 1973 or the IDEA.

E. When applying for the ADC module under the HCBS provider license, the provider shall indicate whether it is providing day habilitation, prevocational/employment-related services or both.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5073. Operational Requirements

A. The client/staff ratio in an ADC facility shall be one staff person per eight clients, unless additional staff coverage is needed to meet the needs of the client, as specified in the service plan.

B. Staff Training

1. ADC Staff in supervisory positions shall have annual training in supervisory and management techniques.

2. Each ADC facility shall have a training supervisor who shall receive at least 15 hours of annual vocational and/or community-based employment training.

3. Once the training supervisor receives all of the required training, he/she shall be responsible for ensuring

that direct care staff receives training on vocational and/or community-based employment training.

C. Food and Nutrition

1. If meals are prepared by the facility or contracted from an outside source, the following conditions shall be met:

a. menus shall be written in advance and shall provide for a variety of nutritional foods;

b. records of menus, as served, shall be filed and maintained for at least 30 days;

c. modified diets shall be prescribed by a physician;

d. only food and drink of safe quality shall be purchased;

e. storage, preparation, and serving techniques shall be provided to ensure nutrients are retained and spoilage is prevented;

f. food preparation areas and utensils shall be kept clean and sanitary;

g. there shall be an adequate area for eating; and

h. the facility shall designate one staff member who shall be responsible for meal preparation/serving if meals are prepared in the facility.

2. When meals are not prepared by the facility, the following conditions shall be met:

a. provisions shall be made for obtaining food for clients who do not bring their lunch; and

b. there shall be an adequate area for eating.

3. Drinking water shall be readily available. If a water fountain is not available, single-use disposable cups shall be used.

4. Dining areas shall be adequately equipped with tables, chairs, eating utensils and dishes designed to meet the functional needs of clients.

5. Adequate refrigeration of food shall be maintained.

D. General Safety Practices

1. A facility shall not maintain any firearms or chemical weapons at any time.

2. A facility shall ensure that all poisonous, toxic and flammable materials are safely stored in appropriate containers and labeled as to the contents. Such materials shall be maintained only as necessary and shall be used in such a manner as to ensure the safety of clients, staff and visitors.

3. Adequate supervision/training shall be provided where potentially harmful materials such as cleaning solvents and/or detergents are used.

4. A facility shall ensure that a first aid kit is available in the facility and in all vehicles used to transport clients.

5. Medication shall be locked in a secure storage area or cabinet.

6. Fire drills shall be performed at least once a month.

E. Physical Environment

1. The ADC building shall be constructed, equipped and maintained to ensure the safety of all individuals. The building shall be maintained in good repair and kept free from hazards such as those created by any damage or defective parts of the building.

2. The provider shall maintain all areas of the facility that are accessible to individuals, and ensure that all structures on the ground of the facility are in good repair and kept free from any reasonable foreseeable hazards to health or safety.

3. The facility shall be accessible to and functional for those cared for, the staff and the public. All necessary accommodations shall be made to meet the needs of clients. Training or supports shall be provided to help clients effectively negotiate their environments.

4. There shall be a minimum of 35 square feet of space per client. Kitchens, bathrooms and halls used as passageways, and other spaces not directly associated with program activities, shall not be considered as floor space available to clients.

5. There shall be storage space, as needed by the program, for training and vocational materials, office supplies, etc.

6. Rooms used for recipient activities shall be well ventilated and lighted.

7. There shall be separate space for storage of a client's personal belongings.

8. Chairs and tables shall be adequate in number to serve the clients.

9. Bathrooms and lavatories shall be accessible, operable and equipped with toilet paper, soap and paper towels or hand drying machines. Every bathroom shall be wheelchair accessible.

a. For existing, licensed ADCs, there shall be one bathroom per every 12 persons at the ADC facility.

b. For newly licensed, newly constructed, renovated or relocated ADCs, there shall be two bathrooms, one for male and one for female, each having a commode/toilet and lavatory for every 15 persons at the ADC facility.

c. Individuals shall be provided privacy when using bathroom facilities.

d. Every bathroom door shall be designed to permit opening of the locked door from the outside, in an emergency, and the opening device shall be readily accessible to the staff.

10. Stairways shall be kept free of obstruction and fire exit doors shall be maintained in working order. All stairways shall be equipped with handrails.

11. There shall be a telephone available and accessible to all clients.

12. The ADC shall be equipped with a functional air conditioning and heating unit(s) which maintains an ambient temperature between 65 and 80 degrees Fahrenheit throughout the ADC.

13. The building in which the ADC is located shall meet the standards of the Americans with Disabilities Act.

F. Employment of Clients

1. The provider shall meet all of the state and federal wage and hour regulations regarding employment of clients who are admitted to the agency.

a. The provider must maintain full financial records of clients' earnings if the facility pays the client.

b. The provider shall have written assurance that the conditions and compensation of work are in compliance with applicable state and federal employment regulations.

c. The provider must have a U.S. Department of Labor Sub-Minimum Wage Certificate if the provider pays sub-minimum wage.

2. Clients shall not be required to perform any kind of work involving the operation or maintenance of the facility without compensation in accordance with the U.S. Department of Labor sub-minimum standard.

3. Clients shall be directly supervised when operating any type of power driven equipment such as lawn mowers or electrical saws, unless:

a. the ID team has determined that direct supervision is not necessary;

b. equipment has safety guards or devices; and

c. adequate training is given to the recipient and the training is documented.

4. Clients shall be provided with the necessary safety apparel and safety devices to perform the job.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Subchapter H. Family Support Module

§5075. General Provisions

A. Providers applying for the Family Support module under the HCBS license shall meet the core licensing requirements as well as the module specific requirements of this Section.

B. The purpose of family support services is to:

1. keep the family of a person with a disability together by promoting unity, independence of the family in problem solving and maintenance of the family as the primary responsible caretaker;

2. determine if barriers to home placement for persons with a disability can be eliminated or relocated through financial assistance for purchases, special equipment and supplies;

3. allow a person with a disability to remain in or return to a family setting as an alternative to placement in a more restrictive setting; and

4. link families of a person with a disability to existing support services and to supplement those services where necessary (i.e. transportation to reach services when not otherwise provided).

C. Services covered by the family support module may include:

1. special equipment;
2. limited adaptive housing;
3. medical expenses and medications;
4. nutritional consultation and regime;
5. related transportation;
6. special clothing;
7. special therapies;
8. respite care;
9. dental care; and
10. family training and therapy.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5077. Operational Requirements

A. Providers shall ensure that each family receiving services is assigned a service coordinator.

B. The service coordinator shall perform the following tasks:

1. prepare a family study, based on a home visit interview with the client, in order to ascertain what appropriate family support services may be provided;

2. visit each client at least quarterly;

3. maintain documentation of all significant contacts; and

4. review and evaluate, at least every six months, the care, support and treatment each client is receiving.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Subchapter I. Personal Care Attendant Module

§5079. General Provisions

A. Providers applying for the Personal Care Attendant module under the HCBS license shall meet the core licensing requirement as well as the module specific requirements of this Section.

B. Personal care attendant services may include:

1. assistance and prompting with:

a. personal hygiene;
b. dressing;
c. bathing;
d. grooming;
e. eating;
f. toileting;
g. ambulation or transfers;
h. behavioral support;
i. other personal care needs; and
j. any medical task which can be delegated;

2. assistance and/or training in the performance of tasks related to:

a. maintaining a safe and clean home environment such as housekeeping, bed making, dusting, vacuuming and laundry;

b. cooking;
c. shopping;
d. budget management;
e. bill paying; and
f. evacuating the home in emergency situations;

3. personal support and assistance in participating in community, health and leisure activities which may include transporting and/or accompanying the participant to these activities;

4. support and assistance in developing relationships with neighbors and others in the community and in strengthening existing informal, social networks and natural supports; and

5. enabling and promoting individualized community supports targeted toward inclusion into meaningful, integrated experiences (e.g. volunteer work and community awareness) activities.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5081. Operational Requirements

A. PCA providers shall schedule personal care attendant staff in the manner and location as required by each client's ISP.

B. PCA providers shall have a plan that identifies at least one trained and qualified back-up worker for each client served.

1. It is the responsibility of the provider to ensure that a trained and qualified back-up worker is available as needed to meet the requirements of the ISP.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORY NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Subchapter J. Respite Care

§5083. General Provisions

A. Providers applying for the Respite Care module under the HCBS license shall meet the core licensing requirement as well as the applicable module specific requirements of this Section.

B. The goal of respite care is to provide temporary, intermittent relief to informal caregivers in order to help prevent unnecessary or premature institutionalization while improving the overall quality of life for both the informal caregiver and the client.

C. Respite care may be provided as an in-home or center-based service. The services may be provided in the client's home or in a licensed respite center.

D. Providers of in-home respite care services must comply with:

1. all HCBS providers core licensing requirements;
2. PCA module specific requirements; and
3. the respite care services module in-home requirements.

E. Providers of center-based respite care services must comply with:

1. all HCBS providers core licensing requirements;
2. respite care services module in-home requirements; and
3. respite care services module center-based requirements.

F. When applying for the respite care service module under the HCBS provider license, the provider shall indicate whether it is providing in-home respite care, center-based respite care or both.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5085. Operational Requirements for In-Home Respite Care

A. All in-home respite care service providers shall:

1. make available to clients, the public and HSS the day and hours that respite is to be provided;
2. make available to clients, the public and HSS a detailed description of populations served as well as services and programming; and

B. In-home respite care service providers shall have adequate administrative, support, professional and direct care staff to meet the needs of clients at all times.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5087. Operational Requirements for Center-Based Respite Care

A. All center-based respite care service providers shall meet the following daily aspects of care.

1. The daily schedule shall be developed in relation to the needs of the clients.
2. Clients shall be assisted in ADL's as needed.
   a. The provider shall ensure that the family supplies the client with his/her own clothing.
3. The provider shall make available to each client an adequate number of supervised recreational activities.

B. All center-based respite care service providers shall meet the following health aspects of care.

1. Responsibility for the health supervision of the client shall be placed with the client's personal physician.
   a. The provider shall have written agreements for obtaining diagnosis and treatment of medical and dental problems for clients who do not have a personal physician. This agreement can be with a local hospital, clinic or physician.
2. Arrangements for medical isolation shall be available. The provider shall inform the family to remove the client when necessary.
3. Medication shall be prescribed only by a licensed physician.

C. Food and Nutrition

1. Planning, preparation and serving of foods shall be in accordance with the nutritional, social, emotional and medical needs of the clients. The diet shall include a variety of food, and be attractively served. Clients shall be encouraged, but not forced, to eat all of the food served.
2. Food provided shall be of adequate quality and in sufficient quantity to provide the nutrients for proper growth and development.
3. Clients shall be provided a minimum of three meals daily, plus snacks.
4. All milk and milk products used for drinking shall be Grade A and pasteurized.
5. There shall be no more than 14 hours between the last meal or snack on one day and the first meal of the following day.

D. The provider shall request from the family that all clients over five years of age have money for personal use. Money received by a client shall be his own personal property and shall be accounted for separately from the provider's funds.

E. Privacy

1. The HCBS provider staff shall function in a manner that allows appropriate privacy for each client.
2. The space and furnishings shall be designed and planned to enable the staff to respect the clients' right to privacy and at the same time provide adequate supervision according to the ages and developmental needs of the client.
3. The provider shall not use reports or pictures, nor release (or cause to be released) research data, from which clients can be identified without written consent from the client, parents or legal guardians.

F. Contact with Family, Friends and Representatives

1. Clients in care shall be allowed to send and receive uncensored mail and conduct private telephone conversations with family members.
2. If it has been determined that the best interests of the client necessitate restrictions on communications or visits, these restrictions shall be documented in the service plan.
3. If limits on communication or visits are indicated for practical reasons, such as expense of travel or telephone calls, such limitations shall be determined with the participation of the client and family.

G. Furnishings and Equipment

1. Furnishings and equipment shall be adequate, sufficient and substantial for the needs of the age groups in care.

2. All bedrooms shall be on or above street grade level and be outside rooms. Bedrooms shall accommodate no more than four residents. Bedrooms must provide at least 60 square feet per person in multiple sleeping rooms and not less than 80 square feet in single rooms.

3. Each resident shall be provided a separate bed of proper size and height, a clean, comfortable mattress and bedding appropriate for weather and climate.

4. There shall be separate sleeping rooms for adults and for adolescents. When possible, there should be individual sleeping rooms for clients whose behavior would be upsetting to others.

5. Appropriate furniture shall be provided, such as a chest of drawers, a table or desk, an individual closet with clothes racks and shelves accessible to the residents.

6. Individual storage space reserved for the client's exclusive use shall be provided for personal possessions such as clothing and other items so that they are easily accessible to the resident during his/her stay.

H. Bath and Toilet Facilities

1. There shall be a separate toilet/bathing area for males and females beyond pre-school age. The provider shall have one toilet/bathing area for each eight clients admitted, but in no case shall have less than two toilet/bathing areas.

2. Toilets should be convenient to sleeping rooms and play rooms.

3. Toilets, bathtubs and showers shall provide for individual privacy unless specifically contraindicated for the individual, as stated in the service plan.

4. Bath/toilet area shall be accessible, operable and equipped with toilet paper, soap and paper towels or hand drying machines.

5. Every bath/toilet shall be wheelchair accessible.

6. Individuals shall be provided privacy when using a bath/toilet area.

7. Every bath/toilet area door shall be designed to permit opening of the locked door from the outside, in an emergency. The opening device shall be readily accessible to the staff.

I. There shall be a designated space for dining. Dining room tables and chairs shall be adjusted in height to suit the ages of the clients.

J. Heat and Ventilation

1. The temperature shall be maintained within a reasonable comfort range (65 to 80 degrees Fahrenheit).

2. Each habitable room shall have access to direct outside ventilation by means of windows, louvers, air conditioner, or mechanical ventilation horizontally and vertically.

K. Health and Safety

1. The facility shall comply with all applicable building codes, fire and safety laws, ordinances and regulations.

2. Secure railings shall be provided for flights of more than four steps and for all galleries more than four feet from the ground.

3. Where clients under age two are in care, gates shall be provided at the head and foot of each flight of stairs accessible to these clients.

4. Before swimming pools are made available for client use, written documentation must be received by DHH confirming that the pool meets the requirements of the Virginia Graeme Baker Pool and Spa Safety Act of 2007 or, in lieu of, written documentation confirming that the pool meets the requirements of ANSI/APSP-7 (2006 Edition) which is entitled the "American National Standard for Suction Entrapment Avoidance in Swimming Pools, Wading pools, Spas, Hot Tubs and Catch Basins."

a. An outdoor swimming pool shall be enclosed by a six foot high fence. All entrances and exits to pools shall be closed and locked when not in use. Machinery rooms shall be locked to prevent clients from entering.

b. An individual, 18 years of age or older, shall be on duty when clients are swimming in ponds, lakes or pools where a lifeguard is not on duty. The individual is to be certified in water safety by the American Red Cross.

c. There shall be written plans and procedures for water safety.

5. Storage closets or chests containing medicine or poisons shall be securely locked.

6. Garden tools, knives and other dangerous instruments shall be inaccessible to clients without supervision.

7. Electrical devices shall have appropriate safety controls.

L. Maintenance

1. Buildings and grounds shall be kept clean and in good repair.

2. Outdoor areas shall be well drained.

3. Equipment and furniture shall be safely and sturdily constructed and free of hazards to clients and staff.

4. The arrangement of furniture in living areas shall not block exit ways.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Subchapter K. Substitute Family Care Module

§5089. General Provisions

A. Providers applying for the Substitute Family Care module under the HCBS license shall meet the core licensing requirements as well as the module specific requirements of this Section. In addition to complying with the appropriate licensing regulations, SFC providers shall also establish:

1. an advisory committee comprised of persons with developmental disabilities and their families to provide guidance on the aspirations of persons with developmental disabilities who live in home and community settings.

2. a medical decision-making committee for each SFC client who is unable to give informed consent for surgical or medical treatment which shall fulfill the requirements for executing medical decision-making for those clients as required by R.S. 40.1299.53 or its successor statute.

B. Substitute family care services provide 24-hour personal care, supportive services, and supervision to adults who meet the criteria for having a developmental disability.

C. The SFC Program is designed to:

1. support individuals with developmental disabilities in a home environment in the community through an array of naturally occurring and arranged community resources similar to those enjoyed by most individuals living in the community in all stages of life;

2. expand residential options for persons with developmental disabilities;

a. This residential option also takes into account compatibility of the substitute family and the participant, including individual interests, age, health, needs for privacy, supervision and support needs;

3. provide meaningful opportunities for people to participate in activities of their choosing whereby creating a quality of life not available in other settings.

4. serve persons who require intensive services for medical, developmental or psychological challenges;

a. The SFC provider is required to provide the technical assistance, professional resources and more intensive follow-up to assure the health, safety and welfare of the client(s).

D. Substitute family care services are delivered by a principal caregiver, in the caregiver's home, under the oversight and management of a licensed SFC provider.

1. The SFC caregiver is responsible for providing the client with a supportive family atmosphere in which the availability, quality and continuity of services are appropriate to the age, capabilities, health conditions and special needs of the individual.

2. The licensed SFC provider shall not be allowed to serve as the SFC caregiver.

E. Potential clients of the SFC program shall meet the following criteria:

1. have a developmental disability as defined in R.S. 28:451.1-455.2 of the Louisiana Developmental Disability Law or its successor statute;

2. be at least 18 years of age; and

3. have an assessment and service plan pursuant to the requirements of the HCBS provider licensing rule;

a. The assessment and service plan shall assure that the individual's health, safety and welfare needs can be met in the SFC setting.

F. SFC Caregiver Qualifications

1. An SFC caregiver shall be certified by the SFC provider before any clients are served. In order to be certified, the SFC caregiver applicant shall:

a. undergo a professional home study;

b. participate in all required orientations, trainings, monitoring and corrective actions required by the SFC provider; and

c. meet all of the caregiver specific requirements of this Section.

2. The personal qualifications required for certification include:

a. Residency. The caregiver shall reside in the state of Louisiana and shall provide SFC services in the caregiver's home. The caregiver's home shall be located in the state of Louisiana and in the region in which the SFC provider is licensed.

b. Criminal Record and Background Clearance. Members of the SFC caregiver's household shall not have any felony convictions. Other persons approved to provide care or supervision of the SFC client for the SFC caregiver shall not have any felony convictions.

i. Prior to certification, the SFC caregiver, all members of the SFC caregiver applicant's household and persons approved to provide care or supervision of the SFC client on a regular or intermittent basis, shall undergo a criminal record and background check.

ii. Annually thereafter, the SFC caregiver, all members of the SFC caregiver applicant's household and persons approved to provide care or supervision of the SFC client on a regular or intermittent basis, shall have background checks.

c. Age. The SFC principal caregiver shall be at least 21 years of age. Maximum age of the SFC principal caregiver shall be relevant only as it affects his/her ability to provide for the SFC client as determined by the SFC provider through the home assessment. The record must contain proof of age.

3. The SFC caregiver may be either single or married. Evidence of marital status must be filed in the SFC provider's records and may include a copy of legal documents adequate to verify marital status.

4. The SFC caregiver is not prohibited from employment outside the home or from conducting a business in the home provided that:

a. the SFC home shall not be licensed as another healthcare provider;

b. such employment or business activities do not interfere with the care of the client;

c. such employment or business activities do not interfere with the responsibilities of the SFC caregiver to the client;

d. a pre-approved, written plan for supervision of the participant which identifies adequate supervision for the participant is in place; and

e. the plan for supervision is signed by both the SFC caregiver and the administrator or designee of the SFC provider.

G. The SFC caregiver shall not be certified as a foster care parent(s) for the Department of Social Services (DSS) while serving as a caregiver for a licensed SFC provider.

1. The SFC provider, administrator or designee shall request confirmation from DSS that the SFC caregiver applicant is not presently participating as a foster care parent and document this communication in the SFC provider's case record.

H. In addition to the discharge criteria in the core requirements, the client shall be discharged from the SFC program upon the client meeting any of the following criteria:

1. incarceration or placement under the jurisdiction of penal authorities or courts for more than 30 days;

2. lives in or changes his/her residence to another region in Louisiana or another state;

3. admission to an acute care hospital, rehabilitation hospital, intermediate care facility for persons with developmental disabilities (ICF/DD) or nursing facility with the intent to stay longer than 90 consecutive days;

4. the client and/or his legally responsible party(s) fails to cooperate in the development or continuation of the service planning process or service delivery;

5. a determination is made that the client's health and safety cannot be assured in the SFC setting; or

6. failure to participate in SFC services for 30 consecutive days for any reason other than admission to an acute care hospital, rehabilitation hospital, ICF/DD facility or nursing facility.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5090. Operational Requirements for Substitute Family Care Providers

A. Training

1. Prior to the introduction of an SFC client into a SFC home, the SFC provider shall ensure that the caregiver receives a minimum of six hours of training designed to assure the health and safety of the client, including any areas relevant to the SFC client's support needs.

a. The provider shall also conduct a formal review of the SFC client's support needs, particularly regarding medical and behavioral concerns as well as any other pertinent areas.

2. Within the first 90 days following the client's move into the home, the SFC provider shall provide and document training to the SFC caregiver(s) on:

a. the client's support plan and the provider's responsibilities to assure successful implementation of the plan;

b. emergency plans and evacuation procedures;

c. client rights and responsibilities; and

d. any other training deemed necessary to support the person's individual needs.

3. Annually, the SFC provider shall provide the following training to the SFC caregiver:

a. six hours of approved training related to the client's needs and interests including the client's specific priorities and preferences; and

b. six hours of approved training on issues of health and safety such as the identification and reporting of allegations of abuse, neglect or exploitation.

4. On an as needed basis the SFC provider shall provide the SFC caregiver with additional training as may be deemed necessary by the provider.

B. Supervision and Monitoring. The SFC provider shall provide ongoing supervision of the SFC caregiver to ensure quality of services and compliance with licensing standards. Ongoing supervision and monitoring shall consist of the following.

1. The SFC provider shall conduct in-person monthly reviews of each SFC caregiver and/or household in order to:

a. monitor the health and safety status of the client through visits;

i. more frequent visits shall be made when concerns are identified;

b. monitor the implementation of the client's service plan to ensure that it is effective in promoting accomplishment of the client's goals;

c. assure that all services included in the service plan are readily available and utilized as planned;

d. assure that the objectives of the medical, behavioral or other plans are being accomplished as demonstrated by the client's progress; and

e. resolve discrepancies or deficiencies in service provision.

2. The SFC provider shall conduct annual reviews of each SFC caregiver and/or household in order to assure the annual certification relating to health, safety and welfare issues and the client's adjustment to the SFC setting. The annual review shall include:

a. written summaries of the SFC caregiver's performance of responsibilities and care for the client(s) placed in the home;

b. written evaluation of the strengths and needs of the SFC home and the client's relationship with the SFC caregiver, including the goals and future performance;

c. review of all of the licensing standards to ensure compliance with established standards;

d. review of any concerns or the need for corrective action, if indicated; and

e. complete annual inventory of the client's possessions.

C. The SFC provider shall assure the following minimum services are provided by the SFC caregiver:

1. 24-hour care and supervision, including provisions for:

a. a flexible, meaningful daily routine;

b. household tasks;

c. food and nutrition;

d. clothing;

e. care of personal belongings;

f. hygiene; and

g. routine medical and dental care;

2. room and board;

3. routine and reasonable transportation;

4. assurance of minimum health, safety and welfare needs;

5. participation in school, work or recreational/leisure activities, as appropriate;

6. access to a 24-hour emergency response through written emergency response procedures for handling emergencies and contact numbers for appropriate staff for after hours; and

a. For purposes of these provisions, after hours shall include holidays, weekends, and hours between 4:31 p.m. and 7:59 a.m. on Monday through Friday;

7. general supervision of personal needs funds retained for the client's use if specified in the service plan.

D. Client Records

1. SFC Providers shall ensure that the SFC caregiver complies with the following standards for client records.

a. Information about clients and services of the contract agency shall be kept confidential and shared with third parties only upon the written authorization of the client or his/her authorized representative, except as otherwise specified in law.

b. The SFC caregiver shall make all client records available to the department or its designee and any other state or federal agency having authority to review such records.

c. The SFC caregiver shall ensure the privacy of the client's protected health information.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5091. Operational Requirements for Substitute Family Care Caregivers

A. The SFC caregiver(s) shall provide adequate environments that meet the needs of the clients.

B. The SFC caregiver's home shall be located within a 25 mile radius of community facilities, resources and services such as medical care, schools, recreation facilities, churches and other community facilities, unless a waiver is granted by the department.

C. The home of the SFC family shall not be used as lodging for any person(s) who is not subject to the prior approval certification process of the SFC family. The SFC family shall notify the administrator, or designee of the SFC provider, of any person(s) allowed to live in the home following the initial certification.

1. In a non-emergent situation, prior notification is required. In an emergent situation, notification shall be made within 48 hours of the additional person's move into the substitute's family home.

2. All persons residing with the SFC family, even on a non-permanent basis, shall undergo criminal record and background checks.

3. The SFC family shall accept persons requiring care or supervision only through the SFC provider with whom they have a current contract.

D. The SFC caregiver shall care for no more than two SFC clients in the caregiver's home. The SFC caregiver shall allow no more than three persons unrelated to the principal caregiver to live in the home. These three persons include the SFC clients.

E. The SFC caregiver shall have a stable income sufficient to meet routine expenses, independent of the payments for their substitute family care services, as demonstrated by a reasonable comparison between income and expenses conducted by the administrator or designee of the SFC provider.

F. The SFC caregiver must have a plan that outlines in detail the supports to be provided. This plan shall be approved and updated as required by the SFC provider. The SFC caregiver shall allow only approved persons to provide care or supervision to the SFC client.

1. An adequate support system for the supervision and care of the participant in both on-going and emergent situations shall include:

a. identification of any person(s) who will supervise the participant on a regular basis which must be prior approved by the administrator or designee of the SFC agency provider;

b. identification of any person(s) who will supervise for non-planned (emergency) assumption of supervisory duties who has not been previously identified and who shall be reported to the agency provider administrator or designee within 12 hours; and

c. established eligibility for available and appropriate community resources.

G. The SFC caregiver and/or household shall receive referrals only from the licensed SFC provider with whom it has a contract.

H. SFC Caregiver's Home Environment

1. The home of the SFC caregiver shall be safe and in good repair, comparable to other family homes in the neighborhood. The home and its exterior shall be free from materials and objects which constitute a danger to the individual(s) who reside in the home.

2. SFC homes featuring either a swimming or wading pool must ensure that safety precautions prevent unsupervised accessibility to clients.

3. The home of the SFC caregiver shall have:

a. functional air conditioning and heating units which maintain an ambient temperature between 65 and 80 degrees Fahrenheit;

b. a working telephone;

c. secure storage of drugs and poisons;

d. secure storage of alcoholic beverages;

e. pest control;

f. secure storage of fire arms and ammunition;

g. household first aid supplies to treat minor cuts or burns;

h. plumbing in proper working order and availability of a method to maintain safe water temperatures for bathing; and

i. a clean and sanitary home, free from any health and/or safety hazards.

4. The SFC home shall be free from fire hazards such as faulty electrical cords, faulty appliances and non-maintained fireplaces and chimneys, and shall have the following:

a. operating smoke alarms within 10 feet of each bedroom;

b. portable chemical fire extinguishers located in the kitchen area of the home;

c. posted emergency evacuation plans which shall be practiced at least quarterly; and

d. two unrestricted doors which can be used as exits.

5. The SFC home shall maintain environments that meet the following standards.

a. There shall be a bedroom for each client with at least 80 square feet exclusive of closets, vestibules and bathrooms and equipped with a locking door, unless contraindicated by any condition of the client.

i. The department may grant a waiver from individual bedroom and square feet requirements upon good cause shown, as long as the health, safety and welfare of the client are not at risk.

b. Each client shall have his own bed unit, including frame, which is appropriate to his/her size and is fitted with a non-toxic mattress with a water proof cover.

c. Each client shall have a private dresser or similar storage area for personal belongings that is readily accessible to the client.

d. There shall be a closet, permanent or portable, to store clothing or aids to physical functioning, if any, which is readily accessible to the client.

e. The client shall have access to a working telephone.

f. The home shall have one bathroom for every two members of the SFC household, unless waived by the department.

g. The home shall have cooking and refrigeration equipment and kitchen and or dining areas with appropriate furniture that allows the client to participate in food preparation and family meals.

h. The home shall have sufficient living or family room space, furnished comfortably and accessible to all members of the household.

i. The home shall have adequate light in each room, hallway and entry to meet the requirements of the activities that occur in those areas.

j. The home shall have window coverings to ensure privacy.

I. Automobile Insurance and Safety Requirements

1. Each SFC caregiver shall have a safe and dependable means of transportation available as needed for the client.

2. The SFC caregiver shall provide the following information to the SFC provider who is responsible for maintaining copies in its records:

a. current and valid driver's licenses of persons routinely transporting the client;

b. current auto insurance verifications demonstrating at least minimal liability insurance coverage;

c. documentation of visual reviews of current inspection stickers; and

d. documentation of a driving history report on each family member who will be transporting the client.

3. If the client(s) are authorized to operate the family vehicle, sufficient liability insurance specific to the client(s) use shall be maintained at all times.

J. Client Records

1. The SFC caregiver shall forward all client records, including progress notes and client service notes to the SFC provider on a monthly basis. The following information shall be maintained in the client records in the SFC caregiver's home:

a. client's name, sex, race and date of birth;

b. client's address and the telephone number of the client's current place of employment, school or day provider;

c. clients' Medicaid/Medicare and other insurance cards and numbers;

d. client's social security number and legal status;

e. name and telephone number of the client's preferred hospital, physician and dentist ;

f. name and telephone number of the closest living relative or emergency contact person for the client;

g. preferred religion (optional) of the client;

h. Medicaid eligibility information;

i. medical information, including, but not limited to:

i. current medications, including dosages, frequency and means of delivery;

ii. the condition for which each medication is prescribed; and

iii. allergies;

j. identification and emergency contact information on persons identified as having authority to make emergency medical decisions in the case of the individual's inability to do so independently;

k. progress notes written on at least a monthly basis summarizing services and interventions provided and progress toward service objectives; and

i. Checklists alone are not adequate documentation for progress notes;

l. a copy of the client's ISP and any vocational and behavioral plans.

2. Each SFC family shall have documentation attesting to the receipt of an adequate explanation of:

a. the client's rights and responsibilities;

b. grievance procedures;

c. critical incident reports; and

d. formal grievances filed by the client.

3. All records maintained by the SFC caregiver shall clearly identify the:

a. date the information was entered or updated in the record;

b. signature or initials of the person entering the information; and

c. documentation of the need for ongoing services.

K. The SFC caregiver shall be required to take immediate actions to protect the health, safety and welfare of clients at all times.

1. When a client has been involved in a critical incident or is in immediate jeopardy, the SFC caregiver shall seek immediate assistance from emergency medical services and local law enforcement agencies, as needed.

2. If abuse, neglect or exploitation is suspected or alleged, the SFC caregiver is required to report such abuse, neglect or exploitation in accordance with R.S.40:2009.20 or any successor statute.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Subchapter L. Supervised Independent Living Module

§5093. General Provisions

A. Providers applying for the Supervised Independent Living Module under the HCBS license shall meet the core licensing requirements as well as the module specific requirements of this Section.

B. When applying for the SIL module under the HCBS provider license, the provider shall indicate whether the provider is initially applying as an SIL or as an SIL via shared living conversion process, or both.

C. Clients receiving SIL services must be at least 18 years of age. An SIL living situation is created when an SIL client utilizes an apartment, house or other single living unit as his place of residence.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5094. Operational Requirements for the Supervised Independent Living Module

A. A provider shall ensure that the living situation is freely selected by the client and that the living situation shall be:

1. accessible and functional, considering any physical limitations or other disability of the client;

2. free from any hazard to the health or safety of the client;

3. properly equipped with accommodations for activities of daily living;

4. in compliance with applicable health, safety, sanitation and zoning codes;

5. a living situation that affords the client individual privacy;

6. arranged such that if there is more than one client in the living situation, the living environment does not conflict with the individual clients ISP;

7. equipped with a separate functional kitchen area including space for food storage and a preparation area.

8. equipped with a separate functional private bathroom. There shall be at least one bathroom for every two clients residing at the SIL. Entrance to a bathroom from one bedroom shall not be through another bedroom. Entrance to the client's bathroom shall be accessible without the client having to traverse through another client's bedroom;

9. equipped with a separate living area;

10. equipped with a separate private bedroom with a locking door, if not contraindicated by a condition of the client residing in the room.

a. There shall be at least one bedroom for each two clients living in the SIL. There shall be a window in each bedroom. Each bedroom shall contain a minimum of 80 square feet for single resident bedrooms or 120 square feet for two resident bedrooms. This square footage shall be exclusive of closets, vestibules and bathrooms.

b. There shall be no more than two clients per bedroom. Each client shall be provided his own bed. However, a married couple may share a bed;

11. equipped with hot and cold water faucets that are easily identifiable and are equipped with a method for scald control;

12. equipped with functional utilities, including:

a. water;

b. sewer; and

c. electricity;

13. equipped with functional air conditioning and heating units which maintain an ambient temperature between 65 and 80 degrees Fahrenheit throughout the SIL;

14. kept in a clean, comfortable home-like environment;

15. equipped with the following furnishings:

a. a bed unit per client which includes a frame, clean mattress and clean pillow;

b. a private dresser or similar storage area for personal belongings that is readily accessible to the resident. There shall be one dresser per client;

c. one closet, permanent or portable, to store clothing or aids to physical functioning, if any, which is readily accessible to the resident. There shall be one closet per client;

d. a minimum of two chairs per client;

e. a table for dining;

f. window treatments to ensure privacy; and

g. adequate light in each room, hallway and entry to meet the requirements of the activities that occur in those areas; and

16. equipped with a functional smoke detector and fire extinguisher.

B. An SIL shall provide any client placed in the living situation:

1. 24-hour access to a working telephone in the SIL;

2. access to transportation; and

3. access to any services in the client's approved ISP.

C. The department shall have the right to inspect the SIL and client's living situation.

D. An SIL provider shall ensure that no more than four clients are placed in an apartment, house or other single living unit utilized as a supervised independent living situation.

1. A SIL living situation shall make allowances for the needs of each client to ensure reasonable privacy which shall not conflict with the program plan of any resident of the living situation.

2. No clients shall be placed together in a living situation against their choice. The consent of each client shall be documented in the clients' record.

E. Supervision

1. For purposes of this Section, a supervisor is defined as a person, so designated by the provider agency, due to experience and expertise relating to client needs.

2. The licensed/certified professional shall meet the following requirements:

a. have one year of experience working directly with persons with mental retardation or other developmental disabilities and is one of the following:

i. a doctor of medicine or osteopathy;

ii. a registered nurse;

iii. an individual who holds at least a bachelor's degree in a health care service field such as occupational therapy, physical therapy, psychology, or social work.

3. A supervisor or a licensed/certified professional qualified in the state of Louisiana must have a minimum of three documented contacts per week with the client, with at least one contact being face-to-face in the home with the client. The other two contacts may be made by telephone.

a. No combination of SIL telephone contacts and the face-to-face contact will be accepted as having met more than one of the required contacts on the same date. Providers may make as many contacts in a day as are necessary to meet the needs of the client. However, only one of those contacts will be accepted as having met one of the three required contacts.

4. Attempted face-to-face contacts or telephone contacts are unacceptable and will not count towards meeting the requirements.

F. In addition to the core licensing requirements, the SIL provider shall:

1. provide assistance to the client in obtaining and maintaining housing;

2. allow participation in the development, administration and oversight of the client's service plan to assure its effectiveness in meeting the client's needs; and

3. assure that bill payment is completed monthly in the plan of care, if applicable.

G. An SIL provider shall assess the following in conjunction with the client or client's legal representative when selecting the location of the SIL situation for the client:

a. risks associated with the location;

b. client cost;

c. proximity to the client's family and friends;

d. access to transportation;

e. proximity to health care and related services;

f. client choice;

g. proximity to the client's place of employment; and

h. access to community services.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§5095. Supervised Independent Living Shared Living Conversion Process

A. The SIL Shared Living Conversion process is a situation in which a home and community-based shared living model, for up to six persons, may be chosen as a living option for participants in the Residential Options Waiver or any successor waiver.

B. Only an existing ICF/DD group or community home with up to 8 beds as of promulgation of the final Rule governing these provisions, may voluntarily and permanently close its home and its related licensed, Medicaid certified and enrolled ICF/DD beds to convert to new community-based waiver opportunities (slots) for up to six persons in shared living model or in combination with other ROW residential options. These shared living models will be located in the community.

1. Notwithstanding any other provision to the contrary, an SIL Shared Living Conversion model shall ensure that no more than six ROW waiver clients live in an apartment, house or other single living situation upon conversion.

C. The DHH Office for Citizens with Developmental Disabilities (OCDD) shall approve all individuals who may be admitted to live in and to receive services in an SIL Shared Living Conversion model.

D. The ICF/DD provider who wishes to convert an ICF/DD to an SIL via the Shared Living Conversion model shall be approved by OCDD and shall be licensed by HSS prior to providing services in this setting, and prior to accepting any ROW participant or applicant for residential or any other developmental disability service(s).

E. An ICF/DD provider who elects to convert to an SIL via the Shared Living Conversion model may convert to one or more conversion models, provided that the total number of SIL Shared Living Conversion slots; beds shall not exceed the number of Medicaid facility need review bed approvals of the ICF(s)/DD so converted.

1. The conversion of an ICF(s)/DD to an SIL via the Shared Living Conversion process may be granted only for the number of beds specified in the applicant's SIL Shared Living Conversion model application to OCDD.

2. At no point in the future may the provider of a converted SIL, which converted via the Shared Living Conversion process, be allowed to increase the number of SIL slots approved at the time of conversion.

3. Any remaining Medicaid facility need review bed approvals associated with an ICF/DD that is being converted cannot be sold or transferred and are automatically considered terminated.

F. An ICF/DD provider who elects to convert to an SIL via the Shared Living Conversion process shall obtain the approval of all of the residents of the home(s) (or the responsible parties for these residents) regarding the conversion of the ICF/DD prior to beginning the process of conversion.

G. Application Process

1. The ICF/DD owner or governing board must sign a conversion agreement with OCDD regarding the specific beds to be converted and submit a plan for the conversion of these beds into ROW shared living or other ROW residential waiver opportunities, along with a copy of the corresponding and current ICF/DD license(s) issued by HSS.

a. This conversion plan must be approved and signed by OCDD and the owner or signatory of the governing board prior to the submittal of a HCBS provider, SIL module licensing application to DHH-HSS.

2. A licensed and certified ICF/DD provider who elects to convert an ICF/DD to an SIL via the Shared Living Conversion process shall submit a licensing application for a HCBS provider license, SIL Module. The ICF/DD applicant seeking to convert shall submit the following information with his licensing application:

a. a letter from OCDD stating that the owner or governing board has completed the assessment and planning requirements for conversion and that the owner or governing board may begin the licensing process for an HCBS provider, SIL Module;

b. a letter of intent from the owner or authorized representative of the governing board stating:

i. that the license to operate an ICF/DD will be voluntarily surrendered upon successfully completing an initial licensing survey and becoming licensed as an SIL via the Shared Living Conversion process; and

ii. that the ICF/DD Medicaid facility need review bed approvals will be terminated upon the satisfactory review of the conversion as determined by OCDD, pursuant to its 90 day post conversion site visit; and

3. an executed copy of the conversion agreement.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Subchapter M. Supported Employment Module

§5099. General Provisions

A. The provider applying to be licensed as a supported employment provider agency shall meet all of the HCBS provider core licensing requirements with the exception of the following requirements. The supported employment provider agency is not required to:

1. return all telephone calls from clients within one hour, other than during working hours;

2. have written policies and procedures approved by the owner or governing body that addresses client funds and emergency preparedness;

3. have written policies and procedures for behavior management, provided that the provider has no client with behavior management issues;

4. ensure that the administrator shall be available to be onsite at the supported employment provider location within one hour;

5. have nursing services staff and direct care staff;

6. have a client's assessment of needs conducted by a registered nurse; and

7. maintain two weeks of progress notes at the client's home.

B. The administrator of the supported employment provider agency shall be exempt from the education qualifications listing in the core licensing requirements of this Chapter.

C. The assessment of needs shall be done prior to placement of the client on a job site. A Medicaid HCBS comprehensive assessment approved by a DHH program office for a Medicaid recipient shall not substitute for the assessment of needs. A comprehensive plan of care approved by the department for Medicaid or waiver reimbursement shall not substitute for the ISP.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and R.S. 40:2120.1.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Family Impact Statement

In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature, the impact of this proposed Rule on the family has been considered. It is anticipated that this proposed Rule will have no impact on family functioning, stability, and autonomy as described in R.S. 49:972.

Public Comments

Interested persons may submit written comments to Don Gregory, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. He is responsible for responding to inquiries regarding this proposed Rule.

Public Hearing

A public hearing on this proposed Rule is scheduled for Wednesday, July 27, 2011 at 9:30 a.m. in Room 118, Bienville Building, 628 North Fourth Street, Baton Rouge, LA. At that time all interested persons will be afforded an opportunity to submit data, views or arguments either orally or in writing. The deadline for the receipt of all written comments is 4:30 p.m. on the next business day following the public hearing.

Bruce D. Greenstein
Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES
RULE TITLE: Home and Community-Based Service Providers—Minimum Licensing Standards

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

It is anticipated that implementation of this proposed rule will have no programmatic fiscal impact to the state other than the cost of promulgation for FY 11-12. It is anticipated that $14,104 (SGF) will be expended in FY 11-12 for the state's administrative expense for promulgation of this proposed rule and the final rule.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

It is anticipated that the implementation of this proposed rule will not affect revenue collections since the licensing fees, in the same amounts, will continue to be collected.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS (Summary)

This rule, which continues the provisions of the July 1, 2011 emergency rule, proposes to revise and combine the existing licensing standards for providers of adult day care services, family support services, personal care attendant services, respite care services and supervised independent living services, and to adopt minimum licensing standards for providers of substitute family care and supported employment services in order to establish comprehensive home and community-based services (HCBS) provider licensing standards and a single HCBS license. It is anticipated that implementation of this proposed rule will not have economic cost or benefits to HCBS providers for FY 11-12, FY 12-13 and FY 13-14 since the required licensing fees have not changed.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

This rule has no known effect on competition and employment.

Don Gregory
Medicaid Director
1106#052

H. Gordon Monk
Legislative Fiscal Officer
Legislative Fiscal Office

NOTICE OF INTENT

Department of Health and Hospitals
Bureau of Health Services Financing

Nursing Facilities
Minimum Licensing Standards
Approval of Facility Plans (LAC 48:I.9707)

The Department of Health and Hospitals, Bureau of Health Services Financing proposes to amend LAC 48:I.9707 in the Medical Assistance Program as authorized by R.S. 36:254 and R.S. 40:2009.1-2116.4. This proposed Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950, et seq.

The Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing repealed the existing nursing facility licensing regulations and established new licensing regulations in order to assure that a high quality of care was provided to persons residing in nursing facilities (*Louisiana Register,* Volume 24, Number 1). The department promulgated an Emergency Rule which amended the January 20, 1998 Rule to revise the provisions governing the approval of facility plans in order to require nursing facilities to comply with the Facility Guidelines Institute's requirements for the design and construction of healthcare facilities, and to allow certain facilities to opt out of compliance under certain conditions (*Louisiana Register,* Volume 37, Number 6). This proposed Rule is being promulgated to continue the provisions of the July 1, 2011 Emergency Rule.

Title 48
PUBLIC HEALTH—GENERAL
Part I. General Administration
Subpart 3. Licensing and Certification
Chapter 97. Nursing Facilities
Subchapter A. General Provisions
§9707. Approval of Plans

A. Plans and specifications for new construction of, or to a nursing facility, and any major alterations to a nursing facility shall be submitted for approval to the Department of Health and Hospitals, or the specific entity designated by the department, to conduct reviews of plans and specifications of such new construction or major alterations.

B. The plans and specifications shall comply with all of the following:

1. these nursing facility licensing requirements;

2. the Facility Guidelines Institute (FGI) *Guidelines for Design and Construction of Healthcare Facilities*, specifically the Section(s) regarding nursing facilities;

a. Nursing facilities that submit plans prior to January 1, 2014 may opt out of complying with the specific reference in the FGI *Guidelines for Design and Construction of Healthcare Facilities* regarding the use of central air handling systems for outside air requirements for resident bedrooms; and

3. the Office of the State Fire Marshal's requirements for plan submittals and compliance with all codes required by that office.

C. The applicant must furnish one complete set of plans and specifications to the Department of Health and Hospitals or the specific entity designated by the department to conduct plan reviews, together with fees and other information as may be required.

1. …

2. No residential conversions shall be considered for a nursing facility license.

D. - E. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 40:2009.1-2116.4.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing LR 24:46 (January 1998), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Family Impact Statement

In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature, the impact of this proposed Rule on the family has been considered. It is anticipated that this proposed Rule will have no impact on family functioning, stability, and autonomy as described in R.S. 49:972.

Public Comments

Interested persons may submit written comments to Don Gregory, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. He is responsible for responding to inquiries regarding this proposed Rule.

Public Hearing

A public hearing on this proposed Rule is scheduled for Wednesday, July 27, 2011 at 9:30 a.m. in Room 118, Bienville Building, 628 North Fourth Street, Baton Rouge, LA. At that time all interested persons will be afforded an opportunity to submit data, views or arguments either orally or in writing. The deadline for the receipt of all written comments is 4:30 p.m. on the next business day following the public hearing.

Bruce D. Greenstein
Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES
RULE TITLE: Nursing Facilities
Minimum Licensing Standards
Approval of Facility Plans

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

It is anticipated that implementation of this proposed rule will have no programmatic fiscal impact to the state other than the cost of promulgation for FY 11-12. It is anticipated that $410 (SGF) will be expended in FY 11-12 for the state's administrative expense for promulgation of this proposed rule and the final rule.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

It is anticipated that the implementation of this proposed rule will not affect revenue collections since the licensing fees, in the same amounts, will continue to be collected.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS (Summary)

This rule, which continues the provisions of the July 1, 2011 emergency rule, proposes to amend the minimum licensing standards for nursing facilities to revise the provisions governing the approval of facility plans to require facilities to comply with the Facility Guidelines Institute's requirements for the design and construction of healthcare facilities, and to allow certain facilities to opt out of compliance under certain conditions (approximately 10 nursing facilities impacted). It is anticipated that implementation of this proposed rule will not have economic cost but may provide economic benefits to certain nursing facilities for FY 11-12, FY 12-13 and FY 13-14 if they have submitted plans prior to January 2014; these facilities may opt out of compliance requirements which could alleviate financial hardships associated with construction delays/prohibitive costs due to the new licensing regulations.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

This rule has no known effect on competition and employment.

Don Gregory	H. Gordon Monk
Medicaid Director	Legislative Fiscal Officer
1106#069	Legislative Fiscal Office

NOTICE OF INTENT

Department of Health and Hospitals
Bureau of Health Services Financing

Nursing Facilities—Reimbursement Methodology—Direct Care Multiplier and Fair Rental Value Component
(LAC 50:II.20005)

The Department of Health and Hospitals, Bureau of Health Services Financing proposes to amend LAC 50:II.20005 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This proposed Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq.

In anticipation of projected expenditures in the Medical Vendor Program exceeding the funding allocated in the General Appropriations Act for state fiscal year 2011, the Department of Health and Hospitals, Bureau of Health Services Financing amended the provisions governing the reimbursement methodology for nursing facilities to reduce the per diem rates paid to non-state nursing facilities (*Louisiana Register*, Volume 37, Number 4).

Act 150 of the 2010 Regular Session of the Louisiana Legislature directed the department to amend the case mix reimbursement methodology for nursing facilities to revise the provisions governing the direct care and care related costs, to change the minimum occupancy penalty, and to provide for changes in the frequency of rate rebasing and related matters. In compliance with the directives of Act 150, the department promulgated a Notice of Intent which proposed to amend the provisions governing the reimbursement methodology for nursing facilities to increase the direct care and care related price multiplier, provide for the exclusion of certain costs from the direct care and care related median cost, and to increase the fair rental value minimum occupancy percentage (*Louisiana Register,* Volume 37, Number 3). A public hearing was held April 28, 2011. As a result of the comments received, the department promulgated an Emergency Rule which revised and republished the provisions of the March 20, 2011 Notice of Intent (*Louisiana Register,* Volume 37, Number 6). This proposed Rule is being promulgated to continue the provisions of the July 1, 2011 Emergency Rule.

Title 50
PUBLIC HEALTH—MEDICAL ASSISTANCE
Part II. Nursing Facilities
Subpart 5. Reimbursement
Chapter 200. Reimbursement Methodology
§20005. Rate Determination
[Formerly LAC 50:VII.1305]

A. - D.1.c. ...

d. Effective July 1, 2011, the statewide direct care and care related price is established at 112.40 percent of the direct care and care related resident-day-weighted median cost.

1.e. - 3.b.ii. ...

iii. Effective July 1, 2011, the nursing facility's annual fair rental value shall be divided by the greater of the facility's annualized actual resident days during the cost reporting period or 85 percent of the annualized licensed capacity of the facility to determine the FRV per diem or capital component of the rate. Annualized total patient days will be adjusted to reflect any increase or decrease in the number of licensed beds as of the date of rebase by applying to the increase or decrease the greater of the facility's actual occupancy rate during the base year cost report period or 85 percent of the annualized licensed capacity of the facility.

D.3.b.iv. - G. ...

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254, R.S. 46:2742, and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Human Resources, Office of Family Security, LR 10:467 (June 1984), repealed and promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 28:1791 (August 2002), amended LR 31:1596 (July 2005), LR 32:2263 (December 2006), LR 33:2203 (October 2007), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 36:325 (February 2010), repromulgated LR 36:520 (March 2010), amended LR 36:1556 (July 2010), amended LR 36:1782 (August 2010), amended LR 36:2566 (November 2010), amended LR 37:1174 (April 2011), amended LR 37:

Implementation of the provisions of this Rule may be contingent upon the approval of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), if it is determined that submission to CMS for review and approval is required.

Family Impact Statement

In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature, the impact of this proposed Rule on the family has been considered. It is anticipated that this proposed Rule will have no impact on family functioning, stability or autonomy as described in R.S. 49:972.

Public Comments

Interested persons may submit written comments to Don Gregory, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. He is responsible for responding to inquiries regarding this proposed Rule.

Public Hearing

A public hearing on this proposed Rule is scheduled for Wednesday, July 27, 2011 at 9:30 a.m. in Room 118, Bienville Building, 628 North Fourth Street, Baton Rouge, LA. At that time all interested persons will be afforded an opportunity to submit data, views or arguments either orally or in writing. The deadline for the receipt of all written comments is 4:30 p.m. on the next business day following the public hearing.

Bruce D. Greenstein
Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES
RULE TITLE: Nursing Facilities—Reimbursement Methodology—Direct Care Multiplier and Fair Rental Value Component

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

It is anticipated that the implementation of this proposed rule will result in estimated state general fund programmatic savings of $59,582 for FY 11-12. The impact on state general funds in FY 12-13 and future fiscal years is unknown due to changes in nursing facility occupancy. To the extent that nursing facility occupancy increases, the savings reflected in FY 11-12 could decrease. It is anticipated that $410 ($205 SGF and $205 FED) will be expended in FY 11-12 for the state's administrative expense for promulgation of this proposed rule and the final rule. The numbers reflected above are based on a blended Federal Medical Assistance Percentage (FMAP) rate of 69.34 percent in FY 11-12. The enhanced rate of 69.78 percent for the last nine months of FY 12 is the federal rate for disaster-recovery FMAP adjustment states

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

It is anticipated that the implementation of this proposed rule will reduce federal revenue collections by approximately $135,008 for FY 11-12. The impact on revenue collections in FY 12-13 and future fiscal years is unknown due to changes in nursing facility occupancy. To the extent that nursing facility occupancy increases and results in an increase in expenditures,

the revenue collections reflected in FY 11-12 could increase. It is anticipated that $205 will be expended in FY 11-12 for the federal administrative expenses for promulgation of this proposed rule and the final rule. The numbers reflected above are based on a blended Federal Medical Assistance Percentage (FMAP) rate of 69.34 percent in FY 11-12. The enhanced rate of 69.78 percent for the last nine months of FY 12 is the federal rate for disaster-recovery FMAP adjustment states.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS (Summary)

This proposed rule, which continues the provisions of the July 1, 2011 emergency rule, amends the provisions governing the reimbursement methodology for nursing facilities to increase the direct care and care related price multiplier and to increase the fair rental value minimum occupancy percentage as directed by Act 150 of the 2010 Regular Session of the Louisiana Legislature (approximately 6,500,000 total Medicaid days annually). It is anticipated that implementation of this proposed rule will reduce program expenditures in the Medicaid Program by approximately $195,000 for FY 11-12. The impact on program expenditures in FY 12-13 and future fiscal years is unknown due to changes in nursing facility occupancy. To the extent that nursing facility occupancy increases, the savings reflected in FY 11-12 could decrease.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

It is anticipated that the implementation of this proposed rule will not have an effect on competition and employment.

Don Gregory Medicaid Director 1106#070	H. Gordon Monk Legislative Fiscal Officer Legislative Fiscal Office

NOTICE OF INTENT

Department of Health and Hospitals
Bureau of Health Services Financing

Rural Health Clinics—Diabetes Self-Management Training
(LAC 50:XI.Chapters 163-165 and 16701)

The Department of Health and Hospitals, Bureau of Health Services Financing proposes to amend LAC 50:XI.Chapters 163-165 and §16701 in the Medical Assistance Program as authorized by R.S. 36:254 and pursuant to Title XIX of the Social Security Act. This proposed Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:953(B)(1) et seq.

Act 11 of the 2010 Regular Session of the Louisiana Legislature authorized the Department of Health and Hospitals, through its primary and preventive care activity, to provide reimbursement to providers for rendering services that will educate and encourage Medicaid enrollees to obtain appropriate preventive and primary care in order to improve their overall health and quality of life. In keeping with the intent of Act 11, the Department of Health and Hospitals, Bureau of Health Services Financing proposes to amend the provisions governing rural health clinics to provide Medicaid reimbursement for diabetes self-management training (DSMT) services. It is anticipated that this new service will promote improved patient self-management skills which will reduce diabetes-related complications that adversely affect quality of life, and subsequently reduce Medicaid costs associated with the care of recipients diagnosed with diabetes-related illnesses. The February 20, 2011 Emergency Rule also reorganized the existing provisions governing provider participation and services in a more clear and concise manner in the Louisiana Administrative Code. The department amended the February 20, 2011 Emergency Rule to clarify the provisions governing service limits *(Louisiana Register,* Volume 37, Number 6*)*. This proposed Rule is being promulgated to continue the provisions of the February 20, 2011 and the June 20, 2011 Emergency Rules.

Title 50
PUBLIC HEALTH—MEDICAL ASSISTANCE
Part XI. Clinic Services
Subpart 15. Rural Health Clinics
Chapter 163. Services
§16301. Scope of Services

A. Medicaid reimbursement is limited to medically necessary services that are covered by the Medicaid State Plan and would be covered if furnished by a physician. The following services shall be covered:

1. services furnished by a physician, within the scope of practice of his profession under Louisiana law;
2. services furnished by a:
   a. physician assistant;
   b. nurse practitioner;
   c. nurse midwife;
   d. clinical social worker;
   e. clinical psychologist; or
   f. dentist;
3. services and supplies that are furnished as an incident to professional services furnished by all eligible professionals;
4. other ambulatory services; and
5. diabetes self-management training (DSMT) services.

B. Effective February 20, 2011, the department shall provide coverage of diabetes self-management training services rendered to Medicaid recipients diagnosed with diabetes.

1. The services shall be comprised of one hour of individual instruction and nine hours of group instruction on diabetes self-management.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1904 (October 2006), repromulgated LR 32:2267 (December 2006), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§16303. Service Limits

A. Rural health clinic visits (encounters) are limited to 12 visits per year for medically necessary services rendered to Medicaid recipients who are 21 years of age or older. Visits for Medicaid recipients who are under 21 years of age and for prenatal and postpartum care are excluded from the service limitation.

1. - 3. Repealed.

B. Recipients of DSMT services shall receive up to 10 hours of services during the first 12-month period beginning with the initial training date.

1. After the first 12-month period ends, recipients shall only be eligible for two hours of individual instruction on diabetes self-management per calendar year.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1905 (October 2006), repromulgated LR 32:2267 (December 2006), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Chapter 165. Provider Participation

§16501. Provider Enrollment

A. In order to enroll and participate in the Medicaid Program, a RHC must submit a completed provider enrollment packet.

1. - 4. Repealed.

B. The effective date of enrollment to participate in the Medicaid Program shall not be prior to the date of receipt of the completed enrollment packet.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1905 (October 2006), repromulgated LR 32:2267 (December 2006), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

§16503. Standards for Participation

A. Rural health clinics must comply with the applicable licensure, accreditation and program participation standards for all services rendered. If a RHC wishes to initiate participation, it shall be responsible for meeting all of the enrollment criteria of the program. The RHC provider shall:

1. maintain an acceptable fiscal record keeping system that readily distinguishes one type of service from another type of service that may be provided;

2. retain all records necessary to fully disclose the extent of services provided to recipients for five years from the date of service and furnish such records, and any payments claimed for providing such services, to the Medicaid Program upon request; and

3. abide by and adhere to all federal and state regulations and policy manuals.

B. Medicaid enrollment can be no sooner than Medicaid's receipt of the complete enrollment packet. A complete enrollment packet for RHCs must include a copy of the CMS provider certification letter approving rural health clinic status.

C. In order to receive Medicaid reimbursement for DSMT services, a RHC must have a DSMT program that meets the quality standards of one of the following accreditation organizations:

1. the American Diabetes Association;

2. the American Association of Diabetes Educators; or

3. the Indian Health Service.

D. All DSMT programs must adhere to the national standards for diabetes self-management education.

1. Each member of the instructional team must:

a. be a certified diabetes educator (CDE) certified by the National Certification Board for Diabetes Educators; or

b. have recent didactic and experiential preparation in education and diabetes management.

2. At a minimum, the instructional team must consist of one the following professionals who is a CDE:

a. a registered dietician;

b. a registered nurse; or

c. a pharmacist.

3. All members of the instructional team must obtain the nationally recommended annual continuing education hours for diabetes management.

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1905 (October 2006), repromulgated LR 32:2267 (December 2006), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Chapter 167. Reimbursement Methodology

§16701. Prospective Payment System

A. - B.2.NOTE. …

3. Effective for dates of service on or after February 20, 2011, the Medicaid Program shall include coverage for diabetes self-management training services rendered by qualified health care professionals in the RHC encounter rate.

a. Separate encounters for DSMT services are not permitted and the delivery of DSMT services alone does not constitute an encounter visit.

C. - D. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 36:254 and Title XIX of the Social Security Act.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary, Bureau of Health Services Financing, LR 32:1905 (October 2006), repromulgated LR 32:2267 (December 2006), amended by the Department of Health and Hospitals, Bureau of Health Services Financing, LR 37:

Implementation of the provisions of this Rule may be contingent upon the approval of the U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS), if it is determined that submission to CMS for review and approval is required.

Family Impact Statement

In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature, the impact of this proposed Rule on the family has been considered. It is anticipated that this proposed Rule may have an adverse impact on family functioning, stability and autonomy as described in R.S. 49:972 by increasing access to diabetes self-management training, which is expected to improve the health outcomes of Medicaid recipients diagnosed with diabetes.

Public Comments

Interested persons may submit written comments to Don Gregory, Bureau of Health Services Financing, P.O. Box 91030, Baton Rouge, LA 70821-9030. He is responsible for responding to inquiries regarding this proposed Rule.

Public Hearing

A public hearing on this proposed Rule is scheduled for Wednesday, July 27, 2011 at 9:30 a.m. in Room 118, Bienville Building, 628 North Fourth Street, Baton Rouge, LA. At that time all interested persons will be afforded an opportunity to submit data, views or arguments either orally or in writing. The deadline for receipt of all written comments is 4:30 p.m. on the next business day following the public hearing.

Bruce D. Greenstein
Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES
RULE TITLE: Rural Health Clinics—Diabetes Self-Management Training

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

It is anticipated that the implementation of this proposed rule will result in estimated state general fund programmatic costs of $1,815 for FY 10-11 $6,207 for FY 11-12 and $6,302 for FY 12-13. However, the cost is expected to be offset by an indeterminable amount from the anticipated savings realized from a corresponding reduction in expenditures for services related to diabetes treatment. It is anticipated that $902 ($451 SGF and $451 FED) will be expended in FY 10-11 for the state's administrative expense for promulgation of this proposed rule and the final rule. The numbers reflected above are based on a blended Federal Medical Assistance Percentage (FMAP) rate of 69.34 percent in FY 11-12. The enhanced rate of 69.78 percent for the last nine months of FY 12 is the federal rate for disaster-recovery FMAP adjustment states.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

It is anticipated that the implementation of this proposed rule will increase federal revenue collections by approximately $4,492 for FY 10-11 $14,037 for FY 11-12 and $14,550 for FY 12-13. It is anticipated that $451 will be expended in FY 10-11 for the federal administrative expenses for promulgation of this proposed rule and the final rule. The numbers reflected above are based on a blended Federal Medical Assistance Percentage (FMAP) rate of 69.34 percent in FY 11-12. The enhanced rate of 69.78 percent for the last nine months of FY 12 is the federal rate for disaster-recovery FMAP adjustment states.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS (Summary)

This proposed rule, which continues the provisions of the February 20, 2011 and June 20, 2011 emergency rules, amends the provisions governing rural health clinics (RHCs) to provide Medicaid reimbursement for diabetes self-management training (approximately 100 recipients), and reorganizes the existing provisions governing provider participation and services in a more clear and concise manner in the Louisiana Administrative Code. It is anticipated that implementation of this proposed rule will increase programmatic expenditures in the Medicaid Program by approximately $5,405 for FY 10-11, $20,244 for FY 11-12 and $20,852 for FY 12-13.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

It is anticipated that the implementation of this proposed rule will not have an effect on competition and employment.

Dan Gregory	H. Gordon Monk
Medicaid Director	Legislative Fiscal Officer
1106#071	Legislative Fiscal Office

NOTICE OF INTENT

Department of Health and Hospitals
Office of the Secretary

Community and Family Support System—Flexible Family Fund (LAC 48:I.Chapter 161)

The Department of Health and Hospitals, Office of the Secretary and the Department of Children and Family Services, Office of the Secretary has amended the entire Chapter 161 of Part I concerning the Community and Family Support System Flexible Family Fund as authorized by R.S. 28:821. This Rule is promulgated in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq.

Act 378 of the 1989 Regular Session of the Louisiana Legislature and Act 1011 of the 1991 Regular Session of the Louisiana Legislature created and continued the Community and Family Support System (R.S. 28:821 et seq.). The original Rule was promulgated to implement the Cash Subsidy Program to provide a cash stipend to families of eligible children with severe and profound disabilities to offset the cost of keeping their children at home. The Rule was amended in June 20, 2007 to recognized human services districts and human services authorities (in addition to state program offices) and return management of the program waiting lists to the administration of these regional governing agencies. This proposed amendment introduces a universal screening protocol for all children with indentified qualifying exceptionalities for severity of functional limitation and changes terminology for qualifying exceptionalities to reflect current usage. This amendment also changes the name of the program from cash subsidy to flexible family fund.

Title 48
PUBLIC HEALTH—GENERAL
Part I. General Administration
Subpart 11. Community and Family Support System
Chapter 161. Community and Family Support System—Flexible Family Fund

§16101. Introduction

A. The first and primary natural environmental for all people is the family. Children, regardless of the severity of their disability, need families and enduring relationships with adults in a nurturing home environment. As with all children, children with developmental disabilities need families and family relationships to develop to their fullest potential. Services for persons with developmental disabilities should be responsive to the needs of the individual and the individual's family, rather than fitting the person into existing programs. Family supports are those supports that enable a family to keep their child with developmental disabilities at home.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:821 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary and the Department of Social Services, Office of the Secretary, LR 18:186 (February 1992), repromulgated LR 33:1135 (June 2007), amended by the Department of Health and Hospitals, Office of the Secretary and the Department of Children and Family Services, Office of the Secretary, LR 37:

§16103. Definitions

Agency—the Department of Health and Hospitals, Office for Citizens with Developmental Disabilities (OCDD) Regional Offices and Human Services Districts (Districts) and Human Services Authorities (Authorities) providing developmental disabilities services which shall administer the flexible family fund for the exceptionalities of developmental delay for children between the ages of 3 through 8 years, autism, mental disability/severe, mental disability/profound, deaf-blind (deaf and blind), traumatic brain injury, multiple disabilities, other health impairment and orthopedic impairment, and the Office of Behavioral

Health (OBH) and districts and authorities providing behavioral health services which shall administer the flexible family fund for the exceptionality, emotional disturbance.

Appropriate Documentation for Exceptionalities Served by the OCDD and Districts and Authorities Providing Developmental Disabilities Services—the most recent report, current within a year, which demonstrates parental participation with the Louisiana State Department of Education (Department of Education) in development of specialized educational services and/or authorization of specialized educational settings for children with special needs or a report from a licensed health professional which states that a child's exceptionality conforms to standards established in the Department of Education's Bulletin 1508 for autism. Only documentation that is current within a year can be accepted into consideration for eligibility determination. Appropriate documentation includes the individualized family services plan (for EarlySteps eligibility for infants and toddlers until age 3), also referred to as the IFSP; the individualized education plan (IEP); the independent education evaluation (IEE); or an approved home study plan. A report from a licensed health professional which states that a child's exceptionality conforms to standards established in the Department of Education's Bulletin 1508 for autism may also be considered as appropriate documentation.

Appropriate Documentation for the Exceptionality served by the OBH and Districts and Authorities Providing Behavioral Health Services—the most recent report, current within a year, which demonstrates parental participation with the Louisiana State Department of Education (Department of Education) in development of specialized educational services and/or authorization of specialized educational settings for children with special needs. Appropriate documents includes the pupil appraisal evaluation or the individualized education plan (IEP), the independent education evaluation (IEE), current within a year; or, evidence of an interagency service coordination process; or, a certification from a licensed health professional that the child meets the Department of Education's criteria for emotional disturbance; or, a current treatment plan from a licensed community behavioral health center. A report from a licensed health professional which states that a child's exceptionality conforms to standards established in the Department of Education's Bulletin 1508 for emotional disturbance may also be considered as appropriate documentation.

Child—an individual under the age of 18.

Developmental Disability—defined in accordance with the Developmental Disability Law at R.S. 28:451.2(12).

Flexible Family Fund (formerly *cash subsidy program*)—a monetary payment to eligible families of children with severe or profound developmental disabilities to offset the costs of keeping their child at home.

Licensed Health Professional—a person credentialed to provide health services by a professional board established and approved by the state of Louisiana, including those boards which examine physicians, psychiatrists, psychologists, social workers, counselors, nurse practitioners, etc.

Qualifying Exceptionality—only the following exceptionalities identified through the Department of Education's evaluation process or licensed health professional may be considered for the flexible family fund from the OCDD and districts and authorities providing developmental disabilities services: autism, deaf-blindness (deaf and blind), mental disability/severe, mental disability/profound, multiple disabilities, orthopedic impairment, other health impairment, traumatic brain injury, and developmentally delayed for children between the ages of three through eight years; other exceptionalities listed through that process are not eligible for participation in the flexible family fund except that the exceptionality, emotional disturbance may be considered for the flexible family fund from the OBH and districts and authorities providing behavioral health services.

Responsible Care Giver—a child's natural or adoptive mother or father or the person who is responsible for the primary care and management of the child.

Universal Screening Protocol—a tool used to determine severity of functional limitation for all applicants for the flexible family fund for children with developmental disabilities.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:821 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary and the Department of Social Services, Office of the Secretary, LR 18:186 (February 1992), amended LR 23:862 (July 1997), LR 28:1019 (May 2002), LR 33:1135 (June 2007), amended by the Department of Health and Hospitals, Office of the Secretary and the Department of Children and Family Services, Office of the Secretary, LR 37:

§16105. Application Process

A. Applications for flexible family fund will be accepted by mail only and only in the OCDD regional office or OBH or district or authority providing developmental disability or behavioral health services in which the child resides. There is no closing date for accepting applications.

B. The responsible care giver is responsible for completing the application and submission of appropriate documentation of a qualifying exceptionality. The responsible care giver is responsible for all aspects of the application process and for maintaining eligibility of their child.

C. To be complete~~,~~ the documentation listed in §16103 of this Chapter, which identifies a qualifying exceptionality must accompany the application for the flexible family fund and the application must be signed by the responsible care giver and received by the appropriate agency through the mail.

D. Applications for the flexible family fund shall be screened at the point of initial application to determine whether the child has a qualifying exceptionality and the child is appropriately served by the agency to ensure that applications are routed to the appropriate agency.

E. Only complete applications will be placed on the waiting list for eligibility determination with a post mark date of application of the envelope containing the complete application. Applications that are not complete will be returned to the responsible care giver with instructions on how to complete the application.

F. Applications will be maintained on the waiting list by date/time order of application, only in the region in which the child lives; no child may be placed on a waiting list or

receive a flexible family fund from more than one region or agency.

G. Responsible care givers will receive confirmation of the date of receipt of the initial completed application and of their post marked date of application on the waiting list for eligibility determination, and annually thereafter.

H. A re-application can be submitted at any time a flexible family fund is terminated for any reason other than exceeding the eligible age for participation in the flexible family fund.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:821 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary and the Department of Social Services, Office of the Secretary, LR 18:186 (February 1992), amended LR 23:862 (July 1997), LR 28:1020 (May 2002), LR 33:1136 (June 2007), amended by the Department of Health and Hospitals, Office of the Secretary and the Department of Children and Family Services, Office of the Secretary, LR 37:

§16107. Determining Children Eligible for the Flexible Family Fund

A. In all cases, the exceptionality reported on the most current, current within a year, appropriate documentation referenced in §16103 of this Chapter shall be used to make a determination of eligibility for the flexible family fund.

B. Only evaluations reported through the appropriate documentation of exceptionalities identified in §16103 of this Chapter will be accepted for consideration for exceptionalities served by the OCDD, OBH, or districts or authorities providing developmental disabilities services or behavioral health services.

C. Children must be involved in an educational setting approved by the Department of Education; documentation of such approval must be received on an annual basis.

D. All children must meet the criteria for developmental disability and severity of exceptionality, as determined by the universal screening protocol, to be eligible to participate in the flexible family fund through the OCDD or district or authority providing developmental disabilities services.

E. If a child is classified with an exceptionality of emotional disturbance or presents other appropriate documentation that identifies an emotional disturbance, the child shall be screened by the OBH or district or authority providing behavioral health services to determine whether they meet the severity criteria specific to that exceptionality to be eligible to receive the flexible family fund.

F. Children who are adopted are eligible to participate in the flexible family fund, including families who are receiving a specialized adoption subsidy; families who have more than one child who is eligible to participate in the flexible family fund will be eligible for the flexible family fund amount for each qualifying child.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:821 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary and the Department of Social Services, Office of the Secretary, LR 18:186 (February 1992), amended LR 23:863 (July 1997), LR 28:1020 (May 2002), LR 33:1136 (June 2007), amended by the Department of Health and Hospitals, Office of the Secretary and the Department of Children and Family Services, Office of the Secretary, LR 37:

§16109. Children Ineligible for the Flexible Family Fund

A. These children cannot participate in the flexible family fund:

1. children living in subsidized out-of-home settings such as state-funded foster care;

2. children living and/or attending schools outside the state of Louisiana; and

3. children in residence at the Louisiana School for the Deaf and the Louisiana School for the Visually Impaired.

B. Any removal of the flexible family fund recipient from the home of the responsible care giver that exceeds 30 days may be considered an out-of-home placement, except that acute care hospitalization does not disqualify a child, and psychiatric hospitalizations of up to 90 days are not automatically considered out-of-home placements. With appropriate documentation, the responsible agency shall make an individual assessment of the continuation of the flexible family fund in light of family situation and circumstances.

C. It will be the responsibility of the responsible care giver to notify the agency when a child is removed from the home; failure to notify the responsible agency of such removal shall be potential grounds for termination of the flexible family fund.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:821 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary and the Department of Social Services, Office of the Secretary, LR 18:187 (February 1992), amended LR 23:863 (July 1997), LR 28:1021 (May 2002), LR 33:1136 (June 2007), amended by the Department of Health and Hospitals, Office of the Secretary and the Department of Children and Family Services, Office of the Secretary, LR 37:

§16111. Eligibility Determination

A. The OCDD regional offices and the OBH or districts or authorities providing developmental disabilities or behavioral health services shall be responsible for determination of eligibility of all applicants for the flexible family fund for which they have responsibility.

B. An initial (face to face) determination for eligibility for the flexible family fund will be made at the time that a flexible family fund opportunity becomes available at a site agreeable to both the agency and the responsible care giver; subsequent (annual) re-determinations of eligibility shall be made in a manner suitable to both the agency and the responsible care giver.

C. At any time a responsible care giver cannot provide adequate and appropriate documentation of a qualifying exceptionality pursuant to §16103 of this Chapter, the responsible care giver may request the local school agency or licensed health provider to re-evaluate the child's exceptionality.

1. If the request for re-evaluation occurs at the initial determination of eligibility, the eligibility determination process will be held open for the period of re-evaluation, plus 10 working days. If the child can then be determined to be eligible, the flexible family fund will begin in the month that the next opportunity becomes available.

2. If the request for re-evaluation occurs at the annual determination of eligibility, the flexible family fund will be discontinued until the re-evaluation becomes available, plus 10 working days. If the child can then be determined to be eligible, the flexible family fund will resume in the month when the determination is made.

D. The OCDD regional offices and the OBH and districts and authorities providing developmental disabilities or

behavioral health services shall be responsible to maintain a waiting list of all flexible family fund applicants to the agency according to their post marked date of application. Flexible family fund opportunities will be offered to applicants by date/time order of application (first come, first serve) within the agency's regional responsibility.

E. There shall be no financial criteria for eligibility for the flexible family fund.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:821 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary and the Department of Social Services, Office of the Secretary, LR 18:187 (February 1992), amended LR 23:863 (July 1997), LR 28:1021 (May 2002), LR 33:1137 (June 2007), amended by the Department of Health and Hospitals, Office of the Secretary and the Department of Children and Family Services, Office of the Secretary, LR 37:

§16113. Payment Guidelines

A. The amount of the flexible family fund shall be $258 monthly to families of eligible children with severe and profound disabilities to off-set the cost of keeping their child at home; families will not be required to document how the subsidy is used.

B. The termination date for a child attaining age 18 years shall be the last day of the birthday month.

C. If for any reason a recipient receives excess payment, repayment of that amount will be requested. Failure to cooperate with repayment will be referred to DHH for recoupment.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:821 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary and the Department of Social Services, Office of the Secretary, LR 18:188 (February 1992), amended LR 23:864 (July 1997), LR 28:1021 (May 2002), LR 33:1137 (June 2007), amended by the Department of Health and Hospitals, Office of the Secretary and the Department of Children and Family Services, Office of the Secretary, LR 37:

§16115. Terminations

A. Reasons for termination may include the following:

1. child moves out of state;
2. family requests termination of the flexible family fund payment;
3. child is placed into a subsidized living setting or resides in a school away from the home or in another state;
4. death of the child;
5. fraud;
6. termination or limitation of funding of the program;
7. failure to comply with the provisions of the individual agreement or the flexible family fund including the requirement to maintain quarterly contact with the agency administering the flexible family fund;
8. child's exceptionality or degree of severity no longer meets eligibility criteria; child attains age 18 years; and
9. responsible care giver fails to maintain the child in an approved educational program.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:821 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary and the Department of Social Services, Office of the Secretary, LR 18:188 (February 1992), amended LR 23:864 (July 1997), LR 28:1022 (May 2002), LR 33:1137 (June 2007), amended by the Department of Health and Hospitals, Office of the Secretary and the Department of Children and Family Services, Office of the Secretary, LR 37:

§16117. Ongoing Monitoring

A. The responsible care giver is responsible to maintain contact with the agency administering the flexible family fund at least every 90 days to verify that the child is in the home and the conditions of the individual agreement and flexible family fund are being met.

B. Such quarterly contact shall be accepted by mails, e-mail, fax, face-to-face meetings and telephone provided the responsible care giver attests that the conditions of eligibility continue to be in effect; failure to report significant changes in the child status which may result in disqualification to participate in the flexible family fund shall be subject to termination of the subsidy.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:821 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary and the Department of Social Services, Office of the Secretary, LR 18:188 (February 1992), amended LR 23:865 (July 1997), LR 28:1022 (May 2002), LR 33:1137 (June 2007), amended by the Department of Health and Hospitals, Office of the Secretary and the Department of Children and Family Services, Office of the Secretary, LR 37:

§16119. Appeals

A. All persons receiving an eligibility determination shall have access to the Department of Health and Hospital's appeal process and shall be informed of their right of appeal and the process to make an appeal at the point of initial eligibility determination and at termination of a flexible family fund for any reason other than exceeding the eligible age for participation in the program.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:821 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary and the Department of Social Services, Office of the Secretary, LR 18:188 (February 1992), amended LR 23:865 (July 1997), LR 28:1022 (May 2002), LR 33:1137 (June 2007), amended by the Department of Health and Hospitals, Office of the Secretary and the Department of Children and Family Services, Office of the Secretary, LR 37:

§16121. Program Evaluation

Repealed.

AUTHORITY NOTE: Promulgated in accordance with R.S. 28:821 et seq.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of the Secretary and the Department of Social Services, Office of the Secretary, LR 18:188 (February 1992), amended LR 23:865 (July 1997), LR 28:1022 (May 2002), LR 33:1138 (June 2007), repealed by the Department of Health and Hospitals, Office of the Secretary and the Department of Children and Family Services, Office of the Secretary, LR 37:

Family Impact Statement

In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature, the impact of this proposed Rule on the family has been considered. It is anticipated that the implementation of this proposed Rule will have a positive effect on the family functioning, stability and autonomy as described in R.S. 49:972, as it will change the focus of eligibility determination from categorical exceptionalities exclusively to testing for severity of functional limitations so that the Flexible Family Fund more accurately targets the intended recipients–children with severe and profound disabilities.

Public Comments

Interested persons may submit written comments to Julia Kenny, Office for Citizens with Developmental Disabilities, P.O. Box 3117, Baton Rouge, LA 70821-3117. She is responsible for responding to inquiries regarding this proposed Rule.

Public Hearing

A public hearing on this proposed Rule is scheduled for Wednesday, July 27, 2011 at 11 a.m. in Room 118, Bienville Building, 628 North Fourth Street, Baton Rouge, LA. At that time all interested persons will be afforded an opportunity to submit data, views or arguments either orally or in writing. The deadline for receipt of all written comments is 4:30 p.m. on the next business day following the public hearing.

Bruce D. Greenstein
Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES
RULE TITLE: Community and Family Support System—Flexible Family Fund

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

This rulemaking proposes an amendment of the Rule establishing a cash subsidy program for eligible children with severe and profound developmental disabilities (LAC 48:I.Chapter 161). The proposed amendment introduces a universal screening protocol for all children with indentified qualifying exceptionalities for severity of functional limitation and changes terminology for qualifying exceptionalities to reflect current usage. The proposed amendment also changes the name of the program to Flexible Family Fund.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

The implementation of this proposed rule will not affect revenue collections for state or local governmental units.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS (Summary)

This rule will have a positive impact on families by changing the focus of eligibility determination from categorical exceptionalities to severity of functional limitations so that Flexible Family Fund (formerly the cash subsidy program) more accurately targets the intended recipients – children with severe and profound disabilities. Some families with children that have severe and profound developmental disabilities that are not receiving Flexible Family Fund payments will now be eligible to receive funds from the Flexible Family Fund. However, some families with children that have moderate developmental disabilities and current receive Flexible Family Fund payments will no longer be eligible based on the universal screening protocol. The department anticipates the net impact of new families qualifying and current families becoming ineligible is zero.

There are no costs for directly affected persons or non-governmental groups associated with this rule.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

This rule has no known impact on competition and employment.

Julia Kenny
Assistant Secretary
1106#045

H. Gordon Monk
Legislative Fiscal Officer
Legislative Fiscal Office

NOTICE OF INTENT

Department of Health and Hospitals
Office of Public Health

Milk Code
(LAC 51:VII; VIII; XXI.105; XXII.1115, 4525, and 4527)

Under the authority of R.S. 40:4, 40:5, and 40:922, and in accordance with R.S. 49:950 et seq., the Administrative Procedure Act, notice is hereby given that the state health officer, acting through the Department of Health and Hospitals, Office of Public Health (DHH-OPH), intends to repeal Part VIII (Frozen Desserts) of the Louisiana State Sanitary Code (LAC 51) in its entirety and incorporate frozen dessert regulations under Part VII (currently titled Milk, Milk Products, and Manufactured Milk Products). The existing regulations in both Part VII and Part VIII are also being amended to update the regulations. These updated regulations are proposed to all be housed in Part VII and it is planned to be titled Dairy Products Regulations. Upon promulgation as a final rule, Part VII will then incorporate all milk, milk products, manufactured milk products, frozen desserts, dairy products, and manufacturing/processing regulations under this one Part.

Additionally, amendments are proposed to Section 105 of Part XXI (Day Care Centers and Residential Facilities) as well as to Section 1115 of Part XXIII (Retail Food Establishments) and enacting sections 4525 and 4527 of Part XXIII so that the requirements of these particular Sections (concerning how dairy products are used/handled) under these other Parts of the Louisiana State Sanitary Code (Title 51) will comport with the requirements of the proposed Part VII (Dairy Products Regulations).

Title 51
PUBLIC HEALTH—SANITARY CODE
Part VII. Dairy Products Regulations
Chapter 1. Milk and Dairy Products
§101. Definitions

A. Unless otherwise specifically provided herein, the following words and terms used in this part of the sanitary code, and all other parts which are adopted or may be adopted, are defined for the purposes thereof as follows:

3-A Standards—standards for dairy equipment and accepted practices promulgated jointly by the Sanitary Standards Subcommittee of the Dairy Industry Committee, the Committee on Sanitary Procedure of the International Subcommittee of the International Association for Food Protection and the Milk Safety Branch, the U. S. Food and Drug Administration (FDA), Public Health Service (PHS), Center for Food Safety and Applied Nutrition, Department of Health and Human Services. Equipment manufactured in conformity with the 3-A Standards complies with the sanitary design and construction standards of this Part. Copies may be obtained from 3-A Sanitary Standards Incorporated, 6888 Elm Street Suite 2D, McLean, Virginia 22101; (Internet URL address: "http://www.3-A.org/").

Abnormal Milk—any milk or milk product shall be deemed to be abnormal if:

a. it is visibly changed in color, odor and/or texture from that of normal color, odor and/or texture;

b. prior to milking of the animal, it is known to be unsuitable for human consumption (such as milk containing colostrum); or,

c. it is unfit for human consumption following treatment of the animal with veterinary products (*i.e.*, antibiotics and other drugs which have withhold requirements) or following treatment or consumption of medicines or insecticides or other toxic compounds not approved for use on dairy animals by the FDA, Environmental Protection Agency (EPA) or the state health officer.

Acidified Milk and Acidified Milk Products, Acidified Filled Milk and Acidified Filled Milk Products, Acidified Anomalous Milk and Acidified Anomalous Milk Products—a milk product obtained by souring milk or milk products, filled milk or filled milk products or anomalous milk or anomalous milk products after pasteurization, ultra-pasteurization or aseptic processing with acetic acid, adipic acid, citric acid, fumaric acid, glucono-delta-lactone, hydrochloric acid, lactic acid, malic acid, phosphoric acid, succinic acid, tartaric acid or other substances, with or without the addition of characterizing microorganisms. Nutritive carbohydrate sweeteners or other sweeteners approved for use by the FDA, flavoring ingredients, stabilizers or salt may be added. All ingredients shall have been declared to be safe and suitable by the FDA. The acidified products shall contain a titratable acidity of not less than 0.5 percent calculated as lactic acid.

Adulterated Milk, Milk Products, or Dairy Products—any milk, milk products, or dairy products shall be deemed to be adulterated:

a. if it is defined in these regulations and fails to conform to its definition or if it otherwise fails to conform to its standard of identity;

b. if it contains any unwholesome substance; or,

c. if [other than in anomalous (substitute) milk and anomalous (substitute) milk products, filled milk and filled milk products, and imitation milk or imitation milk products] any substance has been substituted wholly, or in part, for any substance naturally inherent in the milk, milk product, or dairy product.

Aged Cheese—see ripened or aged cheese.

Air Gap—the unobstructed vertical distance through the free atmosphere of at least twice the diameter of the largest incoming water, dairy product, Clean-In-Place (CIP) solution or other liquid supply pipe, faucet or valve to the flood level rim of the receiving vessel or receptacle, to prevent back siphonage of solutions in the receiving vessel or receptacle. The distance of the air gap is to be measured from the bottom of the inlet supply pipe, faucet or valve to the top of the effective overflow, i.e., flood level rim of the receiving vessel. In no case may the effective air gap be less than one inch (2.54 cm.). Tanks or vats or any other receiving vessel with water inlets below the flood level rim shall comply with the American Society of Mechanical Engineers (ASME) standard A112.1.2 (1991).

Anomalous (Substitute) Milk and Anomalous (Substitute) Milk Products—food that is not in conformity with the definitions and standards of identity contained in this Part or Title 21, Code of Federal Regulations (21 CFR) Part 131 (Milk and Cream), 21 CFR 133.128 (Cottage Cheese) and 21 CFR 133.129 (Dry Curd Cottage Cheese), but is made in semblance of, and resembles a standardized milk or milk product [milk and milk products that are in conformity with the definitions and standards of identity contained in 21 CFR Part 131 (Milk and Cream), 21 CFR 133.128 (Cottage Cheese) and 21 CFR 133.129 (Dry Curd Cottage Cheese)] in physical characteristics, sensory properties, manner in which it is manufactured or processed, functional attributes, propensity to support the growth of pathogenic microorganisms of human significance and being of such nature that it is not nutritionally inferior to, and may be used interchangeably with, the milk or milk product it resembles. These products are usually packed in containers similar to those in which Grade A milk and milk products are packaged, such as paper cartons, plastic bottles or jugs, pouches, plastic cups, tubs, etc. Anomalous (substitute) milk or anomalous (substitute) milk products are manufactured or processed in whole or in part from milk or milk products. The state health officer may, utilizing the aforesaid criteria, specify that a food is an anomalous (substitute) milk or milk product. Foods that have been retort processed after packaging or which have been dried shall not be included in this definition. Anomalous (substitute) milk and anomalous (substitute) milk products shall conform with the requirements contained in 21 CFR §101.13 (Nutrient content claims-general principles). Anomalous (substitute) milk and anomalous (substitute) milk products shall be labeled with a descriptive name which shall be suggestive enough to reveal the basic composition of the product and alleviate any questions regarding the product's identity (some names commonly used are "dairy blend", "dairy beverage", "shakes", "cultured dairy blends", etc).

a. These products may be reduced fat, lowfat, non fat or flavored. All dairy ingredients used in these products (milk, lower fat milks, condensed, evaporated or concentrated milks, dry milks, whey, protein concentrate, milk protein concentrate, filtered milk, etc.) shall be Grade A. The descriptive name (term) shall not selectively exaggerate the presence of one or more ingredients over all other ingredients present in the product as to be misleading or deceptive. Labels for anomalous (substitute) milk or milk products shall be approved by the state health officer prior to the product being offered for sale in the state. In cases in which there is a difference in performance characteristics that materially limit the use of the product, the label shall include a disclaimer, adjacent to the most prominent claim, informing the consumer of such difference (e.g., "not recommended for melting"). Anomalous (substitute) milk and anomalous (substitute) milk products shall conform to the Grade A bacteriological standards/specifications contained in this Part. Plants that manufacture or process anomalous (substitute) milk or anomalous (substitute) milk products for sale in the state shall conform with the requirements for Grade A dairy plants contained in this Part.

Anomalous (Substitute) Dairy Products—any food that is not in conformity with the standards of identity contained in this Part, 21CFR Part 131, 21 CFR Part 133, 21 CFR Part 135, 21 United States Code (USC) Part 321a, but is made in semblance of and resembles a dairy product that is in conformity with the aforesaid standards of identity in physical characteristics, sensory properties, manner in which it is manufactured or processed, functional attributes, propensity to support the growth of pathogenic

microorganisms of human significance and being of such nature that it is not nutritionally inferior to, and may be used interchangeably with, the dairy product it resembles. Anomalous (substitute) dairy products are manufactured in whole or in part from butter, cheese (whether natural or processed), milk, lower fat milks, nonfat (fat free, skim) milk, cream, whey, buttermilk (whether dry, evaporated, concentrated, stabilized or frozen) and any other food which the state health officer may, utilizing the above criteria, specify that a food is anomalous (substitute) dairy product. Anomalous (substitute) dairy products shall conform with the bacteriological standards/specifications contained in this part, determined by the state health officer to be applicable to such products. Anomalous (substitute) dairy products that have been retort processed after packaging or which have been concentrated, condensed and dried shall be included in this definition. Plants that manufacture or process anomalous (substitute) dairy products shall conform with the requirements for dairy plants contained in this Part, determined by the state health officer to be applicable to such plants.

Approved by the FDA or With the Concurrence of the FDA—the equipment, processes, policies, decisions or any other items referenced are consistent with published requirements, policies, standards and recommendations contained in publications in the Pasteurized Milk Ordinance (PMO), Procedures Governing the State-Public Health Service/Food and Drug Administration Program of the National Conference on Interstate Milk Shipments, Methods of Making Sanitation Ratings of Milk Shippers, Memoranda, etc., acceptable to the FDA Milk Safety Branch (HFS-626)(FDA/CFSAN/OC/DCP/MST) or concurrence has been obtained by the state health officer from the Milk Safety Branch/Team.

Aseptic Processing—the filling of a commercially sterilized, cooled dairy product into presterilized containers, followed by aseptic hermetical sealing with presterilized closure in an atmosphere free of microorganisms in such a manner that conforms with the requirements of 21 Code of Federal Regulations (CFR) 113 and the provisions of *§ 7, Item 16p* of the PMO. The product must maintain commercial sterility under normal non-refrigerated conditions.

Audit—an evaluation made by the state health officer of a dairy facility, the operations conducted therein, the facility's Hazard Analysis Critical Control Points (HACCP) plan and records documenting the implementation of the HACCP system, to determine whether or not all food safety hazards, reasonably likely to occur in each product produced or processed by the facility are being effectively controlled on a continual basis and to determine whether or not the plant is in compliance with the requirements contained in this Part. Personnel conducting such audits shall have been trained in accordance with the requirements for such regulatory auditors contained in the *PMO,* Appendix K, § IV (3).

Automatic Milking Installation (AMI)—an automated milking system, used to milk cows and other hooved mammals, that conforms with the requirements contained in Appendix Q of the PMO.

Bacterial Plate Count, Direct Microscopic Count, Coliform Determinations, Mastitis Tests—the results of laboratory analysis of milk or dairy products samples taken upon separate days, irrespective of the date of grading or regrading. Laboratory tests shall conform to the procedures in the *"Standard Methods for the Examination of Dairy Products*" (17th Edition, 2004, as amended) American Public Health Association.

Bacteriological Analytical Manual (BAM)—the bacteriological analytical manual found on the FDA/CFSAN (FDA/Center for Food Safety and Applied Nutrition) internet site and is designated the BAM online; (Internet URL address: http://www.cfsan.fda.gov /~ebam/bam-mm.html#updates).

Boiled Custard—see *Egg Nog*.

Blended Dry Dairy Products and Dry Blended Dairy Products—products in which the predominant ingredient is a dry dairy product and results from the blending of dry dairy products or the blending of dry dairy products with other safe and suitable dry non-milk derived ingredients approved by the state health officer. These foods may be blended before or after drying.

Broke and Trim—paper and paperboard that have been discarded anywhere in the process of manufacture, such as on paper-making machines in the form of trim. This may also include unprinted trim from the converting process, provided the trim has been handled, treated and transported in a clean, sanitary manner.

BTU—interstate milk shippers bulk tank unit identification number (for groups of dairy farms that pool part or all of their milk produced for sale to a dairy plant).

Bulk Milk Tank Truck Operator/Sampler—a person who collects official samples of raw milk and may transport raw milk from a farm to a milk plant, receiving station or transfer station and has in his/her possession a permit to sample such products issued by a state regulatory agency.

Bulk Milk Pickup Tanker—a milk tank truck and its appurtenances used by a bulk milk tank truck operator/sampler to transport bulk raw milk for pasteurization from dairy farms to a milk plant, receiving station or transfer station.

Butter—the dairy product resulting from the churning of the pasteurized, ultra-pasteurized or aseptically processed milk fat of milk or cream, or both, with or without common salt, with or without additional coloring matter, and containing not less than 80 percent, by weight of milk fat for all tolerances having been allowed. Butter shall be manufactured only in dairy plants that conform to each of the requirements for butter plants contained in Chapter 23 of this Part.

Buttermilk—the fluid dairy product resulting from the manufacture of butter from milk, cream or from the souring, or treatment by a lactic acid or other culture approved by the state health officer, of pasteurized, ultra-pasteurized or aseptically processed milk or lower fat milks. It shall contain not less than 8.25 percent of milk solids-non-fat. It may contain concentrated milk or lower fat milks, dry milk, whey, lactose, lactalbumins, lactoglobulins or modified whey.

Butter Plants—dairy plants that manufacture, process or package butter or butter related products.

Butter Products (*Butter Related Products*)—dairy products that contain butter as the predominant ingredient. They may contain other safe and suitable ingredients

Generally Recognized As Safe (GRAS) by the FDA and the state health officer. The products may contain less than 80 percent by weight of milk fat and may be whipped or otherwise modified in texture. These products shall conform to the bacteriological requirements for butter contained in this Part and shall be manufactured in a dairy plant that conforms to each requirement for butter plants contained in Chapter 23 of this Part.

CFU—colony-forming units.

Certified by the FDA—the person certified has successfully completed the certification process administered by PHS/FDA and possesses a current, valid, certificate of certification issued by the PHS/FDA.

Cheese—the product resulting from the drained curd (coagulated mass) obtained by the coagulation of milk, lower fat milks (whether concentrated, condensed or reconstituted) which may be enriched with milk fat or other derived ingredients GRAS by the FDA. The coagulation may be accomplished by:

a. inoculating with lactic acid and producing microorganisms, with or without rennet and with or without other safe and suitable coagulating enzymes GRAS by the FDA and the state health officer;

b. rennet or other coagulating enzymes that are GRAS; and

c. the addition of lactic acid, citric acid, phosphoric acid, hydrochloric acid, D-glucono-delta-lactone or other coagulating substances that are GRAS. The curd may be modified by cutting, warming, stirring, pressing, draining, molding, ripening, fermenting, blending, seasoning with ingredients that are GRAS, colored with colorings that are GRAS. Functional ingredients that are GRAS may be used. The manner in which cheese is processed, the milk or dairy product from which it is processed, the specific lactic acid producing and in some cases gas forming microorganisms, coagulating enzymes, functional and optional ingredients vary according the type or variety of cheese or related cheese product. There are numerous types and varieties of cheese, including American Cheese, Asiago Cheese, Blue Cheese, Brick Cheese, Camembert Cheese, Cheddar Cheese, Colby Cheese, Cream Cheese, Edam Cheese, Feta Cheese, Gouda Cheese, Limburger Cheese, Mozzarella Cheese, Muenster Cheese, Neufchatel Cheese, Parmesan Cheese, Process Cheese, Provolone Cheese, Ricotta Cheese, Romano Cheese, Roquefort Cheese, Swiss Cheese and many other types and varieties. Each type and variety of cheese shall conform with the standard of identity for such cheese contained in this Part or the *PMO, 21 CFR or 7 CFR*. These regulations shall apply to all cheese made from the milk of any hooved mammal, provided that where the milk or part of the milk used in the manufacture of cheese is the milk of hooved mammals other than cows, the cheese shall be so labeled.

Cheese Manufacturing Plants—dairy plants that manufacture, process, cut, slice or package cheese and cheese related products.

Cheese Products, Cheese Foods (Cheese Related Products)—foods that contain cheese as the predominant ingredient. They may contain other safe and suitable ingredients GRAS by the FDA and the state health officer. These products may be modified in texture, taste and color. These products shall conform to the bacteriological requirements for cheese contained in this Part and shall be manufactured in a dairy plant that conforms to the requirements for cheese manufacturing plants contained in Chapter 25 of this Part.

Clean—surfaces that have had the effective and thorough removal of product and contaminants.

Cleaned-In-Place (CIP)—the procedure by which sanitary pipelines or other pieces of dairy equipment are mechanically cleaned-in-place by circulation of cleaning and sanitizing solutions.

Cleaned-Out-of Place (COP)—the procedure by which pieces of dairy equipment are placed in a vat equipped with a system that cleans by circulation of cleaning and sanitizing solutions.

Cleaning and Sanitizing Tag (Wash Tag)—tag affixed to the outlet valve or in the near vicinity of the outlet valve of the milk tank truck, which verifies proper cleaning and sanitizing.

Closure—a cap, lid, seal, tube, valve, lidding material or other device in or on a container used for the purpose of enclosing or dispensing the contents.

Coatings—any layer or covering which is applied to the product contact surface.

Code of Federal Regulations (CFR)— the April 1, 2010 edition, as amended, of Title 21 (21 CFR = Food and Drugs) and the January 1, 2010 edition, as amended, of Title 7 (7 CFR = Agriculture) of the document, so titled and published by the United States Office of the Federal Register, National Archives and Records Administration.

Component Part—any item that by itself, does not perform any function, but when assembled with one or more component parts or closures, becomes a part of the single service container or closure. These may include, but are not limited to, blanks, sheeting, filling valve parts, tubes, dispensing devices and sampling containers. All material used for fabrication of a component part must meet the requirements of the *Federal Food, Drug and Cosmetic Act,* as amended.

Concentrated or Condensed Milk—a fluid product, unsterilized and unsweetened, resulting from the removal of a considerable portion of the water from the milk, which when combined with potable water in accordance with instructions printed on the container label, results in a product conforming with the milk fat and milk solids not fat levels of milk as defined in this Part.

Cooling Pond—a man-made structure that conforms with the requirements of this Part and the PMO designed for the specific purpose of cooling cows.

*Cottage Cheese**—the soft uncured cheese prepared from the curd obtained by adding harmless lactic acid-producing bacteria, with or without rennet, to pasteurized nonfat (fat free, skim) milk. It contains not more than 80 percent moisture content to not less than 0.5 percent or not more than 2 percent. All cottage cheese sold in the State shall be Grade A.

Cream—liquid milk product high in fat separated from milk which may have been adjusted by adding thereto: milk, concentrated milk and lower fat milks or dry milk or lower fat dry milks and may be modified by whipping, acidifying or culturing. Cream contains not less than 18 percent milk fat.

Creamed Cottage Cheese—the soft uncured cheese prepared by mixing cottage cheese with pasteurized cream or a pasteurized mixture of cream with milk or nonfat (fat free, skim) milk, which contains not less than 4 percent of milk fat by weight, nor more than 80 percent of moisture.

Creole Cream Cheese or Creole Cheese—the soft uncured cheese prepared by culturing pasteurized, ultra-pasteurized or aseptically processed milk, nonfat milk or lowfat milk with harmless lactic acid bacteria and coagulating milk with this culture or rennet or other safe and suitable milk clotting enzymes. The curd is drained in molds prior to packaging. Prior to packaging a creaming mixture may or may not be added to the curd. All dairy ingredients used in Creole Cream Cheese and Creole Cheese shall be Grade A. Dairy plants in which these cheeses are manufactured shall conform with the requirements for Grade A milk and milk products contained in this Part.

Cultured Milk and Cultured Milk Products, Cultured Anomalous Milk and Cultured Anomalous Milk Products and Cultured Filled Milk and Cultured Filled Milk Products—foods produced by culturing pasteurized, ultra-pasteurized or aseptically processed milk or milk products, anomalous milk or anomalous milk products or filled milk or filled milk products with characterizing microorganisms. Sweeteners, flavor and aroma producing ingredients, salt, citric acid or sodium citrate may be added. All ingredients shall have been declared safe and suitable for use in the products by FDA and the state health officer. The cultured products shall contain a titratable acidity of not less than 0.5 percent by weight calculated as lactic acid. The name of these cultured products shall be accompanied by a declaration indicating the presence of any characterizing flavoring and by a declaration such as a traditional name of the microorganisms used thereby indicating the presence of the microbial organisms used as ingredients, e.g., "Kefir Cultured Milk", "Kefir Milk with Vegetable Fat", "Kefir Cultured Dairy Beverage", "Acidophilis Cultured Milk", etc. When lactic acid producing microorganisms are used, the food may be named "Cultured Buttermilk".

Dairy Facility—includes dairy farms, milk tank trucks, milk tank truck cleaning facilities, receiving stations, transfer stations, dairy plants, finished product depots, finished product transfer points, single service containers and closures for milk and milk products manufacturing plants and vehicles used to transport dairy products.

Dairy Farm—any place or premises where one or more cows, goats, sheep, water buffaloes or other hooved mammals are kept for milking and from which a part or all of the milk produced is provided, sold, or offered for sale to a dairy plant, transfer station, or receiving station possessing a permit from the state milk regulatory agency.

Dairy Plant—any place, premises or establishment where milk, milk products (including frozen desserts, frozen dessert mixes, filled milk or filled milk products, anomalous milk, anomalous milk products or anomalous dairy products) and dairy products are collected, handled, processed, stored, pasteurized, ultra-pasteurized, aseptically processed, churned, frozen, dried, blended, concentrated, condensed, packaged or prepared for distribution and where milk tank trucks are cleaned and sanitized when received.

Dairy Plant Receiver/Sampler—a person who collects official milk and milk product samples from milk transport tank trucks and other types of containers of milk and milk products being received by a dairy plant or receiving station and may also unload such milk transport tank trucks and containers.

Dairy Product Condensing, Concentrating, Drying or Blending Plants—dairy plants that condense, concentrate, dry or blend dry dairy products.

Dairy Product Distributor—any person who offers for sale or sells to another any processed milk or dairy products for human consumption as such.

Dairy Products—include but are not limited to milk and milk products, anomalous milk and anomalous milk products, filled milk and filled milk products, whey and whey products, imitation milk and imitation milk products (whether the aforesaid products have been acidified, condensed, concentrated, cultured, dried, flavored, frozen or stabilized), frozen desserts, frozen dessert mixes, butter, butter products, cheese (whether natural or processed), cheese products and any food which is prepared or manufactured in whole or in part from any of the aforesaid products which the state health officer may hereafter so designate. All dairy products produced, manufactured or sold in the state shall comply with the chemical and bacteriological standards and specifications contained in this Part, determined by the state health officer to be applicable to each product. Dairy products processed, manufactured or sold in the state shall be processed or manufactured in plants that are in conformity with the requirements for dairy plants contained in this Part as determined by the state health officer to be applicable to each plant.

Dry Cream—product obtained by removal of water only, from pasteurized milk or cream or a mixture thereof, which may have been homogenized. Alternatively, dry cream may be obtained by blending dry milks and dry cream, provided, that the resulting product is equivalent in composition to that obtained by the method described in the first sentence of this paragraph, it contains not less than 40 percent but less than 75 percent by weight of milk fat on an as is basis and it contains not more than 5 percent by weight of moisture on a milk solids not-fat basis. Safe and suitable sweeteners, fruit and fruit juices, characterizing flavoring ingredients, colorings and artificial flavorings as approved by the state health officer may be added.

Dry Milk (Powdered Milk)—the product resulting from the removal of water from milk or lower fat milks and contains the milk fat, lactose, milk proteins and milk minerals in the same relative proportions as in the milk from which it is made. It contains not more than 2.5 percent by weight of moisture. Said product has been processed in compliance with Chapter 21 of this Part.

Dry Dairy Products—include dry milk (powdered milk), nonfat dry milk [powdered nonfat (fat free, skim) milk], instant nonfat dry milk, dry whey, dry buttermilk and any other products resulting from the combination of dry milk products with other wholesome dry ingredients, and which comply with and have been processed in compliance with the applicable provisions of Chapter 21 of this Part.

Egg Nog or Boiled Custard—food consisting of a mixture of milk, nonfat (fat free, skim) milk, nonfat dry milk, buttermilk, whey, lactose, lactalbumins, lactoglobulins or modified whey. It shall contain not less than 1.0 percent by weight of egg yolk solids in the finished food and

nutritive carbohydrate sweeteners. Egg nog or boiled custard shall contain not less than 6 percent milk fat and not less than 8.25 percent milk solids not fat. The food shall be pasteurized, ultra-pasteurized or aseptically processed.

EPA—United States Environmental Protection Agency.

Evaluation of Milk Laboratories—2007 Revision, published by the U. S. Department of Health and Human Services, Public Health Service, Food and Drug Administration.

Extra Grade and Standard Grade Dry Dairy Products—products resulting from the drying of pasteurized milk or milk products in dairy plants that are in substantial compliance with all of the requirements of this Part for dairy products condensing, dairy products drying or dairy products blending plants.

FDA—United States Department of Health and Human Services, Food and Drug Administration.

FDD—flow diversion device.

Filled Dairy Products—any food product made by combining, blending or compounding milk or derivatives of milk with any fat or oil other than milk fat so that the resulting product resembles in sensory properties and physical characteristics (taste, appearance, texture or consistency) a dairy product. The above definition shall not include any distinctive proprietary food compound not readily mistaken for a dairy product in taste or appearance. Filled dairy products shall conform with the microbiological requirements of this Part determined by the state health officer to be applicable to the product and shall be processed in plants that conform with the requirements of this Part, determined by the state health officer to be applicable to such plant facility.

Filled Milk and Filled Milk Products—any milk, lower fat milks, cream (whether or not condensed, evaporated, concentrated, powdered, dried or desiccated) to which has been added, or which has been blended or compounded with, any fat or oil other than milk fat, so that the resulting product is in imitation of, or is in semblance of, and resembles, milk, lower fat milks or cream (whether or not condensed, concentrated, powdered, dried or desiccated) in physical characteristics, sensory properties, functional attributes and being of such nature that it may be used interchangeably with the milk or milk product it resembles (whether condensed, concentrated, powdered, dried or desiccated). Filled milk or filled milk products shall be labeled with a descriptive name, which is suggestive enough to identify the milk or milk product it resembles, followed by a qualifier that accurately describes what the product is (examples: "Filled Milk - Non Fat Milk with Vegetable Fat", "Filled Cream - Non Fat Dry Milk with Vegetable Fat", etc.). This definition shall not include any distinctive proprietary food compound readily mistaken in physical characteristics, sensory properties, and functional attributes such that it resembles milk or milk products (whether or not condensed, concentrated, powdered, dried or dessicated) but is of such a nature that it is not reasonably likely to be used interchangeably for a milk or milk product. Nothing in this definition shall be used to prevent the use, blending or compounding of chocolate as a flavor to milk, lower fat milks or cream to which no other fats or oils have been added, blended or compounded. Filled milk and filled milk products shall conform with the microbiological standards for Grade A milk and milk products contained in this Part. Plants that process or manufacture filled milk or filled milk products shall conform with the requirements for Grade A dairy plants contained in this Part.

Finished Dairy Products Depots—establishments in which dairy products contained in their final packages are unloaded from refrigerated transport trucks, stored and reloaded onto refrigerated delivery trucks for transport to retail sales outlets or to other finished dairy products depots or transfer points.

Finished Dairy Product Transfer Points—premises upon which dairy products in their final containers are unloaded from refrigerated transport trucks and loaded into delivery trucks or other refrigerated transport trucks.

Federal Information Processing Standards (FIPS) Number—a voluntary national uniform coding system number that is used to identify the milk plant at which the pasteurizing, ultra-pasteurizing, aseptic processing, condensing, concentrating or drying has been accomplished.

Flavored Dairy Products—such products to which have been added flavoring ingredients that are generally recognized as safe by the FDA and the state health officer and may contain nutritive sweeteners or stabilizers that are generally recognized as safe by the state health officer.

Food Allergens—proteins in foods that are capable of inducing an allergic reaction or response in some individuals. There is scientific consensus that the following foods account for more than 90 percent of all food allergies: peanuts, soybeans, milk, eggs, fish, crustacea, tree nuts, and wheat.

Frozen Dessert Manufacturing Plants—dairy plants that manufacture, process, freeze or partially freeze frozen desserts and provide or sell those products to institutional food service programs, restaurants, groceries, supermarkets, soda fountains, delicatessens and other retail outlets located on premises other than the premises on which they were frozen or partially frozen. Frozen dessert manufacturing plants are also dairy plants that manufacture or process mixes from which frozen desserts are produced.

Frozen Dessert Mixes—foods made with ingredients in such proportions that the mix when frozen will meet the definitions and standards of identity prescribed for the frozen products.

Frozen Desserts—any food produced by freezing or partially freezing, with or without stirring, any combination of two or more of the following: milk or milk products, vegetable fat, animal fat, eggs or egg products and other food products approved by the state health officer, nutritive sweetening ingredients, artificial sweetening ingredients, nut meats, fruit or fruit juices, citric or other organic food acid, other wholesome flavoring agents and colors, and harmless stabilizer; and shall be deemed to include ice cream, fruit ice cream, nut ice cream, sherbets, frozen yogurt, water ices, goat ice cream, sheep ice cream, water buffalo ice cream or any other food product deemed by the state health officer to be a frozen dessert and shall conform with the standards of identity contained in this Part.

Fruit Sherbet—a frozen dessert made from one or more milk or milk products determined to be safe and suitable by the FDA and the state health officer, water, and one or more sweetening ingredients determined to be safe and suitable by the state health officer with not more than 0.5 percent of

stabilizer or binder with fruit or fruit juice ingredients in such an amount that the finished product shall contain not less than 20 percent by weight of such fruit ingredient, with or without addition of organic food acid. The finished product shall contain not less than 0.35 percent of organic acid calculated as lactic acid. The quantity of milk or milk products used shall be such that the finished product shall contain not less than 1 percent of milk fat and not more than 10 percent of total milk solids. The finished product shall weigh not less than 6 pounds per gallon.

Frozen Lowfat Yogurt—a frozen dessert prepared with one or more of the optional milk or milk products sweetened with one or more of the optional sweetening agents, with or without eggs or egg products, fruit or fruit juices, confection or other optional flavoring ingredients, with or without harmless coloring, which is cultured after pasteurization by one or more strains of *Lactobacillus bulgaricus* and *Streptococcus thermophilus*. The standard plate count requirement for the product shall apply only to the mix prior to culturing. The finished product shall weigh not less than 5 pounds per gallon. For the purpose of this regulation, the strains of bacteria may be collectively referred to as yogurt culture. It shall contain not less than 0.5 percent and not more than 2.0 percent by weight of milk fat.

Frozen Nonfat Yogurt—a frozen dessert prepared with one or more of the optional milk or milk products sweetened with one or more of the optional sweetening agents with or without eggs or egg products, fruit or fruit juices, confection or other optional flavoring ingredients, with or without harmless coloring, which is cultured after pasteurization by one or more strains of *Lactobacillus bulgaricus* and *Streptococcus thermophilus*. The standard plate count requirement for the product shall apply only to the mix prior to culturing. The finished product shall weigh not less than 5 pounds per gallon. For the purpose of this regulation, the strains of bacteria may be collectively referred to as yogurt culture. It shall contain less than 0.5 percent by weight of milk fat.

Frozen Yogurt—a frozen dessert prepared with one or more of the optional milk or milk products of this Part, sweetened with one or more of the optional sweetening agents, with or without eggs or egg products, fruit or fruit juices, confection or other optional flavoring ingredients, with or without harmless coloring, which is cultured after pasteurization by one or more strains of *Lactobacillus bulgaricus* and *Streptococcus thermophilus*. The standard plate count requirement for the product shall apply only to the mix prior to culturing. The finished yogurt shall weigh not less than 5 pounds per gallon. For the purpose of this regulation, the strains of bacteria may be collectively referred to as yogurt culture. It shall contain not less than 3.25 percent by weight of milk fat.

Generally Recognized as Safe (GRAS)—a food or ingredient used in a food, that is generally recognized as safe and suitable for a specific use by the FDA.

GMP—see *Good Manufacturing Practices*.

Goat Milk—the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one or more healthy goats. Goat milk sold in retail packages shall contain not less than 2.2 percent milk fat and not less than 7.5 percent milk solids non fat. Goat milk shall be produced according to the sanitary standards of this Part. The word "milk" shall be interpreted to include goat milk.

Good Manufacturing Practices (GMP)—practices used in the manufacturing, packing or holding of dairy products that comply with the requirements contained in this Part and in *21 CFR 110*.

Grade A Concentrated Milk and Concentrated Milk Products—the unsterilized and unsweetened dairy products resulting from the removal of a considerable portion of the water from Grade A raw milk for pasteurization in a dairy plant that is in substantial compliance for all of the sanitation requirements for Grade A in this Part.

Grade A Dry Buttermilk and Dry Buttermilk Products—the products resulting from the drying of pasteurized liquid buttermilk that was derived from the churning of Grade A pasteurized-cream in a dairy plant that is in substantial compliance with the Grade A requirements of this Part.

Grade A Dry Whey or Dry Whey Products—the products obtained by the drying of Grade A whey for condensing or concentrating or by the drying of Grade A pasteurized condensed whey, while leaving all other constituents in the same relative proportions as in the Grade A whey for condensing or concentrating.

Grade A Nonfat Dry Milk—the product resulting from the drying of Grade A raw milk for pasteurization from which the milk fat has been removed in a dairy plant that is in substantial compliance with all of the sanitation requirements for Grade A of this Part.

Grade A Pasteurized Condensed Whey—the liquid substance obtained by partial removal of water from Grade A whey for condensing or concentrating, while leaving all other constituents in the same relative proportions as in the Grade A whey for condensing or concentrating.

Grade A Whey for Condensing or Concentrating—whey from cheese made from Grade A raw milk for pasteurization which has been pasteurized or heat-treated to a temperature of at least 64EC (147EF) and held continuously at that temperature for at least 21 seconds or to at least 67EC (153EF) and held continuously at that temperature for at least 15 seconds in equipment meeting the pasteurization requirements of this Part.

GRAS—see *Generally Recognized as Safe.*

HACCP—hazard analysis critical control point.

Half and Half—food consisting of a mixture of milk and cream which contains not less than 10.5 percent but less than 18 percent milk fat. It shall be pasteurized, ultra-pasteurized or aseptically processed and may be homogenized. Half and Half may contain flavoring and nutritive sweeteners GRAS by the state health officer and added prior to pasteurization, ultra-pasteurization or aseptic processing.

Heavy Cream—cream that contains not less than 36 percent milk fat. It is pasteurized, ultra-pasteurized or aseptically processed, may be homogenized and may contain other ingredients approved by the state health officer.

HHST—high heat-short time pasteurization.

HTST—high temperature-short time pasteurization.

Homogenized—dairy products that have been treated to insure break-up of the fat globules to such an extent that after 48 hours of quiescent storage at 4.4EC (40EF), no visible cream separation occurs in the dairy product; and the fat percentage of the top 100 milliliters of dairy product in a

quart, or proportionate volumes in containers of other sizes, does not differ by more than 10 percent from the fat percentage of the remaining milk as determined after thorough mixing.

Hooved Mammals Milk—the normal lacteal secretion, practically free of colostrum, obtained by the complete milking of one or more healthy hooved mammals. This product shall be produced according to the sanitary standards of this Part.

Ice Cream—a frozen dessert produced by freezing, while stirring, a pasteurized, ultra-pasteurized or aseptically processed frozen dessert mix consisting of one or more dairy products, other than cheese, filled milk or filled milk products, determined by the FDA, to be safe and suitable for use in ice cream, and may contain caseinates and hydrolyzed milk proteins of a type and in amounts determined to be appropriate by the FDA, sweetened with safe and suitable sweeteners approved by the FDA and may also contain eggs, egg products, fruit, fruit flavoring, nuts, natural or artificial flavors, coloring and other food products, each of which have been determined by the FDA to be safe and suitable for use in ice cream. Ice cream shall contain not less than 10 percent of milk fat, 10 percent of non fat milk solids, by weight, provided that the non fat milk solids level may reduced as the milk fat level increases per the following chart:

Percent Milk Fat	Minimum Percent Non Fat Solids
10	10
11	9
12	8
13	7
14	6

a. In ice cream which contains bulky flavors (fruit, nuts, etc.) the weights of milk fat and total milk solids shall be not less than 10 percent and 20 percent, respectively, of the remainder obtained by subtracting the weight of the bulky flavors from the weight of the finished product; but, in no case shall the weight of milk fat or total milk solids be less than 8 percent and 16 percent, respectively, of the total weight of the finished product. Ice cream may contain safe and suitable stabilizers in amounts not more than 0.5 percent by weight of the total weight of the product. Ice cream shall contain not less than 1.6 pounds of total solids per gallon and shall weigh not less than 4.5 pounds per gallon. The term "ice cream" includes goat ice cream, sheep ice cream, water buffalo ice cream and ice cream made from the milk of other hooved mammals, fruit ice cream, nut ice cream, provided the labeling of such products comply with the labeling requirements contained in §121 of this Part.

Imitation Milk or Imitation Milk Products—foods that are made in semblance of and resemble a milk or milk product in physical characteristics, sensory properties, functional attributes and being of such nature that they may be used, interchangeably with the milk or milk product they are in semblance of and resemble, but are nutritionally inferior to said milk or milk product. If, by this definition, a food is an imitation of a milk or milk product, the label shall bear the term "imitation" in a uniform type and size and prominence immediately before the name of the imitated milk or milk product. Imitation milk or milk products shall conform with the microbiological requirements for the milk or milk product which they are an imitation, contained in this Part. Plants that manufacture or process imitation milk or milk products shall conform with the requirements for dairy plants that manufacture or process the milk or milk product of which they are an imitation, contained in this Part.

IMS—Interstate Milk Shipper.

IMS List Sanitation Compliance and Enforcement Rating of Interstate Milk Shippers—a list published quarterly by the U. S. Department of Health and Human Services, Public Health Service, Food and Drug Administration, Center for Food Safety and Applied Nutrition. The list consists of interstate milk shippers certified by State Milk sanitation authorities as having attained required milk sanitation compliance ratings; (to subscribe online, see http://www.cfsan.fda.gov/~ear/imsl-l.html).

Inspection—a series of observations, made by the state health officer, to determine whether or not a dairy facility, the operations conducted therein, and the products being produced, processed or handled are in compliance with the requirements of this Part.

Lactase Enzyme Preparation—derived from the nonpathogenic, nontoxicogenic yeast *Kluyveromyces lactis.* It is used to convert lactose to glucose and galactose. The current GMPs require the use of lactase enzyme in milk to produce "lactase-treated" milk, which contains less lactose than regular milk, or "lactose-reduced" milk, which contains at least 70 percent less lactose than regular milk (21 CFR §184.1388 Lactase enzyme preparation from *Kluyveromyces lactis).*

Lactose Reduced Milk, Lactose Reduced Lowfat Milk or Lactose Reduced Nonfat (Fat free, skim) Milk—the product resulting from the treatment of milk, lowfat milk or nonfat (fat free, skim) milk with safe and suitable enzymes to convert sufficient amounts of the lactose to glucose and/or galactose so that the remaining lactose is less than 30 percent of the lactose in milk, lowfat milk or nonfat (fat free, skim) milk.

Lower Fat—a general term related to any type of dairy product which contains less milk fat than that required by the definition and/or standard of identity for the primary (or traditional) dairy product. Such dairy products are to be labeled as "reduced fat", "low fat", "non fat (fat free, skim)" or "light", the term being determined by the content of or the absence of milk fat in the finished product and the type of product.

Low Fat Cottage Cheese—the same as Cottage Cheese except that it contains 0.5 percent to 2.0 percent butterfat by weight and a maximum of 82.5 percent moisture. The label must bear the phrase "contains not more than 2.0 percent butterfat."

Low Fat Milk—milk from which a sufficient portion of milk fat has been removed to reduce its milk fat content to not less than 0.5 percent nor more than 1.5 percent.

Low Fat Yogurt—the same as Yogurt, except that it contains a lower butterfat content. It must contain at least 0.5 percent but not more than 2.0 percent butterfat.

Manufacture—when used contextually with frozen desserts shall include all other similar terms, such as produce, process, convert, freeze and partially freeze.

Manufacturer—any person or company in the business of manufacturing a single service container or closure product which is to be used by a milk plant for the packaging or sampling of a finished Grade A milk or milk product.

Manufacturing Grade Milk—milk for manufacturing purposes that conforms with the requirements of this Part.

Manufacturing Line—a manufacturing process such as extrusion, blow mold, etc.

Manufacturing/Processing—making of a food from one or more ingredients and synthesizing, preparing, treating, modifying or manipulating food, including food crops or ingredients such as cutting, peeling, trimming, washing, waxing, bottling, labeling, packaging, etc.

Metals—metals which are nontoxic, nonabsorbent and corrosion-resistant under conditions of intended use.

Methods of Making Sanitation Ratings of Milk Shippers—2007 Revision, as amended, published by the U. S. Department of Health and Human Services, Public Health Service, FDA; (Internet URL address: http://www.cfsan.fda.gov/~ear/mmethods.html").

Milk—the lacteal secretion, practically free from colostrum, obtained by the complete milking of one or more healthy cows. Milk that is in its final packaged form for beverage use shall have been pasteurized, ultra-pasteurized or aseptically processed and shall contain not less than 8.25 percent milk solids not fat and not less than 3.25 percent milk fat. Milk may have been adjusted by separating part of the milk fat therefrom or by adding thereto cream, concentrated milk, concentrated low fat milks, dry milk or dry low fat milks. Milk may be homogenized. Water shall not be added to milk or any ingredient used in milk. Milk may be flavored with safe and suitable flavoring ingredients approved by the state health officer. The word "milk" shall be interpreted to include goat, sheep, water buffalo, camel milk and the milk of other hooved mammals.

Milk Fat—the fat of milk.

Milk Plant—any place, premises or establishment where milk or milk products are collected, handled, processed, stored, pasteurized, ultra-pasteurized, aseptically processed, condensed, dried, packaged or prepared for distribution and where milk tank trucks are cleaned or sanitized when received.

Milk Producer—any person who operates a dairy farm and provides, sells, or offers milk for sale to a dairy plant, receiving station, or transfer station.

Milk Products—cream, light cream, light whipping cream, heavy cream, heavy whipping cream, whipped cream, whipped light cream, sour cream, acidified sour cream, cultured sour cream, half-and-half, sour half-and-half, acidified sour half-and-half, cultured sour half-and-half, reconstituted or recombined milk products, concentrated or condensed milk and low fat milk, nonfat (fat free, skim) milk or nonfat (fat free, skim) milk products, dry milk, reduced fat milk, lower fat milk products, dry milk products, frozen milk and concentrated low fat milk, egg nog or boiled custard, buttermilk and low fat buttermilk, cultured milk and cultured reduced fat, cultured low fat milk [including kefir cultured milk, acidophilis cultured milk, cultured buttermilk, yogurt and low fat yogurts (whether spoonable or drinkable)], cultured nonfat (fat free, skim) milk, nonfat yogurt, acidified milk and acidified reduced fat or low fat milk, acidified nonfat (fat free, skim) milk, low-sodium milk and low-sodium reduced fat or low fat milk, low-sodium nonfat (fat free, skim) milk, lactose-reduced milk and lactose-reduced reduced fat or low fat milk, lactose-reduced nonfat (fat free, skim) milk, aseptically processed and packaged milk and aseptically processed and packaged milk products, milk, reduced fat, low fat milk, or nonfat (fat free, skim) milk with or without added safe and suitable microbial organisms and any other milk product made by the addition or subtraction of milk fat or the addition of safe and suitable optional ingredients approved by the FDA, for protein, vitamin or mineral fortification of the milk products contained herein. Milk products also include those dairy foods made by modifying the federally standardized products listed in this Part in accordance with the 21 Code of Federal Regulation (CFR) 130.10 *Requirements for foods named by the use of a nutrient content claim and a standardized term*. This definition shall include imitation milk and imitation milk products, anomalous milk and anomalous milk products, filled milk and filled milk products. Milk and milk products which have been retort processed after packaging or which have been concentrated, condensed or dried shall be included in this definition. Dried blends of milk products and blends of dried products, which have milk or a derivative of milk as their predominant ingredient and are used for human consumption, shall be included in this definition. This definition is not intended to include dietary products (except as defined herein), infant formula, ice cream or other frozen desserts, butter or cheese.

Milk Sanitation Rating Officer—a state employee who has been standardized by the *Public Health Service/Food and Drug Administration* to perform required milk sanitation ratings of farms, plants, or HAACP listing of dairy plants or a combination thereof, has a valid certificate of qualification issued by the *Public Health Service/Food and Drug Administration* and who does not have responsibility for the routine inspections/audits or enforcement action for the plants or farms he/she rates. State program directors, administrators, etc,, may be certified.

Milk Shake—a pasteurized, ultra-pasteurized or aseptically processed dairy product consisting of one or more milk or milk products, determined by the FDA to be safe and suitable flavoring and sweetening ingredients, stabilizers and may contain fruits, nuts, and other bulky flavors determined by the FDA to be safe and suitable. Milk shakes shall contain not less than 4.5 percent milk fat and 8.8 percent solids non fat by weight.

Milk Tank Truck—a bulk milk pickup tanker or a milk transport tank truck.

Milk Tank Truck Cleaning Facility—any place, premise or establishment, separate from a milk plant or receiving station, where milk tank trucks are cleaned and sanitized.

Milk Tank Truck Operator—any person who operates a milk tank truck, bulk milk pickup tanker or a milk transport tank truck and may or may not be a bulk milk tank truck operator/sampler.

a. milk tank truck and milk tank transport operators who are not licensed as bulk milk tank truck operator/samplers shall not perform any of the duties of a bulk milk tank truck operator/sampler that directly involve the collection or measuring of milk for official records; and

b. milk tank truck operators who are not bulk milk tank truck operator/samplers and perform any of the duties of a bulk milk tank truck operator/sampler other than duties involved in the sampling and measuring of the raw milk shall conform with the requirements for such duties contained in this Part related to those non sampling, non measuring duties of the bulk milk tank truck operator/sampler.

Milk Transport Tank Truck—a vehicle, including the truck and tank, used to transport bulk shipments of milk from a milk plant, receiving station or transfer station to another milk plant, receiving station or transfer station.

Misbranded Milk, Milk Products and Other Dairy Products—products which are not labeled in accordance with the requirements of §121 of this Part.

NACMCF—U.S. National Advisory Committee on Microbiological Criteria for Foods.

NCIMS—the cooperative State-Federal program of the National Conference on Interstate Milk Shipments.

Non-Dairy Frozen Desserts—

a. food which is prepared by freezing, while stirring, a non-dairy frozen dessert mix composed of one or more optional characterizing ingredients specified in Subparagraph b of this Paragraph, sweetened with one or more of the optional sweetening ingredients specified in Subparagraph c of this Paragraph. The non-dairy product, with or without water added, may be seasoned with salt. One or more of the ingredients specified in Subparagraph d may be used. Pasteurization is not required. The optional caseinates specified in Clause i of Subparagraph d are deemed not to be dairy products.

b. the optional flavoring ingredients referred to in Subparagraph a of this Paragraph are natural and artificial flavoring and characterizing food ingredients.

c. the optional sweetening ingredients referred to in Subparagraph a of this Paragraph: Sugar (sucrose), dextrose, invert sugar (paste or syrup), glucose syrup, dried glucose syrup, corn sweetener, dried corn sweetener, malt syrup, malt extract, dried malt extract, maltose syrup and dried maltose syrup.

d. other optional ingredients referred to in Subparagraph a of this Paragraph are:

i. Casein prepared by precipitation with gums, ammonium caseinate, caseinate, calcium caceinate, potassium caseinate or sodium caseinate.

ii. hydrogenated and partially hydrogenated vegetable oil.

iii. dipotassium phosphate.

iv. coloring, including artificial coloring.

v. monoglycerides, diglycerides or polysorbates.

vi. thickening ingredients such as agar-agar, algin (sodium alginate), egg white, gelatin, gum acacia, guar seed gum, gum karaya, locust bean gum, oat gum, gum tragacanth, hydroxpropyl, methyl cellulose, carrageenan, salts of carrageenan, furcelleran, propylene glycol alginate, pectin, psyllium seed husk, sodium carboxymethylcellulose.

e. such non-dairy frozen desserts are deemed "processed" when manufactured as a dry powdered mix.

f. dry non-dairy frozen dessert mixes shall be reconstituted with potable water in a sanitary manner and shall be rapidly cooled to a temperature of 45°F or below within four hours of reconstitution.

g. the product shall meet the bacterial standards prescribed in §2705.A.18 of this Part.

h. the name of the food is "non-dairy frozen dessert".

i. the fact that the product offered for sale is a non-dairy frozen dessert shall be conspicuously displayed on or near the dispensing freezer in a manner and print that is easily readable by the consumer.

Nonfat (Fat Free, Skim) Milk—milk from which a sufficient portion of milk fat has been removed to reduce its milk fat percentage to less than 0.5 percent.

Nontoxic Materials—materials which are free of substances which may render the milk injurious to health or which may adversely affect the flavor, odor, composition or bacteriological quality of the product and which meet the requirements of the *Federal Food, Drug and Cosmetic Act,* as amended.

Nutritionally Inferior—foods that contain a reduction of 2.0 percent or more of the daily recommended value (DRV) of protein and potassium and 2.0 percent or more of the U.S. recommended daily intake (RDI) of any vitamin or mineral of the food that they resemble or may be used as a substitute for that food. Foods that are nutritionally inferior to the food which they resemble shall be labeled "imitation". Foods that are not nutritionally inferior to the food which they resemble shall be considered nutritionally equivalent to the food which they resemble.

Official Laboratory—a biological, chemical, radiological, or physical laboratory which is under the direct supervision of the state health officer or which is under the direct supervision of a duly authorized regulatory official which has been approved by the state health officer.

Official Methods of Analysis—18th Edition, Revision 2, 2007, as amended, published by the AOAC International.

NOTE: AOAC International was formally called the Association of Official Analytical Chemists.

Officially Designated Laboratory—a commercial laboratory authorized to analyze official samples by the state health officer or the milk regulatory official of the state in which it is domiciled or a milk industry laboratory officially designated by the state health officer or the milk regulatory official of the state in which it is domiciled.

Overflow Milk or Milk Product—a milk or milk product which has either:

a. been collected in containers from leaking valves, leaking joints in sanitary milk pipelines, spillage at coolers and bottling machines, or broken bottles; or

b. been exposed to contamination by contact with the surfaces of equipment which have not been treated with a bactericide.

PHS—United States Public Health Services.

PHS/FDA—United States Public Health Service/Food and Drug Administration.

PMO—the 2009 Edition, as amended, of the *Grade "A" Pasteurized Milk Ordinance,* Public Health Service/Food and Drug Administration.

Packing or Packaging—placing, putting or repacking food into different containers without making any change to the form of the food. Facilities that pack dairy products shall be considered to be dairy plants.

Paper Stock—any paper made from the following materials:

a. paper and paperboard manufactured from clean, sanitary virgin chemical or mechanical processed pulp or from broke and trim of such paper and paperboard, provided they have been handled, treated and stored in a clean, sanitary manner or reclaimed fiber using acceptable or approved protocol in compliance with Title 21 CFR 176.260; and

b. components meeting the requirements of the *Federal Food, Drug and Cosmetic Act,* as amended.

Pasteurization—the process of heating every particle of a dairy product to the appropriate temperature, contained in the chart below, and held continuously at or above the temperature for at least the corresponding time contained in the chart. The pasteurization process shall be performed in equipment designed, manufactured and operated in accordance with the requirements contained in the PMO. The required recording charts for perishable or refrigerated products shall be retained at the dairy plant for a period of one year after the products were prepared. The required recording charts for frozen, preserved or shelf-stable products shall be retained at the plant for a period of two years.

Temperature	Time
63°C (145°F)*	30 minutes
72°C (161°F)*	15 seconds
89°C (191°F)	1.0 second
90°C (194°F)	0.5 seconds
94°C (201°F)	0.1 seconds
96°C (204°F)	0.05 seconds
100°C (212°F)	0.01 seconds

*If the fat content of the milk product is 10 percent or more, or if it contains added sweeteners, the specified temperature shall be increased by 3°C (5°F).

a. Eggnog shall be heated to at least the following temperature and time specifications.

Temperature	Time
69°C (155°F)	30 minutes
80°C (175°F)	25 seconds
83°C (180°F)	15 seconds

b. Provided further, that should scientific evidence indicate that the above temperatures or times are not adequate to destroy pathogenic microorganisms of human significance or for any other reason, may not be adequate to protect the public's health, the state health officer may, with the concurrence of the FDA, immediately require that all pasteurized or ultra-pasteurized dairy products sold in the state are pasteurized or ultra-pasteurized at temperatures or times recommended to be adequate by the FDA. Provided further that should the FDA hereafter determine that any of the requirements for pasteurization or ultra-pasteurization contained in the PMO are not adequate to protect the public's health and require a change in any of the aforesaid requirements, the state health officer shall immediately require that all pasteurization or ultra-pasteurized products sold in the State conform with the new FDA requirements for pasteurization or ultra-pasteurization. Provided further, that nothing shall be construed as barring any other pasteurization process, which has been recognized by the FDA to be equally efficient and which is approved by the state health officer.

Pasteurized Process Cheese—food prepared by comminuting and mixing, with the aid of heat, one or more cheeses of the same or two or more varieties, except Cream Cheese, Neufchatel Cheese, Cottage Cheese, Lowfat Cottage Cheese, Cottage Cheese Dry Curd, Cook Cheese, Hard Grating Cheese, Semisoft part Skim Cheese, part Skim Spiced Cheese and Skim Milk Cheese for manufacturing with a suitable emulsifying agent approved by the FDA and the state health officer into a homogeneous plastic mass. One or more of the optional suitable ingredients approved by the FDA and the state health officer may be used. During its preparation, pasteurized process cheese is heated for not less than 30 seconds at a temperature of not less than 66EC (150EF). Pasteurized process cheese shall conform with the standard of identity contained in this Part and 21 CFR 133.169. Pasteurized process cheese related products are foods that contain pasteurized process cheese as the predominant ingredient. They may contain suitable fruits, vegetables, nuts or meats that have been GRAS by the FDA and the state health officer. These products shall conform with the microbiological requirements for cheese contained in this Part and shall be manufactured in dairy plants that conform with the requirements for cheese manufacturing plants contained in Chapter 25 of this Part. These products shall conform with the standard of identity contained in §107.

Pasteurized Process Cheese Manufacturing Plants—dairy plants that manufacture, process or package pasteurized process cheese or pasteurized process cheese related products.

Phosphatase Test—an index of the efficiency of the pasteurization process.

Plant or Facility—an establishment or structure(s) under one management at one general physical location (or in case of a mobile facility, traveling to multiple locations) that manufactures/processes, packs or holds food for human consumption. A "plant or facility" may be one food processing plant with multiple buildings in one location. A building that has multiple companies at the same address would be considered to be multiple plants or facilities.

Plastic Molding—

a. forming, extrusion, and laminating resins:

i. resins or an intimate admixture of resins with other ingredients which meet the requirements of the Federal Food, Drug, and Cosmetic Act, as amended; and

ii. plastic composed solely of clean cuttings or re-grind, provided they have been handled and maintained in a sanitary manner.

b. This definition shall not preclude the use of recycled plastic material when it complies with a protocol which has been reviewed and accepted by the FDA.

Powdered or Dry Frozen Dessert Mixes—frozen dessert mixes that have been dried in dairy products drying plants that are in substantial compliance with the provisions for such plants contained in this Part.

Preformed Container—a container in completed form ready for filling.

Product Contact Surface—surfaces of the container or closure with which the product comes in contact.

Production Scrap—material which remains from the manufacture of single service containers or closures which has been handled or treated in such a manner that it does not comply with the definition for broke and trim or re-grind, but may be collected for recycling. It may contain material such as containers or trim that have fallen on the floor.

Quiescently Frozen Confections—a clean and wholesome frozen, sweetened, flavored dessert in the manufacture of which freezing has not been accompanied by stirring or agitation (generally known as quiescent freezing). This confection may be acidulated with food grade acid, may contain milk solids, water, may be made with or without added harmless pure or imitation flavoring, with or without harmless coloring. The finished product shall contain not more than 0.5 of 1 percent by weight of stabilizer composed of wholesome edible material. The finished product shall contain not less than 17.0 percent by weight of total food solids. In the producing of this confection, no processing or mixing prior to quiescent freezing shall be used that develops in the finished confection mix any physical expansion in excess of 10 percent.

Quiescently Frozen Dairy Confections—a clean and wholesome frozen dessert made from water, milk products and sugar, with added harmless pure or imitation flavoring, with or without added harmless coloring, with or without added stabilizer and with or without added emulsifier; and in the manufacture of which freezing has not been accompanied by stirring or agitation (generally known as quiescent freezing). It contains not less than 13.0 percent by weight of total milk solids, not less than 33.0 percent by weight of total food solids, not more than 0.5 percent by weight of stabilizer and not more than 1/5 of 1 percent by weight of emulsifier. Stabilizer and emulsifier must be composed of wholesome, edible material. In the production of quiescently frozen dairy confections, no processing or mixing prior to quiescently freezing shall be used that develops in the finished confection mix any physical expansion in excess of 10.0 percent.

Quiescently Frozen Ice Creams or Sherbets—frozen desserts which conform with the standards of identity contained in §107 of this Part and in the manufacture of which freezing has not been accompanied by stirring or agitation (generally known as quiescent freezing). These products may be produced in various forms and figurations such as "stick novelties", bars, loaves, molded into various shapes and sizes, etc.

Receiving Station—any place, premise, or establishment where raw milk is received, collected, handled, stored or cooled and prepared for shipment to other facilities.

Reclaimed Water (dairy farm) or Reclaimed Water$_{df}$—potable water which has been used for heat exchange purposes in plate or other type heat exchangers or compressors on a Grade A dairy farm and which is later re-used for certain limited purposes as is specified in §525 of this Part.

Reclaimed Water (dairy plant) or Reclaimed Water$_{dp}$—water obtained from the processing of Grade A milk and milk products (for example, condensing water from dairy product evaporators complying with this Part and water reclaimed from milk or dairy products during the evaporation or condensing process) at a dairy plant and which is later re-used for certain limited purposes as is specified in §2117 of this Part.

Reconstituted or Recombined Milk, Reconstituted or Recombined Milk Products, Reconstituted or Recombined Anomalous (Substitute) Milk, or Reconstituted or Recombined Anomalous (Substitute) Milk Products—milk and milk products defined in this Part that result from reconstituting or recombining milk constituents with potable water. The sale of reconstituted or recombined milk or milk products and reconstituted or recombined anomalous (substitute) milk or milk products in the state shall be prohibited.

Reduced Fat Milk—milk which has a milk fat content of 2.0 percent.

Re-Grind—clean plastic material which is trimmed from the container or closure, and imperfectly formed containers or closures which result from the manufacture of single service containers and closures, provided it is handled in a clean, sanitary manner. This may be in its trimmed or molded form and ground in a grinder, approved by the FDA, within the plant. It shall not include any material, container or closure which comes from an unapproved source or whose source, chemical content and treatment is unknown, or which may have poisonous or deleterious material retained in the plastic which migrates to the food at levels exceeding regulatory levels. Re-grind, when transported from one approved plant to another, shall be shipped in clean, sealed, properly labeled containers approved by the FDA. This definition shall not preclude the use of re-grind plastic material when it complies with a protocol which has been reviewed and accepted by the FDA.

Ripened or Aged Cheese—cheese that has been purposely exposed to warm temperatures or held for long periods at colder temperatures to permit bacteria and enzymes to transform the fresh curd into cheese of a specific flavor, texture and appearance. Cheese shall be ripened by placing it in a temperature controlled room at temperatures no lower than 2EC (35EF) and at a selective optimum relative humidity for a minimum of 60 days.

Sample Set—a minimum of four containers shall be tested. For the swab test a minimum of four 50-square centimeter areas of surface from separate containers shall be tested. In the case of containers or closures with a product-contact surface area smaller than 50-square centimeters, more than four containers or closures to equal at least 50-square centimeters times four will be required to be swabbed. Sample set from each manufacturing line shall:

a. for the rinse test, a minimum of four containers shall be tested; and,

b. for the swab test, a minimum of four 50-square centimeter areas of surface from separate containers shall be tested. In the case of containers or closures with a product contact surface area smaller than 50-square centimeters, more than four containers or closures to equal at least 50-square centimeters times four will be required to be swabbed.

Sanitization—is the application of any effective method or substance to a clean surface for the destruction of pathogens and of other microorganisms as far as is practicable. Such treatment shall not adversely affect the equipment, the milk or milk product, or the health of consumers and shall be acceptable to the FDA and the state

health officer. Chemical sanitizers shall meet the requirements contained in Part I of Appendix F of the *PMO*.

SCC—somatic cell count.

Sensitivity Producing Ingredient—ingredients that cause individualistic adverse reactions other than those that result in immunoglobulum Epsilon (IgE) mediated allergies.

Sheep Milk—the lacteal secretion practically free from colostrum, obtained by the complete milking of one or more healthy sheep, and shall comply with all the requirements of this Part. The word milk shall be interpreted to include sheep milk.

Sherbet—a frozen dessert which complies with the definition and standard of identity of sherbet (see 21 CFR 135.140), with the exceptions that artificial flavoring may be substituted in whole or in part for the true fruit ingredient, and the butterfat content shall not be less than 1 percent.

Skim Milk—see *Nonfat* (*Fat Free, Skim*) *Milk*.

Single Service Articles—articles which are constructed wholly, in part, or in combination from paper, paperboard, molded pulp, plastic, metals, coatings or similar materials which are intended by the manufacturer for one usage only.

Single Service Milk Container—any container having a milk or dairy product contact surface and is to be used in the packaging, handling, wrapping or storage of Grade A milk and milk products and which is intended for one use only.

Single Service Milk and Milk Product Container or Closure Manufacturing Plants—fabricators, converters, printers, closure manufacturers, plastic laminators, sheet formers, blow molders, vacuum formers, plastic extruders, injection molders, preformers, manufacturers of valves, valve parts, tubes, dispensing devices and sample containers for use with milk or milk products.

Sour Cream, Acidified Sour Cream—food resulting from the souring by lactic acid producing microorganisms of pasteurized, ultra-pasteurized or aseptically processed cream. Sour cream may contain rennet, flavoring ingredients, salt, sodium citrate and safe and suitable natural and artificial food flavoring. Acidified sour cream also includes cream in which the souring was accomplished with safe and suitable acidifiers with or without addition of lactic acid producing microorganisms.

SPC—standard plate count.

SRO—a milk sanitation rating officer operating under the authority of the state health officer (see *milk sanitation rating officer*).

Standard Methods for the Examination of Dairy Products—the 17th Edition, 2004, as amended, published by the American Public Health Association.

Standard Methods for the Examination of Water and Wastewater—the 21st Edition, 2005, as amended, published by the American Public Health Association.

State Health Officer—the legally appointed or acting State Health Officer of the Department of Health and Hospitals having jurisdiction over the entire state of Louisiana, and includes his/her duly authorized representatives in accordance with R.S. 40:4 and 40:5.

State Food, Drug and Cosmetic Act—R.S. 40:601, et seq., as amended.

Transfer Station—any place, premises, or establishment where milk or milk products are transferred directly from one milk tank truck to another.

UHT—Ultra High Temperature.

USDA—United States Department of Agriculture.

Ultra-Pasteurized—when used to describe a dairy product, shall mean that such product shall have been thermally processed at or above 138ºC (280ºF) for at least two seconds, either before or after packaging, so as to produce a product which has an extended shelf life under refrigerated conditions.

Unripened Cheese—cheese that has not been ripened or aged. Such cheese includes: Alemtejo, Alpinianari, Asadero, Asiago, Bokers, Banburg, Bondon, Cambridge, Cottage, Cream, Creole Cream, Farmers, Ferme Feta, Formagelle, Gournug, Liverot, Malgre, Mignot, Mont d'Or, Mozzarella, Neufchatel, Queso Blanco, Queso de Hoja, Queso del Pais, Queso de Puna, Queso Fresco, Provutura, Ricotta, Scamorze, Villiers and others designated by the state health officer.

Vitamin A Fortification—the addition of vitamin A (retinol), vitamin A acetate (retinyl acetate) or vitamin A palmitate (retinyl palmitate) is mandatory in low fat milk and low fat milk products (except yogurt). In fluid milk, vitamin A is required at levels to achieve nutritional equivalency [300 International Units (IU) per cup, 1200 IU per quart]. However, the FDA and the state health officer would prefer that dairy processors continue to fortify vitamin A to levels of 2000 IU/qt. Other modified fat milk products must be fortified with vitamin A to achieve nutritional equivalency. Vitamin A may be added to other products within the limits of GMP. There is no specified GMP level for vitamin A in milk and milk products. Vitamin A may be required to be added to new low fat products to achieve nutritional equivalency with their full fat counterparts.

Vitamin D Fortification—the addition of vitamin D (vitamin D2 or D3 in crystalline, resin or crystal form) to all milk and milk products is optional. Many standards of identity prescribe the minimum level of vitamin D that must be present when it is added to a product. For example, if vitamin D is added to milk, it must be added at a level so that each quart contains 400 IU of vitamin D. If the standard of identity does not indicate a specific level or the product does not have a standard of identity then, the level at which vitamin D may be added must be in accordance with GMP. The maximum GMP level for vitamin D set for milk is (42 IU/100g)2 and milk products (89 IU/100g)3.

Water Buffalo or other Hooved Mammal Milk—the lacteal secretion practically free from colostrum, obtained by the complete milking of one or more healthy water buffalo or other hooved mammals and shall comply with all of the requirements of this Part. The word milk shall be interpreted to include water buffalo and other hooved mammal milk.

Water Ices—a frozen dessert produced by freezing with or without stirring, does not contain any milk or milk derived ingredients, does not contain any egg ingredient other than egg white and does not contain any food fats, except such as are added in small amounts to accomplish specific functions or, are natural components of flavoring ingredients used in the water ice. Water ice is sweetened with safe and suitable nutritive carbohydrate sweeteners and is characterized by the addition of one or more characterizing fruit ingredients (including fruit juices, concentrated fruit juices) or one or more non fruit characterizing ingredients. Other safe and suitable

ingredients such as ground spice, infusions of coffee or tea, natural or artificial food flavoring (except any having a characteristic fruit or fruit like flavor) may be added. Each ingredient used in water ice shall have been determined by the FDA to be safe and suitable for use in the product.

Whey—the fluid obtained by separating the coagulum from milk, cream, lowfat or nonfat (fat free, skim) milk in the cheese making process.

Whey Products—any fluid product removed from whey or made by the removal of any constituent from whey or by addition of any wholesome substance to whey or parts thereof. Whey products may be condensed, concentrated or dried.

Yogurt (Yogourt, Yoghurt), Spoonable or Drinkable—food produced by culturing of cream, milk, partially skimmed milk or nonfat (fat free, skim) milk used alone or in combination, with characterizing and lactic acid producing microorganisms. Concentrated nonfat (fat free, skim) milk and non fat dry milk may be added. Ingredients, other than flavoring ingredients shall be pasteurized, ultra-pasteurized or aseptically processed prior to the addition of the microorganism culture. Yogurt may be heat treated after culturing is completed. The finished product shall contain not less than 0.9 percent titratable acidity expressed as lactic acid. The word "yogurt" shall include drinkable and spoonable yogurt. All yogurts sold in the state shall conform to the Grade A bacteriological standards/specifications contained in this Part. Plants that manufacture or process yogurts shall conform with the requirements for Grade A dairy plants contained in this Part.

B. Standards of identity listed in §107 of this Part are also herein incorporated as definitions of milk and dairy products. In case of conflicts, the more stringent definition shall apply.

AUTHORITY NOTE: The first source of authority for promulgation of the Sanitary Code is R.S. 36:258(B), with more particular provisions found in Chapters 1 and 4 of Title 40. This Part is promulgated in accordance with specific provisions of R.S. 40: 4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7) (15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1258 (June 2002), amended LR 37:

§103. Local Ordinances

A. Parishes and municipalities may adopt local milk ordinances provided that such ordinances do not conflict with and are not less restrictive than the PMO, this Code, or state statutes pertaining to milk and further provided that such ordinances have been reviewed and approved by the state health officer prior to adoption.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7) (15)(17), R.S. 40:922, and R.S. 40:925.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1262 (June 2002), amended LR 37:

§105. Severability Clause

A. If any provision of this Part, or the application of such provision to any person or circumstance, shall be held invalid, the remainder of this Part, or the application of such provision to persons or circumstances other than those as to which it is held invalid, shall not be affected thereby.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7) (15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1262 (June 2002), amended LR 37:

§107. Standard of Identity

A. All dairy products sold in the state shall conform with the standards of identity (definitions, specifications and requirements) contained in this Section, 21 USC §321a, 21 CFR Part 130, 21 CFR Part 131, 21 CFR Part 133, 21 CFR Part 135 or 21 CFR Part 184, determined by the state health officer, to be applicable to the specific product. A product shall not be in compliance with a standard of identity when :

1. the product contains ingredients that are not provided for in the standard, unless the ingredient is an incidental additive;
2. the product fails to contain one or more ingredients required by the definition and standard; or
3. the product contains an ingredient or component not within the limitation of the definition or standard.

B. The following dairy products which may not be identified under Subsection A of this Section, shall have the standards of identity as defined in §101.A. If there is a conflict between a standard of identity listed in Subsection A of this Section and the same standard of identity is also listed (by reference to its definition in §101.A) in Subsection B of this Section, the standard of identity in Subsection A of this Section shall govern. These products must conform to the standards of identity prescribed by this Section in order to be sold in this state:

1. anomalous (substitute) dairy products;
2. anomalous (substitute) milk and anomalous (substitute) milk products;
3. acidified milk and acidified milk products;
4. butter;
5. buttermilk;
6. cheese;
7. concentrated or condensed milk;
8. cottage cheese;
9. cream;
10. creamed cottage cheese;
11. creole cream cheese or creole cheese;
12. cultured milk and cultured milk products;
13. cultured anomalous milk and cultured anomalous milk products;
14. cultured filled milk and cultured filled milk products;
15. dry cream;
16. dry milk (powdered milk);
17. dry milk products;
18. egg nog or boiled custard;
19. filled dairy products;
20. filled milk and filled milk products;
21. frozen low fat yogurt
22. frozen nonfat yogurt
23. frozen yogurt
24. fruit sherbet;
25. goat milk;
26. half and half;
27. heavy cream;

28. ice cream;
29. imitation milk or imitation milk products;
30. lactose reduced milk;
31. lactose reduced low fat milk
32. lactose reduced nonfat (fat free, skim) milk;
33. low fat cottage cheese;
34. low fat milk;
35. low fat yogurt
36. milk;
37. milk shake;
38. non-dairy frozen desserts;
39. nonfat (fat free, skim) milk;
40. pasteurized processed cheese;
41. quiescently frozen confections;
42. quiescently frozen dairy confections;
43. quiescently frozen ice creams or sherbets;
44. reduced fat milk;
45. ripened or aged cheese
46. sheep milk;
47. sherbet;
48. sour cream or acidified sour cream;
49. water buffalo or other hooved mammal milk;
50. water ices; and
51. yogurt (yogourt, yoghurt), spoonable or drinkable.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S.40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1262 (June 2002), amended LR 37:

Subchapter A. Required Permits

§109. Permits

A. Operators of dairy farms, receiving stations, transfer stations, dairy plants (including frozen dessert manufacturing plants, filled dairy products processing plants, anomalous milk and milk products processing plants, anomalous dairy products processing plants, imitation milk and milk products processing plants, single-service containers and closures for milk and milk products manufacturing plants, milk tank truck cleaning facilities, finished dairy product depots/transfer points and milk tank trucks) that are domiciled within the state shall obtain a permit to operate from the state health officer prior to beginning operation. Bulk milk tank truck operators/samplers and dairy plant receivers/samplers shall obtain a permit from the state health officer prior to performing the duties associated with those positions. Only a person who complies with the requirements of this Part shall be entitled to receive or retain a permit from the state health officer.

B. Persons applying for permits shall complete and sign all forms for permit application and pay any and all fees required by the state health officer.

C. Such a permit may be temporarily suspended by the state health officer upon violation by the holder of any of the terms of these regulations, or for interference with the state health officer in the performance of his duties, or may be revoked after an opportunity for a hearing by the state health officer upon serious or repeated violations.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1262 (June 2002), amended LR 37:

§111. Permits Required for Imported Milk, Milk Products and Frozen Desserts

A. It shall be unlawful for any person, firm or corporation to ship or receive into the state any milk or milk products (except extra grade and standard grade dry milk and milk products), filled milk and filled milk products, anomalous milk and milk products, imitation milk and imitation milk products and frozen desserts from outside of the state that were processed or packaged by a dairy plant that does not possesses a current valid permit from the state health officer. Only a person, firm or corporation who complies with the requirements of this Part shall be entitled to receive or retain such permit.

B. All imported Grade A milk and milk products shall be processed and packaged only by dairy plants currently listed in the *IMS List Sanitation Compliance and Enforcement Rating of Interstate Milk Shippers*.

C. In the event a person requests a permit for a dairy plant domiciled outside the State of Louisiana, the person shall:

1. Complete and sign all forms for permit application required by the state health officer.
2. Pay any and all fees required by the state health officer.
3. Have the regulatory authority, responsible for permitting and inspecting/auditing of dairy plants in the state in which the plant is domiciled, send the following information directly to the state health officer if they are not currently in the IMS list:
   a. a statement indicating whether or not the plant is in substantial compliance with all applicable laws and regulations of the locality, state, province or country in which the plant is domiciled;
   b. a copy of the most recent inspection/audit report completed by the regulatory authority; and
   c. copies of the last three results of bacteriological and chemical analyses performed on the plant's products by the regulatory authority.
4. Provide copies of labels of each product the plant intends selling in Louisiana.
5. Provide a copy of the laws and regulations of the regulatory authority responsible for permitting and inspecting/auditing of the plant when requested by the state health officer.
6. Provide any other information, data or records required by the state health officer.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S.40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1262 (June 2002), amended LR 37:

§113. Requirements for Imported Dairy Products

A. All dairy products (including frozen desserts, filled dairy products, anomalous milk and milk products, anomalous dairy products and imitation milk and imitation milk products) brought into Louisiana from outside of the state shall comply with the standards (specifications) contained in this Part determined to be applicable by the

state health officer. These products shall be produced, processed and handled by facilities that comply with, the requirements of this Part. The production and processing facilities may be inspected by the state health officer; the cost of such inspections shall be borne by the person or firm producing or processing such dairy products or in lieu thereof, the state health officer may accept a certificate of compliance/inspection of a duly authorized agent of the dairy regulatory agency in the state or country wherein the products are produced or processed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1262 (June 2002), amended LR 37:

Subchapter B. Records

§115. Milk Records

A. Each dairy plant, and others receiving milk or dairy products, including frozen desserts, from one or more sources shall keep records of the sources and the amounts of such products received. They shall also keep records showing utilization and disposition of all such products they receive. These records shall include names and amounts of each such product used or disposed of. Such records shall be open to inspection by the state health officer.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1263 (June 2002), amended LR 37:

§117. Falsification of Records

A. Falsification of any records, logs or recording charts shall constitute grounds for the suspension of permit.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

Subchapter C. Registration and Labeling

§119. Registration

A. Each processed dairy product final manufacturer shall register each separate and distinct processed dairy product, in storage, offered for sale or being sold in the state, annually with the state health officer in accordance with the provisions contained in Chapter 4, Part 1, §627 of the State Food, Drug and Cosmetic Law (R.S. 40:601, et seq.). The state health officer shall not register any processed milk or milk product, anomalous milk or anomalous milk product, filled milk or filled milk products, imitation milk or imitation milk products, frozen dessert mixes or mix products processed or packaged by a dairy plant that does not have a current, valid permit for such products issued by the state health officer. The labels for the aforesaid products shall have been reviewed and approved by persons, operating under the authority of the state health officer.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17), R.S. 40:604, and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§121. Labeling

A. All dairy products (including but not limited to, milk, milk products, anomalous milk , anomalous milk products, anomalous dairy products, filled milk, filled milk products, filled dairy products, imitation milk, imitation milk products, imitation dairy products and frozen desserts) being offered for sale, distribution or held in storage within the state shall be labeled in accordance with the requirements of this Code determined to be applicable to such products by the state health officer, the State Food, Drug and Cosmetic Law (R.S. 40:601 *et seq.)*, the *Federal Food, Drug and Cosmetic Act, as amended, the Nutrition Labeling and Education Act of 1990,* as amended, and regulations developed thereunder, the *Code of Federal Regulations* and the *Pasteurized Milk Ordinance (PMO)*.

B. Dairy plants which offer milk, milk products and condensed, concentrated or dry dairy products for sale in the state shall use labels which prominently display the grade of the product when grades for such products have been established by the state health officer.

C. All bottles, containers, wrappers and packages of a capacity of six gallons or less which enclose milk and milk products, shall be conspicuously marked with:

1. the name and address of the plant or Federal Information Processing Standards (FIPS) number [in indelible ink (or equivalent)] of the plant where the contents were pasteurized, ultra-pasteurized or aseptically processed. The name and address of the plant or the FIPS number shall be printed on the container or label in such a manner that it cannot be removed, changed or defaced;

2. a date, code or lot number that identifies the date, run or batch from which the contents originated, shall be prominently displayed on each final container (container that will reach the final consumer) of dairy product in indelible ink (or equivalent). The date, code or batch shall be printed on the container or label in such a manner that it cannot be removed, changed or defaced;

3. the words, “keep refrigerated after opening”, in the case of aseptically processed dairy products;

4. the name of the dairy product followed by the words “with vegetable fat” conspicuously displayed on the principal display panel in cases in which the product is a filled milk, filled milk product or filled dairy product. The letters in the words “with vegetable fat” shall be at least as large and as prominent as the letters in the name of the dairy product. Examples of this requirement include: “low fat milk with vegetable fat”, “cultured cream with vegetable fat”, “evaporated non fat milk with vegetable fat”;

5. the word, “goat”, “sheep”, “water buffalo” or the common name of any other hooved mammals shall precede the name of the milk and milk product when the product is made from the milk of animals other than cows;

6. the words “grade a”, “grade b”, “extra grade” or “standard grade” whichever is appropriate on the exterior surface when grades for the product have been established by the state health officer. Acceptable locations shall include the principal display panel, the secondary or informational panel or the cap/cover;

7. the words, “a product of”, followed by the name of the country in which the product was processed, except in

cases in which the product was processed in the United States or Puerto Rico.

8. the word "reconstituted" or "recombined" if the product was made by reconstitution or recombination; and,

9. the words "made from unpasteurized milk" shall be prominently displayed on the principal display panel of each container of dairy product made from milk, milk products, anomalous milk or anomalous milk products, filled milk or filled milk products, imitation milk or imitation milk products in which each particle has not been pasteurized, ultra-pasteurized or aseptically processed except ripened (aged) cheeses.

D. Approval of the state health officer shall be obtained for all labels used on dairy products prior to the product being offered for sale in Louisiana.

E. All labeling of dairy products shall not be false or misleading in any particular in accord with the requirements of R.S. 40:608 (misbranded food).

F. Containers of dairy products, for which a grading protocol has been established shall be labeled with the appropriate grade of the product.

G. Containers labeled with a grade that contain products that do not conform with the requirements of this Part for that grade shall not be sold or offered for sale in this state.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17), R.S. 40:604, and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

Chapter 3. Sampling, Examination, Inspections, Grading, Enforcement Procedures and Standards of Dairy Products Including Frozen Desserts

§301. General Requirements

A. Each dairy facility (dairy farm, receiving station, transfer station, dairy plant, single service containers and closures for milk and milk products manufacturing plant, milk tank truck, milk tank truck cleaning facility, finished product depot, final product transfer point) domiciled in the state shall conform with each requirement contained in this Part that is determined to be applicable to such facilities by the state health officer. Each dairy product brought into Louisiana from outside of the state for consumption within the state shall comply with each standard and specification determined by the state health officer to be applicable to each type of product and shall be produced, processed, stored, handled and distributed by dairy facilities that comply with each requirement determined by the state health officer to be applicable to each type of dairy facility involved with the products. The state health officer shall enforce each requirement for dairy facilities, contained in this Part, in a manner that is equal, impartial and equitable regardless of facility size, type, state or country in which they are domiciled. Dairy products regulated under the provisions of this Part shall be enforced in the aforesaid manner.

B. Registered sanitarians operating under the authority of the state health officer who meet the training and certification requirements for the inspection and auditing of dairy farms, milk tank trucks, dairy plants and milk and milk product containers and closure manufacturing plants shall perform all inspections and audits required of the state health officer.

C. Registered sanitarians who have extensive knowledge of dairy farm operations, milking operations, farm milk handling operations, construction, cleanliness, sanitation and operation of dairy farms and dairy farm waste facilities may apply for certification as dairy farm inspectors.

D. A certified milk Sanitation Rating Officer (SRO) certified for rating dairy farms by the PHS/FDA shall be the certification authority for dairy farm inspectors. The registered sanitarians applying for certification shall independently inspect, without prompting or any other type assistance, five dairy farms selected at random by the SRO. The SRO shall independently inspect the same five dairy farms. In order to be certified, the applicant shall agree with the SRO 80 percent on individual items of sanitation found to be violative at each of the five dairy farms inspected. After discussion with the SRO the applicant shall demonstrate, to the SRO's satisfaction, that he/she understands the items of sanitation which he/she failed to properly identify during each inspection/audit.

E. Registered sanitarians who have extensive knowledge of dairy plant and single service milk and milk products container manufacturing plant operations, equipment construction, operation, cleaning and sanitation, product processing requirements, CIP systems, pasteurizer operation, testing of pasteurization equipment and controls, butter manufacturing, cheese manufacturing and condensing and drying plant operations and sanitation requirements may apply for certification as dairy plant and single service milk and milk products containers and closures manufacturing plants inspectors. Registered sanitarians who perform Hazard Analysis Critical Control Point (HACCP) audits of dairy plants shall have successfully completed the NCIMS training requirements for state regulatory personnel conducting HACCP audits on dairy plants. SRO's who audit dairy plants shall have successfully completed the NCIMS training requirements for SRO's that perform HACCP listing audits and shall have been standardized by the PHS/FDA.

F. A certified milk Sanitation Rating Officer (SRO) certified for performing NCIMS required milk sanitation rating of milk and milk products receiving stations, transfer stations, milk and milk product plants, milk tank truck cleaning facilities and single service milk and milk products container manufacturing plants by the PHS/FDA shall be the certification authority for dairy plant and single service milk and milk products containers plant inspectors. The registered sanitarians applying for certification shall inspect at least two milk and milk products processing plants, one single service milk and milk products container and closure manufacturing plant, one condensing and drying plant (provided such plant exist within the state) and one cheese manufacturing plant without prompting or assistance of any type. The SRO shall independently inspect the same plants that were inspected by the applicant. In order to be certified, the applicant shall agree with the SRO 80 percent on individual items of sanitation found to be violative at each of the plants inspected. After discussion with the SRO, the applicant shall demonstrate to the SRO's satisfaction, that he/she understands the items of sanitation which he/she failed to properly identify during each inspection.

G. Registered sanitarians who have extensive knowledge of milk tank truck operations, construction, cleaning and sanitization and of all equipment used in the loading,

unloading, cleaning and sanitation of milk tank trucks, requirements for bulk milk tank truck operators/samplers, milk plant receivers/samplers may apply for certification as milk tank truck inspectors.

H. A certified milk SRO certified by PHS/FDA for performing NCIMS required milk sanitation ratings on milk and milk products, receiving stations, transfer stations, milk and milk products plants, milk tank truck cleaning facilities and single service milk and milk products containers and closure manufacturer plants shall be the certification authority for milk tank truck inspectors. The registered sanitarian applying for certification or re-certification shall inspect at least five milk tank trucks selected at random by the SRO without prompting or assistance of any type. The SRO shall independently inspect the same milk tank trucks that were inspected by the applicant. In order to be certified, the applicant shall agree with the SRO 80 percent on individual items of sanitation found to be violative on each of the five milk tank trucks inspected. After discussion with the SRO, the applicant shall demonstrate to the SRO's satisfaction, that he/she understands the items of sanitation which he/she failed to identify during each inspection.

I. Personnel operating under the authority of the state health officer, including farm bulk milk tank truck operators/samplers licensed by the state health officer shall meet all requirements for personnel who collect official samples contained in this Part and the PMO and any NCIMS requirements for such personnel.

J. Personnel operating under the authority of the state health officer who programmatically supervise registered sanitarians who inspect or audit dairy facilities shall meet all certification requirements contained in this part for the certified inspectors whom they supervise. Certification of registered sanitarians who inspect dairy farms and milk tank trucks and inspect or audit dairy plants and single service milk and milk products containers and closure manufacturing plants shall be for a period not to exceed two years and may be revoked by the state health officer for cause.

K. All registered sanitarians operating under the authority of the state health officer who are certified to inspect/audit dairy facilities shall be physically capable of inspecting/auditing all areas of the type of dairy facility and equipment therein, for which they are certified.

L. All registered sanitarians operating under the authority of the state health officer shall conform with the safety, dress, speed limit and other such regulations of the facility pertaining to the employees of that specific facility, while they are on the premises of the facility. They shall also comply with all such requirements of the Milk and Dairy Program.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17)(19)(21) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1263 (June 2002), amended LR 37:

Subchapter A. Sampling and Examination of Dairy Products Including Frozen Desserts

§303. Delivery of Samples

A. All persons engaged in the production, processing, handling or selling of milk, milk products or other dairy products shall deliver to the state health officer, upon request, samples of the dairy products in his possession. The state health officer shall not be required to pay for these samples. Any refusal to deliver such samples in his possession shall be deemed a violation of these regulations. All samples so collected shall be sealed, when possible, in the presence of the person from whom taken.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S.40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1263 (June 2002), amended LR 37:

§305. Samples and Examinations

A. Samples of milk, milk products or other dairy products from stores, soda fountains, restaurants, finished product depots and other places where dairy products are handled, stored or sold shall be examined to determine compliance with the product standards contained in this Part as often as the state health officer may require.

B. The state health officer shall collect samples of milk, milk products or other dairy products being sold within the state that were processed by each dairy plant domiciled in other states or countries and test them for compliance with the standards for such products contained in this Part as required by the state health officer.

C. Samples of milk, milk products or other dairy products shall be taken prior to sale to the final consumer. Samples of dairy products collected from containers other than dairy product storage, processing or bulk transportation tanks or totes that have been opened/uncapped shall not be considered official.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S.40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1263 (June 2002), amended LR 37:

§307. The Official Sampling of Dairy Plant Environments and Dairy Products Including Frozen Desserts

A. Each bulk milk tank truck operator/sampler shall collect a representative sample of raw milk from each farm bulk tank prior to transferring the milk from the farm bulk tank to a milk tank truck each time raw milk is removed from the farm bulk tank. All samples shall be collected as directed by the state health officer and at least one set of samples collected from each farm bulk tank of each dairy farm supply represented in the load shall accompany the load of milk to the dairy plant, receiving station or transfer station at which it is unloaded.

B. Each dairy plant receiver/sampler shall collect a representative sample of raw milk from each tanker of raw milk that unloads at the plant each day. The dairy plant receiver/sampler shall obtain one set of the samples, collected by the bulk milk tank truck operator sampler, from each farm bulk tank of raw milk represented on the loads of raw milk from which the tanker samples were obtained. The dairy plant receiver/sampler shall store all of the samples in a manner consistent with the requirements of this Part and deliver them to the state health officer when requested.

C. The state health officer may sample the environments of each dairy plant using approved methodology for the sampling of plant environments for contamination with

pathogenic microorganisms of human significance as often as he deems necessary. Controlling the environments of dairy plants to prevent contamination with pathogenic microorganisms is of utmost public health importance.

D. During each consecutive six months, at least four samples of raw milk for pasteurization, ultra-pasteurization and aseptic processing shall be collected in at least four separate months, except when three months show a month in which two of the sampling dates were separated by at least 20 days, and delivered in accordance with the requirements of this section from each farm bulk tank of each producer. These samples shall be obtained under the direction of the state health officer or shall be collected from each producer by the state health officer.

E. During each consecutive six months, at least four samples of commingled raw milk for pasteurization, ultra-pasteurization or aseptic processing, collected in at least four separate months, except when three months show a month containing two sampling dates separated by at least 20 days, shall be taken from each dairy plant after receipt of the milk by the plant and prior to pasteurization, ultra-pasteurization or aseptic processing by the state health officer.

F. During each consecutive six months, at least four samples of heat-treated milk and milk products, from each plant offering such products for sale, shall be collected in at least four separate months, except when three months show a month containing two sampling dates separated by at least 20 days, by the state health officer.

G. During each consecutive six months, at least four samples of each type of dairy product being processed by each dairy plant domiciled within the state shall be collected by the state health officer. Each fat level of product, each flavor of flavored products, and each type of cultured product shall be sampled by the state health officer. The state health officer shall attempt to collect these samples of product in each size and type of container packaged by each plant.

H. During each consecutive 12-month period the state health officer shall collect from each dairy plant domiciled in Louisiana at least one sample of each dairy product to which vitamins have been added.

I. If production of any dairy product, for which a grading system is prescribed by this Part, is not on a yearly basis at least five samples shall be taken within a continuous production period.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1263 (June 2002), amended LR 37:

§309. Laboratory Examination of Dairy Products Including Frozen Desserts and Tests for Environmental Pathogens

A. The following laboratory examinations shall be performed on milk and dairy products, including frozen desserts:

1. Standard plate counts, drug residue tests, somatic cell counts and cooling temperature checks shall be performed on raw milk for pasteurization, ultra-pasteurization and aseptic processing from each producer's milk supply domiciled in the state at a frequency required in §307.D on samples collected by the state health officer or under the direction of the state health officer.

2. Standard plate counts, drug residue tests and cooling temperature checks shall be performed on commingled raw milk for pasteurization, ultra-pasteurization and aseptic processing from the supply of each dairy plant domiciled in Louisiana at a frequency required in §305.E on samples collected by the state health officer.

3. Sediment tests, tests for aflatoxins, beta lactams, tetracyclines, sulfonamides, tests for added water and other tests determined to be necessary by the state health officer shall be performed on raw milk samples collected from each farm bulk milk tank truck load of raw milk that unloaded at each dairy plant, transfer station and receiving station on two consecutive days during each consecutive six month period. These tests shall be performed at the Milk and Dairy Residue Monitoring Facility.

4. All raw milk samples collected from each farm bulk milk tank represented on each load of raw milk that was found to have a USDA sediment standard that exceed number three or was found to be positive for any of the other tests listed in §309.A.3 above shall be tested using the same test from which the sediment result that exceed three or the positive result on the other tests were obtained on the sample from the load of raw milk. These tests shall be performed at the Milk and Dairy Residue Monitoring Facility.

5. Standard plate counts, drug residue tests and temperature checks, which are determinated to be necessary by the state health officer, shall be performed on each type of heat treated dairy product processed by each dairy plant domiciled in the state at a frequency required in §307.F on samples collected by the state health officer.

6. Standard plate counts, coliform counts, drug residue tests, phosphatase tests and cooling temperature checks, which are determined to be necessary by the state health officer shall be performed on each type of dairy product, including frozen desserts, processed by each dairy plant domiciled in the state at a frequency required in §307.G on samples collected by the state health officer or under the direction of the state health officer,

7. Standard plate counts, drug residue tests, coliform counts and cooling temperature checks shall be performed on condensed and concentrated dairy products produced by each dairy plant domiciled in the state at a frequency required in §307.G on samples collected by the state health officer or under the direction of the state health officer,

8. Standard plate counts and coliform counts shall be performed on each type of dry dairy product processed or blended by each dairy product drying or dairy product blending plant domiciled in the state at a frequency required in §307.G on samples collected by the state health officer or under the direction of the state health officer,

9. Drug residue tests determined to be appropriate by the state health officer shall be performed on each type of aseptically processed dairy product produced by each dairy plant domiciled in the state at a frequency required in §307.G on samples collected by the state health officer or under the direction of the state health officer.

10. Tests for contamination of finished products with pesticides, herbicides, PCB's, etc., shall be performed at intervals determined by the state health officer, on all finished products being sold or produced in Louisiana.

B. All sampling procedures and required laboratory examinations shall be conducted in laboratories approved by the state health officer and shall be in substantial compliance with the requirements of the *PMO,* the *Standard Methods for the Examination of Dairy Products, the Official Methods of Analysis.* Such procedures, including the certification of sample collectors and examinations shall be evaluated by the state health officer in accordance with the *Evaluation of Milk Laboratories.* Aseptically processed milk and milk products packaged in hermetically sealed containers shall be tested in accordance with the *Bacteriological Analytical Manual.* Examinations and tests to detect adulterants, including pesticides, shall be conducted as the state health officer requires. Assays of dairy products to which vitamin A, vitamin D or vitamins A and D have been added, shall be made at least annually in a laboratory which has been accredited by the U. S. Food and Drug Administration and which is acceptable to the state health officer, using test methods acceptable to the FDA and other official methodologies which give results statistically equivalent to the FDA methods.

C. All facilities fortifying products with vitamins shall keep volume control records. These volume control records shall cross reference the form and amount of vitamin D, vitamin A or vitamins A and D used with the amount of product produced and indicate a percent (plus or minus) of expected use.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1263 (June 2002), amended LR 37:

Subchapter B. Inspections/Audits

§311. Frequency of Inspections/Audits

A. Each dairy farm, dairy plant including frozen desserts manufacturing plant, filled dairy products manufacturing plant, anomalous milk and milk products and other anomalous dairy product manufacturing plant, receiving station, milk tank truck cleaning facility, transfer station, single-service containers and closures for milk and milk products manufacturing plant, finished product depot/transfer point and dairy plant receiver/sampler, bulk milk tank truck operator/sampler and milk tank truck domiciled or operating in the state shall be inspected/audited by the state health officer prior to the issuance of a permit.

B. Following the issuance of a permit the state health officer shall:

1. Inspect the receiving, processing/packaging, cleaning, pre-operation and start-up procedures of each dairy plant including frozen dessert manufacturing plants at least once each month. (For the purposes of this Paragraph, the term "dairy plant" used herein shall not include receiving stations, transfer stations, single-service containers and closures for milk and milk products manufacturing plants, milk tank truck cleaning facilities and finished product depot/transfer points.)

2. Inspect receiving stations, transfer stations, single-service containers and closures for milk and milk products manufacturing plants, milk tank truck cleaning facilities and finished product depot/transfer point at least once each three months.

3. Inspect/audit each dairy plant, including frozen dessert manufacturing plants, that are required by the state health officer to implement HACCP systems or have been authorized by the state health officer to be regulated under the HACCP requirements contained in Chapter 11 of this Part with a frequency goal of at least once each month.

4. Inspect each milk tank truck and its appurtenances at least once each 12 months.

5. Observe and evaluate the receiving and sampling procedures of each dairy plant receiver/sampler at least once each three months to determine compliance with applicable requirements.

6. Observe and evaluate the milk pickup and sampling procedures of each bulk milk tank truck operator/sampler at least once each 24 months to determine compliance with applicable requirements.

7. Inspect each dairy farm with a frequency at least as that required by the Performance-Based Inspection Program.

C. Performance-Based Inspection Program requirements:

1. A risk assessment shall be performed on each dairy farm once each month by evaluating the performance of the farm using the last standard plate count, somatic cell count, sanitation compliance score, sediment score, drug residue test, coliform count of the water supply and other areas of the operation related to product safety as the criteria for establishing the Inspectional Frequency Category for the dairy farm.

2. The state health officer shall inspect dairy farms in each category at a frequency not less than the following intervals:

a. category I: at least once each three months;

b. category II: at least once each two months;

c. category III: at least once each month; and,

d. category IV: within 21days of the last inspection but not before the lapse of three days.

3. The following criteria shall be used to categorize farms into the Inspection/Frequency Categories as defined below:

a. Category I (minimum of one inspection each three months):

i. standard plate count (SPC) not exceeding 10,000 cfu/milliliter (ml.);

ii. somatic cell count (SCC) not exceeding 250,000/ml;

iii. sanitation compliance score 97 percent - 100 percent;

iv. sediment not exceeding four;

v. no drug residue violations;

vi. no violation which may reasonably likely result in adulteration of
the milk supply or an imminent hazard to the public's health; and,

vii. bacteriologically safe water supply.

b. Category II (minimum of one inspection each two months):

i. SPC 11,000 cfu/ml. - 50,000 cfu/ml;

ii. SCC 251,000/ml. - 500,000/ml;

iii. sanitation compliance score 93 percent - 96 percent;

iv. sediment not exceeding four;

v. no drug residue violations;

vi. no violation which may reasonably likely result in adulteration of the milk supply or an imminent hazard to the public's health; and,

vii. bacteriologically safe water supply.

c. Category III (minimum of one inspection each month):

i. SPC 51,000 cfu/ml.—100,000 cfu/ml;

ii. SCC 501,000/ml.—750,000/ml;

iii. sanitation compliance score 90 percent—92 percent;

iv. sediment not exceeding four;

v. no drug residue violations;

vi. no violation which may reasonably likely result in adulteration of the milk supply or an imminent hazard to the public's health; and,

vii. bacteriologically safe water supply.

d. Category IV (inspect within 21days of the last inspection, but not before the lapse of three days):

i. SPC not exceeding 100,000 cfu/ml.;

ii. SCC not exceeding 750,000/ml.;

iii. sanitation compliance score less than 90 percent;

iv. sediment four;

v. one or more drug residue violation(s);

vi. one or more violation(s) that may reasonably likely result inadulteration of the milk supply or an imminent hazard to the public's health;

vii. unsafe water supply.

viii. one or more warning letters issued due to non-compliance of two out of four previous sample results for SPC or SCC during last two months; and,

ix. farm conditions which caused the state health officer to take official regulatory action (i.e.; warning letter, intent to suspend, reinspection, etc).

4. When the risk assessment of a dairy farm indicates a category IV in one or more criteria the next inspection of the dairy farm should include:

a. an evaluation of the cleaning equipment and procedures when the SPC category is IV;

b. an evaluation of milking procedures and the environment of the areas of the farm in which the milking herd is kept when the SCC category is IV;

c. a conference with the owner/operator when the sanitation compliance score category is IV; and,

d. an evaluation of the milking procedures, milking equipment and the environment of the areas of the farm in which the milking herd is kept when the sediment category is IV.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1264 (June 2002), amended LR 37:

§313. Pasteurization Equipment Tests, Examinations and Sealing

A. The state health officer shall perform the tests using the methodology prescribed in the *PMO* on the instruments and devices of each pasteurizer in each dairy plant and frozen dessert manufacturing plant indicated in the table below initially upon installation; and at least once each three months, including the remaining days of the month in which the equipment tests are due and whenever any alteration or replacement is made which may affect the proper operation of the instrument or device. Provided, that the holding time test shall be conducted at least once each six months, including the remaining days of the month in which the equipment test is due. A copy of the test report shall be retained by the plant.

Test No.	Equipment/Device/ Instrument	Test Type
1	Vat, HTST, HHST, aseptic indicating and airspace thermometers	Temperature accuracy
2	Vat, HTST, HHST, aseptic recording thermometer	Temperature accuracy
3	Vat, HTST, HHST, aseptic recording thermometer	Time accuracy
4	Vat, HTST, HHST, aseptic indicating and recording thermometer	Recording vs Indicating thermometer
5.1	HTST, HHST FDD	Leakage pass FDD
5.2	HTST, HHST FDD	FDD freedom of movement
5.3	HTST, HHST FDD	Device assembly (single stem)
5.4	HTST, HHST FDD	Device assembly (dual stem)
5.5	HTST FDD	Manual diversion
5.6	HTST, HHST FDD	Response time
5.7	HTST, HHST FDD	Time delay (inspect)
5.8	HTST, HHST FDD	Time delay (CIP)
5.9	HTST FDD	Time delay (leak detect flush)
6	Vat leak protector valve(s)	Leakage
7	HTST indicating thermometers	Response time
8	HTST recording thermometers	Response time
9.1	HTST pressure switches	Regenerator pressures
9.2.1	HTST, HHST, aseptic differential pressure controllers	Calibration
9.2.2	HTST differential pressure controllers	Regenerator pressure
9.2.3	HHST and aseptic differential pressure controllers	Regenerator pressure
9.3.1	HTST booster pump/FDD	Inter-wiring check
9.3.2	HTST booster pump/metering pump	Inter-wiring check
10.1	HTST FDD	Temperature cut-in/cut-out
10.2	HHST FDD, aseptic divert system (indirect heat)	Temperature cut-in/cut-out
10.3	HHST FDD, aseptic divert system (direct heat)	Temperature cut-in/cut-out
11.1	HTST holding tubes/timing pumps (except meter based)	Holding time
11.2.a	HTST holding tubes/magnetic flow meter based timing systems	Holding time
11.2.b	HTST, HHST, aseptic magnetic flow meter based timing systems	Flow alarm
11.2.c	HTST, HHST, aseptic magnetic flow meter based timing systems	Loss of signal/low flow
11.2.d	HTST magnetic flow meter based timing systems	Flow rate cut-in/cut-out

Test No.	Equipment/Device/ Instrument	Test Type
11.2.e	HTST magnetic flow meter based timing systems	Time delay
11.3	HHST holding tubes indirect heat	Holding time
11.4	HHST holding tubes direct injection heat	Holding time
11.5	HHST holding tubes direct infusion heat	Holding time
12.1	HHST, aseptic systems indirect heating	Sequence logic
12.2	HHST, aseptic systems direct heating	Sequence logic
13	HHST, aseptic systems	Pressure in the holding tubes
14	HHST, aseptic systems using direct injection heating	Pressure differential across injector
15	Vat, HTST, HHST, Aseptic (all electronic controls)	Electro-Magnetic Interference

B. Plants being regulated under the provisions of Chapter 11 (Dairy Plant HACCP System) shall be responsible for the performance for all above required tests should the state health officer fail to perform them at the required frequency.

C. The state health officer shall affix regulatory seals to all pasteurization equipment, as prescribed by the *PMO*, after testing the equipment.

D. The state health officer shall provide the plant a copy of the pasteurization equipment test report.

E. The plant shall notify the state health officer immediately if the regulatory seals are broken.

F. The pasteurization equipment shall not be operated without authorization from the state health officer when any of the required regulatory seals are broken.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1264 (June 2002), amended LR 37:

§315. Milk Sanitation Rating/HACCP Listing Audit

A. Except for those dairy facilities which require a HACCP Listing audit, a milk sanitation rating shall be conducted on each bulk milk tank unit (BTU), single service container and closure manufacturer plant, milk tank truck cleaning facility, receiving station, transfer station, milk and milk products plant, and Grade A condensing and drying plant at least once each year by a certified milk sanitation rating officer using the methodology prescribed in the *Methods of Making Sanitation Rating of Milk Shippers*. Except for those dairy facilities which require a HACCP Listing audit, an inspection of all other dairy plants shall be conducted by a certified milk sanitation rating officer at least once each year using the requirements for that specific type of plant contained in this Part.

B. A HACCP listing audit shall be conducted on each dairy facility being regulated under the HACCP requirements of this Part at least once each year by a certified milk sanitation rating officer that has been standardized and certified as a HACCP listing officer by the FDA.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1264 (June 2002), amended LR 37:

§317. Posting Inspection Reports

A. One copy of each inspection/audit report shall be handed to the operator or posted by the state health officer in a conspicuous place upon an inside wall of one of the dairy farm or dairy plant buildings, and said inspection report shall not be defaced and shall be made available to the state health officer upon request. The original of the inspection report shall be filed with the records of the state health officer.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1264 (June 2002), amended LR 37:

§319. Field Supervision

A. Each Bulk Tank Unit (BTU) or others receiving milk from one or more dairy farms shall provide qualified field persons for the purpose of inspecting and testing sources of supply and assisting producers.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1264 (June 2002), amended LR 37:

Subchapter C. Grading, Enforcement Procedures and Standards

§321. Grading

A. The state health officer shall establish grades and grading protocols for milk, milk products, condensed, concentrated and dried milk products.

B. The state health officer shall grade all milk, milk products, condensed, concentrated and dried milk and milk products produced or processed in the state.

C. The grade of the products shall be based upon:

1. compliance with the regulations governing milk production, milk and milk products and condensed, concentrated or dried dairy products processing and handling contained in this Part; and

2. compliance with the standards for milk and milk products contained in this Part as determined by the examination of at least four samples of milk or milk products and condensed, concentrated or dried dairy products during the current six month period, collected from each supply on separate days production by the state health officer.

D. All cartons, jugs, packages, wrappers, bottles or other containers enclosing graded milk, milk products and condensed, concentrated or dried dairy products shall be conspicuously marked with the grade of the contents on the principal display panel, secondary or informational panel or the cap/cover.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1264 (June 2002), amended LR 37:

§323. Grades of Milk and Milk Products to be Sold

A. All milk and milk products sold to the final consumer or to restaurants, delicatessens, grocery stores and any other

establishments that provide milk or milk products for human consumption shall be Grade A pasteurized, Grade A ultra-pasteurized or Grade A aseptic processed (UHT), provided that dry milk products sold or provided for human consumption may be Extra Grade, provided further that all milk and milk products (except Extra Grade dry milk products) provided to institutions who receive funds from the United States Government or the State of Louisiana for the purchase of milk and milk products shall be Grade A pasteurized, ultra-pasteurized or aseptically processed milk and milk products certified for interstate shipment.

B. Provided, that when the grade of a Grade A product has been lowered to Grade B, the state health officer may authorize the sale of the Grade B milk or milk product for a temporary period, not to exceed 30 days, provided further that the words Grade B shall prominently appear on the principal display panel of all containers of such product.

C. Provided further that extra grade and standard grade dry milk and milk products and ungraded evaporated milk or sweetened condensed milk in containers that have been retort processed after packaging may be sold to the final consumer, restaurants, institutions, grocery stores or other establishments that provide dry milk or milk products or evaporated, concentrated or condensed milk.

D. All raw milk from cows, goats, sheep, water buffaloes and other hooved mammals produced by dairy farms for sale to dairy plants domiciled in Louisiana shall be Grade A raw milk for pasteurization, provided that when the grade of a raw milk supply has been lowered to manufacturing grade raw milk for pasteurization, the state health officer may authorize the sale of manufacturing grade raw milk for pasteurization from the degraded supply for a temporary period, not to exceed 30 days, provided further it is sold for non-Grade A use.

E. The sale, exchange or otherwise providing [including bartering, selling stock in dairy cows in exchange for raw milk, exchanging raw milk in return of animal feed or the cost of animal feed and any other such type arrangement (regardless if there is an actual sale)] of raw milk or dairy products made from raw milk (other than aged/ripened cheese processed in a plant that conforms with the requirements contained in Chapter 25 of this Part) for human or animal consumption is prohibited.

EXCEPTION: This shall not be interpreted to prohibit a farmer from providing raw milk for his/her own animals on his/her own farm.

F. Filled milk, filled milk products, imitation milk products and anomalous milk and milk products shall conform with the bacteriological requirements for Grade A pasteurized, ultra-pasteurized milk, or aseptically processed milk and milk products contained in §355 of this Part and shall be processed and packaged in plants that conform with all of the requirements for dairy plants that process Grade A pasteurized, ultra-pasteurized or aseptically processed milk and milk products contained in §901 (General Requirements for Dairy Plants) of this Part.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S.40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1264 (June 2002), amended LR 37:

§325. Procedure in Emergency

A. During emergency periods, the state health officer may temporarily permit the sale of ungraded milk.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1265 (June 2002), amended LR 37:

§327. Continuous Grading

A. If at any time the lowering of the grade of a raw milk supply or dairy product becomes justified in accordance with §329 or §333 of this Part, the state health officer shall lower the grade of such milk or milk product and shall enforce proper labeling thereof.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1265 (June 2002), amended LR 37:

Subchapter D. Degrading or Suspension of Permit

§329. Degrading or Suspension of Permit Based upon Physical Violations

A. If during an inspection or audit the state health officer finds a violation(s) of this Part, he shall record the violation(s) on an inspection/audit report. A copy of the inspection/audit report shall be handed to the operator or posted in a prominent place on the premises.

B. In cases in which the state health officer finds conditions or violations of this Part that he deems to be of serious nature, violations that have not been corrected since the last inspection or reoccurring violations, he shall notify the operator, in writing, of the conditions or violations and specify a reasonable time, but not before the lapse of three days, in which the conditions or violations shall be corrected. The requirement of giving written notice shall be deemed to have been satisfied by handing it to the operator or posting it in a prominent place on the premises. The operator shall be allowed to request an extension of the time allowed for correction. The state health officer may authorize an extension of time for correction when warranted by the circumstances.

C. When the state health officer has specified a time in which conditions or violations shall be corrected, as in §329.B above, he shall conduct a second inspection after the time specified. In cases in which the second inspection reveals that the conditions or violations have not been corrected to the satisfaction of the state health officer, he may lower the grade of the milk supply or dairy product. In cases in which grades and grading criteria have not been established for a supply or a product and the second inspection reveals that any of the conditions or violations have not been corrected to the satisfaction of the state health officer, he may suspend the permit of the operator.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1265 (June 2002), amended LR 37:

§331. Notification of Laboratory Analyses

A. When two of the last four standard plate counts or temperature checks, sediment tests or somatic cell counts of a raw milk supply fail to meet the requirements contained in this Part, the state health officer shall send written notice thereof by certified or return receipt request mail to the permitee concerned and shall take an additional sample, within 21 days but not before the lapse of three days from the date of receipt of such notice.

B. When two of the last four standard plate counts or temperature checks from a heat treated dairy product supply fail to meet the requirements contained in this Part, the state health officer shall send written notice thereof by certified or return receipt request mail to the permitee concerned and shall take an additional sample, within 21 days but not before the lapse of three days from the date of receipt of such notice.

C. When two of the last four standard plate counts or coliform counts or temperature checks from a pasteurized dairy product, including frozen desserts, filled dairy products and anomalous dairy products fail to meet the requirements contained in this Part, the state health officer shall send written notice thereof by certified or return receipt request mail to the permitee concerned and shall take additional sample, within 21 days but not before the lapse of three days from the date of receipt of such notice.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1265 (June 2002), amended LR 37:

§333. Degrading or Suspension of Permit or Removal of Product from the Market Based upon Laboratory Analyses

A. In cases in which the written notice required in §331 of this Part has been received by the operator and whenever three of the last five samples fail to meet the standard plate count, coliform count, sediment score, temperature check or somatic cell count requirements of this code unless the last individual sample result meets the requirements, the state health officer shall:

1. Degrade the raw milk supply or dairy product to the appropriate grade, in cases in where grades and grading protocol have been established.

2. Suspend the operator's permit in cases where grades and grading protocol have not been established, provided that the state health officer may allow the operator to discontinue the sale of the violative product(s) rather than suspend the permit.

B. Whenever a phosphatase test result is positive, suspend the permit for the product, place all product that is reasonably likely to have not been properly pasteurized under official seizure and require that any such product that has entered commerce be recalled by the processor and disposed of as directed by the state health officer.

C. Whenever pathogenic microorganisms of human significance are found in a dairy plant environment, require the plant operator to submit a written corrective action plan for eliminating and preventing the reoccurrence of the contamination to the state health officer for approval. The state health officer shall, during each inspection/audit determine whether or not the plant is in conformity with the written corrective action plan. Failure to conform with the approved corrective action plan shall be grounds for suspension of permit.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1265 (June 2002), amended LR 37:

§335. Suspension of Permit Based on Laboratory Analyses - Adulteration or Contamination with Pathogenic Microorganisms of Human Significance

A. Should any raw milk supply or dairy product including frozen desserts, anomalous milk and milk products and filled dairy products be found to be adulterated (water, drug residues, pesticide/herbicides, etc.), the state health officer shall immediately suspend the permit and place all product that may reasonably likely be adulterated, under official seizure. The state health officer shall require that the owner of the adulterated product, expeditiously remove any of the product that had entered commerce and to comply with instructions from the state health officer for the disposition of such product.

B. Should any pasteurized dairy product, including frozen desserts, anomalous milk and milk products and filled dairy products be found to contain one or more pathogenic microorganisms of human significance, the state health officer shall immediately suspend the permit and place all contaminated product and all product reasonably likely to be contaminated under official seizure. The state health officer shall require the owner of the product to expeditiously remove any of the product that had entered commerce and to comply with instructions from the state health officer for the disposition of such product. Provided, further, that raw and heat treated dairy products are excluded from this requirement.

C. Whenever the pasteurization recording charts for products requiring pasteurization are not available for review, the state health officer shall suspend the permit for the product and place under official seizure and require that any product involved that has entered commerce be recalled by the processor and disposed of as directed by the state health officer.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1265 (June 2002), amended LR 37:

§337. Suspension of Permit for Reasons Other than Laboratory Analyses

A. The state health officer shall immediately suspend the permit to operate when:

1. the state health officer finds a condition(s) existing on a dairy farm, in a dairy product manufacturing plant (including frozen desserts manufacturing plant and filled dairy products manufacturing), single service milk container or closure manufacturing plant or at a finished product depot/transfer point that he determines is reasonably likely to constitute an imminent hazard to the public's health;

2. a series of observations made during an inspection or audit is determined by the state health officer to indicate

that a plant does not have sufficient control of its operations to prevent a compromise to food safety;

3. the holder of the permit or his employees or agents interfere with the state health officer in the performance of his duties; or,

4. the holder of the permit or his employees have falsified documents, charts or other records pertaining to the safety of dairy products.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1265 (June 2002), amended LR 37:

§339. Seizure and Condemnation of Milk, Dairy Products, Ingredients of Milk and Ingredients of Dairy Products

A. Any milk, milk product or other dairy product, ingredient or component of such products that the state health officer determines to be adulterated, misbranded or not registered or which has been manufactured, processed or packaged in an establishment, which did not, at the time of manufacture, processing or packing, hold a valid permit issued by the state health officer is subject to seizure and condemnation by the state health officer as provided in §§632, 633, 634 and 635 of the State of Louisiana Food, Drug and Cosmetic Law, which is found in Part I, Chapter 4, Title 40 of the Louisiana Revised Statutes, as well as any applicable regulations which implement this law.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1265 (June 2002), amended LR 37:

Subchapter E. Regrading and Reinstatement of Permit

§341. Application for Regrading, Reinstatement of Permit and Permission to Resume Sale of Product

A. Any producer or processor, the grade of whose milk supply or dairy products has been lowered or whose permit has been suspended by the state health officer, and who is properly labeling his dairy products, or who has removed the product from the market and has corrected the condition(s) that resulted in the suspension of the permit or degrade, may at any time make application for the regrading of his product or reinstatement of his permit or for being allowed to resume the sale of a product that has been removed from the market.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1265 (June 2002), amended LR 37:

§343. Regrading or Reinstatement of Permit when Degrade or Suspension was Based on Laboratory Analyses

A. Upon receipt of a satisfactory application from the operator, when the lowered grade or suspension of permit is the result of violative standard plate counts, violative coliform counts, violative temperatures, violative somatic cell counts, or violative sediment scores the state health officer shall take additional samples of the applicant's output at a rate of one sample from a single day's production and not more than two samples per week. The state health officer may:

1. regrade the milk supply or dairy product upward, whenever a minimum of two successive samples meet the grade requirements of a higher grade provided they are the last two samples collected; or

2. reinstate the permit of the manufacturer or allow the sale of a non-grade product that has been removed from the market whenever a minimum of two successive samples meet the bacteriological or chemical standards for such non-graded products, provided they are the last two samples collected.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1265 (June 2002), amended LR 37:

§345. Regrading and Reinstatement of Permit when Degrade or Suspension was Based on Physical Violations

A. Whenever a suspension of a permit or the lowering of grade of a product or supply was the result of a violation of an item of these regulations other than laboratory results, the application referenced in §341 of this Part must be accompanied by a statement signed by the applicant stating that the violative item(s) of the regulations has been corrected. Within one week of receipt of such an application and statement, the state health officer shall make a re-inspection of the applicant's establishment, and thereafter as many additional re-inspections as may be deemed necessary, to verify that the applicant is again complying with the requirements. When the findings justify, he may reinstate the permit and re-grade the milk supply or dairy product upward.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1266 (June 2002), amended LR 37:

§347. Reinstatement of Permit when Suspension was Based upon Adulteration of Product or Contamination of Pasteurized Product or Cheeses with Pathogenic Microorganisms of Human Significance

A. Upon receipt of a satisfactory application and a statement, signed by the applicant, certifying that the cause of the adulteration has been corrected and all product that was involved has been recalled, from an operator whose permit was suspended based upon adulteration of product, the state health officer shall take additional samples of the applicants milk supply or dairy product. The state health officer may reinstate the permit when a sample result indicates the supply or product is in compliance, provided that it is the last sample collected. Provided further that in cases in which the suspension of permit was due to a dairy farm's drug residue violations of *Appendix N* of the *PMO* the state health officer shall make an inspection of the applicant's dairy farm and as many additional inspections as deemed necessary by the state health officer to assure that the applicant is again in substantial compliance with all applicable requirements. Said application shall be

accompanied by a statement, signed by the applicant, to the effect that the cause of the violation has been corrected.

B. Upon receipt of a satisfactory application from an operator whose permit was suspended based upon contamination with pathogenic microorganisms of human significance and a written corrective action plan for eliminating and preventing a reoccurrence of the contamination the state health officer shall:

1. Review the corrective action plan and determine whether or not it is satisfactory. The state health officer may reject the plan when, in the state health officer's opinion, it is not satisfactory.

2. Upon concurring with the corrective action plan; inspect the dairy plant to determine whether the corrective action plan has been implemented to the state health officer's satisfaction. In cases in which the plant is not domiciled in Louisiana, the state health officer may accept certification that the plan has been implemented from the dairy regulatory agency of that state or country. In cases in which the state health officer deems that the regulatory agency of a state or country is not technically capable of providing acceptable assurance that the corrective action plan is being properly implemented, the state health officer shall perform such inspections. The dairy plant shall be required to pay all expenses the state health officer incurs in making the inspections. Failure to adhere to the corrective action plan at any time may constitute grounds for suspension of permit.

3. Take additional samples of the applicant's product(s).

4. The state health officer may reinstate the permit when the samples indicate the product no longer contains pathogenic microorganisms of human significance and the corrective action plan to prevent a reoccurrence of the problem has been implemented to the state health officer's satisfaction.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1266 (June 2002), amended LR 37:

Subchapter F. Standards and Specification for Grades of Milk and Milk Products

§349. Grade A Raw Milk for Pasteurization

A. Grade A raw milk for pasteurization is raw milk produced on dairy farms which are in substantial compliance with all of the requirements of this Part for dairy farms and is in conformity with the following bacteriological, chemical and temperature standards:

1. temperature: cooled to 7°C (45°F) or less within two hours after milking, provided that the blend temperature after the first and subsequent milkings does not exceed 10°C (50EF);

2. standard plate count: individual producer milk shall not exceed 100,000 cfu per ml. prior to commingling with other producer milk;

3. standard plate count: commingled raw milk shall not exceed 300,000 cfu per ml. prior to pasteurization;

4. sediment score of less than four;

5. drug residue: no positive results from any drug residue detection test which has been determined to be appropriate by the state health officer;

6. somatic cell count: individual producer milk shall not exceed 750,000 per ml., provided that goat milk shall not exceed 1,500,000 per ml.; and

7. cryoscope reading: not higher than -0.525°Hortvet.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1266 (June 2002), amended LR 37:

§351. Grade A Raw Milk for Pasteurization (Certified for Interstate Milk Shipment)

A. Grade A raw milk for pasteurization (certified for interstate milk shipment) is raw milk, produced on dairy farms in Louisiana, that meet all requirements of this Part, as well as all the requirements of the National Conference on Interstate Milk Shipments (NCIMS) for Grade A and the requirements for inclusion in the U.S. Food and Drug Administration Interstate Milk Shippers List. In cases of conflicting provisions, the stricter codal requirement, as determined by the state health officer, shall be met.

1. Raw milk produced in Louisiana that is in substantial compliance with the provisions contained in §349.A above may be certified by the state health officer for inclusion in the U.S. Food and Drug Administration Interstate Milk Shippers List.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1266 (June 2002), amended LR 37:

§353. Manufacturing Grade Raw Milk for Pasteurization/Milk for Manufacturing Purpose/Grade B Raw Milk for Pasteurization

A. Manufacturing grade raw milk for pasteurization/mik for manufacturing purpose/Grade B raw milk for pasteurization is raw milk that may not meet bacteriological, somatic cell, chemical, sediment or temperature requirements for Grade A or is produced on dairy farms which may violate one or more of the requirements of this Part provided, that the violation thereof does not reasonably likely constitute an imminent hazard to the public's health, as determined by the state health officer.

B. Manufacturing grade raw milk for pasteurization shall conform to the following bacteriological, chemical or temperature standards.

1. Individual producer raw milk standard plate count shall not exceed 500,000 cfu per ml., prior to commingling with other producer raw milk.

2. Individual producer raw milk shall have sediment score of less than number four.

3. Commingled raw milk standard plate count shall not exceed 3,000,000 cfu per ml. prior to pasteurization.

4. Drug residue: no positive results from drug residue detection test methods contained in §349.A.5 of this Part.

5. Milk temperature shall not exceed 7°C (45°F) upon delivery to the dairy plant unless it is delivered to the dairy plant in less than two hours after milking, provided cans of manufacturing grade milk shall be cooled to 7°C (45°F) or less within four hours after each can has been filled and shall remain at that temperature or less unless delivered to a

receiving station or pasteurization plant within two hours after milking.

C. Manufacturing grade raw milk for pasteurization from degraded Grade A supplies shall be sold for non-Grade A use only and only for a period not to exceed 30 consecutive days and only when authorized by the state health officer.

D. When the state health officer finds a condition or conditions that he determines are reasonably likely to constitute an imminent hazard to the public's health he shall take immediate action to suspend the permit.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1266 (June 2002), amended LR 37:

§355. Grade A Pasteurized, Ultra-pasteurized and Aseptically Processed Milk and Milk Products, Bulk Shipped Grade A Pasteurized or Ultra-pasteurized Milk and Milk Products and Pasteurized Filled Milk and Filled Milk Products

A. Grade A pasteurized, ultra-pasteurized and aseptically processed milk and milk products are the products resulting from Grade A raw milk for pasteurization that has been pasteurized, ultra-pasteurized or aseptically processed and placed in the final container in a dairy plant that is in substantial compliance with all of the requirements for Grade A dairy plants contained in this Part. Bottling/filling/packaging of the milk or milk products shall be done in the plant in which they were pasteurized or ultra-pasteurized.

B. The milk and milk products shall conform to the standards of identity prescribed by this Part.

C. The milk and milk products, and anomalous milk and milk products and filled milk and filled milk products shall conform with the following requirements:

1. temperature: cooled to 7°C (45°F) or less and maintained thereat;

2. standard plate count: not to exceed 20,000 cfu per ml. or gram (g);

3. coliform count: not to exceed 10 per ml. or g. Provided, that in case of bulk milk transport tank shipments, shall not exceed 100 per ml.;

4. drug residue: no positive results from drug residue detection test methods as performed in accord with Appendix G, Part V, Detection of Drug Residues in Milk of the PMO which have been found to be acceptable for use with pasteurized and heat-treated milk and milk products;

5. phosphatase: less than 350 milliunits/L for fluid products and other milk products by the Fluorophos ALP (Alkaline Phosphatase) system or equivalent;

6. cryoscope reading: not higher than -0.525 EHortvet; and,

7. pathogens: no pathogenic microorganisms of human significance.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1266 (June 2002), amended LR 37:

§357. Grade A Bulk Shipped, Heat-Treated Milk and Milk Products

A. Grade A bulk shipped, heat-treated milk and milk products are the products resulting from Grade A raw milk for pasteurization that have been heat-treated in a dairy plant that is in substantial compliance with all of the requirements for Grade A dairy plants contained in this Code and is bulk shipped in bulk milk transport tanks or totes to other food product plants. The raw milk shall have been heated, one time, to temperatures greater than 52°C (125°F) but less than 72°C (161°F) for separation purposes when the resulting shipment(s) of cream, nonfat, reduced fat, low-fat milk are labeled heat-treated. In the case of heat-treated cream, the cream may be heated to less than 75°C (166°F) in a continuing heating process and immediately cooled to 7°C (45°F) or less when enzyme deactivation (such as lipase reduction) for functional purposes is required.

B. The resulting products shall conform with the standards of identity prescribed in this Part.

C. Heat-treated milk and milk products shall conform to the following temperature, bacteriological and chemical standards:

1. temperature: cooled to 7°C (45°F) or less and maintained thereat;

2. standard plate count: not to exceed 20,000 cfu per ml. or g.;

3. drug residue: no positive results from drug residue detection test methods which have been determined to be appropriate by the state health officer; and,

4. cryoscope reading: not higher than -0.525° Hortvet.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§359. Grade A Aseptically Processed Milk and Milk Products/Ultra High Temperature (UHT)

A. Grade A aseptically processed milk and milk products are the products resulting from Grade A raw milk for pasteurization that has been commercially sterilized, cooled, then placed into pre-sterilized containers, followed by aseptic hermetical sealing with a pre-sterilized closure in an atmosphere free of microorganisms. Grade A aseptically, processed milk and milk products shall conform with the requirements of *Title 21, Code of Federal Regulations (CFR), Part 113,* the requirements of the PMO and the requirements of this Part. In addition they shall conform with the following standards:

1. standards of identity prescribed in this Part;

2. drug residue: no positive results from drug residue detection test methods which have been determined to be appropriate by the state health officer;

3. phosphatase: less than 350 milliunits/L for fluid products and other milk products by the Fluorophos ALP system or Charm ALP or equivalent;

4. cryoscope reading: not higher than -0.525EHortvet; and

5. pathogens: no pathogenic microorganisms of human concern.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S.

40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§361. Grade A Pasteurized, Ultra-pasteurized and Aseptically Processed Milk and Milk Products Certified for Interstate Shipment

A. Grade A pasteurized, ultra-pasteurized and aseptically processed milk and milk products (certified for interstate milk shipment) are pasteurized milk and milk products, obtained from sources included in the NCIMS List of certified sources processed in Louisiana dairy plants, that meet all requirements of this Part as well as all the requirements of the National Conference on Interstate Milk Shipments (NCIMS) for Grade A and the requirements for inclusion in the *U.S. Food and Drug Administration Interstate Milk Shippers List* . In cases of conflicting provisions, the stricter codal requirement as determined by the state health officer shall be met.

B. Pasteurized milk and milk products processed in Louisiana that are in substantial compliance with the provisions contained §359.A above may be certified by the state health officer for inclusion in the *U.S. Food and Drug Administration Interstate Milk Shippers List.*

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§363. Grade B Pasteurized Milk and Milk Products

A. Grade B pasteurized milk or milk products are products resulting from Grade A raw milk for pasteurization and may not meet the requirements for Grade A pasteurized milk and milk products or have been pasteurized or ultra-pasteurized and placed in the final container in a dairy plant that may violate one or more of the requirements contained in this Part for Grade A dairy plants provided, further that any violation thereof does not constitute an imminent hazard to the public's health as determined by the state health officer.

B. The milk or milk products shall conform to the standards of identity prescribed by this Part.

C. The milk or milk products shall conform with the following bacteriological, chemical and temperature standards:

1. standard plate count not to exceed 50,000 cfu per ml.;

2. coliform count not to exceed 10 per ml.;

3. phosphatase less than 350 milliunits/L., for fluid products and other milk products by the Fluorophos ALP system or equivalent;

4. cryoscope reading not higher than -0.525°Hortvet;

5. no positive results from drug residue detection test method as performed in accord with Appendix G, Part V, Detection of Drug Residues in Milk of the PMO*;* and

6. no pathogenic microorganisms of human significance.

D. Grade B pasteurized milk or milk products may be sold only from supplies that were Grade A and have been degraded to Grade B for a period not to exceed 30 days and only upon authorization from the state health officer.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

Chapter 5. Requirements for Grade A Dairy Farms

§501. Approval of Plans

A. All milking barns or parlors used on dairy farms from which Grade A raw milk is offered for sale and which are hereafter constructed, reconstructed, or altered shall conform with the requirements of this Part and the PMO. All equipment with which milk comes in contact and automated cleaning equipment shall comply with applicable 3-A Sanitary Standards in design, construction, employment and use. Plans for the construction, reconstruction or alteration of dairy farm facilities domiciled within the state shall be approved by the state health officer prior to construction, reconstruction or alteration.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1266 (June 2002), amended LR 37:

Subchapter A. Health of Dairy Animals

§503. Health of Dairy Animals

A. Tuberculosis. All milk for pasteurization shall be from herds which are located in a modified accredited tuberculosis-free area, as determined by the Animal Health Program, Veterinary Services, the Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture, or the Louisiana State Livestock Sanitary Board and which have been tested for tuberculosis at least once in every six year period. Note that herds located in an area that fails to maintain such accredited status, or that has an incidence of bovine tuberculosis in excess of 0.2 percent shall have been accredited by said the Animal Health Program, Veterinary Services, the Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture, or the Louisiana State Livestock Sanitary Board, for tuberculosis-free, accredited herds, in effect at the time of the adoption of this ordinance. A certificate identifying each animal signed by the veterinarian and filed as directed by the state health officer shall be evidence of the above tests. All milk for pasteurization shall be from herds in areas which have a Modified Accredited Advanced Tuberculosis status, any herd shall have established a tuberculosis testing protocol for livestock that assures tuberculosis protection and surveillance of the dairy industry within the areas and that it is approved by the Food and Drug Administration, the U. S. Department of Agriculture and the state health officer.

B. Brucellosis. All milk for pasteurization shall be from herds under a brucellosis eradication program which meets one of the following conditions:

1. is located in a certified brucellosis-free area as defined by the U. S. Department of Agriculture and enrolled in the testing program for such areas;

2. meets the U.S. Department of Agriculture requirements for an individually certified herd;

3. participates in a milk ring testing program at least two times per year at approximately 180-day intervals and

all herds with positive milk ring results shall have the entire herd blood tested within 30 days from the date of the laboratory ring test; or

4. has an individual blood agglutination test performed annually with an allowable maximum grace period not exceeding two months.

C. Goat milk, sheep milk, water buffalo or other hooved mammal milk for pasteurization, ultra-pasteurization or aseptic processing shall be from a herd or flock which:

1. has passed an annual whole herd or flock brucellosis test as recommended by the state veterinarian or USDA Area Veterinarian in Charge (AVIC) followed by testing replacement animals or any animals entering the milking group or sold as dairy animals;

2. has passed an annual random blood-testing program sufficient to provide a statistical confidence level of 99 percent with a probability value (P-value) of 0.05. Any herd or flock with one or more confirmed positive animals shall go to 100 percent testing until the whole herd tests show no positive animals are found. Random sampling size shall be derived from *Table 1 Regulatory Statistics, 5th. Edition (June 1975) by Victor C. Beal, Jr., Program Development and Application, Veterinary Services, APHIS: Animal Health Programs;* or

3. has passed a USDA approved bulk milk test at the USDA recommended frequency.

D. Lactating animals which show evidence of the secretion of milk with abnormalities in one or more quarters, based upon bacteriological, chemical or physical examination, shall be milked last or with separate equipment and the milk shall be discarded. Lactating animals producing contaminated milk, that is, lactating animals which have been treated with, or have consumed chemical, medicinal or radioactive agents, which are capable of being secreted in the milk and which, in the judgment of the state health officer, may be deleterious to human health, shall be milked last or with separate equipment and the milk disposed of as the state health officer may direct. The state health officer may require the use of the strip cup, a mastitis screening test or bacteriological examination of the milk or any other tests he may determine to be necessary to protect the public's health.

E. For other diseases and residues of toxic substances, such tests and examinations as the state health officer may require, shall be made at intervals and by methods prescribed by him, and any diseased animal or reactors shall be disposed of as he may require.

F. Records supporting the tests required in this section shall be available to the state health officer and be validated with the signature of a licensed and accredited veterinarian or an accredited veterinarian in the employ of an official agency.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1266 (June 2002), amended LR 37:

Subchapter B. Construction and Maintenance of Grade A Dairy Farm Facilities

§505. Surroundings of Dairy Barns

A. The immediate surroundings of the dairy barn shall be kept in a neat and clean condition.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1266 (June 2002), amended LR 37:

§507. Cow Yard

A. All cow yards shall be effectively graded and drained and have no standing pools of water or accumulations of organic waste. A slab of concrete or other impervious material shall be provided, sufficient in size to hold the milking herd. Swine and poultry shall not be allowed in the cow yard.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1266 (June 2002), amended LR 37:

§509. Manure, Sewage and Liquid Waste Disposal

A. All manure shall be removed and stored or disposed of in accordance with Part XXVII in such a manner as best to prevent the breeding of flies therein or the access of cows to piles thereof. Note that in loafing free stall or pen type stables manure droppings shall be removed or clean bedding added at sufficiently frequent intervals to prevent the accumulation of manure on cows' udders and flanks and the breeding of flies.

B. Sewage shall be disposed of in a manner approved by the state health officer.

C. Liquid wastes resulting from the cleaning of cows, cleaning and rinsing of the barn and equipment, shall be properly disposed of so as not to contaminate the milk or milk equipment or milking barn or parlor, or to create a nuisance or a public health hazard.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1267 (June 2002), amended LR 37:

§511. Dairy Barn Required

A. A dairy barn or milking parlor shall be required. The barn or parlor shall be constructed in a manner approved by the state health officer.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922 .

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1267 (June 2002), amended LR 37:

§513. Milking Barn or Parlor Cleanliness

A. The interior shall be kept clean. Floors, walls, windows, pipelines, and equipment shall be free of filth or litter, and shall be clean. Swine and fowl shall be kept out of the milking barn. All pens, calf stalls, etc., shall be located and maintained so as not to have a deleterious effect upon the conditions in the milking area(s) and the milk house/room.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1267 (June 2002), amended LR 37:

§515. Lighting

A. The areas of the milking barn where cows are milked shall be provided with a minimum of 10-foot candles of well distributed light.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1267 (June 2002), amended LR 37:

§517. Ventilation

A. Sections of all dairy barns where cows are kept or milked shall be well ventilated to minimize odor and to prevent condensation upon walls and ceilings.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S.

40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1267 (June 2002), amended LR 37:

§519. Floors

A. The floors and gutters of such parts of all dairy barns in which cows are milked shall be constructed of concrete or other impervious and easily cleaned material which has been approved by the state health officer. It shall be graded to drain and shall be in good repair.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1267 (June 2002), amended LR 37:

§521. Walls and Ceilings

A. The walls and ceilings of all dairy barns shall be smooth, painted or finished in a manner approved by the state health officer and shall be kept clean and in good repair. In case there is a second story above that part of the barn in which cows are milked, the ceiling shall be dust-tight. If the feed room adjoins the milking space it shall be separated therefrom by a dust-tight partition and door. Feed may be stored in the milking portion of the barn only in such a manner as will not increase the dust content of the air, attract flies, or interfere with cleaning of the floor (as in covered, dust-tight boxes, or bins). Open feed dollies may be used for distributing the feed, but not for storing feed in the milking barn. Feed troughs shall be constructed of concrete or other approved impervious and easily cleanable material. A minimum of eight feet ceiling height shall be required in all dairies. When elevated stanchions are used, this height shall be measured from the floor of the elevated portion of the barn.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1267 (June 2002), amended LR 37:

§523. Milk House or Room

A. There shall be provided a milk house or milk room of sufficient size for the cooling, handling, storing of milk and the washing, sanitizing and storing of milk containers and utensils. The milk house or milk room shall conform to the following requirements.

1. It shall be provided with a tight floor constructed of concrete or other impervious easily cleanable material, in good repair, graded to drain through trapped floor drains.

2. It shall have walls and ceilings of such construction as to permit easy cleaning and shall be painted or finished in an manner approved by the state health officer.

3. The milk house shall be provided with a minimum of 20-foot candles of well distributed light.

4. It shall be provided with windows and solid doors. All outside openings shall be effectively protected against entry of insects, dust and airborne contamination. All outside doors shall be self-closing and open outward.

5. It shall be used for no other purpose than those specified above, except as may be approved by the state health officer.

6. It shall not open directly into a stable or into any room used for domestic purposes.

7. The water supply for the milk room and milking operations shall be from a supply easily accessible, constructed and operated according to Part XII of this Code.

8. It shall have water piped into it and protected against normal freezing conditions.

9. It shall be provided with hot and cold running water under pressure. Water volume and temperature shall be adequate for the cleaning of utensils and operation of automated cleaning systems.

10. It shall be equipped with two-compartment stationary wash and rinse vats, large enough to submerge the largest piece of equipment or container.

11. A conveniently located hand washing facility with hot and cold running water under pressure, soap, air dryer or single service towel shall be provided.

12. The floors, walls, ceilings, windows, tables, shelves, cabinets and any equipment located in the milk house shall be clean. Only articles directly related to milk house activities shall be permitted in the milk house. The milk house shall be free of trash, animals and fowl.

13. Incidental articles may be kept in the milk house provided they are kept clean and ample space is available to conduct normal operations in the milk house and they will not contaminate milk.

14. The milk house shall be adequately ventilated to minimize condensation on floors, walls, ceilings and cleaned utensils.

15. Vents and artificial lighting fixtures shall be installed in a manner to preclude the contamination of bulk milk tank interiors or clean utensil storage areas. They shall not be located over bulk milk tank openings.

16. The state health officer may allow the use of a milk tank truck that is constructed, equipped, located and operated in a manner approved by the state health officer for the storage of raw milk.

17. Milk houses or rooms at dairy farms where the raw milk is transferred from the farm bulk milk tank to milk tank trucks for shipment shall be provided with a hose port in the exterior wall through which the hose used to transfer milk from the bulk tank to the milk tank truck shall be placed during the transfer. The port shall be fitted with a tight fitting door that shall be in good repair and kept closed except when the port is in use. A concrete or equally impervious slab shall be provided under the hose port, sufficiently large to protect the hose from contamination during the transfer of

milk. A water hose shall be conveniently located to allow the rinsing of the slab. The area around the slab shall be clean and free of insect harborage or attractants.

18. Milk houses or rooms in which raw milk is shipped in milk cans shall be equipped with mechanical cooling devices, constructed in a manner that meets the 3-A standards or requirements of the PMO, that cool the milk to 7°C (45°F) or less within four hours or less after each can is filled and maintained at that temperature or less until shipped.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1267 (June 2002), amended LR 37:

§525. Reclaimed Water$_{df}$

A. Potable water utilized for heat exchangers or compressors on a Grade A dairy farm may be salvaged and used for certain limited applications in the milking operation on the dairy farm if the following criteria are met:

1. The reclaimed water$_{df}$ piping system shall meet the requirements of Parts XII and XIV of this Code.

2. Any re-circulated cold reclaimed water$_{df}$ which is used in exchangers, including systems in which a freezing point depressant is used, shall be from a safe source and protected from contamination. Such reclaimed water$_{df}$ shall be tested at the minimum frequencies specified in this Section and shall otherwise comply with any other requirements of this Section. Freezing point depressants shall be non-toxic.

3. The reclaimed water$_{df}$ shall be stored in a storage vessel properly constructed of such material that will not contaminate the reclaimed water$_{df}$ system and will protect the system from possible contamination.

4. The storage vessel shall be equipped with a drain and access point to allow for cleaning.

5. No cross-connection shall exist between the reclaimed water$_{df}$ supply and any unsafe or questionable water supply or any other source of pollution. No cross connection shall exist between any potable water supply or potable water distribution system and the reclaimed water$_{df}$ system.

6. There are no submerged inlets through which the reclaimed water$_{df}$ system may be contaminated.

7. The reclaimed water$_{df}$ shall be of satisfactory organoleptic quality and shall have no off flavors or odors.

8. The reclaimed water$_{df}$ shall comply with the bacteriological standards of Appendix G, Section I of the PMO.

9. Samples of the reclaimed water$_{df}$ shall be collected and analyzed prior to initial approval and semi-annually thereafter.

10. Approved chemicals, such as chlorine, with a suitable retention period, may be used to suppress the development of bacterial growth and prevent the development of tastes and odors in the reclaimed water$_{df}$.

11. When chemicals are added to the reclaimed water$_{df}$, a monitoring program for such added chemicals shall be in effect and such chemicals shall not add substances that will prove deleterious to the use of the reclaimed water$_{df}$ or contribute to product contamination.

12. If the reclaimed water$_{df}$ is to be used for the sanitizing of teats or equipment (back-flush systems), approved sanitizers, such as iodine may be added by an automatic proportioning device located downstream from the storage vessel but prior to its end-use application. An approved backflow prevention device shall be installed immediately upstream of the point of chemical addition.

B. Reclaimed water$_{df}$ from the current milking, obtained directly from the discharge of a raw milk heat exchanger or compressor into the wash vat or utensil sink, may be used in the following applications:

1. the one time pre-rinsing of milking equipment, including milk lines, milking claw assembly, milk receiver, etc., and then discharged to waste; or,

2. for non-potable purposes approved by the state health officer, e.g., use as a non-potable water source when the intended use does not require the use of potable water.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1268 (June 2002), amended LR 37:

§527. Toilets

A. Every dairy farm shall be provided with one or more sanitary toilets, conveniently located, constructed according to Parts XIII and XIV of this Code, and operated in a sanitary manner. A covered trash container shall be provided in the toilet room. Materials, equipment or utensils used in milk production shall not be stored in the toilet room.

B. Toilet rooms and appurtenances shall be kept clean.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1268 (June 2002), amended LR 37:

§529. Construction of Containers and Equipment

A. All multi-use containers, utensils and equipment used in the handling, storage or transportation of milk or milk products shall be constructed of smooth, non-absorbent, non-oxidizable and non-toxic material located as to be easily cleaned, shall be free of exposed copper or brass, and shall be kept in good repair. Joints and seams shall be smooth and easily cleanable. Woven wire cloth shall not be used for straining milk. All milk pails shall be of heavy-gauge material and of small mouth design. The design, construction and manner of employment of all milk equipment shall conform with 3-A Standards and the requirements of the PMO, and be approved by the state health officer in writing prior to installation.

B. Systems are acceptable if they are designed, installed and operated in accordance with the following parameters for reverse flush systems:

1. All product contact surfaces shall conform to the construction criteria of §529.A of this Part.

2. An intervening break to the atmosphere shall be provided between the water and/or chemical solution and the product and/or product contact surfaces at all times.

3. If a pre-rinse cycle is used it shall be with potable water.

4. The system shall provide for:

a. A chemical solution cycle with a chemical solution complying with provisions of Appendix F of the PMO.

b. The chemical solution strength shall be limited to that strength necessary to accomplish its intended effect and shall not leave a significant residual in the milk.

c. A post-rinse cycle with safe water. The use of treated water to prevent psychrophilic microorganisms contamination should be considered.

d. A drain cycle with sufficient time to drain or remove all moisture from the product contact surfaces of the reverse flush system.

5. When air under pressure is used in contact with product or solution contact surfaces, it shall comply with the requirements for air under pressure contained in §929(I) of this Part, provided that an exception to the piping downstream from the terminal filter may be granted when:

a. the piping is used only for filtered air;

b. at least one access point is available to determine cleanliness of the air piping; and

c. the piping is of a smooth, non-absorbent, corrosion-resistant, non-toxic material, including any adhesives used in joints. In some installations, a check valve may be required to prevent water and/or chemical solution from entering these air lines.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1268 (June 2002), amended LR 37:

§531. Sanitary Piping

A. All piping used to conduct milk or automated cleaning solutions shall comply with applicable 3-A Sanitary Standards. The installation and use thereof shall be approved, in writing, by the state health officer prior to installation. Detailed plans for mechanically cleaned pipeline systems shall be submitted to the state health officer for written approval prior to installation. No alteration or addition shall be made to any milk pipeline system without prior written approval of the state health officer.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1268 (June 2002), amended LR 37:

Subchapter C. Sanitation

§533. Cleaning of Containers and Equipment

A. All multi-use containers, equipment, and other utensils used in the handling, storage, transportation of milk shall be properly cleaned between each usage, provided that farm bulk tanks shall be emptied and cleaned at least once each 72 hours.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1268 (June 2002), amended LR 37:

§535. Sanitizing Treatment of Containers and Equipment

A. All multi-use containers, equipment, and other utensils used in the handling, storage and transportation of milk shall be properly cleaned then sanitized before each usage. When empty and before being returned to a producer by a dairy plant, each container shall be properly cleaned and sanitized.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1268 (June 2002), amended LR 37:

§537. Storage

A. All containers and other utensils used in the handling, storage, or transportation of milk shall, unless stored in sanitizing solutions, be stored so as to drain and dry, and so as not to become contaminated before use.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1268 (June 2002), amended LR 37:

§539. Handling

A. After sanitizing treatment, the handling of milk containers, utensils or equipment shall be done in such a manner as to preclude the contamination of the milk contact surface.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1268 (June 2002), amended LR 37:

§541. Milk Stools, Surcingles, and Anti-Kickers

A. Milk stools, surcingles and anti-kickers shall be clean and stored above the floor.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1268 (June 2002), amended LR 37:

§543. Flanks, Udders and Teats

A. The flanks, bellies, tails and udders shall be clipped as necessary. Udders and teats shall be free from visible dirt or liquids at the time of milking.

B. The udders and teats of all milk cows, goats, sheep, water buffaloes or other hooved mammals shall be cleaned, rinsed with a bactericidal solution and dried prior to milking.

C. The use of a common towel, sponge or similar device for cleaning udders is prohibited.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1269 (June 2002), amended LR 37:

§545. Handling of Milk with Abnormalities

A. Milk from lactating animals being treated with medicinal agents, which are capable of being secreted in the milk, shall not be offered for sale for such a period as is recommended by the attending veterinarian or as indicated on the package label of the medicinal agent.

B. Milk with abnormalities shall not be offered for sale and shall be so handled to preclude the infection of other lactating animals or the contamination of milk utensils.

C. Lactating animals secreting milk with abnormalities shall be milked last or in separate equipment which effectively prevents the contamination of the milk to be offered for sale.

D. Equipment, utensils and containers used for the milking or handling of milk with abnormalities shall be properly cleaned and sanitized after use and prior to being used for the handling of milk to be offered for sale.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1269 (June 2002), amended LR 37:

§547. Protection from Contamination

A. No milk shall be strained or poured in the dairy barn.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1269 (June 2002), amended LR 37:

§549. Cooling

A. Raw milk for pasteurization shall be cooled to 10EC (50EF) or less within four hours of the commencement of the first milking and to 7EC (45EF) or less within two hours after the completion of milking. Provided, that the blend temperature after the first milking and subsequent milkings does not exceed 10EC (50EF). Provided, further, that Grade A raw milk for pasteurization, that is shipped in milk cans, shall be cooled to 7EC (45EF) or less within four hours after each can has been filled.

B. The construction and operation of all raw milk cooling equipment shall comply with 3-A Standards or §2113(H) of this Part as appropriate.

C. All farm bulk milk tanks manufactured after January 1, 2000 shall be equipped with a temperature recording device approved by the state health officer with concurrence of the FDA.

1. The recording device shall be operated continuously and be maintained in a properly functioning manner. Circular charts shall not overlap.

2. The recording device shall be calibrated with a traceable standard thermometer at least once in each six month period in a manner acceptable to the state health officer. The calibration shall be documented on records available for review by the state health officer.

3. Recording thermometer charts shall be maintained on the premises for a period of a minimum of six months and available to the state health officer.

4. The recording thermometer should be installed in an area convenient to the milk storage tank and acceptable to the state health officer.

5. The recording thermometer sensor shall be located to permit the registering of the temperature of the contents when the tank contains no more than 10 percent of its calibrated capacity.

6. The recording thermometers shall comply with the requirements for such thermometers contained in the *PMO*.

7. A recording thermometer or any other device that meets the specifications of the *PMO* and is acceptable to the state health officer can be used to monitor and record the bulk tank temperature.

8. The recording thermometer charts shall properly identify the producer, date and signature of the person removing the chart.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1269 (June 2002), amended LR 37:

§551. Cow Feed

A. No cows shall be fed any substance in a state of putrefaction or any swill or unwholesome feed. This regulation shall not be construed to prohibit the use of properly prepared ensilage.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1269 (June 2002), amended LR 37:

§553. Insect and Rodent Control

A. Effective measures shall be taken to prevent the contamination of milk, containers, equipment, and utensils by insects, rodents, and by chemicals used to control such vermin. Milk houses shall be free of insects and rodents. Surroundings shall be kept neat, clean, and free of conditions which might harbor or be conducive to the breeding of insects and rodents. Feed shall be stored in such a manner that it does not attract birds, rodents or insects.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1269 (June 2002), amended LR 37:

§555. Personal Cleanliness

A. All persons coming in contact with milk, containers or equipment shall wear clean outer garments and shall keep their hands clean at all times while thus engaged.

B. Milkers' hands shall be clean and dried with a clean towel immediately before milking and following any interruption in the milking operation. A faucet dedicated to the rinsing of milkers hands shall be conveniently located in the milking area. Wet-hand milking is prohibited.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1269 (June 2002), amended LR 37:

§557. Clarifiers in the Milk House

A. It shall be unlawful for a milk producer to use any clarifiers, equipment or device in the milk house or dairy barn that would remove or alter a portion or all of the constituents of the milk, provided that this would not prohibit the use of single service filters in the milk house to remove hair or foreign particles that may accidentally gain access to the milk.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1269 (June 2002), amended LR 37:

§559. Drug and Chemical Control

A. Cleaners and sanitizers shall be stored in properly identified, dedicated end-use containers.

B. Animal drugs, medications and their administration equipment shall be stored in such a manner that milk, milking equipment and cleaning equipment are not subject to contamination.

C. Animal drugs and medications shall be properly labeled and segregated (lactating from non-lactating).

D. Unapproved drugs shall not be used.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1269 (June 2002), amended LR 37:

§561. Personal Cleanliness [formerly paragraph 7:075]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1269 (June 2002), repealed LR 37:

Chapter 7. Sampling, Hauling and Transporting of Milk

§701. Milk Tank Trucks

A. The construction of all milk tank trucks shall comply with applicable 3-A Standards and the requirements of the PMO.

B. Permitting. Each tank truck that loads or unloads milk or other dairy products in the State of Louisiana shall bear a current, valid milk tank truck permit issued by the state health officer, provided that milk tank trucks bearing a permit issued by a milk or dairy regulatory agency from another state whose milk tank truck regulations and inspectional procedures have been determined, by the state health officer, to be equivalent to those contained in this Part may be loaded or unloaded for an indefinite period until such milk tank trucks have been inspected and permitted by the state health officer. Milk tank trucks bearing a permit issued by a milk or dairy regulatory agency from another state whose permitting regulations or inspectional procedures for milk tank trucks have been determined, by the state health officer, not to be equivalent to those contained in this Part, may be loaded or unloaded for a period not to exceed five times in a one month period, provided further that each dairy plant maintain a log showing the dates and times each milk tank truck is loaded or unloaded and such log is made available to the state health officer for review. When such milk tank trucks have been loaded or unloaded more than five times in a one month period at a dairy plant in Louisiana, the plant shall contact the state health officer expeditiously and make necessary arrangements to have such milk tank trucks inspected and permitted. After the plant has done this, they may continue to load or unload such milk tank trucks until they have been inspected by the state health officer. Upon inspecting the milk tank truck, should the state health officer determine that it is not in substantial compliance with this Part and deny the issuance of a permit for the milk tank truck, it shall not load or unload dairy products in the state until all violations have been corrected and verified in a manner approved by the state health officer.

1. Under no circumstances or situations shall milk or other dairy products be loaded onto or unloaded from a tank truck that does not bear a current, valid permit issued by an official milk or dairy regulatory agency without prior authorization from the state health officer.

2. Owners of milk tank trucks that bear a current, valid permit issued by other state official milk or dairy regulatory agencies shall not be required to pay any inspection or permit fees of any kind or type.

3. The state health officer shall perform an inspection of the milk tank truck and its appurtenances prior to the issuance of the permit. This inspection shall be comprehensive and shall include a visual inspection of all of the product contact surfaces of the interior of the tank (interior surfaces of the tank, CIP equipment and any other product contact surfaces). This may be done by the inspector entering the interior of the tank or by using instruments that enable the inspector to visually observe all product contact surfaces in the interior of the tank. All other product surfaces (including pumps, valves, hoses, sampling equipment, etc.) shall be inspected.

4. Milk tank trucks that are found to be in compliance with §701.A above and are in substantial compliance with all other requirements of this Code, but are not equipped with an internal CIP system which complies with 3-A Standards shall be issued a restricted permit. This restricted permit shall authorize them to be unloaded only at plants that have cleaning systems (including manual cleaning and sanitizing programs), approved by the state health officer, capable of properly cleaning and sanitizing the vehicle. Provided, that arrangements may be made to have the milk tank truck properly cleaned and sanitized at a permitted dairy plant or milk tank truck cleaning facility that is capable of properly cleaning and sanitizing such trucks, as determined by the state health officer, within four hours after the milk tank truck is unloaded and prior to next use. Milk tank trucks that haul multiple loads within a 24 hours period, and are not empty for periods exceeding four hours each, during that time period, are excluded from this requirement, provided that they are cleaned and sanitized at a dairy plant or cleaning station that can accommodate such milk tank trucks.

5. Permits shall be valid for a period of one year unless suspended or revoked by the state health officer for cause.

6. A decal indicating the permit number and date of expiration shall be affixed to the milk tank truck trailer, in an area near the rear of the milk tank, where it can easily be seen.

7. Dairy plants that do not have facilities for properly cleaning and sanitizing milk tank trucks shall not unload milk tank truck loads of milk or dairy products. Provided, that the milk tank truck may be unloaded when arrangements are made by the dairy plant for the milk tank truck to be properly cleaned and sanitized at a permitted dairy plant or milk tank truck cleaning facility capable of properly cleaning and sanitizing the milk tank truck within four hours after being unloaded and prior to next use.

8. Milk tank trucks shall transport milk products only, provided that the state health officer may authorize the

transporting of other food grade products. Milk tank trucks that have transported egg products shall not be used for transportation of milk products.

9. Milk tank trucks that have transported unpasteurized products shall not be used to transport pasteurized products that will not be re-pasteurized.

C. The following applies to the suspension of permit, removal from service, and/or inspection reports relative to milk tank trucks:

1. When the state health officer determines that a milk tank truck has significant cleaning, construction or repair defects he shall:

a. in cases in which the milk tank truck has been issued a Louisiana permit, suspend the permit immediately until such time as the discrepancies are corrected and verified by an inspection by the state health officer; or

b. in cases in which the milk tank truck has been issued a permit by a state other than Louisiana:

i. Refuse to issue a permit for the milk tank truck.

ii. Notify the operator that the milk tank truck shall not be authorized to transport milk products in the State of Louisiana until such time as the discrepancies have been corrected and verified by the milk regulatory agency that issued the permit in a manner acceptable to the state health officer.

iii. Include, on the inspection report, a statement indicating that the milk tank truck shall not be authorized to transport milk products in Louisiana until the discrepancies have been corrected and verified by the milk regulatory agency that issued the permit.

iv. Expeditiously contact the milk regulatory agency that issued the permit, give notification of the problem and make necessary arrangements to have that regulatory agency notify the state health officer when the discrepancies have been corrected and verified.

2. Each time a milk tank truck permitted by a state other than Louisiana has been inspected by the state health officer, he shall send a copy of the inspection report to the state milk regulatory agency that issued the permit.

D. The following cleaning and sanitizing requirements apply to milk tank trucks.

1. Each milk tank truck shall be properly cleaned and sanitized at a dairy plant or milk tank truck cleaning facility possessing a valid permit, issued by the state health officer or the official state agency having regulatory authority over the plant or facility, prior to first use. When time elapsed after cleaning and sanitizing and before first use exceeds 96 hours, the tank shall be re-sanitized. Provided, when the time elapsed between cleaning and sanitizing and before first use exceeds seven days, the milk tank truck shall be properly cleaned and sanitized prior to use.

2. It shall be the responsibility of the dairy plant or milk tank truck cleaning facility that cleans and sanitizes the milk tank truck to properly clean and sanitize the interior of the tank, the outlet valve(s), dome dust cover, dome cover, tank cover gasket and tank cover vent.

3. It shall be the responsibility of the operator of the milk tank truck to properly clean and sanitize milk hose(s), pumps, sampling equipment and pump compartments of bulk milk pickup tank trucks. These appurtenances shall be properly cleaned and sanitized by the milk tank truck operator each time the milk tank truck is cleaned and sanitized, regardless of whether they were used or not used in the loading of the milk tank truck. Removable fittings on the hoses shall be disassembled and properly cleaned at least once each week.

4. It is allowable to pickup multiple loads within a 24-hour period provided that the milk tank is washed and sanitized after each day used, provided further that the time interval between any unloading and loading during that 24-hour period does not exceed four hours.

5. It is allowable for a milk tank truck to be unloaded at one facility and proceed to a permitted facility to be washed and sanitized, provided that the time interval between unloading and washing does not exceed four hours.

6. Milk tank trucks shall be cleaned and sanitized only at facilities possessing a valid permit for such activities issued by the state health officer or by the milk regulatory agency in the state in which the facility is located.

7. The following cleaning and sanitization tag/record requirements are applicable to milk tank trucks:

a. The operator of the milk tank truck shall be responsible for assuring that the milk tank truck has been properly cleaned, sanitized and has a cleaning and sanitization tag placed on the tank truck by the facility that last cleaned and sanitized the tank truck. A milk tank truck that does not have a valid cleaning and sanitization tag shall not be loaded or unloaded until the proper cleaning and sanitization can be verified and approval is received from the state health officer.

b. A cleaning and sanitization tag shall be affixed to the outlet valve or in an area in the vicinity of the outlet valve of the milk tank truck by the plant or cleaning facility that cleaned and sanitized the truck. The tag shall remain in place and intact until the tank truck is next cleaned and sanitized. When the milk tank truck is cleaned and sanitized, the cleaning and sanitization tag shall be removed and stored at that location for a period of not less than 15 days. In cases in which the tank truck is only sanitized and not cleaned and sanitized, the date, time, facility's name and location, and initials of the person that sanitized the truck shall be annotated on the existing tag. This tag shall remain in place and intact until the tank truck receives a complete cleaning and sanitization.

c. The following information shall be recorded on the cleaning and sanitization tag:

i. identification of the milk tank truck;

ii. date, time, facility's name and location where the milk tank truck was cleaned and sanitized;

iii. signature or initial of person who cleaned and sanitized the milk tank truck;

iv. the numbers of the numbered seals placed on the tank truck; and

v. date, time, facility name and location where product was unloaded from the truck.

d. The maintenance of all information on the cleaning and sanitization tag shall be the responsibility of bulk milk hauler/sampler or the milk tank truck operator until the tank truck is cleaned and sanitized.

8. The date, time, facility's name and location of the last cleaning and sanitization of the milk tank truck shall be provided to the State Health Officer during any milk tank

truck inspection and such information shall be recorded on the milk tank truck's inspection report.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1269 (June 2002), amended LR 37:

§703. Sealing and Protection of Milk Tank Trucks

A. Tamper evident, numbered seals shall be placed on all outer openings of the tank (C.I.P. fittings, valves, vents, hatches, dust covers and doors of the valve, pump and sample compartment) by the milk receiver/sampler immediately upon completion of washing and sanitizing of the milk tank truck, provided that the operator of the milk tank truck may lock the doors of the valve, pump and sample compartments with padlocks instead of being sealed.

B. The tank truck shall be constructed in such a manner as to preclude the opening of any sealed portion of the tank truck without breaking the seals (hinges on dust cover, doors, etc.).

C. In cases in which a milk tank truck is unloaded at a dairy plant, is not washed and sanitized and will be used to haul milk or milk products, it shall be sealed and protected as prescribed in §703.A above and the date, time, location the milk tank truck was unloaded shall be recorded on the cleaning and sanitizing tag by the milk receiver/sampler.

D. The seal numbers shall be annotated on the cleaning and sanitization tag.

E. It shall be the responsibility of the milk tank truck operator to insure that the milk tank truck has been properly cleaned and sanitized.

F. It shall be the responsibility of the milk tank truck operator to insure that the milk tank truck has been properly sealed and compartments are locked or sealed and maintained in such manner at all times that the milk tank truck is not being loaded, unloaded or under immediate control of the operator.

G. The milk tank truck operator shall check the integrity of all seals and locks upon arrival at the first farm or other facility from which milk or milk products are to be loaded.

H. When seals must be broken in order to load the truck, the operator shall store the seals in a secure location on the truck and record the seal numbers and reason for breaking the seals on the cleaning and sanitization tag or on the manifest.

I. If at any time the operator discovers that a seal has been broken or removed without his/her knowledge, he/she shall immediately notify the state health officer and ensure that the milk tank truck is not unloaded without permission from the state health officer.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1270 (June 2002), amended LR 37:

§705. Manifest for Bulk Milk Tank Trucks

A. Bulk milk tank trucks that pick up milk from dairy farms and haul it to dairy plants shall have a shipping statement (manifest) containing:

1. name and address of tank truck owner;
2. tank truck permit number and state issuing permit;
3. bulk milk tank truck operator/sampler(s) name(s) and permit number(s) and state issuing permit(s); and,
4. the bulk milk tank truck operator/sampler signature.

B. The following information concerning each individual dairy farm having milk represented on the load shall be annotated on the manifest by the bulk milk tank truck operator/sampler:

1. name and permit number of dairy farm;
2. date and time milk was picked up;
3. identity of bulk tank on farms where milk was picked up from two or more farm bulk tanks;
4. temperature of the milk in each bulk tank;
5. milk gauge reading of each bulk tank;
6. pounds of milk collected from each bulk tank;
7. the initials of the bulk milk tank truck operator/sampler who picked up the milk; and,
8. the BTU permit number of the BTU to which the farm belonged.

C. The following information shall be annotated on manifest at point and time of unloading of bulk milk tank truck by the receiver/sampler:

1. the name and permit number of the plant or receiving station at which the tank truck was unloaded;
2. the date and time the tank truck was unloaded (this shall also be recorded on the cleaning and sanitizing tag);
3. the temperature of the load of milk;
4. the numbers of the numbered seals on the milk tank truck;
5. the date and time of the last cleaning and sanitization of the tank truck as annotated on the cleaning and sanitization tag; and,
6. the dairy plant receiver/sampler's permit number and signature.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1270 (June 2002), amended LR 37:

§707. Bulk Milk Tank Truck Operator/Sampler

A. A bulk milk tank truck operator/sampler is a person who collects official raw milk samples and may transport raw milk from dairy farms to milk plants, receiving stations, transfer stations or other food processing plants.

B. Milk tank truck and milk tank transport operators who are not licensed as bulk milk tank truck operator/samplers shall not perform any of the duties of a bulk milk tank truck operator/sampler that directly involves the collection of official samples or measuring of milk for official records.

C. Milk tank truck operators who are not bulk milk tank truck operator/samplers and perform any of the duties of a bulk milk tank truck operator/sampler that do not involve the collection of samples or measuring of milk shall conform with the requirements for such duties contained in this Part.

D. Bulk milk tank truck operator/samplers shall obtain a permit to operate a bulk milk pickup tank truck and collect official samples of raw milk prior to the performance of these duties.

E. The bulk milk tank truck operator/sampler must be instructed in proper procedures of milk pick up and sample collection prior to permit application.

F. The bulk milk tank truck operator/sampler shall obtain a passing score on a test administered by the state

health officer and demonstrate his ability to perform the required milk pick up and sampling duties to the state health officer prior to being issued a permit.

G. Each bulk milk tank truck operator/sampler shall attend one of the bulk milk pickup tanker operator/sampler seminars conducted biannually by the state health officer and receive a passing score on the test administered as part of the seminar. Failure to attend the required seminar or failure to achieve a passing score on the test shall result in suspension of his/her permit.

H. The examination shall be composed of a minimum of 20 questions broken down into the following areas:

1. six questions relating to sanitation and personal cleanliness;

2. six questions relating to sampling and weighing procedures;

3. four questions relating to equipment (including proper use, care, cleaning, etc); and

4. four questions relating to proper record keeping requirements.

I. Candidates failing the exam (a score of less than 70 percent) shall be denied permits or licenses until such time as they achieve a passing score.

J. The bulk milk hauler/sampler shall insure that he/she has the following equipment at all times while engaged in picking up and hauling milk:

1. sample rack and compartment to hold all samples collected;

2. refrigerant to hold temperature of milk samples between 0° - 4.4°C (32° - 40°F);

3. sample dipper or other sampling devices of sanitary design approved by the state health officer;

4. sterile sample bags, tubes or bottles; stored properly;

5. calibrated pocket thermometer; certified for accuracy every six months; accuracy K 1°C (2°F);

6. approved sanitizing agent and sample dipper container;

7. watch for timing milk agitation; and

8. appropriate sanitizer test kit.

K. Specific procedures that shall be performed by each milk tank truck operator/sampler:

1. The bulk milk hauler/sampler shall insure that all outer openings of the milk tank truck are properly sealed with numbered seals at all times the milk tank truck is not being loaded, unloaded or under his/her immediate supervision; padlocks may be used on the valve, pump and sample compartments.

2. The bulk milk hauler/sampler shall check the integrity of all seals and padlocks upon arrival at the first point at which the milk tank truck is to be loaded.

3. If any seal must be broken in order to load the truck, the bulk milk tank truck operator/sampler shall record the number of the seal(s) broken on the cleaning and sanitizing tag or manifest, this record may be referred to as a "broken seal record". The broken seal shall be placed in a secure place in the milk tank truck so that it can be presented to the milk receiver/sampler at the unloading point.

4. If at any time should the bulk milk tank truck operator/sampler find that any numbered seal or padlock securing the outer openings of the milk tank truck has been removed without his/her permission, he/she shall immediately notify the state health officer and then follow instructions given by the state health officer.

L. The specific procedures used by an individual bulk milk tank truck operator must be such that they preclude contamination of the milk and milk contact surfaces. The individual bulk milk tank truck operator shall insure the accuracy of all measurements taken, that samples collected are representative of the product sampled and that records and reports are accurate and complete.

M. The following are examples of acceptable procedures used in the measurement, sampling and pick up of milk from farm bulk tanks by the bulk milk tank truck operator/sampler:

1. he/she shall practice good hygiene, shall maintain a neat and clean appearance and not use tobacco in the milk house;

2. wash hands thoroughly and dry with a clean single service towel or acceptable air dryer immediately prior to measuring and sampling the milk;

3. examine the milk by sight and smell for any off odor or any other abnormalities that would classify the milk as not being acceptable. Reject if necessary;

4. measure the milk prior to agitation. If the agitator is running upon arrival at the milk house, the measurement shall be taken only after the surface of the milk has became quiescent;

5. carefully insert the measuring rod, after it has been wiped dry with a single service towel, into the tank. Repeat this procedure until two identical measurements are taken. Record measurements on the farm weight ticket;

6. do not contaminate the milk during measurement;

7. agitate the milk a sufficient time to obtain a homogeneous blend. Tanks with a capacity of less than 1,500 gallons, five minutes, and more than 1,500 gallons, 10 minutes;

8. while the milk is being agitated, insert thermometer into milk and determine temperature of the milk. Rinse thermometer and place it into holder. Record temperature;

9. while the tank is being agitated, bring the sample container, dipper, dipper container or single service sampling tubes and sanitizing agent for the outlet valve into the milk house. Remove the cap from the tank outlet valve and examine for milk deposits or foreign matter and then sanitize if necessary. Protect the hose cap from contamination when removing it from the transfer hose and during storage;

10. collect samples only after the milk has been properly agitated. Remove the dipper or sampling device from the sanitizing solution or sterile container and rinse at least twice in the milk;

11. collect a representative sample or samples from the bulk tank. When transferring milk from the sampling equipment, caution should be used to assure that no milk is spilled into the tank. Do not fill the sampling container more than ¾ full. Close the cover on the sample container;

12. rinse the dipper and place in its carrying container;

13. close the cover or lid of the bulk tank;

14. identify samples at the point of collection with the producer's number annotated on the sample container;

15. take a temperature control sample at the first stop of each load. This sample must be labeled with time, date, temperature, producer and bulk milk tank truck operator/sampler identification;

16. place the sample or samples immediately into the sample storage case;

17. record milk temperature, time, date of pick up and bulk milk tank truck operator/sampler identification on the farm weight ticket. He/she shall check the accuracy of the thermometer on each bulk tank monthly and record results on document that remains in the farm. Pocket thermometer must be sanitized before use;

18. once the measurement and sampling procedures are completed, with the agitator still running, open the outlet valve and start the pump. Turn off the agitator when the level of milk is below the level that will cause over agitation;

19. when the milk has been removed from the tank, disconnect the transfer hose from the outlet valve and cap the hose;

20. observe the inside surfaces of the bulk tank for foreign matter or extraneous material and record any objectionable observations on the farm weight ticket;

21. with the outlet valve open, thoroughly rinse the entire inside surface of the tank with warm water;

22. samples shall be cooled to and held between 0EC (32EF) and 4.4EC (40EF) during transit to the laboratory;

23. means shall be provided to properly protect the samples in the sample case. Keep refrigerant at an acceptable level;

24. racks must be provided so that the samples are properly cooled in an ice bath and are not submerged in the coolant; and,

25. adequate insulation of the sample container box or ice chest shall be provided to maintain the proper temperature of the samples.

N. At least one sample of raw milk collected by the bulk milk tank operator/sampler from each farm bulk milk tank represented on each load shall accompany the load to the dairy plant at which it will be unloaded.

O. The bulk milk tank truck operator/sampler shall follow the practices and procedures described in *Appendix B*, Milk Sampling, Hauling and Transportation of the *PMO* as well as those contained in this Part.

P. An on-site evaluation of the bulk milk tank truck operator/sampler's techniques should be made by the state health officer at least once each 24 months.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1270 (June 2002), amended LR 37:

§709. Posting Inspection Reports [formerly paragraph 7:080]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1270 (June 2002), repealed LR 37:

§711. Field Supervision [formerly paragraph 7:081]

Repealed.

AUTHORITY NOTE: Promulgated in accordance the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5 (15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1270 (June 2002), repealed LR 37:

§713. Degrading on Physical Violation [formerly paragraph 7:082]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5 (15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1270 (June 2002), repealed LR 37:

§715. Notification of Laboratory Analysis [formerly paragraph 7:083]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5 (15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1270 (June 2002), repealed LR 37:

§717. Degrading on Laboratory Analysis [formerly paragraph 7:084]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5 (15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1270 (June 2002), repealed LR 37:

§719. Insanitary Conditions [formerly paragraph 7:085]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5 (15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1270 (June 2002), repealed LR 37:

§721. Continuous Grading [formerly paragraph 7:086]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5 (15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1271 (June 2002), repealed LR 37:

§723. Adulterated Milk [formerly paragraph 7:087]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5 (15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1271 (June 2002), repealed LR 37:

§725. Application for Regrading [formerly paragraph 7:088]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5 (15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1271 (June 2002), repealed LR 37:

§727. Regrading on Laboratory Results [formerly paragraph 7:089]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5 (15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28;1271 (June 2002), repealed LR 37:

§729. Regrading on Physical Violations [formerly paragraph 7:090]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5 (15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1271 (June 2002), repealed LR 37:

Chapter 9. General Requirements for Dairy Plants

§901. General Requirements

A. The requirements contained within this chapter pertain to Grade A dairy plants and dairy plants in general. Some types of dairy plants are not required to conform with each of these requirements. Those requirements to which specific types of dairy plants shall be required to conform shall be listed in the chapter of this Part that pertains to that specific type of plant.

B. The state health officer has the authority to require an individual dairy plant to implement any additional requirements he/she determines necessary to prevent a compromise to food safety in that individual dairy plant. Failure to comply with such requirements may constitute grounds for suspension or denial of permit.

C. Dairy plants that produce Grade A pasteurized, ultra-pasteurized or aseptically processed milk and milk products shall conform with each of the requirements contained in this Chapter, provided that dairy plants that produce Grade A pasteurized, ultra-pasteurized or aseptically processed milk and milk products which have been required or authorized by the state health officer to be regulated under the provisions of Chapter 11 of this Part [Hazard Analysis Critical Control (HACCP) systems] shall conform with the requirements contained in Chapter 11 of this Part.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1271 (June 2002), amended LR 37:

§903. Approval of Plans

A. All milk, milk products plants and other dairy plants domiciled in the State from which dairy products are processed, packaged or offered for sale in the state and which are hereafter constructed, reconstructed, or renovated shall conform with the requirements of this Part. Prior to construction, reconstruction or alterations, written approval of plans and specifications shall be obtained from the state health officer.

B. Prior to installation or modification, written approval shall be obtained from the state health officer of plans and specifications for the design, construction and manner of employment for all equipment used in dairy plants.

C. Written, detailed plans describing the processing of each product shall be submitted to the state health officer for approval prior to manufacture of product and prior to any process or product changes.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1271 (June 2002), amended LR 37:

Subchapter A. Milk, Milk Products and Non Milk Derived Ingredients Receiving

§905. Raw Milk Receiving

A. All milk and other dairy products received by each dairy plant, including receiving stations and transfer stations, shall be from sources which possess a current valid permit issued by the state health officer.

B. Milk or dairy products shall not be loaded onto or unloaded from tank trucks that do not bear a current, valid permit issued by an official milk or dairy regulatory agency.

C. For any milk tank truck that bears a permit of an official state milk or dairy regulatory agency from another state whose milk tank truck regulations have been determined by the state health officer not to be equivalent to those contained in this Part, each dairy facility shall maintain a log showing the dates and times that each and every such truck has been loaded or unloaded. Such logs shall be made available for review by the state health officer. When such milk tank trucks have been loaded or unloaded by a dairy facility more than five times in a one month period, the dairy facility shall expeditiously notify the state health officer and make necessary arrangements for the state health officer to inspect and permit such milk tank trucks. The facility may continue to load and unload such milk tank trucks until the state health officer has inspected and permitted them.

D. Each dairy facility (including dairy plants, receiving stations, transfer stations and milk tank truck cleaning facilities) that cleans and sanitizes milk tank trucks or other confined spaces which hold dairy products, such as tanks, shall be equipped with approved, functional equipment, devices, etc., and provide all services and programs necessary to satisfy the confined space entry safety requirements of the Occupational Safety and Health Administration (OSHA) thereby permitting personnel to safely enter the interior of the milk tank trucks and other confined spaces. The dairy facility shall allow the state health officer to use all such equipment, devices, services and programs, etc., and shall provide the state health officer with any assistance necessary to enable the state health officer (or his authorized representative) to safely enter and inspect the interior of the milk tank trucks or other confined spaces. Dairy facilities, as identified above, which fail to provide the state health officer with any assistance necessary and required under OSHA regulations to safely enter and inspect the interior of milk tank trucks or other confined spaces may be held liable should the safety of the state health officer (or his authorized representative) be in peril while inside of milk tank trucks or any other confined space.

E. When the area in which milk tank trucks are unloaded is not totally enclosed or doors of the unloading area are open during unloading, a filter approved by the state health officer, shall be placed on the manhole or air inlet of the milk tank truck and a roof or ceiling must be provided over the area.

F. All milk or other dairy products received by each dairy plant, including receiving stations, shall be received by a dairy receiver/sampler possessing a current, valid dairy plant receiver/sampler permit issued by the state health officer.

G. Each dairy plant, including receiving stations receiving raw milk, shall be equipped with a drug residue screening laboratory approved by the state health officer.

H. The construction of the laboratory, the laboratory equipment, sampling procedures and laboratory examinations shall be in compliance with the *PMO*, the *Official Methods of Analysis* and the *Standards Methods for the Examination of Dairy Products* and shall be approved by the state health officer.

I. All drug residue analyses shall be performed by approved analysts certified by the state health officer.

J. Each dairy plant and receiving station shall maintain all records of testing required by the state health officer.

K. A sample of raw milk shall be collected from each milk tank truckload of raw milk by a dairy plant receiver/sampler and tested for drug residues in the milk drug residue screening laboratory of the dairy plant prior to the milk tank truck being unloaded.

L. In cases where a dairy plant receives raw milk in cans, a composite sample composed of raw milk from each can of raw milk shipped from each individual dairy farm, shall be collected and tested for drug residues prior to the milk from that individual dairy farm being commingled with any other milk.

M. In cases where a dairy plant processes raw milk produced by a dairy farm located on the same premises, all raw milk produced by the dairy farm shall be tested for drug residues prior to processing.

N. When any sample referred to in §905(K),(L) or (M) above is found to be positive for drug residues, the dairy plant or receiving station shall:

1. refuse to unload the milk tank truck, not commingle any cans of milk from that farm with any other milk, not commingle any milk found to be positive for drug residues with any other milk and isolate the contaminated milk from any other milk;
2. immediately notify the state health officer;
3. insure that the contaminated milk remains on the premises of the dairy plant or receiving station and ensure that it is isolated from any other milk until the state health officer determines the disposition of the milk and authorizes it to be moved; and,
4. immediately cease processing of any product that has inadvertently become commingled with milk contaminated with drug residues, isolate the product, notify the state health officer and expeditiously remove all such product that has entered commerce.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1272 (June 2002), amended LR 37:

§907. Dairy Plant Receivers/Samplers

A. Prior to performing the duties associated with same, dairy plant receivers/samplers shall obtain a permit from the state health officer for receiving tank truck or other type of container loads of milk and milk products as well as to collect and handle official samples of milk and milk products.

B. Prior to applying for a permit, the person desiring to become permitted as a dairy plant receiver/sampler shall be instructed in the proper procedures for loading and receiving loads of milk and milk products and for collecting/handling official samples of milk and milk products. These procedures shall be properly performed by each dairy plant receiver/sampler. The instructions of dairy plant receivers/samplers shall minimally include the following:

1. obtaining producer samples from the hauler;
2. checking temperature of the pilot sample;
3. immediately placing samples in an approved refrigerator;
4. checking the manifest for accuracy;
5. verifying that the bulk milk tank truck operator/sampler that picked up milk from the farm has a current, valid permit;
6. verifying that the milk tank truck has a current, valid permit issued by an official state milk or dairy products regulatory agency whose milk tank truck regulations are equivalent to those contained in this Part;
7. recording the permit number, the date and the time that milk tank trucks which bear current, valid permits issued by an official state milk or dairy products regulatory agency whose milk tank trucks regulations have been determined by the state health officer not to be equivalent to those contained in this Part, and notifying facility management when such milk tank trucks have been loaded or unloaded more than five times in any one month period;
8. verifying that the load is from an approved source;
9. checking the cleaning and sanitization tag;
10. recording the date and time the product was unloaded on the cleaning and sanitizing tag;
11. reporting any discrepancies in any of the above to his/her supervisor immediately and does not proceed any further without orders from supervisor;
12. verify the identity of each milk tank truck operator and that he/she is an authorized operator of the vehicle;
13. checking the seals to verify that they are present, intact and agree with the numbers recorded on the cleaning and sanitization tag and that any seals that have been broken are available and agree with the number of the broken seal numbers on the sanitization tag or manifest;
14. immediately notifying the state health officer if seals are missing or if the seal record does not match the intact seals or the operator is unable to produce broken seals for seal numbers recorded on "broken seal record" on the cleaning and sanitization tag. In any such case, the milk tank truck shall not be unloaded without authorization from the state health officer;
15. examining the load of milk or milk products for foreign matter;
16. collecting official samples of milk and milk products from the load;
17. checking and recording the temperature of the load;
18. testing or having a sample from each load of raw milk tested for drug residue;
19. placing dome filter over the dome;
20. unloading the tanker in the manner prescribed by the dairy plant;
21. cleaning and sanitizing the interior of the tank using the procedures prescribed by the plant. When an automated cleaning system is used, the milk tank truck permit number shall be recorded in the appropriate place on the CIP recording chart;

22. cleaning and sanitizing the dome cover, dust cover, gasket, vent and outlet valve(s);

23. inspecting the pump compartment, sample compartment, pump, hoses, sample chest, sample canister, sampling dipper and all other milk and handling appurtenances;

24. placing numbered seals on the dome dust cover, C.I.P. fittings and all other openings of the tank or ensuring that padlocks have been locked as provided in §703.A;

25. recording the cleaning and sanitizing date and time and seal numbers, on the cleaning and sanitization tag;

26. upon verifying that the requirement in §907.B.21.-25. above has been properly satisfied, affixing a cleaning and sanitization tag to the outlet valves; and,

27. cleaning, sanitizing and storing receiving equipment properly.

C. The dairy plant receiver/sampler shall obtain a passing score on a test administered by the state health officer prior to being issued a permit.

D. Bi-annually, each dairy plant receiver/sampler shall attend one of the bulk milk pickup tanker operator/sampler and dairy plant receiver/sampler seminars conducted by the state health officer and receive a passing score on the test administered as part of the seminar. Failure to attend the required seminar or failure to achieve a passing score on the test shall result in suspension of his/her permit.

E. The state health officer shall evaluate the performance of each dairy plant receiver/sampler at least once each three-month period.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1272 (June 2002), amended LR 37:

§909. Receiving and Handling of Milk Derived and Non-Dairy Ingredients

A. Non-milk derived ingredients used in the manufacturing of dairy products shall have been determined by the FDA to be GRAS for use in dairy products.

B. All dairy ingredients used in the manufacture of dairy products shall be produced, packed, held and shipped in a manner consistent with the requirements of this Part.

C. All non-milk derived ingredients shall be purchased only from suppliers which certify or guarantee that their products have been produced and handled in a manner that will assure a safe and wholesome ingredient which will not adulterate the finished product. Records of such verification or guarantee shall be available for review by the state health officer.

D. A safety and quality inspection of all incoming milk derived and non-milk derived ingredients shall be performed. Records of the results of this inspection, corrective action taken when problems are identified and the date and initials of the person performing the inspection shall be maintained and made available to the state health officer. The inspection shall include an evaluation for conditions related to:

1. product identity and labeling;
2. package condition and integrity;
3. bulging;
4. leaking;
5. dirt/grime;
6. insect infestation;
7. rodent damage; and,
8. off-odors and non-food materials (especially toxic compounds) or residues of such materials in the truck or other conveyance.

E. All ingredients used in the manufacture of dairy products shall be stored and handled in such a manner as to preclude their contamination. Particular attention shall be given to closing or resealing of containers that have been opened and the contents of which have been partially used.

F. Dusty raw ingredient blending or liquification operations which create powdery conditions shall not be conducted in areas where pasteurized products are handled or stored.

G. Dairy products operations in which ingredients are exposed shall be conducted in processing areas. Except when ingredients are being added, all openings into vessels and lines containing product shall be covered. The outer box or wrapper of powdered ingredients shall be removed prior to dumping into mixing vessels.

H. All liquid ingredients which will support bacterial growth shall be kept or immediately cooled to 7EC (45EF) or below.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1272 (June 2002), amended LR 37:

Subchapter B. Dairy Plant Construction, Sanitation and Operation

§911. Immediate Surroundings

A. The immediate surroundings of the dairy plant shall be well drained and kept neat, clean, and free from conditions which might attract flies, insects or rodents or otherwise constitute a nuisance.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1272 (June 2002), amended LR 37:

§913. Floors

A. The floors of all rooms in which milk or dairy products are received, handled or stored or in which utensils are cleaned shall be constructed of concrete or other equally impervious and easily cleanable material and shall be smooth, properly drained, provided with trapped drains, kept clean and in good repair.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1272 (June 2002), amended LR 37:

§915. Walls and Ceilings

A. Walls and ceilings of rooms in which milk and dairy products are handled or stored or in which utensils are cleaned shall be constructed of concrete or other equally impervious and easily cleanable material and kept clean and in good repair.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1272 (June 2002), amended LR 37:

§917. Doors and Windows

A. The dairy plant shall be provided with solid doors which shall be kept closed during the presence of dusty conditions, smoke or fumes. All outside openings shall be effectively protected against the entry of insects, rodents, dust and airborne contamination. Screen doors shall be self-closing and open outward.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S.

40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1272 (June 2002), amended LR 37:

§919. Light and Ventilation

A. All rooms in which milk or dairy products are handled or processed and in which milk containers, equipment and utensils are cleaned shall be provided with a minimum of 40-foot candles of evenly distributed light. Dry and cold storage areas shall be provided with a minimum of 15-foot candles of evenly distributed light.

B. Ventilation shall be sufficient in all areas of the plant to prevent excessive odors and the formation of excessive water condensation. Vents or lighting fixtures shall be installed in a manner to preclude the contamination of product, ingredients, packaging material, packaged products or product contact surfaces of equipment.

C. All bulk dairy product storage tanks shall be vented into a room used for processing or packaging or in a storage tank alley. Vents located elsewhere shall be equipped with air filters approved for that use by the state health officer.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1272 (June 2002), amended LR 37:

§921. Separate Rooms

A. There shall be separate rooms for:

1. the pasteurizing, ultra-pasteurizing and aseptically processing, cooling and packaging of milk and dairy products;

2. the cleaning of milk cans, bottles, totes, cases and other containers;

3. the fabrication of containers and closures for milk and dairy products;

4. cleaning and sanitizing facilities for milk tank trucks in plants receiving milk in such tanks;

5. receiving cans of milk and dairy products and cleaning and sanitizing such cans in milk plants that receive milk in cans;

6. the processing of cheese or any other dairy products in vats or other types of vessels that are uncovered while product is in them. Provided, that in dairy plants that currently have such open vats or other types of vessels in processing rooms, the state health officer may allow the use of these vats/vessels during periods in which there are no processing or cleaning activities being conducted while the vats/vessels are uncovered. Provided further, that such vats/vessels shall be equipped with properly constructed covers which are tight fitting and designed in such manner as to preclude contamination of product and shall be kept in place during the "setting operation"; and,

7. the boiler and other non-processing mechanical equipment, shop rooms and repair areas.

B. The state health officer shall have the authority to require individual plants to provide separate rooms for any purpose he determines to be necessary to prevent a compromise to food safety.

C. Rooms in which milk or dairy products are handled, processed or stored or in which dairy product containers, utensils and equipment are cleaned or stored, shall not open directly into any stable, farmstead or area in which meat, poultry or any other non-dairy foods of animal origin are handled or stored, any restaurant food preparation area or any room used for domestic purposes. All rooms shall be of sufficient size for their intended purposes.

D. Separate areas or rooms and equipment shall be provided for receiving, handling, storage and disposal of returned dairy products that have left direct control of the plant and shall be used for this purpose only. They shall be kept neat, clean and maintained in such a manner as to preclude contamination of other products and equipment or attraction of flies and rodents. Such products shall not be used for human consumption.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1273 (June 2002), amended LR 37:

§923. Toilet Facilities

A. Every dairy plant shall be provided with flush toilet facilities conforming to the regulations of Part XIII and Part XIV of this Code. Toilet rooms shall not open directly into any room in which milk, milk products, equipment, or containers are handled or stored. The doors of all toilet rooms shall be self-closing. Toilet rooms shall be kept in clean condition and in good repair. Toilet rooms shall be well ventilated by use of mechanical exhaust which discharges to the outside atmosphere. Hand washing facilities provided with hot and cold running water under pressure, soap, air dryer or single service towel shall be provided in the toilet room. Signs shall be posted in all toilet rooms informing employees that they are required to wash their hands before returning to work.

B. Toilets shall be conveniently located in or immediately adjacent to the plant and shall not be located in residences.

C. A covered trash container shall be provided in each toilet room.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1273 (June 2002), amended LR 37:

§925. Water Supply

A. The water supply shall comply with Part XII of this Code.

B. Potable water supplies for dairy plants shall comply with the following:

1. Water for dairy plant purposes shall be from supplies approved by the state health officer and properly located, protected and operated. It shall be accessible and of a safe, sanitary quality.

2. There shall be no cross-connection between the safe water supply and any unsafe or questionable water supply, or any source of pollution through which the safe water supply might become contaminated. A connection between the water supply piping and a make-up tank (such as for cooling or condensing), unless protected by an air gap or effective back-flow preventer, constitutes a violation of this requirement.

3. New individual water supplies and water supply systems which have been installed, repaired or otherwise become contaminated shall be disinfected before being placed in use. The supply or water supply system shall be made free of the disinfectant (or lowered until the disinfectant residual is equal to the normal disinfectant residual coming from the existing water supply system) by pumping to waste before any sample for bacteriological testing shall be collected.

4. Samples for bacteriological testing of individual water supplies and water supply systems shall be taken by the state health officer upon the initial approval of the physical structure, each six months thereafter and when any repair or alteration of the individual water supply or water supply system has been made. Samples shall be taken by the state health officer and examinations shall be conducted in an official laboratory. To determine if water samples have been taken at the frequency established in this section, the interval shall include the designated six-month period plus the remaining days of the month in which the sample is due.

5. Besides meeting bacteriological standards of Appendix G, Section I of the PMO, of potable water supplied by individual water supplies shall also comply with applicable chemical, physical, and radiological standards. Samples for same shall be submitted by the milk or dairy facility to a certified chemical laboratory/drinking water (as defined in Part XII of this Code) every five years. The state health officer shall determine which chemical, physical, or radiological contaminants or parameters the water should be tested for. Copies of the laboratory results of samples shall be submitted to the state health officer by the milk or dairy facility.

6. The water samples shall be tested in a laboratory, approved by the state health officer using the methodology prescribed by *Appendix G* of the *PMO*. The state health officer shall take appropriate regulatory action on violative water samples in accordance with the requirements of the *PMO*.

7. Current records of water test results shall be retained on file by the state health officer and by the plant.

C. Any potable water system associated with a milk or dairy facility which has at least 15 service connections or regularly serves an average of 25 individuals daily for at least 60 days out of the year is considered a public water system and must also be regulated under provisions applicable to public water systems as required in Part XII of this Code. If a potable water system meets this criteria and the source of supply of such system is from a water well, such water well shall be constructed in accord with public water system standards. With the exception of achieving and maintaining potable water quality standards as specified in other Paragraphs of this Section, compliance with other provisions under Part XII of this Code which are applicable only to public water systems shall not be required if the public water system meets all of the following conditions:

1. consists only of distribution and storage facilities (and does not have any collection and treatment facilities);

2. obtains all of its water from, but is not owned or operated by, a public water system to which such regulations apply;

3. does not sell water to any person; and,

4. is not a carrier which conveys passengers in interstate commerce.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1273 (June 2002), amended LR 37:

§927. Hand-washing Facilities

A. Hand-washing facilities provided with hot and cold running water under pressure through a mixing faucet, soap, air dryer or single service sanitary towels shall be conveniently located to all areas in which dairy products are handled and equipment is cleaned. The use of a common towel is prohibited.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1273 (June 2002), amended LR 37:

§929. Protection from Contamination

A. Dairy plant operations shall be so conducted and equipment and facilities located in such manner as to prevent contamination of dairy products, ingredients, packaging materials, equipment, containers and utensils.

B. All milk products or ingredients which have been spilled, overflowed or leaked shall not be used for human consumption.

C. The storage, handling or use of poisonous or toxic materials shall be performed in such a manner as to preclude contamination of milk products, ingredients, packaging materials or product contact surfaces of equipment, containers or utensils. All containers containing poisonous or toxic materials, including cleaning and sanitizing compounds, shall be distinctly and prominently labeled.

D. All equipment and piping containing cleaning solutions/compounds shall be physically separated from equipment containing dairy products.

E. All equipment and piping containing pasteurized food products shall be physically separated from equipment and piping containing unpasteurized food products.

F. Pasteurized dairy products shall not be permitted to come in contact with equipment or piping with which unpasteurized dairy products or non-dairy products have been in contact, unless such equipment has first been properly cleaned and sanitized.

G. All water used to flush pasteurized product out of lines, vessels or equipment shall be pasteurized or treated by other treatment approved by the state health officer with the concurrence of the FDA. All lines, vessels or equipment that have contained water or product that was not pasteurized or

treated, as afore provided, shall be cleaned and sanitized prior to use for pasteurized products.

H. The dairy plant shall be used for no other purpose than the processing of dairy products and the operations incident thereto, provided that the state health officer may authorize the processing or handling of products other than dairy products in such a manner as to preclude the contamination of dairy products, product contact surfaces of all equipment, piping or containers.

I. Air under pressure that comes in contact with dairy products or product contact surfaces shall be free from oil, dust, rust, excessive moisture, extraneous materials or odor and shall comply with the requirements for air under pressure contained in the *PMO*.

J. Steam that is used in contact with dairy products shall comply with the applicable standards of the *PMO* and be of culinary quality.

K. Equipment and operations shall be so located within the dairy plant as to prevent overcrowding and contamination of product, equipment, containers, packaging materials or ingredients by splash, condensation, manual contact or drippings, spillage or splash from overhead piping, cooling equipment, platforms, etc.

L. Effective insect and rodent control programs shall be conducted. Dogs, cats and other animals or fowl and birds shall not be allowed in the dairy plant.

M. Multi-use containers or equipment used for dairy products, such as milk crates, bossy carts, milk cans, etc., that have been on premises where swine or poultry are kept, or premises where raw poultry or pork products are processed or have been used to store raw poultry or pork products shall not be used in the processing or handling of dairy products.

N. Eggs and raw egg products shall be handled or stored in areas separated from dairy products in such a manner as to preclude contamination of floors, conveyors, cases, etc., used for dairy products handling or storage, provided, that delivery vehicles are exempt from this requirement when adequate steps are taken to preclude contamination of dairy products or containers/crates from broken eggs or leaking raw egg products.

O. Fork lifts, pallet jacks and other materials handling equipment that have been in contact with driveways, concrete/ground surfaces of the exterior of the dairy plant or have been used in areas where meat, poultry, pork and returned dairy products are handled shall not enter the areas of the dairy plant where dairy products are handled, processed or stored or areas in which containers and equipment are cleaned, sanitized or stored.

P. Entry into each specific area of the plant where dairy products are handled, processed, packaged or stored shall be restricted to personnel whose presence is necessary for conducting, supervising or inspecting operations in that specific area. Training activities may be allowed.

Q. Each entrance into each area where dairy products are handled, processed, packaged, stored or dairy equipment is cleaned shall be provided with footwear baths containing sanitizers that effectively sanitize footwear. These footwear baths shall be so located and maintained in such a manner as to effectively sanitize the footwear of all persons entering these areas. Spray type devices and other devices approved by the state health officer that adequately perform the same function as the footwear baths may be used.

R. Lighting fixtures shall be constructed and installed in such a manner as to preclude the contamination of products, ingredients, packaging material, packaged products or product contact surfaces of equipment.

S. Graded dairy products, not in the final package, shall not be permitted to come in contact with products of a lower grade or with ungraded products or with utensils, piping or equipment which has been in contact with lower grade or ungraded products unless such utensils, piping or equipment have been properly cleaned prior to use for higher graded product.

T. Returned dairy products (dairy products that have left the direct control of the plant that processed them) shall be handled in such a manner that they do not come in physical contact or contact through drippage or spillage with any area in which other products are stored or handled. They shall not come in such contact with any equipment used in the handling of other products. The returned dairy products shall be clearly identified and other prudent measures taken to preclude contamination or integration with wholesome products.

U. All floor drains in areas of the plant used for receiving, processing, handling dairy products and where containers, utensils and equipment are cleaned shall be kept in good repair, cleaned and sanitized at least once each week. Brushes used to clean floor drains should be color coded and said brushes shall not be used for any other purpose.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1273 (June 2002), amended LR 37:

§931. Reclaim or Rework Operations

A. Reclaim or rework operations are all activities associated with the recovery, handling and storage of processed or partially processed products for use as an ingredient in products to be used for human consumption.

B. Product that has left the direct control of the plant or has been temperature-abused, tampered with or exposed to chemical or biological contamination shall not be reclaimed or reworked for use as an ingredient in other products for human consumption.

C. Reclaimed or reworked products and reclaim or rework operations shall conform with the following requirements.

1. Reclaim areas and equipment shall be constructed, maintained and protected in a manner that is in substantial compliance with the requirements for the production and processing equipment areas contained in this Part.

2. Product that has left the direct control of the plant in which it was packaged shall not be reclaimed or reworked.

3. All product to be reclaimed shall be maintained at 7°C (45°F) or below. Product salvaged from defoamers and tank or line rinsing shall be immediately cooled to 7°C (45°F) or below.

4. Packages of product to be reclaimed or reworked shall be clean and free of contamination. Product from open,

leaking or badly damaged containers shall not be reclaimed or reworked.

5. Packaged product shall be opened in such a manner as to minimize the potential for contamination. Containers shall not be opened by slashing, smashing or breaking.

6. Woven wire strainers shall not be used in reclaim or rework operations.

7. Reclaim or rework dump stations and tanks shall be covered except when product is actually being dumped through the openings.

8. Reclaim or rework storage tanks shall be equipped with approved thermometers.

9. Cleaning and sanitization requirements shall be the same as those for raw dairy ingredient handling equipment.

10. Reclaimed or reworked product shall be handled as a raw dairy ingredient.

11. Reclaimed or reworked products when used as an ingredient shall be added to the final product prior to pasteurization.

12. It is recommended that higher than minimum temperatures and times be used in the pasteurization of product containing reclaimed or reworked ingredients.

13. The milk plant shall take appropriate steps to preclude the contamination of products or equipment with allergenic or sensitive producing ingredients, reclaimed or reworked ingredients or substances that will not be appropriately declared in the labeling of the final container of product.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1273 (June 2002), amended LR 37:

§933. Dairy Plant Cleanliness

A. All rooms in which milk and dairy products are handled, processed or stored, or in which containers, utensils or equipment are cleaned or stored, shall be kept clean, neat and free of evidence of insects and rodents. Approved pesticides shall be stored, handled and used so as not to present a health hazard. Only equipment directly related to processing operations or to handling of containers, utensils and equipment shall be permitted in the receiving, pasteurizing, ultra-pasteurizing, aseptic processing, cooling, packaging and bulk milk and dairy products storage areas.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1273 (June 2002), amended LR 37:

§935. Sanitary Piping

A. All sanitary piping, fittings, connections and automated cleaning systems shall comply with applicable 3-A Standards or the construction thereof shall be approved in writing by the state health officer, and shall consist of smooth, impervious, corrosion-resistant, non-toxic, easily cleanable material. All piping, fittings and connections shall be in good repair. Pasteurized milk and milk products shall be transferred from one piece of equipment to another only through sanitary piping.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1273 (June 2002), amended LR 37:

§937. Construction and Repair of Containers and Equipment

A. All multi-use containers and equipment with which milk or dairy products come into contact and automated cleaning equipment shall comply with applicable 3-A Standards. They shall be of smooth, impervious, corrosion-resistant, non-toxic material; shall be constructed for ease of cleaning and be easily accessible or demountable for manual cleaning or be designed for mechanical cleaning. All product contact surfaces shall be readily accessible for inspection, shall be self-draining and shall be kept in good repair. All single-service milk containers and closures used for milk, milk products or other dairy products shall be manufactured by plants certified by FDA and listed in the latest publication of the *IMS List Sanitation Compliance and Enforcement Ratings of Interstate Milk Shippers* or shall comply with all requirements of this Part. Gaskets and other articles with which milk or dairy products come in contact shall be non-toxic, and shall have been manufactured, packaged, transported and handled in a sanitary manner. Articles intended for single-service use shall not be reused. The design, construction and method of employment of all dairy equipment shall be approved by the state health officer prior to installation.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1273 (June 2002), amended LR 37:

§939. Thermometers

A. Unless the thermometers and other temperature monitoring instruments and recording devices used in dairy plants are accurate within known limits, there can be no assurance that proper temperatures for cooling, pasteurization, ultra-pasteurizing, aseptic processing, storage, cleaning, etc., are being applied.

B. All thermometers, temperature monitoring instruments, and recording devices used in dairy plants shall conform with the requirements for such thermometers, temperature monitoring instruments, and recording devices contained in the *PMO*.

C. The operator shall record the temperature, as shown by the indicating thermometer, on the recording chart each time a chart is placed in each recorder and at least once during each 24-hour period of operation.

D. The dairy plant shall test and calibrate all indicating and recording thermometers used in the dairy plant (including CIP system and dairy product storage tank and product storage rooms recording thermometers) at least once in each three-month period using a test thermometer approved by the state health officer. Provided that any thermometers tested and calibrated by the state health officer need not be tested and calibrated by the dairy plant until the lapse of three months from the date they were tested and calibrated by the state health officer.

E. During each inspection of each milk plant's processing operation, the state health officer shall examine and initial a representative sample of each type of recording charts and logs to verify the calibration of monitoring

devices and to verify that the operations were conducted in accordance with the requirements of this Part.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§941. Pasteurization, Ultra-Pasteurization and Aseptic Processing

A. All dairy products (e.g., milk solids, whey, nonfat dry milk, condensed milk, cream, nonfat (fat free, skim) milk, etc.), eggs, egg products, cocoa, cocoa products, frozen dessert mixes, emulsifiers, stabilizers, vitamins, sweeteners and any other approved ingredients (with the exception of those ingredients listed in Subsection B of this Section shall be added prior to pasteurization, ultra pasteurization or aseptic processing.

B. The only ingredients which shall be added after pasteurization or ultra pasteurization are those flavoring ingredients which are:

1. fresh fruits or vegetables and only when they are added to cultured dairy products having a pH of less than 4.7 and only in a dairy plant having a quality assurance program which is considered adequate by the state health officer;
2. subjected to prior heat treatment sufficient to destroy all pathogenic microorganisms;
3. a water activity of 0.85 (Aw) or less;
4. high acid content products;
5. roasted nuts;
6. dry sugars;
7. flavor extracts containing high alcohol content; or
8. safe and suitable bacterial cultures.

C. Such additions shall be made only with approval of the state health officer with the concurrence of FDA and in a manner which prevents product contamination.

D. Pasteurization and ultra-pasteurization shall be performed in equipment and using procedures that conform with the requirements of *PMO* and current applicable 3-A Standards and are approved by the state health officer.

E. Aseptic processing shall be performed in accordance with *Title 21 CFR Parts 108 and 113* and the requirements of *PMO*.

F. Pasteurization, ultra-pasteurization and aseptic processing shall be controlled as a CCP in plants being regulated under HACCP.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§943. Cleaning and Sanitization of Containers and Equipment

A. All multi-use containers and equipment used in the processing, handling, storage or transportation of milk and dairy products shall be properly cleaned after each use and shall be cleaned at least once each 24 hours of use, provided:

1. storage tanks shall be cleaned each time they are emptied and shall be emptied at least every 72 hours;
2. storage tanks used to store raw milk or heat treated milk products longer than 24 hours and silo tanks used to store raw milk or heat treated milk products shall be equipped with a seven-day temperature recording device complying with the requirements for such devices contained in the *PMO* and shall be approved by the state health officer prior to installation;
3. upon review of information provided by the milk plant supporting the cleaning of multi-use containers and equipment at frequencies extending beyond the 24 hour requirement, the state health officer may with the concurrence of the FDA, on a case by case basis, authorize cleaning intervals greater than 24 hours;
4. records shall be available to the state health officer to verify that storage tanks have been properly cleaned at least once each 72 hours or at the frequency established by the state health officer in concurrence with the FDA.

B. Milk and milk product pipelines and equipment designed for mechanical CIP cleaning shall meet the following requirements.

1. An effective cleaning and sanitization regimen that shall be followed for each separate cleaning and sanitization operation shall be posted near the cleaned -in-place equipment controls.
2. A temperature recording device complying with the requirements for such recording device contained in the *PMO* and approved by the state health officer shall be installed in the cleaning and sanitizing solution return line or other area, approved by the state health officer with the concurrence of the FDA, to record the temperatures and times during which the line or equipment is exposed to cleaning and sanitizing solutions. The state health officer may require that pressure gauges, other instruments or logs be provided to verify that cleaning and sanitization was properly performed.
3. Charts/records/logs used to verify proper cleaning and sanitizing shall be retained for a minimum of three months.
4. During each inspection of the cleaning and sanitizing operations of each plant, the state health officer shall examine and initial a representative sample of each type of charts/records/logs to verify that the operations were conducted in accordance with the posted cleaning and sanitization regimens.

C. All multi-use containers and equipment shall be effectively sanitized before first use by means approved by the state health officer. Assembled equipment shall be sanitized prior to each first use.

D. Piping, equipment and containers used to process, conduct or package aseptically processed milk and dairy products beyond the final heat treatment process, shall be sterilized before any aseptically milk or milk product is packaged and shall be re-sterilized whenever any unsterile product has contaminated it.

E. Multi-use milk crates and bossy carts shall be properly cleaned and sanitized before each use and before being brought into any area of the plant where milk and dairy products are pasteurized, processed, cooled or packaged.

F. Cleaning procedures; including solution mixing directions, strengths, testing procedures, temperature requirements, circulation times, etc., shall be posted adjacent to all equipment used to clean or sanitize dairy equipment.

G. The posted procedures shall be followed in the cleaning and sanitization of the equipment.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§945. Storage of Cleaned Containers and Equipment

A. After cleaning, all multi-use milk or dairy product containers, utensils and equipment shall be transported and stored to assure complete drainage, unless stored in sanitizing solutions, and shall be protected from contamination before use.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§947. Storage of Single-service Containers, Utensils and Materials

A. Single-service caps, cap stock, parchment paper, films, containers, gaskets and other single-service articles for use in contact with dairy products including frozen desserts products shall be purchased from sources approved by the state health officer and stored in the original container or in equipment designed for storage of single service articles and shall be kept therein in a clean, dry place until used; and shall be handled in a sanitary manner.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§949. Packing, Bottling and Wrapping

A. Bottling, packaging and wrapping of milk and dairy products shall be done at the place of pasteurization, ultra-pasteurization or aseptic processing in mechanical equipment that complies with applicable 3-A Standards and the *PMO, Item 18p*.

B. Upright open containers and container closures shall be protected from contamination by the use of overhead shields and drip deflectors.

C. Air directed at the contact surfaces of containers or closures shall comply with the requirements for such air, contained in the *PMO*.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§951. Capping

A. Capping or closing of milk and dairy product containers shall be done in a sanitary manner in mechanical equipment that complies with applicable 3-A Standards and the *PMO, Item 19p*. Single service containers and closures used for milk and milk products shall have been manufactured by plants that comply with the single service container and closure requirements of this Code. The cap or closure shall protect the milk pouring lip to at least its largest diameter and, with regard to fluid product containers, removal cannot be made without detection.

B. Hand capping is prohibited.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§953. Delivery Containers

A. All pasteurized, ultra-pasteurized and aseptically processed milk and dairy products shall be placed in their final delivery containers in the plant in which they are pasteurized, ultra-pasteurized or aseptically processed. It shall be unlawful for hotels, soda fountains, restaurants, grocery stores, markets and similar establishments to sell or serve any milk or milk products except in the original containers received from the plant in which it was pasteurized, ultra-pasteurized or aseptically processed or from a bulk container dispensing device that conforms with 3-A Standards. Packaging of milk and milk products from such dispensers is prohibited. This requirement shall not apply to cream consumed on the premises or milk and milk products in portions less than 1/2 pint used in mixed drinks, cereals, desserts or other foods. In these instances, pouring from a commercially filled container of not more than one gallon capacity is acceptable. (see LAC 51:XXIII.1115.B)

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§955. Cooling of Dairy Products

A. All raw milk and milk products shall be received and maintained at 7°C (45°F) or less until processed, except that acid-type whey with a titratable acidity of 0.40% or above, or a pH of 4.6 or below, is exempted from these temperature requirements. Provided, that all balance or surge tanks (continuous flow with a retention time not to exceed one hour) for raw milk and milk products, pasteurized milk and milk products and whey and whey products may be maintained at any temperature for up to 24 hours.

B. All whey and whey products for condensing and/or drying are maintained at a temperature of 7°C (45°F) or less; or 57°C (135°F) or greater until processed. Storage tanks containing whey and whey product above 7°C (45°F) and below 57°C (135°F) shall be emptied, cleaned and sanitized after each 4 hours of use or less. (Nothing shall be construed as barring other time and temperature relationships, which have been recognized to be equally efficient and which are approved by the state health officer).

C. All pasteurized milk and milk products, except the following, are cooled immediately in approved equipment prior to filling or packaging to a temperature of 7°C (45°F) or less, unless drying is commenced immediately after condensing:

1. those to be cultured;

2. cultured sour cream at all milkfat levels with a pH of 4.70 or below. (Critical factors including, but not limited to, pH and cooling time and temperature shall be monitored and documented by the processing facility for verification by the state health officer. pH limit with a ph variance of +0.05 units to account for reproducibility and inaccuracies in pH measurements. Formulation or processing changes that affect critical factors shall be communicated to the state health officer);

3. acidified sour cream at all milkfat levels with a pH of 4.60 or below. (Critical factors including, but not limited to, pH and cooling time and temperature shall be monitored and documented by the processing facility for verification by the state health officer. pH limit with a ph variance of +0.05

units to account for reproducibility and inaccuracies in pH measurements. Formulation or processing changes that affect critical factors shall be communicated to the state health officer);

4. all yogurt products at all milkfat levels with an initial pH of 4.80 or below at filling. (Critical factors including, but not limited to, pH and cooling time and temperature shall be monitored and documented by the processing facility for verification by the state health officer. pH limit with a ph variance of +0.05 units to account for reproducibility and inaccuracies in pH measurements. Formulation or processing changes that affect critical factors shall be communicated to the state health officer);

5. cultured buttermilk at all milkfat levels with a pH of 4.60 or below. (Critical factors including, but not limited to, pH and cooling time and temperature shall be monitored and documented by the processing facility for verification by the state health officer. pH limit with a pH variance of +0.05 units to account for reproducibility and inaccuracies in pH measurements. Formulation or processing changes that affect critical factors shall be communicated to the state health officer); and

6. all condensed whey and whey products shall be cooled during the crystallization process to 10°C (50°F) or less within 72 hours of condensing, including the filling and emptying time, unless filling occurs above 57°C (135°F), in which case, the 72 hour time period begins when cooling is started. (Nothing shall be construed as barring other time and temperature relationships, which have been recognized to be equally efficient and which are approved by the state health officer).

D. All pasteurized milk and milk products, except the following, shall be stored at a temperature of 7°C (45°F) or less and be maintained thereat following filling or until further processed:

1. Cultured sour cream at all milkfat levels with a pH of 4.70 or below. (Critical factors including, but not limited to, pH and cooling time and temperature shall be monitored and documented by the processing facility for verification by the state health officer. pH limit with a pH variance of +0.05 units to account for reproducibility and inaccuracies in pH measurements. Formulation or processing changes that affect critical factors shall be communicated to the state health officer) and cooled to 7°C (45°F) or less within 168 hours of filling. (Temperature monitored at the slowest cooling portion, i.e., middle of the container, of the slowest cooling container, i.e., in the middle of the pallet).

2. Acidified sour cream at all milkfat levels with a pH of 4.60 or below. (Critical factors including, but not limited to, pH and cooling time and temperature shall be monitored and documented by the processing facility for verification by the state health officer. pH limit with a pH variance of +0.05 units to account for reproducibility and inaccuracies in pH measurements. Formulation or processing changes that affect critical factors shall be communicated to the state health officer) and cooled to 7°C (45°F) or less within 168 hours of filling (Temperature monitored at the slowest cooling portion, i.e., middle of the container, of the slowest cooling container, i.e., in the middle of the pallet).

3. All yogurt products at all milkfat levels with an initial pH of 4.80 or below. (Critical factors including, but not limited to, pH and cooling time and temperature shall be monitored and documented by the processing facility for verification by the state health officer. pH limit with a pH variance of +0.05 units to account for reproducibility and inaccuracies in pH measurements. Formulation or processing changes that affect critical factors shall be communicated to the state health officer) at filling, with a pH of 4.60 or below within 24 hours of filling (critical factors including, but not limited to, pH and cooling time and temperature shall be monitored and documented by the processing facility for verification by the state health officer. pH limit with a pH variance of +0.05 units to account for reproducibility and inaccuracies in pH measurements. Formulation or processing changes that affect critical factors shall be communicated to the state health officer) and cooled to 7°C (45°F) or less within 168 hours of filling (Temperature monitored at the slowest cooling portion, i.e., middle of the container, of the slowest cooling container, i.e., in the middle of the pallet).

4. Cultured buttermilk at all milkfat levels with a pH of 4.60 or below (Critical factors including, but not limited to, pH and cooling time and temperature shall be monitored and documented by the processing facility for verification by the state health officer. pH limit with a pH variance of +0.05 units to account for reproducibility and inaccuracies in pH measurements. Formulation or processing changes that affect critical factors shall be communicated to the state health officer) and cooled to 7°C (45°F) or less with 24 hours of filling (Temperature monitored at the slowest cooling portion, i.e., middle of the container, of the slowest cooling container, i.e., in the middle of the pallet).

E. All pasteurized milk and milk products to be condensed and/or dried, shall be stored at a temperature of 10°C (50°F) or less and be maintained thereat until further processed. If storage tanks are used between the condenser and dryer, any such storage tank(s) containing pasteurized milk or milk products stored above 10°C (50°F) and below 57°C (135°F) shall be completely emptied and cleaned after each six hours of operation or less (Nothing shall be construed as barring other time and temperature relationships, which have been recognized to be equally efficient and which are approved by the state health officer).

F. Each refrigerated room in which milk and milk products are stored, except aseptically processed milk and milk products, is equipped with an indicating thermometer that complies with the applicable specifications of Appendix H, Subsection IV (Indicating thermometers used in refrigerated rooms where milk and milk products are stored) of the PMO. Such thermometer shall be located in the warmest zone of the refrigerated room.

G. Each storage tank shall be equipped with an indicating thermometer, the sensor of which shall be located to permit the registering of the temperature of the contents when the tank contains no more than 20 percent of its calibrated capacity. Such thermometer shall comply with the applicable specifications of Appendix H, Subsection IV (Indicating thermometer used in storage tanks) of the PMO. See §943.A.2 of this Part for recording device requirements in certain circumstances.

H. On delivery vehicles, the temperature of milk and milk products shall not exceed 7°C (45°F).

I. All surface coolers comply with the following specifications:

1. The sections of open-surface coolers shall be so installed as to leave a gap of at least 6.4 millimeters (0.25 inches) between the header sections to permit easy cleaning.

2. Where header ends are not completely enclosed within the cooler covers, condensation or leakage from the headers shall be prevented from entering the milk or milk product by so shaping the exposed header faces, above and below all gaps, that condensation is directed away from the tubes, and by using deflectors at the bottom of the headers, or by shortening the bottom trough, or by some other approved method.

3. The location of supports of cooler sections shall prevent condensation and leakage from entering the milk or milk product.

4. All open-surface coolers shall be provided with tight-fitting shields that protect the milk and milk product from contamination by insects, dust, drip, splash or manual contact.

J. Recirculated cooling water, which is used in coolers and heat exchangers, including those systems in which a freezing point depressant is used, is from a safe source and protected from contamination. Such water shall be tested semiannually and shall comply with the bacteriological standards of Appendix G, Section I of the PMO. Samples shall be taken by the state health officer and examination shall be conducted in an DHH-OPH Certified Bacteriological/Drinking Water Laboratory. Recirculated cooling water systems, which become contaminated through repair work or otherwise, shall be properly disinfected and tested before being returned to use. Freezing point depressants and other chemical additives, when used in recirculating systems, shall be non-toxic under conditions of use. Recirculated cooling water contained in corrosion resistant, continuous piping, with no joints or welds, which fail to meet applicable American Society of Mechanical Engineers (ASME) or equivalent standards in the non-potable water contact areas, may be considered to be protected from contamination, as required above, when cooled by non-potable water flowing over the exterior of the piping, within open evaporative type cooling tower. In these systems, the recirculated cooling water piping shall be properly maintained and shall be installed so that it is at least 2 pipe diameters above the flood rim of the cooling tower.

K. Water from an open, evaporative cooling tower may be used to cool water in an intermediate cooling media loop that will subsequently be used to cool product, provided that the water in the intermediate cooling media loop is effectively protected against infiltration and contamination by tower water at all times. If a plate type or double/triple tube type heat exchanger is used to exchange heat between the water from the open tower and the water in the intermediate cooling media loop it must be protected by an Isolation System to assure that there is no possibility of contamination of the intermediate cooling media loop water by the tower water. The isolation system shall include:

1. tower water heat exchangers shall be constructed, installed and operated so that the intermediate cooling media water in the heat exchanger will automatically be under greater pressure than the open tower water in the heat exchanger at all times;

2. the tower water heat exchanger shall be effectively isolated from the tower water system and the tower water side of the heat exchanger shall drain during shut down;

3. the Isolation System shall be controlled with a pressure differential controller set to a minimum of 6.9 kPa (1 psi). Pressure sensors shall be installed at the tower water inlet to the heat exchanger and intermediate cooling water outlet of the heat exchanger. The differential pressure controller will be interwired with the related supply valves and/or pumps to automatically shut down all supply pumps and return valves in the Isolation System to a fail-safe position to isolate the heat exchanger from the open tower water system, as would occur in a shut down or power failure;

4. the intermediate cooling water shall rise to a vertical elevation of at least 30.5 centimeters (12 inches) above the highest tower water heat exchanger Isolation System, and shall be open to the atmosphere at this elevation. During a shut down the intermediate cooling water shall not drain from the tower water heat exchanger;

5. the Isolation System shall meet one of the following:

a. in a system with tower water supplied directly from the tower water distribution line without a balance tank, or with a balance tank higher than the lowest water level in the tower water heat exchanger, refer to Figures 8, 9, and 10 in Appendix D, Section VII of the *PMO*. In this application, the Isolation System shall begin at the normally closed tower water supply stop "block" valve and ends at the check-valve in the line returning to the open cooling tower. Isolation is accomplished by meeting all of the following:

i. closing the tower water supply valve. This tower water supply valve shall be a normally closed (spring-to-close) valve;

ii. opening a full port vent valve on the supply side of the tower water heat exchanger and a full port drain valve prior to a check-valve in the tower water return line. This drain valve shall be normally open (spring-to-open);

iii. the drain valve and any pipes or pumps located between the drain valve and the heat exchanger must be lower than the lowest liquid level in the heat exchanger;

iv. de-energize any dedicated tower water supply pump, if present, located between the tower water reservoir and the tower water heat exchanger; and

v. if a tower water return pump is used, a bypass line may be used to flood the dry pump at start up;

b. in a system with the overflow of an atmospheric balance tank lower than the lowest water level in the heat exchanger, refer to Figures 11 and 12 in Appendix D, Section VII of the *PMO*. In this application, the Isolation System shall begin at the tower water balance tank and end at the check-valve in the line returning to the open cooling tower. Isolation is accomplished by meeting all of the following:

i. de-energizing the "local tower water supply pump", if present;

ii. opening a full port vent valve on the supply side of the tower water heat exchanger;

iii. open a full port drain valve prior to a check-valve in the tower water return line. This drain valve must be normally open (spring-to-open); and

iv. the drain valve and any pipes or pumps located between it and the heat exchanger must be lower than the lowest liquid level in the heat exchanger;

c. variations from the above isolation systems may be individually evaluated and found to also be acceptable by the state health officer, if the level of protection required by this Subsection is not compromised.

6. A means to test the response of this isolation system must be developed and available at the milk plant. The accuracy of the required differential pressure controller shall be checked by the state health officer on installation; every six months thereafter; and following repair or replacement.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§957. Use of Overflow, Leaked, Spilled or Mishandled Dairy Products

A. The use of overflow, leaked, spilled or mishandled dairy products for human consumption is prohibited.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§959. Sale of Reconstituted or Recombined Milk or Milk Products and Reconstituted or Recombined Anomalous (Substitute) Milk or Milk Products

A. The sale of reconstituted or recombined milk or milk products and reconstituted or recombined anomalous (substitute) milk or milk products shall be prohibited.

B. No reconstituted or recombined milk or milk products, (to include whole milk, reduced fat milk, lowfat milks, nonfat milk, flavored milks, creams, half-and-half) and reconstituted or recombined anomalous (substitute) milk and milk products shall be permitted to be held, kept, offered for sale, sold or delivered, provided in an emergency, the sale of reconstituted fluid milk products may be authorized by special permit from the state health officer and shall be labeled in accordance with the labeling requirements of this Part.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§961. Use of Inhibitors

A. The addition of any substance to dairy products for the purpose of preventing growth of bacteria is prohibited (see definition of adulterated milk, milk products, or dairy products, §101 of this Part).

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§963. Denaturing of Milk or Dairy Products

A. The state health officer may immediately denature, with rennet or some harmless coloring matter, dairy products found to be adulterated, misbranded with respect to grading or sold without a permit.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§965. Dipping or Transferring Dairy Products

A. Dairy products shall not be dipped or transferred from one container to another on the street or in any vehicle or store or in any place except in dairy plants possessing a permit for such activity issued by the state health officer, provided, that milk producers may transfer raw milk from milking pails or milking machines to milk cans or bulk tanks in the milk house/room on dairy farms in a sanitary manner.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§967. Apparatus, Containers, Equipment and Utensils

A. Apparatus, containers, equipment and utensils used in the production, handling, storage, processing or transporting of dairy products shall not be used for any other purpose without the authorization of the state health officer.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§969. Personnel Health

A. No persons affected with any disease capable of being transmitted to others through the contamination of food shall work at a dairy plant in any capacity which brings them into direct contact with finished products, such as pasteurized, ultra-pasteurized or aseptically processed milk or dairy products or which brings them into direct contact with associated pasteurized, ultra-pasteurized or aseptically processed dairy product-contact surfaces.

B. Dairy plant employees, or applicants to whom a conditional offer of employment has been made, shall be responsible to report to the dairy plant management if he/she:

1. is diagnosed with an illness due to Hepatitis A virus, Salmonella typhi, Shigella species, Norwalk-like viruses, Staphylococcus aureus, Streptococcus pyogenes, Escherichia coli, Campylobacter jejuni, Entamoeba histolytica, Giardia lamblia, Non-typhoidal Salmonella, Rotovirus, Taenia solium, Yersinia enterocolitica, Vibrio cholerae O1, tuberculosis or other infectious or communicable disease that has been declared by the state health officer to be transmissible to others through the handling of food, or has been clearly shown to be so based upon verifiable epidemiological data;

2. has been exposed to, or is suspected of causing, a confirmed foodborne disease outbreak of one of the diseases specified in §971, including an outbreak at an event such as a family meal, church supper or ethnic festival because the employee or applicant to whom a conditional offer of employment has been made:

a. prepared food implicated in the outbreak;

b. consumed food implicated in the outbreak; or

c. consumed food at the event prepared by a person who is infected or ill.

3. lives in the same household as a person who attends or works in a day care center, school, or similar institution experiencing a confirmed outbreak of one of the diseases specified in §969.B.1 above.

C. Similarly, dairy plant employees shall be instructed by the dairy plant management to report to the dairy plant management if the employee, or applicant to whom a conditional offer of employment has been made if he/she;

1. has a symptom associated with acute gastrointestinal illness such as diarrhea, fever, loss of appetite for three or more days, vomiting, jaundice; or

2. has a pustular lesion such as a boil or infected wound that is:

a. on the hands, wrists or exposed portions of the arms, unless the lesion is covered by a durable, moisture proof, tight-fitting barrier; or

b. on other parts of the body if the lesion is open or draining, unless the lesion is covered by a durable, moisture proof, tight-fitting barrier.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§971. Notification of Disease

A. Dairy plant operators and dairy plant management who have received reports, under §969, from employees who have handled pasteurized, ultra-pasteurized or aseptically processed milk, pasteurized milk products or associated product-contact surfaces shall immediately report these facts to the state health officer.

B. When a person has been reported under §969, or is otherwise known to meet one or more of the conditions listed under §969, and it is found that such person may have handled pasteurized, ultra-pasteurized or aseptically processed milk, pasteurized milk products or associated product-contact surfaces, the state health officer is authorized to require any or all the following measures:

1. the immediate restricting of that person from duties which require handling finished product such as, but not limited to, pasteurized milk or dairy products, or the handling of related product-contact surfaces. This restriction may be lifted after an appropriate medical clearance or cessation of symptoms or both, according to the following criteria in the following table;

Removal of Restrictions When Infection or High Risk of Infection is Discovered	
Health Status	**Removing Restrictions**
Is diagnosed with an illness due to Hepatitis A virus, *Salmonella typhi*, Shigella species, Norwalk and Norwalk-like viruses, *Staphylococcus aureus, Streptococcus pyogenes, Escherichia coli* 0157:H7, enterohemorrhagic *Escherichia coli*, enterotoxigenic *Escherichia coli*, *Campylobactor jejuni, Entamoeba histolytica, Giardia lamblia*, Non-typhoidal Salmonella, Rotovirus, *Taenia solium, Yersinia enterocolitica, Vibrio cholerae* O1, tuberculosis or other infectious or communicable disease that has been declared by the state health officer to be transmissible to others through the handling of food or has ben clearly shown to be so based upon verifiable epidemiological data.	Restrictions lifted by medical clearance.
Meeting a high risk scenario as specified in §969.B.2 or 3 and/or experiencing symptoms in §969.C.1 or 2.	Restrictions lifted when symptoms cease or medical documentation is provided that infection does not exist.
Asymptomatic, but stools positive for *Salmonella typhi, Shigella or Escherichia* coli 0157:H7.	Restrictions lifted by medical clearance.
Past illness from *Salmonella typhi, Shigella, Escherichia coli* 0157:H7 or other human pathogens for which humans have been determined to be carriers.	Restrictions lifted by medical clearance.
In the case of diagnosed or suspected Hepatitis A, onset of jaundice within the last seven days.	Restrictions lifted by medical clearance.
In the case of diagnosed or suspected Hepatitis A, onset of jaundice occurred more than seven days ago.	Restrictions lifted by medical clearance or jaundice ceases.

2. the immediate exclusion of the affected dairy products from distribution and use when medically appropriate; and

3. the immediate requesting of medical and microbiological examination of the person at risk.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§973. Procedure when Infection Suspected

A. When suspicion arises as to the possibility of transmission of infection from any person concerned with the handling of dairy products, the state health officer is authorized to require any or all of the following measures:

1. the immediate exclusion from dairy products handling;

2. the immediate exclusion of the dairy products which may have in some manner been handled by such person from distribution and use; and

3. adequate medical and microbiological examination of the person or his associates, and of his and their body discharges or body fluids.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§975. Personal Cleanliness

A. All persons while coming in contact with dairy products, dairy containers, or dairy equipment shall conform to the following.

1. Clean outer garments shall be worn. Shorts shall not be worn as outer garments.

2. Hands shall be kept clean at all times.

3. Other than wedding bands, no jewelry, watches, chains, artificial nails, etc., shall be worn on hands, arms, around the neck or exposed flesh.

4. Adequate hair and facial hair covering shall be worn at all times.

5. Pens, pencils, thermometers or any other objects that may fall into product or equipment shall not be carried/worn above the level of the person's waist.

6. The use of tobacco is prohibited except in designated areas in which the use of tobacco would not have a deleterious effect upon food safety.

7. Food or drink shall not be brought into or consumed in areas in which products are being processed or where equipment or containers are being cleaned or stored.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§977. Allergen and Sensitivity Producing Ingredient

A. Allergens of public health significance include: eggs and egg products, milk and dairy products, peanuts and peanut products, seafood/shellfish, seeds, soy and soy products, tree nuts, wheat and wheat products and sulfites.

B. Sensitivity producing ingredients are those ingredients that cause individualistic adverse reactions other than those which result in Immunoglobulin Epsilon (I-g-E) mediated allergies.

C. Allergens and sensitivity producing ingredients shall be appropriately declared in the labeling of all foods that contain allergens and sensitivity producing ingredients.

D. The dairy plant shall take appropriate steps to preclude the contamination of products that do not contain allergens or sensitivity producing ingredients with any allergenic materials or sensitivity producing ingredients. The plant shall also take appropriate steps to insure that only ingredients or substances that are listed in the labeling are in the final product. These steps shall include:

1. proper cleaning of all equipment used in the production of products containing allergens or sensitivity producing ingredients prior to the production of products that do not contain allergens or sensitivity producing ingredients (such as cleaning of equipment used to process egg nog prior to processing dairy products not containing egg products or cleaning equipment used to process dairy products prior to processing juices, flavoring non-dairy items, etc.); and

2. insuring that CIP systems and CIP solutions that have been used to clean equipment that was used to process products containing allergen or sensitivity producing ingredients does not contain allergen or sensitivity producing ingredients residues when used to clean or sanitize equipment to be used to process products that do not contain sensitivity producing ingredients.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§979. Storage of Bottled or Packaged Milk and Dairy Products

A. Bottled milk or packaged milk or dairy products, if stored in water or ice, shall be so stored that the tops of bottles or pouring spouts of cartons will not be submerged in the water or the ice, provided that milk or dairy products packaged in pouches shall not be stored in water or ice.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§981. Sale of Warm Milk

A. Any hotel, soda fountain, restaurant, grocery store, supermarket or similar establishment which sells or serves any milk or milk products may receive such milk or milk products at a temperature of 7°C (45ºF) or less but, in any instance, shall be cooled and maintained at 5ºC (41ºF), provided that Ultra High Temperature (UHT) processed and packaged products are exempt from this requirement prior to being opened.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§983. Cleaning of Containers

A. When milk or dairy products are delivered, in multi use containers the person receiving such milk or dairy products shall thoroughly clean the containers before returning such containers.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§985. Rat Proofing

A. All buildings used in the production, processing and handling of dairy products shall be constructed and maintained in such a manner as to preclude rodents from entering such buildings. Effective measures shall be taken as to eliminate rodents on the outer premises of such buildings.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§987. Waste Disposal

A. All wastes shall be properly handled and disposed of as specified by the state health officer, in accordance with Part XXVII of the Sanitary Code.

B. Trash, solid waste and defiled dairy products shall be stored in covered, impervious, leak-proof containers in such a manner that it does not attract insects or rodents.

C. Liquid waste from stopped up or backed up drains in areas where dairy products are received, processed, handled or stored reasonably constitutes an imminent hazard to the public's health and shall be eliminated expeditiously. Dairy products in containers which have been in contact with such aforementioned wastes and trash shall not be used for human consumption.

D. The waste resulting from the cleaning, rinsing and sanitization of containers and equipment and the cleaning of floors, walls, and vehicles and any waste from flush toilet facilities shall be disposed of so as not to contaminate the products or equipment, or to create a nuisance or a public health hazard.

AUTHORITY NOTE Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§989. Vehicles

A. All vehicles used to transport dairy products in their final containers shall be constructed with permanent tops, sides, fronts and backs. Doors of a size necessary to allow the loading and unloading are permitted. The tops, sides, fronts, backs and doors or the interior of the compartment(s) in which the dairy products are transported shall be constructed of smooth, impervious and easily cleanable material. The floors of such compartments shall be constructed of metal or equally impervious materials and shall be easily cleanable and kept clean.

B. All vehicles used to transport dairy products in their final containers shall be provided with refrigeration equipment capable of cooling the ambient temperature of the compartments, in which dairy products are transported, to a temperature not to exceed 7°C (45°F).

C. The construction and operation of vehicles shall be such that dairy products are maintained at temperatures of 7°C (45°F) or less and protected from contamination.

D. Dairy products transported in vehicles with other products or materials shall be transported in a compartment(s) separated from other products or materials and maintained in such a manner as to preclude contamination of the dairy product. Provided, that the state health officer may authorize the transportation of items he may determine which are not reasonably likely to constitute a potential for contamination of the dairy products contained in the compartment.

E. The transportation of eggs or egg products, raw meat, raw poultry, raw fish or seafood in the same compartment(s) with dairy products shall be prohibited without written authorization from the state health officer. Such written authorization shall be predicated upon:

1. the state health officer's approval of a written plan, submitted by the operator, describing in detail the manner in which the dairy products will be protected from contamination;

2. the state health officer's approval of a written plan, submitted by the operator, describing, in detail, the procedures to be used by the operator to verify that the plan is being followed; and

3. failure of the operator to fulfill the requirements of the plan, shall be grounds for the seizure and condemnation of the product involved.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

Chapter 11. Dairy Plant Hazard Analysis Critical Control Point (HACCP) Systems

§1101. Hazard Analysis Critical Control Point (HACCP) Systems

A. HACCP systems are science-based systems used to ensure that food safety hazards are controlled to prevent unsafe food from reaching the consumer.

B. HACCP Definitions

Centralized Deviation Log—a centralized log or file identifying data detailing any deviation from critical limits and the corrective actions taken as required by this document.

Control—to manage the conditions of an operation to maintain compliance with established criteria, control also means that correct procedures are being followed and criteria are being met.

Control Measure—any action or activity that can be used to prevent, eliminate, or reduce a significant hazard that is managed as a critical control point.

Control Point—any step at which biological, chemical or physical factors can be controlled.

Corrective Action—procedures followed when a deviation occurs.

Critical Control Point (CCP)—a step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Critical Limit—the value(s) to which a biological, chemical or physical parameter must be controlled at a CCP to prevent, eliminate or reduce to an acceptable level the occurrence of a food safety hazard.

Critical Listing Element—a condition that constitutes a major dysfunction likely to result in a potential compromise to food safety and shall be grounds for suspension of a permit.

Deficiency—an element inadequate or missing from the requirements of the HACCP system or of this document.

Deviation—a failure to meet a critical limit.

Hazard Analysis Critical Control Point (HACCP)—a systematic approach to the identification, evaluation and control of significant dairy products safety hazards.

HACCP Plan—the written document which is based upon the principles of HACCP and which delineates the procedures to be followed.

HACCP System—the implemented HACCP plan and pre-requisite programs including other applicable NCIMS requirements contained in the PMO.

HACCP Team—the group of people within, employed by a facility or assisting, who are responsible for developing, implementing and maintaining the HACCP system.

Hazard—a biological, chemical or physical agent that is reasonably likely to cause illness or injury in the absence of its control.

Hazard Analysis—the process of collecting and evaluating information on hazards associated with the food under consideration to decide which are significant and must be addressed in the HACCP plan.

Listing Audit—an evaluation conducted by a certified milk sanitation rating officer (that has been stardardized and certified as a HACCP listing officer by FDA) using the methodology prescribed in the *Methods of Making Sanitation Rating of Milk Shippers* of the entire dairy facility to ensure compliance with Chapter 11 of this Part.

Monitor—to conduct a planned sequence of observations or measurements to assess whether a CCP is under control or to assess the conditions and practices of all required Pre-requisite Programs (PPs) and to produce an accurate record for future use in verification.

Non-Conformity—a failure to meet specified requirements of the HACCP system or of this document.

Pre-Requisite Program (PP)—procedures, including good manufacturing practices, that address operational conditions providing the foundation for the HACCP system.

Potential Hazard—any hazard to be evaluated by the hazard analyses.

Validation—the element of verification focused on collecting and evaluating scientific and technical information to determine whether the HACCP plan, when properly implemented, will effectively control the hazards.

Verification—those activities, other than monitoring, that determine the validity of the HACCP plan and that the system is operating according to the plan.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1274 (June 2002), amended LR 37:

§1103. General Requirements

A. All dairy plants, including cheese manufacturing plants and frozen dessert manufacturing plants, that are required by this Part or have been required or authorized by the state health officer to implement HACCP systems shall develop and implement HACCP systems conforming with the requirements of this Chapter.

B. The state health officer shall require that dairy plants, including cheese manufacturing plants and frozen dessert manufacturing plants, implement a HACCP system that conforms with the requirements of this Part, when in his opinion, it is in the best interest of the public health. Each dairy plant's HACCP system, when implemented shall provide a level of product safety equivalent to the level provided by similar dairy plants that are being regulated under the provisions of other Chapters of this Part.

C. Dairy plants being regulated under the provisions of this Chapter shall comply with the following provisions of the requirements contained in this Part:

1. permits (in accordance with §109 of this Part);
2. permits required for imported milk, milk products and frozen desserts (in accordance with 111 of this Part);
3. requirements for imported dairy products (in accordance with §113 of this Part);
4. milk records (in accordance with §115 of this Part);
5. falsification of records (in accordance with §117 of this Part);
6. registration (in accordance with §119 of this Part);
7. labeling (in accordance with §121 of this Part);
8. delivery of samples (in accordance with §303 of this Part);
9. pasteurization equipment tests, examination and sealing (in accordance with §313 of this Part);
10. grades of milk and milk products to be sold (in accordance with §323 of this Part);
11. procedures in emergency (in accordance with §325 of this Part);
12. continuous grading (in accordance with §327 of this Part);
13. application for regrading, reinstatement of permit and permission to resume sale of product (in accordance with §341 of this Part);
14. Grade A raw milk for pasteurization (in accordance with §349 of this Part);
15. Grade A raw milk for pasteurization (certified for interstate milk shipment) (in accordance with §351 of this Part);
16. manufacturing grade raw milk for pasteurization (milk for manufacturing purpose) (in accordance with §353 of this Part);
17. Grade A pasteurized, ultra-pasteurized and aseptically processed milk and milk products, bulk shipped Grade A pasteurized or ultra-pasteurized milk and milk products and pasteurized filled milk and filled milk products (in accordance with §355 of this Part);
18. Grade A bulk shipped, heat-treated milk and milk products (in accordance with §357 of this Part);
19. Grade A aseptically processed milk and milk products (in accordance with §359 of this Part);
20. Grade A pasteurized, ultra-pasteurized and aseptically processed milk and milk products certified for interstate shipment (in accordance with §361 of this Part);
21. milk tank trucks (in accordance with §701 of this Part);
22. sealing and protection of milk tank trucks (in accordance with §703 of this Part);
23. labeling (in accordance with §705 of this Part);
24. bulk milk tank truck operator/sampler (in accordance with §707 of this Part);
25. general requirements (in accordance with §901 of this Part);
26. approval of plans (in accordance with §903 of this Part);
27. dairy plant receivers/samplers (in accordance with §907 of this Part);
28. sale of reconstituted or recombined milk or milk products and anomalous (substitute) milk or milk products (in accordance with §959 of this Part);
29. use of inhibitors (in accordance with §961 of this Part);
30. dipping or transferring dairy products (in accordance with §965 of this Part); and
31. vehicles (in accordance with §989 of this Part).

D. The state health officer may authorize dairy plants that request permission to be regulated under the provisions of this Part to be regulated in such a manner.

E. Following are the seven HACCP principles to be included in a HACCP Plan:

1. conduct a hazard analysis for each product and process;
2. determine critical control points;
3. establish critical limits;
4. establish monitoring procedures;
5. establish corrective actions;
6. establish verification procedures; and,
7. establish record-keeping and documentation procedures.

F. Dairy plants regulated under the provisions of this Part shall perform the following HACCP Preliminary Steps:

1. Assemble a multi-disciplinary HACCP team of plant/consultant personnel.
   a. Team responsibilities:
      i. develop and update all written documentation;
      ii. implement HACCP program;
      iii. periodically verify and validate HACCP system;
      iv. provide opportunities for necessary training;
      v. maintain effective communication with plant management; and,
      vi. interact with regulatory personnel during audits/inspections.

2. Describe the product and its distribution.

a. product description to include composition, safety characteristics, water activity, pH, and temperature requirements;

b. list of ingredients and packaging materials;

c. processing methods;

d. method of distribution; and,

e. distribution condition including frozen, refrigerated, shelf-stable.

3. Identify the intended use and consumers.

a. intended use-ingredient, retail, institutional;

b. intended and likely consumers—children, adults, elderly, healthy, sick, teenagers; and,

c. distribution area—local, regional, nationwide, international.

4. Construct a flow diagram for each product/like product and each type of process, raw materials, packaging, sequence of all processing steps including addition of rework, use of air or gases, filters, screens, clarifiers, metal detectors, storage and distribution.

5. Conduct on-site verification of each flow diagram to (each product type and process shall have a different flow diagram) ensure that the intended flow diagram is accurate, complete and is the actual flow of products through the processing flow.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1276 (June 2002), amended LR 37:

§1105. Pre-requisite Programs (PPs)

A. HACCP is not a stand-alone program but is part of a larger control system. PPs are the universal procedures used to control the conditions of the plant environment that contribute to the overall safety of the product. They represent the sum of programs, practices and procedures that must be applied to produce and distribute safe products in a clean, sanitary environment. They differ from CCPs in that they are background programs that reduce the potential for the occurrence of a food safety hazard. Frequently, both HACCP plan CCPs and PPs control measures are necessary to control a food safety hazard.

B. HACCP may be implemented only in a facility that is constructed and operated in a manner that provides a sanitary environment. Dairy plant premises, building construction, maintenance and housekeeping shall be maintained in a manner sufficient to provide such an environment.

C. Dairy plants that are required to develop and implement HACCP systems by this Part shall develop and implement the following pre-requisite programs that conform with the following requirements prior to the implementation of the HACCP Plan:

1. safety of the water, steam or ice that comes into contact with food or food contact surfaces;

2. condition and cleanliness of the food contact surfaces of equipment;

3. prevention of cross-contamination from insanitary objects and or practices to food products, packaging material and other food contact surfaces, including utensils, gloves, outer garments, etc., and from raw product to processed product (e.g., pasteurizer pressure differential);

4. maintenance of hand washing, hand sanitizing and toilet facilities;

5. protection of food, food packaging material and food contact surfaces from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate and other chemical, physical and biological contaminants;

6. proper labeling, storage and use of toxic compounds;

7. control of employee health conditions that could result in the microbiological contamination of food, food packaging materials and food contact surfaces; and,

8. pest exclusion from the food plant.

D. Each dairy plant shall monitor the conditions and practices of all required PPs with sufficient frequency to ensure conformance with those conditions and that are appropriate both to the plant and to the safety of the food being processed. Each milk plant, receiving station or transfer station shall correct those conditions and practices that are not in conformance.

E. Each dairy plant shall maintain records that document the ongoing application of the PPs including a brief written description, monitoring and correction records.

F. In addition to the required prerequisite programs, any other prerequisite programs that are being relied upon in the hazard analysis to reduce the likelihood of hazards such that they are not reasonably likely to occur shall also be monitored and documented.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1276 (June 2002), amended LR 37:

§1107. Hazard Analysis

A. Each dairy plant shall develop, or have developed for it, a written hazard analysis to determine whether there are food hazards that are reasonably likely to occur for each type of dairy product processed by that dairy plant, receiving station or transfer station and to identify the control measures that the dairy plant, receiving station or transfer station can apply to control those hazards.

B. The plant shall develop or have developed for it a hazard analysis each time a product, product ingredient or process is added or changed.

C. The hazard analysis shall include hazards that can be introduced both within and outside the processing plant environment, including hazards that can occur during production, transportation, processing and distribution.

D. The hazard analysis shall be submitted in writing to the state health officer for approval prior to processing of a product or change of process for which the hazard analysis was made.

E. A hazard that is reasonably likely to occur is one for which a prudent dairy plant operator would establish controls because experience, illness data, scientific reports or other information provide a basis to conclude that there is a reasonable possibility that, in the absence of these controls, the hazard will occur in the particular type of product being processed. The hazard analysis shall be developed by an individual(s) trained in accordance with this program and shall be subject to the record keeping requirement as described in this document.

1. In evaluating what food hazards are reasonably likely to occur, at a minimum, consideration should be given to the following:

a. microbiological contamination;

b. parasites;

c. chemical contamination;

d. unlawful drug and pesticide residues;

e. natural toxins;

f. unapproved use of food or color additives;

g. presence of undeclared ingredients that may be allergens or sensitivity producing ingredients; and

h. physical hazards.

2. Dairy plant operators shall evaluate product ingredients, processing procedures, packaging, storage and intended use; facility and equipment function and design; and plant sanitation including employee hygiene to determine the potential effect of each on the safety of the finished product for the intended consumer.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1276 (June 2002), amended LR 37:

§1109. HACCP Plan

A. Dairy plants that are required by the state health officer to implement a HACCP system or have authorization from the state health officer to be regulated under the provisions of this Chapter shall have and implement a written HACCP plan whenever a hazard analysis reveals one or more hazards that are reasonably likely to occur. The HACCP plan shall be developed by an individual(s) who meets the requirements contained in the PMO and shall be subject to record keeping requirements as described in this Code. A HACCP plan shall be specific to each location and product. The plan may group types of products together, or group types of production methods together, if the hazards, critical control points, critical limits and procedures required for each are essentially identical and that any required features of the plan that are unique to a specific product or method are clearly delineated in the plan and are observed in practice.

B. Written HACCP plans shall be submitted to the state health officer for review and approval prior to processing a product addressed by the plan and prior to processing a new product or making changes in a product or the manner in which a product is processed. Such review and approval shall be performed by a registered sanitarian that meets the PMO requirements for auditing HACCP plants.

C. The HACCP plan shall, at a minimum:

1. include complete up-to-date process flow diagrams for all products manufactured. Flow diagrams may be combined when process, products and hazards are similar;

2. list all hazards that are reasonably likely to occur as identified in the hazard analysis specified above, and that must be controlled for each type of product;

3. list the critical control points for each of the identified hazards, including the appropriate:

a. critical control points designed to control hazards that could occur or could be introduced in the plant environment;

b. critical control points designed to control hazards introduced outside the plant environment, including hazards that occur before arriving at the dairy plant, receiving station or transfer station; and,

c. critical control points for pasteurization as described in *Appendix H,* Section VIII of the PMO (Milk and milk products HACCP CCP models for pasteurization equipment);

4. list the critical limits that shall be met at each of the critical control points;

5. list the procedures, and the frequency with which they are to be performed, that will be used to monitor each of the critical control points to ensure compliance with the critical limits;

6. include any corrective action plans that have been developed in accordance with the corrective action requirements as described in this document, and that are to be followed in response to deviations from critical limits at critical control points;

7. list the verification procedures and the frequency with which they are to be performed, that the dairy plant will use in accordance with verification and validation requirements as described in this Part;

8. provide for a record keeping system that documents the monitoring of the critical control points in accordance with the record requirements as described in this Part. The records shall contain the actual values and observations obtained during monitoring.

D. Sanitation. Sanitation controls may be included in the HACCP plan. However, to the extent that they are monitored in accordance with the pre-requisite programs, they need not be included in the HACCP plan.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1277 (June 2002), amended LR 37:

§1111. Corrective Actions

A. Whenever a deviation from a critical limit occurs, a dairy plant shall take corrective action as follows.

1. Dairy plants may develop written corrective action plans, which become part of their Hazard Analysis and Critical Control Point (HACCP) plans, in accordance with this Part, by which dairy plants predetermine the corrective actions that they will take whenever there is a deviation from a critical limit. A corrective action plan that is appropriate for a particular deviation is one that describes the steps to be taken and assigns responsibility for taking those steps, to ensure that:

a. no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation.

b. if such product has entered commerce, it is expeditiously removed; and,

c. the cause of the deviation is corrected.

2. When a deviation from critical limit occurs, and the dairy plant does not have a corrective action plan that is appropriate for that deviation, the dairy plant shall:

a. segregate and hold the affected product.

b. perform or obtain a review to determine the acceptability of the affected product for distribution. The review shall be performed by an individual or individuals qualified by training or experience to perform such a review.

c. take corrective action, when necessary, with respect to the affected product to ensure that no product enters commerce that is either injurious to health or is otherwise adulterated as a result of the deviation.

d. take corrective action, when necessary, to correct the cause of the deviation; and,

e. perform or obtain timely validation as required in this document, by a qualified individual(s), to determine whether modification of the HACCP plan is required to reduce the risk of recurrence of the deviation, and modify the HACCP plan as necessary.

3. All corrective action taken in accordance with this Section shall be fully documented in records that are subject to verification.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1277 (June 2002), amended LR 37:

§1113. Verification and Validation

A. Every dairy plant shall verify that the hazard analysis and critical control point (HACCP) system is being implemented according to design:

1. verification activities shall include:

a. the calibration of CCP process-monitoring instruments, (pasteurization tests, thermometers, etc.) and instruments/equipment used to monitor PPs;

b. a review, including signing and dating, by an individual who has been trained in accordance with the training requirements contained in this Part, of the records that document:

i. the monitoring of CCPs. The purpose of the monitoring of CCPs review shall be, at a minimum, to ensure that the records are complete and to verify that the records document values that are within the critical limits. This review shall occur at a frequency that is appropriate to the importance of the record and as specified in the HACCP plan;

ii. the taking of corrective actions. The purpose of corrective actions review shall be, at a minimum, to ensure that the records are complete and to verify that appropriate corrective actions were taken in accordance with the corrective action requirements of §1111 of this Part. This review shall occur at a frequency that is appropriate to the importance of the record. A centralized deviation log is required; and

iii. the calibrating of any process monitoring instruments used at CCPs and the performance of any periodic end-product or in-process testing that is part of the dairy plant, receiving station or transfer station's verification activities. The purpose of the calibrating of any process monitoring instruments used at CCPs and the performance of any periodic end-product or in-process testing that is part of the dairy plant reviews shall be, at a minimum, to ensure that the records are complete and that these activities occurred in accordance with the dairy plant written procedures. These reviews shall occur within a reasonable time after the records are made;

c. the taking of corrective action procedures whenever any verification procedure establishes the need to take a corrective action;

2. the calibration of CCP process-monitoring instruments, and the performance of any periodic end-product and in-process testing shall be documented in records that are subject to the record keeping requirements in this Part.

B. Validation of the HACCP Plan. Every dairy plant shall validate that the HACCP plan is adequate to control hazards that are reasonably likely to occur. This validation shall occur at least once within 12 months after implementation and at least annually thereafter or whenever any changes in the process occur that could affect the hazard analysis or alter the HACCP plan and prerequisite program.

1. Such changes may include raw materials or source of raw materials; product formulation; processing methods or systems, including computers and their software; packaging; finished product distribution systems; or the intended use or intended consumers of the finished product. Consumer complaints may also reveal a need for validation.

2. The validation shall be performed by a qualified individual(s) and shall be subject to the record keeping requirements of §1115 of this Part. The HACCP plan shall be modified immediately whenever a validation reveals that the plan is no longer adequate to fully meet the requirements of this Part.

C. Validation of the hazard analysis. Whenever a dairy plant has no HACCP plan because a hazard analysis has revealed no hazards that are reasonably likely to occur, the dairy plant shall reassess the adequacy of the hazard analysis whenever there are any changes in the process that could reasonably affect whether a hazard exists.

1. Such changes may include raw materials; product formulation; processing methods or systems, including computers and their software; packaging; finished product distribution systems; or the intended use or intended consumers of the finished product and consumer complaints.

2. The validation shall be performed by a qualified individual(s) trained in accordance with the training requirements of this Part.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1277 (June 2002), amended LR 37:

§1115. Records

A. Dairy plants shall use consistent terminology to identify each piece of equipment, record, document or program throughout their written HACCP system. Dairy plants shall maintain the following records documenting the dairy plant, receiving station or transfer station's hazard analysis and critical control point (HACCP) system:

1. records documenting the ongoing application of the pre-requisite programs, including a brief written description monitoring and correction records;

2. the written hazard analysis;

3. the written HACCP plan;

4. records documenting the ongoing application of the HACCP plan that include:

a. monitoring of critical control points and their critical limits, including the recording of actual times, temperatures, or other measurements, as prescribed in the establishment's HACCP plan; and

b. corrective actions, including all actions taken in response to a deviation; and a centralized deviation log is required.

5. records documenting verification of the HACCP system and validation of the HACCP system including, HACCP plan, hazard analysis and pre-requisite programs; and

6. Records and documents shall be dated and each page of documents and forms marked with a new date or version number whenever updated.

B. General Requirements. All records required by this Part shall include:

1. the identity and location of the dairy plant, receiving station or transfer station;

2. the date and time of the activity that the record reflects;

3. the signature or initials of the person(s) performing the operation or creating the record; and,

4. where appropriate, the identity of the product and the production code, if any. Processing and other information shall be entered on records at the time that it is observed. The records shall contain the actual values and observations obtained during monitoring.

C. Documentation. The records in §1115.A.1-3 shall be signed and dated by the most responsible individual onsite at the dairy plant, receiving station or transfer station. These signatures shall signify that these records have been accepted by the firm.

1. The records in §1115.A.1-3 shall be signed and dated:

a. upon initial acceptance;

b. upon any modification; and

c. upon verification and validation in accordance with the requirements of §1113 of this Part.

D. Record Retention. In the case of perishable or refrigerated products, all records required by this Part shall be retained at the dairy plant facility for at least one year after the date that such products were prepared and, in the case of frozen, preserved, or shelf - stable products, two years or the shelf life of the product, whichever is greater, after the date that the products were prepared unless longer retention time is required by other regulations.

1. Records that relate to the adequacy of equipment or processes used, such as commissioning or process validation records, including the results of scientific studies and evaluations, shall be retained at the dairy plant facility for at least two years after the date that the dairy plant, receiving station or transfer station last used such equipment or process.

2. Off-site storage of processing records is permitted after six months following the date that the monitoring occurred, if such records can be retrieved and provided on-site within 24 hours of request for official review. Electronic records are considered to be on-site if they are accessible from an on-site location.

3. If the processing facility is closed for a prolonged period, the records may be transferred to some other reasonably accessible location but shall be immediately returned to the processing facility for official review upon request by the state health officer.

E. Official review. All records required by this Section shall be available for official review by the state health officer.

F. Records maintained on a computer. The maintenance of records on computer, in accordance with the above, is acceptable.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1277 (June 2002), amended LR 37:

§1117. Training and Standardization

A. HACCP training for industry and state regulatory personnel shall be based on the August 14, 1997 "Hazard Analysis and Critical Control Points Principles and Application Guidelines" of the U.S. National Advisory Committee on Microbiological Criteria for Foods (NACMCF), current FDA and NCIMS HACCP requirements and the requirements of this Part. State regulatory personnel responsible for auditing dairy plants being regulated under this Part shall have the training required to inspect dairy plants and specialized training in conducting HACCP System Audits that is approved by the FDA.

B. Only industry personnel who have received the training requirements contained in §1117.A shall be responsible for the following functions:

1. developing the hazard analysis including delineating control measures as required;

2. developing a HACCP plan that is appropriate for each individual dairy plant;

3. validating and modifying the HACCP Plan in accordance with the corrective action procedures and the validation activities contained in this Part; and,

4. performing required HACCP plan record reviews.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1277 (June 2002), amended LR 37:

§1119. Audit of Dairy Plants that Operate under the HACCP Systems Defined in this Part

A. Procedures that shall be used by the state health officer in the audit of dairy plants which are required to implement HACCP Systems:

1. conduct a pre-audit management interview during which he shall review and discuss the plant HACCP system including:

a. changes in management structure;

b. the hazard analysis—ensure that all food hazards are addressed;

c. changes in the HACCP plan;

d. changes in the prerequisite programs (PPs);

e. changes in the flow diagrams; and

f. changes in products or process;

2. review past audit reports and correction of deficiencies;

3. perform a comprehensive in-plant review of the facilities, equipment, operations and implementation of the HACCP system;

4. review records of the implementation of the plant's HACCP system;

5. review the plant's compliance with other applicable requirements of this Part including:

a. raw milk supply source;

b. labeling compliance;

c. adulteration;

d. permit requirements;

e. drug residue testing;

f. regulatory sample compliance; and

g. pasteurization equipment design, construction and operation;

6. conduct an exit interview with plant management and the plant HACCP team, which includes:

a. discussing the findings and observations;

b. establishing time lines for the correction of all identified deficiencies and non conformities; and

c. preparing and issuing the audit report;

7. take appropriate action to verify that all deficiencies have been corrected within the established time frame as soon as practical after the established time or date;

8. take immediate action when an imminent health hazard is observed to prevent further movement of products until such hazards have been eliminated;

9. initiate regulatory enforcement such as permit suspension, revocation or other equivalent measures when the dairy plant has failed to recognize or correct a deficiency or non conformity;

10. critical listing elements. It is essential that each regulatory audit includes a thorough review of each of the critical listing elements of the plant's HACCP System;

a. Deficiencies or non conformities related to Critical Listing Elements require immediate attention and constitute grounds for suspension of the permit;

b. The following are critical listing elements:

i. hazard analysis—flow diagram and a hazard analysis has been conducted and written for each kind or group of dairy products, including frozen desserts, which are processed;

ii. HACCP plan—a written HACCP plan prepared for each kind or group of dairy products, including frozen desserts, which are processed;

iii. HACCP plan—critical limits (CL) are adequate to control the hazard identified.

iv. HACCP plan—corrective action taken for products produced during a deviation from the critical limits defined in the plan;

v. HACCP plan—verification and validation—calibration of CCP process monitoring instruments and equipment was performed as required and at the frequency defined in the plan;

vi. HACCP system records—information on HACCP records were not falsified;

vii. Other NCIMS requirements—in coming milk supply from NCIMS listed source(s) with sanitation scores of 90 or better or acceptable HACCP Listing;

viii. other NCIMS requirements—drug residue control program implemented; and,

ix. HACCP system audit findings—follow up action—no major HACCP system dysfunction exists, but if a series of observations made during an audit indicate that a plant does not have sufficient control of its HACCP system or operations to prevent a compromise to food safety, this shall constitute grounds for immediate suspension of permit.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1277 (June 2002), amended LR 37:

§1121. Manufactured Milk Products Plants, Manufactured Milk Concentration Plants and Cream Stations [formerly paragraph 7:130]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1277 (June 2002), repealed LR 37:

§1123. Insanitary Handling of Butter, Cheese and Other Manufactured Milk Products [formerly paragraph 7:134]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1278 (June 2002), repealed LR 37:

§1125. Rat Proofing [formerly paragraph 7:135]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1278 (June 2002), repealed LR 37:

§1127. Future Butter Plants, Cheese Plants, Manufactured Milk Products, Plants and Cream Stations [formerly paragraph 7:136]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1278 (June 2002), repealed LR 37:

§1129. Notification of Disease [formerly paragraph 7:137]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1278 (June 2002), repealed LR 37:

§1131. Suspension and Reissuing of Permits [formerly paragraph 7:138]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, , LR 28:1278 (June 2002), repealed LR 37:

Chapter 13. Receiving Stations

§1301. Receiving Station Requirements

A. Receiving stations that are required or have been authorized by the state health officer to be regulated under the HACCP requirements of this Part, shall conform with each of the HACCP requirements contained in Chapter 11 of this Part.

B. Receiving stations shall comply with the applicable provisions of the following general requirements for dairy plants:

1. permits (in accordance with §109 of this Part);
2. permits required for imported milk, milk products and frozen desserts (in accordance with §111 of this Part);
3. requirements for imported dairy products (in accordance with §113 of this Part);
4. milk records (in accordance with §115 of this Part);
5. falsification of records (in accordance with §117 of this Part);
6. delivery of samples (in accordance with §303 of this Part);
7. the official sampling, of dairy plant environments and dairy products including frozen desserts (in accordance with §307 of this Part);
8. posting inspection reports (in accordance with §317 of this Part);
9. field supervision (in accordance with §319 of this Part);
10. grades of milk and milk products to be sold (in accordance with §323 of this Part);
11. application for regrading, reinstatement of permit and permission to resume sale of product (in accordance with §341 of this Part);
12. grade A raw milk for pasteurization (in accordance with §349 of this Part);
13. manufacturing grade raw milk for pasteurization (milk for manufacturing purpose) (in accordance with §353 of this Part);
14. grade A pasteurized, ultra-pasteurized and aseptically processed milk and milk products, bulk shipped grade A pasteurized or ultra-pasteurized milk and milk products and pasteurized filled milk and filled milk products (in accordance with §355 of this Part);
15. grade A bulk shipped, heat-treated milk and milk products (in accordance with §357 of this Part);
16. milk tank trucks (in accordance with §701 of this Part);
17. sealing and protection of milk tank trucks (in accordance with §703 of this Part);
18. labeling (in accordance with §705 of this Part);
19. general requirements (in accordance with §901 of this Part);
20. raw milk receiving (in accordance with §905 of this Part);
21. dairy plant receivers/samplers (in accordance with §907 of this Part);
22. receiving and handling of milk derived and non-dairy ingredients (in accordance with §909 of this Part);
23. immediate surroundings (in accordance with §911 of this Part);
24. floors (in accordance with §913 of this Part);
25. walls and ceilings (in accordance with §915 of this Part);
26. doors and windows (in accordance with §917 of this Part);
27. light and ventilation (in accordance with §919 of this Part);
28. separate rooms (in accordance with §921 of this Part);
29. toilet facilities (in accordance with §923 of this Part);
30. water supply (in accordance with §925 of this Part);
31. protection from contamination (in accordance with §929 of this Part);
32. reclaim or rework operations (in accordance with §931 of this Part);
33. dairy plant cleanliness (in accordance with §933 of this Part);
34. sanitary piping (in accordance with §935 of this Part);
35. construction and repair of containers and equipment (in accordance with §937 of this Part);
36. thermometers (in accordance with §939 of this Part);
37. cleaning and sanitization of containers and equipment (in accordance with §943 of this Part);
38. storage of single-service containers, utensils and materials (in accordance with §947 of this Part);
39. cooling of milk and dairy products (in accordance with §955 of this Part);
40. use of inhibitors (in accordance with §961 of this Part);
41. apparatus, containers, equipment and utensils (in accordance with §967 of this Part);
42. personnel health (in accordance with §969 of this Part);
43. notification of disease (in accordance with §971 of this Part);
44. procedure when infection suspected (in accordance with §973 of this Part);
45. personal cleanliness (in accordance with §975 of this Part);
46. cleaning of containers (in accordance with §983 of this Part).
47. rat proofing (in accordance with §985 of this Part); and
48. waste disposal (in accordance with §987 of this Part).

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1278 (June 2002), amended LR 37:

§1303. Permits [formerly paragraph 7:140]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5 (15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1278 (June 2002), repealed LR 37:

§1305. Labeling [formerly paragraph 7:141]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5 (15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1278 (June 2002), repealed LR 37:

§1307. The Examination of Dry Milk or Dry Milk Products [formerly paragraph 7:142]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5 (15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1279 (June 2002), repealed LR 37:

§1309. Requirements for Grade A Dry Milk [formerly paragraph 7:143]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5 (15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1279 (June 2002), repealed LR 37:

§1311. Requirements for Extra Grade Dry Milk Products [formerly paragraph 7:144]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5 (15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1279 (June 2002), repealed LR 37:

§1313. Requirements for Standard Grade Dry Milk Products [formerly paragraph 7:145]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5 (15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1280 (June 2002), repealed LR 37:

§1315. Suspension of Permit or Registration Certificate [formerly paragraph 7:146]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5 (15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1280 (June 2002), repealed LR 37:

§1317. Floors [formerly paragraph 7:147]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1280 (June 2002), repealed LR 37:

§1319. Walls and Ceilings [formerly paragraph 7:148]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1280 (June 2002), repealed LR 37:

§1321. Doors and Windows [formerly paragraph 7:149]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1280 (June 2002), repealed LR 37:

§1323. Lighting and Ventilation [formerly paragraph 7:150]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1280 (June 2002), repealed LR 37:

§1325. Miscellaneous Protection from Contamination [formerly paragraph 7:151]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1280 (June 2002), repealed LR 37:

§1327. Toilet Facilities [formerly paragraph 7:52]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1281 (June 2002), repealed LR 37:

§1329. Water Supply [formerly paragraph 7:153]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1281 (June 2002), repealed LR 37:

§1331. Hand-Washing Facilities [formerly paragraph 7:154]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1281 (June 2002), repealed LR 37:

§1333. Sanitary Piping [formerly paragraph 7:155]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1281 (June 2002), repealed LR 37:

§1335. Construction and Repair of Containers and Equipment [formerly paragraph 7:156]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1281 (June 2002), repealed LR 37:

§1337. Disposal of Wastes [formerly paragraph 7:157]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1281 (June 2002), repealed LR 37:

§1339. Cleaning and Bactericidal Treatment of Containers and Equipment [formerly paragraph 7:158]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1281 (June 2002), repealed LR 37:

§1341. Storage of Containers and Equipment [formerly paragraph 7:159]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1281 (June 2002), repealed LR 37:

§1343. Handling of Containers and Equipment [formerly paragraph 7:160]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1282 (June 2002), repealed LR 37:

§1345. Storage of Single-Service Containers and Materials [formerly paragraph 7:161]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1282 (June 2002), repealed LR 37:

§1347. Cooling [formerly paragraph 7:162]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1282 (June 2002), repealed LR 37:

§1349. Package and Packaging [formerly paragraph 7:163]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1282 (June 2002), repealed LR 37:

§1351. Employee Health [formerly paragraph 7:164]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1282 (June 2002), repealed LR 37:

§1353. Cleanliness of personnel [formerly paragraph 7:165]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1282 (June 2002), repealed LR 37:

§1355. Vehicles [formerly paragraph 7:166]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1282 (June 2002), repealed LR 37:

§1357. Notification of Disease [formerly paragraph 7:167]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1282 (June 2002), repealed LR 37:

§1359. Dry Milk or Dry Milk Products from Points beyond Limits of Routine Inspections [formerly paragraph 7:168]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1282 (June 2002), repealed LR 37:

Chapter 15. Transfer Stations

§1501. Transfer Station Requirements

A. Transfer stations that are required or have been authorized by the state health officer to be regulated under the HACCP requirements of this Part, shall conform with each of the HACCP requirements contained in Chapter 11 of this Part.

B. Transfer stations shall comply with the applicable provisions of the following general requirements for dairy plants:

1. permits (in accordance with §109 of this Part);
2. permits required for imported milk, milk products and frozen desserts (in accordance with §111 of this Part);
3. requirements for imported dairy products (in accordance with §113 of this Part);
4. milk records (in accordance with §115 of this Part);
5. falsification of records (in accordance with §117 of this Part);
6. delivery of samples (in accordance with §303 of this Part);
7. the official sampling of dairy plant environments and dairy products including frozen desserts (in accordance with §307 of this Part);
8. posting inspection reports (in accordance with §317 of this Part);
9. field supervision (in accordance with §319 of this Part);
10. grades of milk and milk products to be sold (in accordance with §323 of this Part);
11. application for regrading, reinstatement of permit and permission to resume sale of product (in accordance with §341 of this Part);
12. grade A raw milk for pasteurization (in accordance with §349 of this Part);
13. manufacturing grade raw milk for pasteurization (milk for manufacturing purpose) (in accordance with §353 of this Part);
14. grade A pasteurized, ultra-pasteurized and aseptically processed milk and milk products, bulk shipped grade A pasteurized or ultra-pasteurized milk and milk products and pasteurized filled milk and filled milk products (in accordance with §355 of this Part);
15. grade A bulk shipped, heat-treated milk and milk products (in accordance with §357 of this Part);
16. milk tank trucks (in accordance with §701 of this Part);

17. sealing and protection of milk tank trucks (in accordance with §703 of this Part);

18. labeling (in accordance with §705 of this Part);

19. general requirements (in accordance with §901 of this Part);

20. approval of plans (in accordance with §903 of this Part);

21. raw milk receiving (in accordance with §905 of this Part);

22. confined space entry (in accordance with §905(D) of this Part);

23. dairy plant receivers/samplers (in accordance with §907 of this Part);

24. immediate surroundings (in accordance with §911 of this Part);

25. floors (in accordance with §913 of this Part);

26. light and ventilation (in accordance with §919 of this Part);

27. toilet facilities (in accordance with §923 of this Part);

28. water supply (in accordance with §925 of this Part);

29. hand washing facilities (in accordance with §927 of this Part);

30. protection from contamination (in accordance with §929 of this Part);

31. dairy plant cleanliness (in accordance with §933 of this Part);

32. sanitary piping (in accordance with §935 of this Part);

33. construction and repair of containers and equipment (in accordance with §937 of this Part);

34. thermometers (in accordance with §939 of this Part);

35. cleaning and sanitization of containers and equipment (in accordance with §943 of this Part);

36. storage of single-service containers, utensils and materials (in accordance with §947 of this Part);

37. cooling of milk and dairy products (in accordance with §955 of this Part);

38. notification of disease (in accordance with §971 of this Part);

39. personal cleanliness (in accordance with §975 of this Part);

40. rat proofing (in accordance with §985 of this Part);

41. waste disposal (in accordance with §987 of this Part); and

42. vehicles (in accordance with §989 of this Part).

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

Chapter 17. Finished Dairy Products Depots and Transfer Points

§1701. Approval of Plans

A. All finished dairy product depots or finished dairy product transfer points that are domiciled within the state and which are hereafter constructed, reconstructed or altered shall conform to the requirements contained in this Chapter. Prior to construction, reconstruction or alteration of such facilities, written approval of plans and specifications shall be obtained from the state health officer.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§1703. Basic Requirements for Finished Dairy Product Depots

A. Finished product depots shall conform with the following general requirements for dairy plants:

1. permits (in accordance with §109 of this Part);

2. permits required for imported milk, milk products and frozen desserts (in accordance with §111 of this Part);

3. requirements for imported dairy products (in accordance with §113 of this Part);

4. milk records (in accordance with §115 of this Part);

5. falsification of records (in accordance with §117 of this Part);

6. registration (in accordance with §119 of this Part);

7. labeling (in accordance with §121 of this Part);

8. delivery of samples (in accordance with §303 of this Part);

9. posting inspection reports (in accordance with §317 of this Part);

10. grades of milk and milk products to be sold (in accordance with §323 of this Part);

11. application for regrading, reinstatement of permit and permission to resume sale of product (in accordance with §341 of this Part);

12. regrading or reinstatement of permit when degrade or suspension was based on laboratory analyses (in accordance with §343 of this Part);

13. regrading and reinstatement of permit when degrade or suspension was based on physical violations (in accordance with §345 of this Part);

14. general requirements (in accordance with §901 of this Part);

15. approval of plans (in accordance with §903 of this Part);

16. receiving and handling of milk derived and non-dairy ingredients (in accordance with §909 of this Part);

17. immediate surroundings (in accordance with §911 of this Part);

18. floors (in accordance with §913 of this Part);

19. walls and ceilings (in accordance with §915 of this Part);

20. light and ventilation (in accordance with §919 of this Part);

21. toilet facilities (in accordance with §923 of this Part);

22. water supply (in accordance with §925 of this Part);

23. hand washing facilities (in accordance with §927 of this Part);

24. protection from contamination (in accordance with §929 of this Part);

25. reclaim or rework operations (in accordance with §931 of this Part);

26. dairy plant cleanliness (in accordance with §933 of this Part);

27. thermometers (in accordance with §939 of this Part);

28. cooling of milk and dairy products (in accordance with §955 of this Part);

29. use of overflow, leaked, spilled or mishandled dairy products (in accordance with §957 of this Part);

30. sale of reconstituted or recombined milk or milk products and anomalous (substitute) milk or milk products (in accordance with §959 of this Part);

31. dipping or transferring dairy products (in accordance with §965 of this Part);

32. personal health (in accordance with §969 of this Part);

33. notification of disease (in accordance with §971);

34. procedure when infection suspected (in accordance with §973 of this Part);

35. storage of bottled or packaged milk and dairy products (in accordance with §979 of this Part);

36. sale of warm milk (in accordance with §981 of this Part);

37. rat proofing (in accordance with §985 of this Part);

38. waste disposal (in accordance with §987 of this Part); and

39. vehicles (in accordance with §989 of this Part).

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§1705. Basic Requirements for Finished Dairy Product Transfer Points

A. Finished dairy product transfer points shall conform with the following general requirements for dairy plants:

1. permits (in accordance with §109 of this Part);

2. permits required for imported milk, milk products and frozen desserts (in accordance with §111 of this Part);

3. requirements for imported dairy products (in accordance with §113 of this Part);

4. milk records (in accordance with §115 of this Part);

5. falsification of records (in accordance with §117 of this Part);

6. labeling (in accordance with §121 of this Part);

7. delivery of samples (in accordance with §303 of this Part);

8. grades of milk and milk products to be sold (in accordance with §323 of this Part);

9. application for regrading, reinstatement of permit and permission to resume sale of product (in accordance with §341 of this Part);

10. immediate surroundings (in accordance with §911 of this Part);

11. toilet facilities (in accordance with §923 of this Part);

12. water supply (in accordance with §925 of this Part);

14. thermometers (in accordance with §939 of this Part);

15. sale of reconstituted or recombined milk or milk products and anomalous (substitute) milk or milk products (in accordance with §959 of this Part);

16. storage of bottled or packaged milk and dairy products (in accordance with §979 of this Part);

17. sale of warm milk (in accordance with §981 of this Part);

18. rat proofing (in accordance with §985 of this Part);

19. waste disposal (in accordance with §987 of this Part); and

20. vehicles (in accordance with §989 of this Part).

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

Chapter 19. Milk Tank Truck Cleaning Facilities

§1901. Approval of Plans

A. All milk tank truck cleaning facilities that are hereafter constructed, reconstructed or altered in the state shall conform to the requirements of these regulations. Written approval shall be obtained from the state health officer of plans and specifications prior to construction, reconstruction or alteration.

B. Prior to installation or modification, written approval of plans and specifications for the design, construction and the employment of equipment shall be obtained from the state health officer.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§1903. Basic Requirements for Milk Tank Truck Cleaning Facilities

A. All milk tank truck cleaning facilities shall conform with the following general requirements for dairy plants:

1. permits (in accordance with §109 of this Part);

2. falsification of records (in accordance with §117 of this Part);

3. application for regrading, reinstatement of permit and permission to resume sale of product (in accordance with §341 of this Part);

4. general requirements (in accordance with §901 of this Part);

5. immediate surroundings (in accordance with §911 of this Part);

6. floors (in accordance with §913 of this Part);

7. light and ventilation (in accordance with §919 of this Part);

8. toilet facilities (in accordance with §923 of this Part);

9. water supply (in accordance with §925 of this Part);

10. hand washing facilities (in accordance with §927 of this Part);

11. protection from contamination (in accordance with §929 of this Part);

12. dairy plant cleanliness (in accordance with §933 of this Part);

13. sanitary piping (in accordance with §935 of this Part);

14. construction and repair of containers and equipment (in accordance with §937 of this Part);

15. thermometers (in accordance with §939 of this Part);

16. cleaning and sanitization of containers and equipment (in accordance with §943 of this Part);

17. storage of cleaned containers and equipment (in accordance with §945 of this Part);

18. storage of single-service containers, utensils and materials (in accordance with §947 of this Part);

19. use of overflow, leaked, spilled or mishandled dairy products (in accordance with §957 of this Part);

20. apparatus, containers, equipment and utensils (in accordance with §967 of this Part);

21. personal cleanliness (in accordance with §975 of this Part);

22. allergen control and sensitivity producing ingredient (in accordance with §977 of this Part); and

23. waste disposal (in accordance with §987 of this Part).

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§1905. Supplemental Requirements for Milk Tank Truck Cleaning Facilities

A. Milk tank truck cleaning facilities shall conform with the following additional requirements.

1. Milk tank truck cleaning facilities shall clean or sanitize tank trucks that transport food grade products only. The cleaning or sanitization of any tank truck, tote or any type of container that has contained products that are not food grade is prohibited.

2. All equipment used in the cleaning and sanitization of milk tank trucks shall be dedicated to the cleaning and sanitization of milk tank trucks and shall not be used in the cleaning and sanitization of tank trucks that transport other food grade products without written approval of the state health officer.

3. Each dairy facility (including dairy plants, receiving stations, transfer stations and milk tank truck cleaning facilities) that cleans and sanitizes milk tank trucks shall be equipped with approved, functional equipment, devices, etc., and provide all services and programs necessary to satisfy the confined space entry safety requirements of the Occupational Safety and Health Administration (OSHA) thereby permitting personnel to safely enter the interior of the milk tank trucks. The dairy facility shall allow the state health officer to use all such equipment, devices, services, and programs, etc., and shall provide the state health officer with any assistance necessary to enable the state health officer (or his authorized representative) to safely enter and inspect the interior of the milk tank trucks. Dairy facilities, as identified above, which fail to provide the state health officer with any assistance necessary and required under OSHA regulations to safely enter and inspect the interior of milk tank trucks or other confined spaces may be held liable should the safety of the state health officer (or his authorized representative) be in peril while inside of milk tank trucks.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

Chapter 21. Dairy Products Condensing, Dairy Products Concentrating, Dairy Products Drying or Dry Dairy Products Blending Plants

§2101. Approval of Plans

A. All dairy product condensing, concentrating, drying or blending plants that are domiciled within the State and in which condensed, concentrated or dry dairy products are condensed, concentrated, dried or blended and which are hereafter constructed, reconstructed or altered shall conform in their construction to the requirements contained in Chapter 9 of this Part. Prior to construction, reconstruction or alteration, written approval of plans and specifications shall be obtained from the state health officer.

B. Prior to installation or modification, written approval shall be obtained from the state health officer of plans and specifications for the design, construction and manner of employment for all equipment.

C. Written, detailed plans describing the processing of each product shall be submitted to the state health officer for approval prior to product manufacture and prior to any product or process change.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2103. Basic Requirements for Condensed, Concentrated, Dry and Blended Dry Dairy Products and Dairy Plants that Condense, Concentrate, Dry or Blend Dry Dairy Products

A. Dairy plants which condense, concentrate, dry or blend dry dairy products which are required or have been authorized by the state health officer to be regulated under the HACCP requirements of this Part shall conform with each of the HACCP requirements contained in Chapter 11 of this Part.

B. Dairy plants that condense, concentrate, dry or blend dry dairy products shall conform with the following general requirements for dairy plants:

1. definitions (in accordance with §101 of this Part);

2. standards of identity (in accordance with , §107 of this Part);

3. permits (in accordance with §109 of this Part);

4. permit required for imported milk; milk products and frozen desserts (in accordance with , §111 of this Part);

5. requirements for imported dairy products (in accordance with §113 of this Part);

6. milk records (in accordance with §115 of this Part);

7. falsification of records (in accordance with §117 of this Part);

8. registration (in accordance with §119 of this Part);

9. labeling (in accordance with §§121 and 2121 of this Part);

10. delivery of samples (in accordance with §303 of this Part);

11. pasteurization equipment tests, examinations and sealing (in accordance with §313 of this Part);

12. posting inspection reports (in accordance with §317 of this Part);

13. grading (in accordance with §321 of this Part);

14. grades of milk and milk products to be sold (in accordance with §323 of this Part);

15. application for regrading, reinstatement of permit and permission to resume sale of product (in accordance with §341 of this Part);

16. regrading and reinstatement of permit when degrade or suspension was based on physical violations (in accordance with §345 of this Part);

17. reinstatement of permit when suspension was based upon adulteration of product or contamination of pasteurized

product or cheeses with pathogenic microorganisms of human significance (in accordance with §347 of this Part);

18. grade A raw milk for pasteurization (in accordance with §349 of this Part);

19. grade A raw milk for pasteurization (certified for interstate milk shipment) (in accordance with §351 of this Part);

20. grade A pasteurized, ultra-pasteurized and aseptically processed milk and milk products, bulk shipped grade A pasteurized or ultra-pasteurized milk and milk products and pasteurized filled milk and filled milk products (in accordance with §355 of this Part);

21. grade A pasteurized, ultra-pasteurized and aseptically processed milk and milk products certified for interstate shipment (in accordance with §361 of this Part);

22. milk tank trucks (in accordance with §701 of this Part);

23. sealing and protection of milk tank trucks (in accordance with §703 of this Part);

24. general requirements (in accordance with §901 of this Part);

25. approval of plans (in accordance with §903 of this Part);

26. raw milk receiving (in accordance with §905 of this Part);

27. receiving and handling of milk derived and non-dairy ingredients (in accordance with §909 of this Part);

28. immediate surroundings (in accordance with §911 of this Part);

29. floors (in accordance with §913 of this Part);

30. walls and ceilings (in accordance with §915 of this Part);

31. doors and windows (in accordance with §917 of this Part);

32. light and ventilation (in accordance with §919 of this Part);

33. separate rooms (in accordance with §921 of this Part);

34. toilet facilities (in accordance with §923 of this Part);

35. water supply (in accordance with §925 of this Part);

36. hand washing facilities (in accordance with §927 of this Part);

37. protection from contamination (in accordance with §929 of this Part);

38. reclaim or rework operations (in accordance with §931 of this Part);

39. dairy plant cleanliness (in accordance with §933 of this Part);

40. sanitary piping (in accordance with §935 of this Part);

41. construction and repair of containers and equipment (in accordance with §937 of this Part);

42. thermometers (in accordance with §939 of this Part);

43. pasteurization, ultra-pasteurization and aseptic processing (in accordance with §941 of this Part);

44. cleaning and sanitization of containers and equipment (in accordance with §943 of this Part);

45. storage of cleaned containers and equipment (in accordance with §945 of this Part);

46. storage of single-service containers, utensils and materials (in accordance with §947 of this Part);

47. packing, bottling and wrapping (in accordance with §949 of this Part);

48. cooling of milk and dairy products (in accordance with §955 of this Part);

49. use of overflow, leaked, spilled or mishandled dairy products (in accordance with §957 of this Part);

50. sale of reconstituted or recombined milk or milk products and anomalous (substitute) milk or milk products (in accordance with §959 of this Part);

51. use of inhibitors (in accordance with §961 of this Part);

52. dipping or transferring dairy products (in accordance with §965 of this Part);

53. apparatus, containers, equipment and utensils (in accordance with §967 of this Part);

54. personnel health (in accordance with §969 of this Part);

55. notification of disease (in accordance with §971 of this Part);

56. procedure when infection suspected (in accordance with §973 of this Part);

57. personal cleanliness (in accordance with §975 of this Part);

58. allergen and sensitivity producing ingredient (in accordance with §977 of this Part);

59. cleaning of containers (in accordance with §983 of this Part);

60. rat proofing (in accordance with §985 of this Part);

61. waste disposal (in accordance with §987 of this Part); and

62. vehicles (in accordance with §989 of this Part).

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

Subchapter A. Supplemental Requirements for Dairy Plants that Condense, Concentrate, Dry or Blend Dry Dairy Products

§2105. General Requirements

A. In addition to the requirements for dairy plants, all dairy plants that condense, concentrate, dry or blend dry dairy products shall conform with the additional requirements contained in this Subchapter.

B. Pasteurization, ultra-pasteurization or aseptic processing shall be performed in accordance with the requirements for pasteurization or ultra-pasteurization contained in the PMO.

C. In all cases, pasteurization, ultra-pasteurization or aseptic processing of raw milk, raw milk products, whey or whey products shall be performed before any raw milk, raw milk products, whey or whey products enter the evaporator, reverse-osmosis, ultra-filtration or condensing equipment and shall be performed in the plant in which the evaporation or condensing is done.

D. All condensed/concentrated milk transported to a dairy products drying plant shall be re-pasteurized at the plant at which it is dried. When condensed whey contains at least 40 percent total solids and has been partially crystallized by cooling, it may be transported to a separate

drying plant for drying without re-pasteurization provided, the following conditions are complied with:

1. The condensed/concentrated, partially crystallized whey shall be cooled and maintained at 7°C (45°F) or less;

2. Milk transport tanks used to transport the condensed/concentrated, partially crystallized whey shall be cleaned and sanitized prior to filling and are sealed after filling until unloaded; and,

3. Separate unloading pumps and pipelines shall be provided and used only for the unloading of the condensed/concentrated, partially crystallized whey. Such pumps and pipelines shall be cleaned and sanitized as a separate cleaning circuit.

E. All monitoring devices, such as metal detectors, etc., shall be calibrated at the frequency recommended by the manufacturer with the concurrence of the FDA.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2107. Cleaning and Sanitizing of Containers and Equipment

A. The product contact surfaces of all multi-use containers and equipment used in the processing, drying, storing, handling and transporting of milk, milk products, dairy products, whey, whey products, condensed or dry milk and buttermilk shall be properly cleaned and sanitized before each use. Each dairy plant that condenses, concentrates, dries or blends dry dairy products shall develop and implement effective cleaning and sanitizing programs based upon the recommendations of the manufacturer of the equipment and the recommendations contained in the PMO, Appendix F. Each dairy plant handling dry or blended dry dairy products shall be equipped with a heavy duty industrial type vacuum cleaner, so designed as not to recontaminate the atmosphere for cleaning areas in which powder accumulates.

B. Non-product contact surfaces of utensils and equipment shall be kept clean.

C. Effective cleaning and sanitizing regimen instructions, including solution mixing directions, solution strength requirements, testing and recording procedures, temperature requirements, circulation times and all other pertinent information necessary to properly clean and sanitize equipment, shall be posted adjacent to all equipment used in cleaning and sanitizing dairy equipment.

D. The posted procedures and instructions shall be followed in the cleaning and sanitization of dairy equipment.

E. Storage tanks shall be cleaned and sanitized when emptied and shall be emptied at least every 72 hours provided, that the state health officer may with the concurrence of FDA authorize an interval greater than 72 hours, determined on a case by case basis.

F. Drying equipment, blending equipment, cloth-collector systems, packaging equipment and multi-use dry dairy products and dry whey storage containers shall be cleaned at intervals and by methods recommended by the manufacturer or the PMO, Appendix F and approved by the state health officer. Such methods may include cleaning without water by use of vacuum cleaners, brushes or scrapers; such equipment and brushes shall be used exclusively for cleaning product contact surfaces. After cleaning, such equipment is sanitized by a method approved by the state health officer. Cloth collector systems and all dry product contact surfaces downstream from the dryer shall be sanitized or purged at intervals and by methods recommended by the manufacturer and approved by the state health officer. Sanitary single service outer clothing and shoe covers shall be provided for personnel and worn exclusively when it is necessary to enter the interior of the dryer to perform the cleaning operation.

G. Storage bins or totes used to transport dry products shall be dry cleaned after each usage and wet-cleaned and sanitized at regular intervals.

H. Pipelines and equipment designed for mechanical cleaning shall meet the following requirements:

1. operating instructions shall be posted near the cleaning equipment and shall be followed;

2. a temperature recording device, complying with the requirements contained in the *PMO* or a recording device which has been approved by the FDA and found to provide sufficient information to adequately evaluate the cleaning and sanitizing regimen and which is approved by the state health officer, shall be installed in the return solution line or other appropriate area to record the temperature and time during which the line or equipment is exposed to cleaning and sanitizing solutions;

3. pipelines and equipment designed for automated mechanical cleaning of evaporators shall have a pH recording device in the return lines to record the pH and time which the line or equipment is exposed during cleaning and sanitizing operations. These charts shall be identified, dated and initialed by the operator and maintained for three months;

4. temperature and pH recording charts shall be signed, dated and retained for three months;

5. during each inspection, the state health officer shall examine and initial a representative sample of each type of temperature recording charts to verify the time of exposure to solutions and their temperatures.

I. All multi-use containers, equipment, and utensils shall be sanitized before use, employing one or a combination of the following methods or any other method which has been demonstrated to be equally efficient and has been approved by the state health officer:

1. exposure to an enclosed jet of steam for not less than one minute;

2. complete immersion in hot water at a temperature of at least 77°C (170°F), for at least five minutes or exposure to a flow of hot water at a temperature of at least 77°C (170°F), as determined by use of a suitable accurate thermometer located at the outlet, for at least five minutes;

3. exposure to hot air at a temperature of at least 83°C (180°F) for at least 20 minutes as measured by an acceptable indicating thermometer located in the coldest zone;

4. complete immersion for at least one minute in, or exposure for at least one minute to a flow of a chemical sanitizer of acceptable strength. All product-contact surfaces must be wetted by the sanitizing solution, and piping so treated must be filled. Sanitizing sprays may be used. Chemical solutions, once used, shall not be reused for sanitizing but may be reused for other purposes approved by FDA. Assembled equipment shall be sanitized prior to each day's run;

5. All thermometers and temperature recorders shall be calibrated at least once every three-month period and a log identifying the thermometers calibrated, date and the initials of the person performing the calibration shall be maintained and made available to the state health officer; and

6. All other monitoring devices and equipment such as metal detectors, etc., shall be calibrated at the frequency recommended by the manufacturer and a log identifying the device or equipment calibrated, date calibrated, the name and initials of the person performing the calibration shall be maintained and made available to the state health officer.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2109. Packaging and Container Filling

A. The filling of condensed and dry dairy product containers shall be done only by mechanical equipment and by methods which preclude contamination.

B. Approval in writing by the state health officer, shall be obtained prior to the installation, operation or modification of any such equipment.

C. Dry dairy products shall be packaged in unused single service containers, which protect the contents from contamination. These containers shall be obtained from a source approved by the state health officer and after packaging shall be stored in a sanitary manner.

D. Condensed and dry dairy product containers shall be stored in a sanitary manner.

E. Condensed and dry dairy products may be transported from one plant to another for further processing or packaging, provided that the products are transported in sealed containers whose construction conforms with 3-A Standards.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2111. Container Closure, Sealing and Storage

A. Closing or sealing of dry dairy products shall be done in a sanitary manner.

B. The closing and sealing of containers of sizes of 6 gallons (net contents) or less shall be done in mechanical equipment, approved by the state health officer, using methods which preclude product contamination.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2113. Cooling of Milk, Milk Products, Whey, Whey Products, and Condensed Dairy Products

A. All raw milk and dairy products shall be maintained at 7°C (45°F) or less until processed except that acid-type whey with a titratable acidity of 0.40 percent or above, or a pH of 4.6 or below, is exempted from these temperature requirements.

B. All whey and whey products for condensing or drying shall be maintained at a temperature of 7°C (45°F) or less; or 57°C (135°F) or greater until processed. Storage tanks containing whey and whey products above 7°C (45°F) and below 57°C (135°F) shall be emptied, cleaned and sanitized after each four hours of use or less.

1. Whey and whey products in balance (constant level) tanks or hot wells may be allowed to remain at temperatures above 7°C (45°F) and below 57°C (135°F) for a period not to exceed four hours.

2. The balance tank or hot well shall be emptied, cleaned and sanitized at least once each four hours of operation.

3. Whey and whey products in balance tanks or hot wells that are maintained at temperatures of 57°C (135°F) or above are exempt from the four hour cleaning and sanitizing requirement as long as a continuous flow is maintained (with a retention time not to exceed one hour). All such balance tanks or hot wells shall be cleaned and sanitized at least once every 24 hours.

C. All pasteurized milk and dairy products (including pasteurized whey and condensed dairy products), except those to be dried immediately, shall be cooled immediately in approved equipment to a temperature of 7°C (45°F) or less. All pasteurized milk and dairy products (including pasteurized whey and condensed dairy products), shall be stored at a temperature of 7°C (45°F) or less and be maintained thereat until further processing. Whenever pasteurized milk and dairy products are to be condensed and/or dried and storage tanks are used between the condenser and dryer, any such storage tank(s) containing pasteurized milk or milk products (including pasteurized whey and condensed dairy products), stored above 7°C (45°F) and below 57°C (135°F) shall be completely emptied, cleaned, and sanitized after four hours of operation or less.

D. All indicating and recording thermometers shall be calibrated at least once each three-month period and a log indicating each thermometer and recorder calibrated and the initials of the person performing the calibration shall be maintained and made available to the state health officer.

E. All condensed whey and whey products shall be cooled during the crystallization process to 7°C (45°F) or less, within 72 hours of condensing including the filling and emptying time, unless filling occurs above 57°C (135°F), in which case, the 72 hour time period begins when the cooling is started.

F. Each refrigerated room in which milk , dairy products or whey are stored shall be equipped with an indicating thermometer approved by the state health officer. Such thermometer shall be located in the warmest zone of the refrigerator room.

G. Each storage tank shall be equipped with an indicating thermometer, the sensor of which shall be located to permit the registering of the temperature of the contents when the tank contains no more than 20 percent of its calibrated capacity.

H. All surface coolers shall comply with the following specifications:

1. The section of open-surface coolers shall be so installed as to leave a gap of at least 6.4 millimeters (0.25 inch) between the header sections to permit easy cleaning;

2. Where header ends are not completely enclosed within the cooler covers, condensation or leakage from the headers shall be prevented from entering the product by so shaping the exposed header faces, above and below all gaps,

that condensation is directed away from the tubes, and by using deflectors at the bottom of the headers, or by shortening the bottom trough or by some other approved method;

3. The location of supports of cooler sections shall prevent drip from entering the milk or dairy products ; and,

4. All open surface coolers shall be provided with tight-fitting shields which protect the product from contamination by flies, dust, drip, splash or manual contact.

I. Re-circulated cooling water which is used in coolers and exchangers, including those systems in which a freezing point depressant is used, shall be from a safe source and protected from contamination. Such water shall be tested at the minimum frequencies specified in §2117 of this Part and shall otherwise comply with the requirements of §2117 of this Part. Re-circulated water systems which become contaminated through repair work or otherwise shall be properly treated and tested before being returned to use. Freezing point depressants, when used in re-circulating systems, shall be non-toxic.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2115. Separate Rooms

A. There shall be separate rooms for:

1. pasteurizing, processing, cooling, condensing, drying and blending of milk, dairy products, whey, whey products, buttermilk or condensed products;

2. packaging or filling of bulk bins, drums, bags or other bulk containers;

3. hopper or dump room for the transfer of bulk dry dairy products from bags or drums to the hoppers or conveyors which lead to the container fillers;

4. repackaging room for the filling of small packages with dry dairy products from bulk containers;

5. cleaning of milk cans and containers and dry product containers;

6. receiving cans of milk and dairy products in plants receiving cans of milk;

7. receiving milk, cleaning and sanitizing milk tank trucks in plants receiving milk or whey in tank trucks; and

8. boilers and other non-processing mechanical equipment and shop areas.

B. Rooms in which milk, dairy products, whey or whey products are handled, processed, stored, dried, condensed or in which containers, utensils and equipment are cleaned or stored, shall not open directly into any stable, farmstead or area in which meat, poultry or any non-dairy foods of animal origin are handled or stored or any room used for domestic purposes.

C. All rooms shall be of sufficient size for their intended purposes.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

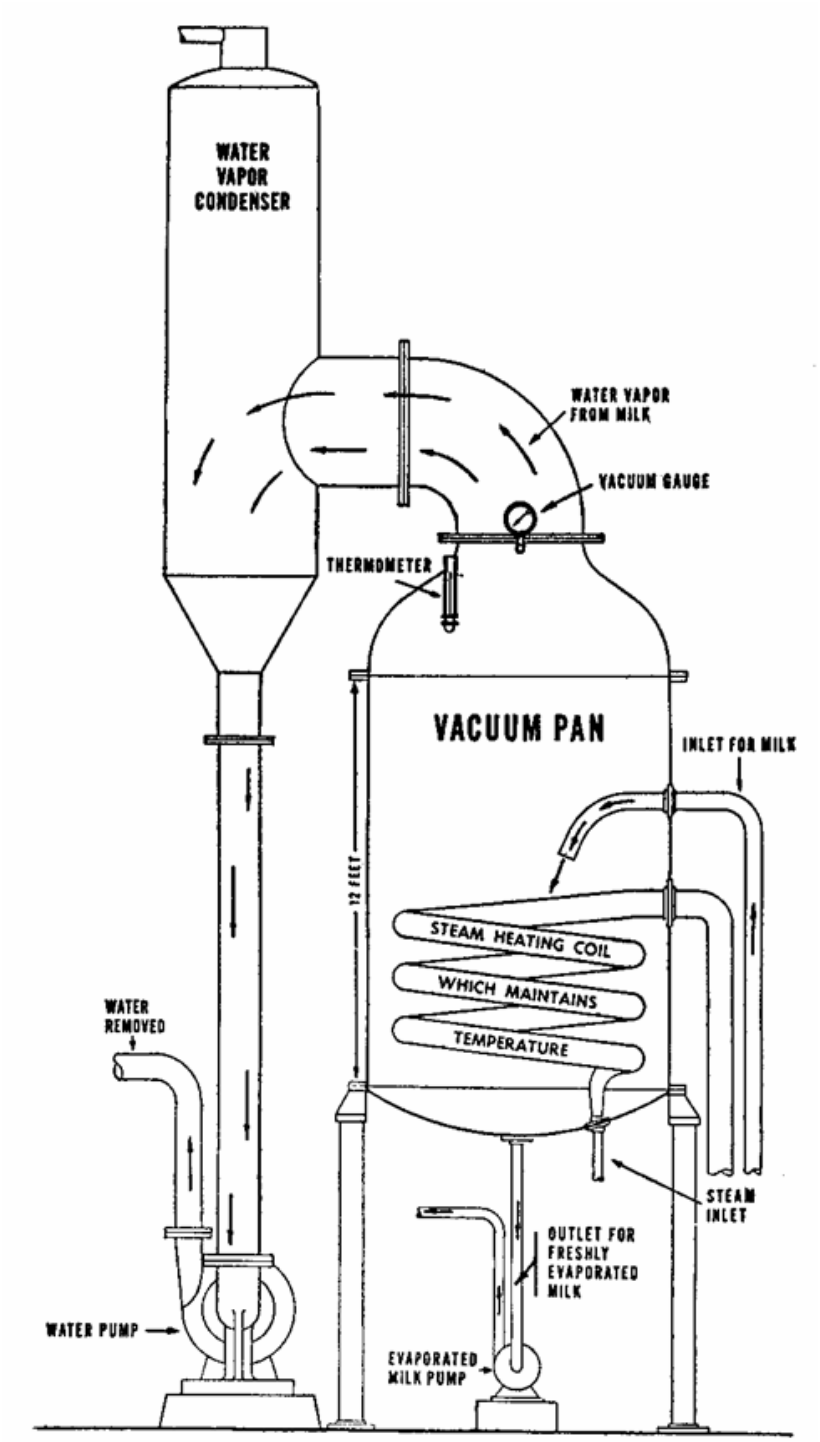
HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2117. Reclaimed Water$_{dp}$

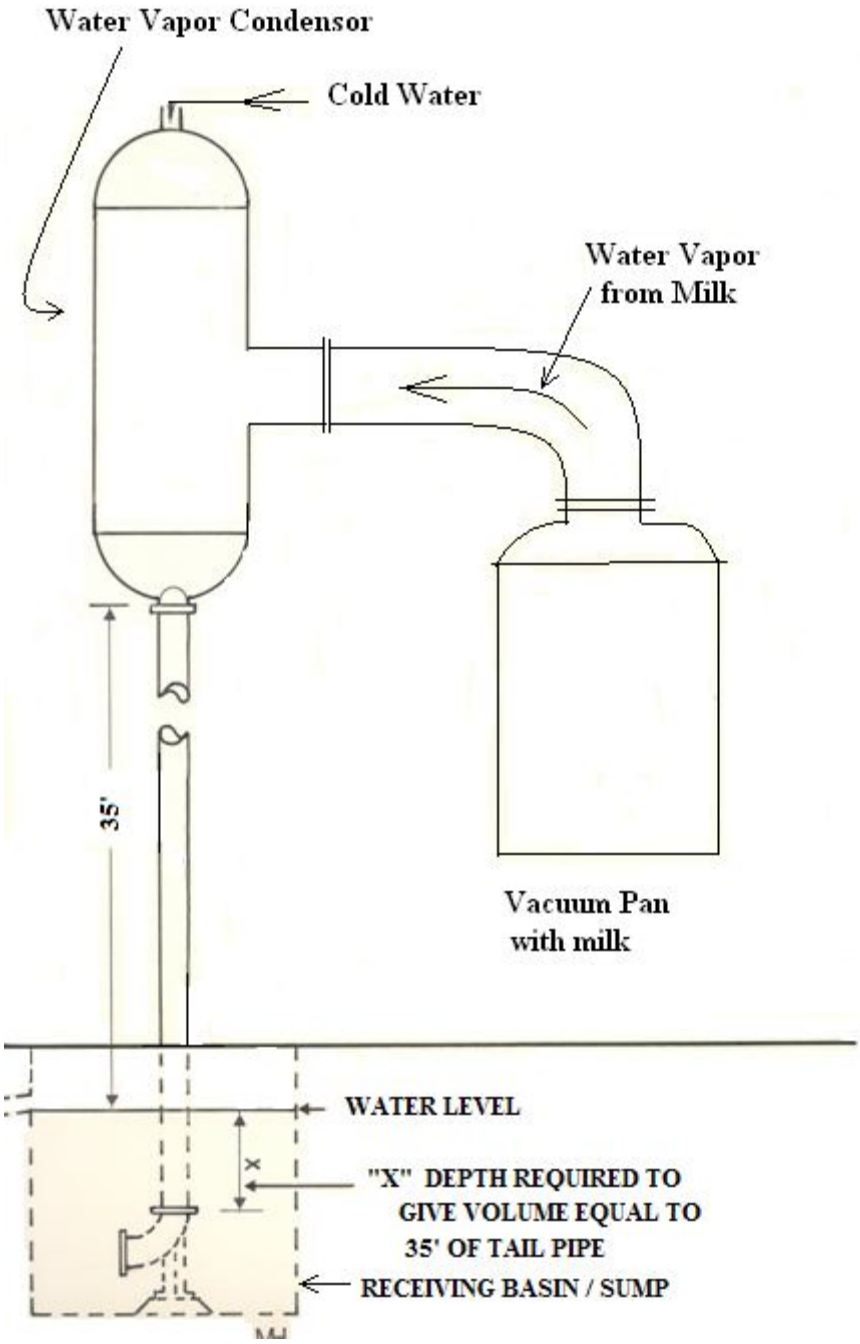
A. Condensing water for dairy product evaporators, and water used to produce vacuum or to condense vapors in vacuum heat processing equipment, shall be from a source complying with §925.B.1 of this Part. Provided, that when approved by the state health officer, water from sources not complying with §925.B.1 of this Part may be used when the condenser or vacuum heat equipment is constructed and operated to preclude contamination of such equipment, or its contents, by condensing water or by water used to produce vacuum. Means of preventing such contamination include:

1. use of a surface type condenser in which the condensing water is physically separated from the vapors and condensate; or

2. use of reliable safeguards to prevent the overflow of condensing water from the condenser into the evaporator. Such safeguards include a barometric leg extending at least 35 feet vertically from the invert of the outgoing condensing water line to the free level at which the leg discharges, and/or a safety shutoff valve, located on the water feed line to the condenser, automatically actuated by a control which will shutoff the in-flowing water when the water level rises above a predetermined point in the condenser. This valve may be actuated by water, air or electricity, and shall be designed so that failure of the primary motivating power will automatically stop the flow of water into the condenser.



VACUUM PAN DETAIL
(For Informational Purposes Only)
FIGURE 2117.A



BAROMETRIC LEG DETAIL (For Informational Purposes Only)
FIGURE 2117.A.2

B. Condensing water for dairy product evaporators complying with this Section and water reclaimed from milk or dairy products may be reused when all necessary means of protection are afforded and it complies with the procedures outlined in this Part and the PMO.

C. Reclaimed $water_{dp}$ shall comply with the following requirements:

1. Reclaimed $water_{dp}$ shall comply with the bacteriological standards of Appendix G, Section I of the PMO.

2. Samples of reclaimed $water_{dp}$ shall be collected daily for two weeks following initial approval of the installation and semi-annually thereafter, provided, that daily tests shall be conducted for one week following any repairs or alterations to the system.

3. The organic content of reclaimed $water_{dp}$ shall be less than 12.0 milligrams per liter as measured by the chemical oxygen demand or permanganate consumed test; or a standard turbidity of less than 5.0 units.

4. Automatic fail-safe monitoring devices shall be used to monitor and automatically divert to the sewer any reclaimed $water_{dp}$ which exceeds the standards.

5. The reclaimed $water_{dp}$ shall be of satisfactory organoleptic quality and shall have no off-flavors, odors or slime formations.

6. The reclaimed $water_{dp}$ shall be sampled and tested organoleptically at weekly intervals.

7. Approved chemicals, such as chlorine, with suitable detention period may be used to suppress the development of bacterial growth and prevent the development of tastes and odors in reclaimed $water_{dp}$.

8. The addition of approved chemicals shall be by an automatic proportioning device prior to the reclaimed $water_{dp}$ entering the storage tank to assure satisfactory quality reclaimed $water_{dp}$ in the storage tank at all times.

9. When chemicals are added, a daily testing program for such added chemicals shall be in effect and shall not add substances that will prove deleterious to use of the reclaimed $water_{dp}$ or contribute to product contamination.

10. The storage vessel shall be properly constructed of such material that it will not contaminate the reclaimed $water_{dp}$ and can be satisfactory cleaned.

11. The distribution system within a plant for such reclaimed $water_{dp}$ shall be a separate system with no cross-connections to a municipal or private water system or any other potable water distribution system.

12. All physical, chemical, radiological and microbiological tests on the reclaimed $water_{dp}$ shall be conducted in accordance with the latest edition of *Standard Methods for the Examination of Water and Wastewater*

D. When §2117.C.1 through §2117.C.12 of this Section are satisfied and documented, reclaimed $water_{dp}$ may be used for the following limited applications:

1. pre-rinsing of the product contact surfaces where pre-rinses will not be used in food products; and,

2. cleaning solution make-up water; provided that for either of these uses, the following additional items are complied with:

a. there is no carry-over of reclaimed $water_{dp}$ from one day to the next, and any reclaimed $water_{dp}$ collected is used promptly or the temperature of all reclaimed $water_{dp}$ in the storage and distribution system is maintained at 63EC (145EF) or higher by automatic means; or, the reclaimed $water_{dp}$ is treated with a suitable, approved chemical to suppress bacterial propagation by means of an automatic proportioning device, prior to the reclaimed $water_{dp}$ entering the storage tank;

b. distribution lines and hose stations are clearly identified in accordance with §605 of the Louisiana State Plumbing Code, 2000 Edition, as limited use reclaimed $water_{dp}$;

c. water handling practices and guidelines are clearly described and prominently displayed at appropriate locations within the plant; and

d. these water lines are not permanently connected to product vessels, without a break to the atmosphere and sufficient automatic controls, to prevent the inadvertent addition of this water to product streams.

E. Reclaimed $water_{dp}$ may be used as boiler feed-water for boilers which are not used for generating culinary steam, or in a thick, double walled, enclosed heat exchanger.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2119. Air for Dairy Product Drying Equipment and Air under Pressure-Direct Contact with Milk and Dairy Products or Milk and Dairy Product Contact Surfaces

A. Air for dairy product drying equipment shall conform with the following:

1. Air intake and pipeline filters shall consist of fiberglass with downstream backing dense enough to prevent fiberglass break off from passing through, cotton flannel, wool flannel, spun metal, electrostatic material, or other equally acceptable filtering media, which do not release to the air toxic volatiles or other contaminants or volatiles which may impart any flavor or odor to the product. Disposable media filters shall consist of cotton flannel, wool flannel, spun metal, non-woven fabric, United States Pharmacopeia (USP) absorbent cotton fiber, or suitable inorganic materials which, under conditions of use, are non-toxic and non-shedding. Chemical bonding material contained in the media shall be non-toxic, non-volatile, and insoluble under all conditions of use. Disposable media shall not be cleaned and reused.

2. The efficiency of the initial or primary supply air filters for air which will be heated before it comes in contact with non-food contact surfaces shall be designed, selected to operate at a face velocity, and installed in a manner which will allow the filter manufacturer's rating to be 90 percent or higher, when tested in accordance with the American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) Synthetic Dust Arrestance test (ASHRAE Standard 52.1-1992). The efficiency of the initial or primary supply air filters for air, which will not be heated before it comes in contact with non-food contact surfaces shall be of a design, selected to operate at a face velocity, and installed in a manner which will allow the filter manufacturer's rating to be 85 percent or higher when tested in accordance with the ASHRAE Atmospheric Dust Spot Method (ASHRAE Standard 52.1-1992).

3. Air-intakes for drying equipment shall be located so as to minimize atmospheric contamination and shall be

equipped with suitable single-service filters or multi-use systems approved by the state health officer.

B. Air under pressure which comes into direct contact with milk or dairy products or milk or dairy product contact surfaces shall comply with §929.I of this Part and the following:

1. Air intake and pipeline filters shall consist of fiberglass with downstream backing dense enough to prevent fiberglass break off from passing through, cotton flannel, wool flannel, spun metal, electrostatic material, or other equally acceptable filtering media, which do not release to the air toxic volatiles or other contaminants or volatiles which may impart any flavor or odor to the product. Disposable media filters shall consist of cotton flannel, wool flannel, spun metal, non-woven fabric, USP absorbent cotton fiber, or suitable inorganic materials which, under conditions of use, are non-toxic and non-shedding. Chemical bonding material contained in the media shall be non-toxic, non-volatile, and insoluble under all conditions of use. Disposable media shall not be cleaned and reused.

2. The efficiency of the initial or primary supply air filters for air which will be heated before it comes in contact with milk or dairy products or milk or dairy product contact surfaces shall be designed, selected to operate at a face velocity, and installed in a manner which will allow the filter manufacturer's rating to be 90 percent or higher, when tested in accordance with the American Society of Heating, Refrigerating and Air-Conditioning Engineers (ASHRAE) Synthetic Dust Arrestance test (ASHRAE Standard 52.1 - 1992). The efficiency of the initial or primary supply air filters for air, which will not be heated before it comes in contact with milk or dairy products or milk or dairy product contact surfaces shall be of a design, selected to operate at a face velocity, and installed in a manner which will allow the filter manufacturer's rating to be 85 percent or higher when tested in accordance with the ASHRAE Atmospheric Dust Spot Method (ASHRAE Standard 52.1 - 1992).

3. Air which will come into direct contact with milk or dairy products or milk or dairy product contact surfaces shall first pass through the initial or primary supply air filters meeting the requirements of Paragraph 2 of this Subsection. The initially filtered air in the pipeline downstream from the initial or primary supply air filters shall be used as the supply air for downstream (secondary) air filters on the air pipeline. The efficiency of such secondary air filters shall be at least 98 percent in accord with the Society of Automotive Engineers (SAE) Standard J726 - June 1987 using the Air Cleaner (AC) coarse test dust. All air that comes into direct contact with milk or dairy products or milk or dairy product contact surfaces shall additionally pass through further downstream (tertiary) air filters on the air pipeline. The filter efficiency of the final filter before coming into direct contact with milk or dairy products or milk or dairy product contact surfaces shall be at least 99 percent as measured by the Dioctylphthalate Fog Method (DOP) test (with a mean particle diameter of 0.3 microns) per Military Standard 282 (MIL-STD-282: Method 102.9.1). When commercially sterile air is required, the final filter efficiency shall be at least 99.99 percent as measured by the DOP test.

C. Air exhausts from dryer systems shall be covered when dryers are not in operation.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2121. Supplemental Labeling Requirements for Condensed, Concentrated, Dry or Blend Dry Dairy Products

A. All containers and packages enclosing condensed, concentrated, dry or blend dry dairy products defined in § 101 of this Code shall be labeled in accordance with the applicable requirements of the *Federal Food, Drug and Cosmetic Act,* as amended*, the State Food, Drug and Cosmetic Law (R.S. 40:601, et seq.), the Nutrition Labeling and Education Act of 1990,* as amended, and the regulations developed thereunder, the requirements of this Part and in addition shall be conspicuously and permanently labeled or marked with:

1. the name of the contents as prescribed by this Part, and the common name of the ingredients;

2. the grade of the product when grades for the product have been established;

3. the identity of the plant in which the product was manufactured or processed by either name and address or by permit number and identity of the state issuing such permit or by FIPS number;

4. a code or lot number identifying the contents with a specific date, run, or batch of the product, and the quantity of the contents of the container;

5. the word "goat", "sheep", "water buffalo" or the common name of other hooved mammals shall precede the name of the milk or dairy product when the product is made from the milk of animals other than cows; and,

6. the words, "a product of", followed by the name of the country in which the product was processed in cases in which the product was not processed in the United States or Puerto Rico.

B. Required labeling information shall be in letters of an acceptable size, kind and color satisfactory to the state health officer and shall contain no marks or words which are misleading. Other information, such as a registered trademark design, which is not misleading and does not obscure any of the labeling requirements above may also be included.

C. Milk tank trucks transporting whey, condensed whey or concentrated/condensed dairy products to a drying plant from another dairy plant, receiving or transfer station are required to be marked with the name and address of the dairy plant or hauler and shall be sealed; in addition, for each shipment a shipping statement shall be prepared containing at least the following information:

1. shipper's name; address and permit number;

2. permit identification of hauler, if not employee of shipper;

3. point of origin of shipment;

4. tanker permit number;

5. name of product;

6. weight of product;

7. grade of product;

8. temperature of product when applicable;

9. date of shipment;

10. name of supervising regulatory agency at the point of origin;

11. whether the contents are raw, pasteurized, or in the case of cream, lowfat or nonfat milk, whether it has been heat-treated; and,

12. seal number on inlet and outlet.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

SubChapter B. Specifications for Grade A Condensed and Dry Dairy Products and Blended Dry Dairy Products

§2123. Grade A Condensed Milk and Condensed Milk Products

A. Grade A condensed milk and condensed milk products shall conform to the standards of identity prescribed by this Part.

B. Grade A condensed milk and condensed milk products shall conform with the following microbiological, chemical and temperature requirements:

1. temperature—cooled to 7EC (45EF) or less immediately after processing and maintained thereat unless drying is commenced immediately after condensing;

2. standard plate count—not to exceed 30,000 cfu per gram;

3. coliform count—not to exceed 10 per gram, provided, that in the case of bulk milk transport tank shipments the coliform count shall not exceed 100 per gram;

4. phosphatase—less than 350 milliunits per liter for fluid products and less than 500 milliunits per liter for other milk products by the Fluorophos ALP system or equivalent;

5. drugs—no positive results from drug residue detection test methods which the state health officer has determined to be appropriate; and,

6. pathogens—no pathogenic microorganisms of human significance.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2125. Grade A Nonfat Dry Milk

A. Grade A nonfat dry milk shall conform with the standards of identity prescribed by this Part.

B. Grade A nonfat dry milk shall conform with the following microbiological, chemical and physical requirements not to exceed:

1. milk fat—1.25 percent;

2. moisture—4.00 percent;

3. titratable acidity—0.15 percent;

4. solubility index—1.25ml;

5. standard plate count—not to exceed 30,000 cfu per gram;

6. coliform count—not to exceed 10 per gram;

7. scorched particles—disc B - 15.0 per gram;

8. drugs—no positive results from drug residue detection test methods which the state health officer has determined to be appropriate; and,

9. pathogens—no pathogenic microorganisms of human significance.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2127. Grade A Whey for Condensing or Concentrating

A. The processes used in the production of Grade A whey for condensing and concentrating shall be performed in cheese manufacturing plants that are in substantial compliance with the sanitation requirements for Grade A dairy plants contained in this Part.

B. Grade A whey for condensing and concentrating shall conform to the following temperature and chemical standards:

1. temperature—maintained at a temperature of 7EC (45EF) or less, or 63EC (145EF) or greater, except for acid-type whey with a titratable acidity of 0.40 percent or above, or a pH of 4.6 or below.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2129. Grade A Pasteurized Condensed Whey

A. Grade A pasteurized condensed whey shall conform with the following bacteriological, chemical and temperature standards:

1. temperature—cooled to 10°C (50°F) or less during crystallization, within 72 hours of condensing;

2. standard plate count—not to exceed 30,000 cfu per gram;

3. coliform count—not to exceed 10 per gram;

4. phosphatase—less than 350 milliunits per liter for fluid products and less than 500 milliunits per liter for other milk products by the Fluorophos ALP system or equivalent;

5. drugs—no positive results from drug residue detection test methods which the state health officer has determined to be appropriate for condensed whey; and,

6. pathogens - no pathogenic microorganisms of human significance.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2131. Grade A Dry Whey or Dry Whey Products

A. Grade A dry whey or dry whey products shall conform with the following bacteriological standards:

1. standard plate count—not to exceed 30,000 cfu per gram;

2. coliform count—not to exceed 10 per gram;

3. drugs—no positive results from drug residue detection test methods which the state health officer has determined to be appropriate for use with dry wheyand dry whey products; and,

4. pathogens—no pathogenic microorganisms of human significance.

B. The product shall conform with the standards of identity prescribed by this Part.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2133. Grade A Dry Buttermilk and Dry Buttermilk Products

A. Grade A Dry Buttermilk or Dry Buttermilk Products shall conform with the following bacteriological and chemical standards:

1. standard plate count—not to exceed 30,000 cfu per gram;

2. coliform count—not to exceed 10 per gram;

3. drugs—no positive results on drug residue detection test methods which the state health officer has determined to be appropriate for use with dry buttermilk and dry buttermilk products; and,

4. pathogens—no pathogenic microorganisms of human significance.

B. The product shall conform with the standards of identity prescribed by this Part.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2135. Other Grade A Condensed, Concentrated or Dry Dairy Products

A. Other condensed, concentrated or dry dairy products which are designated Grade A by the NCIMS shall be processed in dairy plants that are in substantial compliance with the requirements for Grade A dairy plants contained in this Part and shall conform with the following.

1. All such products shall conform with the standards of identity prescribed by this Part.

2. The products shall conform with the following bacteriological, chemical and temperature requirements:

a. standard plate count—not to exceed 30,000 cfu per gram;

b. coliform count—not to exceed 10 per gram;

c. drugs—no positive results from drug residue detection test methods which the state health officer has determined to be appropriate; and,

d. pathogens no pathogenic microorganisms of human significance.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2137. Blended Dry Dairy Products

A. The manufacture of blended dry dairy products shall be performed in a plant that is in substantial compliance with the requirements of this Part for dairy products condensing, dairy products drying or dairy products blending plants.

B. Blended dry dairy products shall conform with the following bacteriological standards:

1. standard plate count—not to exceed 30,000 cfu per gram;

2. coliform count—not to exceed 10 per gram;

3. drugs—no positive results from drug residue detection test methods which the state health officer has determined to be appropriate; and,

4. pathogens—no pathogenic microorganisms of human significance.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

Subchapter C. Specifications for Extra Grade and Standard Grade Dry Dairy Products

§2139. Extra Grade and Standard Grade Dry Dairy Products

A. Extra grade and standard grade dry dairy products shall be manufactured from Grade A raw milk for pasteurization or manufacturing grade (milk for manufacturing purposes) for pasteurization.

B. Extra grade and standard grade dry dairy products shall conform with the standards of identity prescribed by this Part.

C. Extra grade and standard grade dry dairy products shall have no positive results from drug residue detection test methods which the state health officer has determined to be appropriate.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2141. Bacteriological Requirements for Extra Grade Dry Dairy Products

A. Extra grade dry dairy products shall conform with the bacteriological requirements indicated below.

1. Dry whole milk:

a. standard plate count - not to exceed 10,000 cfu per gram;

b. coliform count - not to exceed 10 per gram; and

c. pathogens—no pathogenic microorganisms of human significance.

2. Instant nonfat dry milk:

a. standard plate count—not to exceed 10,000 cfu per gram;

b. coliform count—not to exceed 10 per gram; and,

c. pathogens—no pathogenic microorganisms of human significance.

3. Nonfat dry milk (spray process):

a. standard plate count—not to exceed 10,000 cfu per gram;

b. coliform count—not to exceed 10 per gram; and,

c. pathogens—no pathogenic microorganisms of human significance.

4. Nonfat dry milk (roller process):

a. standard plate count—not to exceed 50,000 cfu per gram;

b. coliform count—not to exceed 10 per gram; and,

c. pathogens—no pathogenic microorganisms of human significance.

5. Dry whey:

a. standard plate count—not to exceed 30,000 cfu per gram;

b. coliform count—not to exceed 10 per gram; and,

c. pathogens—no pathogenic microorganisms of human significance.

6. Dry buttermilk:

a. standard plate count—not to exceed 20,000 cfu per gram;

b. coliform count—not to exceed 10 per gram; and,

c. pathogens—no pathogenic microorganisms of human significance.

7. Edible dry casein (acid):

a. standard plate count—not to exceed 30,000 cfu per gram;

b. coliform count—negative (0 cfu) per 0.1 gram; and,

c. pathogens—no pathogenic microorganisms of human significance.

B. Instant nonfat dry milk and dry whey that does not meet the bacteriological requirements for Grade A or extra grade shall not be sold or otherwise provided for human consumption.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2143. Bacteriological Requirements for Standard Grade Dry Dairy Products

A. Standard grade dry dairy products shall conform with the bacteriological requirements indicated below:

1. Dry whole milk:

a. standard plate count—not to exceed 50,000 cfu per gram;

b. coliform count—not to exceed 10 per gram; and,

c. pathogens—no pathogenic microorganisms of human significance.

2. Nonfat dry milk (spray process):

a. standard plate count—not to exceed 75,000 cfu per gram;

b. coliform count—not to exceed 10 per gram; and,

pathogens—no pathogenic microorganisms of human significance.

3. Nonfat dry milk (roller process):

standard plate count—not to exceed 100,000 cfu per gram;

coliform count—not to exceed 10 per gram; and,

c. pathogens—no pathogenic microorganisms of human significance.

4. Dry buttermilk:

a. standard plate count—not to exceed 75,000 cfu per gram;

b. coliform count—not to exceed 10 per gram; and,

c. pathogens—no pathogenic microorganisms of human significance.

5. Edible dry casein (acid):

a. standard plate count—not to exceed 100,000 cfu per gram;

b. coliform count—not more than 2 cfu per 0.1 gram; and,

c. pathogens—no pathogenic microorganisms of human significance.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

Chapter 23. Butter Plants

§2301. Approval of Plans

A. All butter plants that are domiciled within the state and in which butter or butter related products are processed or packaged and which are hereafter constructed, reconstructed or altered shall conform in their construction to the requirements of these regulations. Prior to construction, reconstruction or alteration, written approval of plans and specifications shall be obtained from the state health officer.

B. Prior to installation or modification, written approval shall be obtained from the state health officer of plans and specifications for the design, construction and manner of employment for all equipment.

C. Written detailed plans describing the processing of each product shall be submitted to the state health officer for approval prior to manufacture of each product and prior to any product or process changes.

D. Butter plants that are required or have been authorized by the state health officer to be regulated under the HACCP requirements of this Part shall conform with each of the HACCP requirements contained in Chapter 11 of this Part.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2303. Basic Requirements for Dairy Plants that Manufacture, Process or Package Butter and Butter Related Products

A. Dairy plants that manufacture, process or package butter or butter related products shall conform with the following general requirements for dairy plants:

1. definitions (in accordance with §101 of this Part);

2. standards of identity (in accordance with §107 of this Part);

3. permits (in accordance with §109 of this Part);

4. permits required for imported milk, milk products and frozen desserts (in accordance with §111 of this Part);

5. milk records (in accordance with §115 of this Part);

6. falsification of records (in accordance with §117 of this Part);

7. registration (in accordance with §119 of this Part);

8. labeling (in accordance with §121 of this Part);

9. delivery of samples (in accordance with §303 of this Part);

10. pasteurization equipment tests, examinations and sealing (in accordance with §313 of this Part);

11. field supervision (in accordance with §319 of this Part);

12. application for regrading, reinstatement of permit and permission to resume sale of product (in accordance with §341 of this Part);

13. reinstatement of permit when suspension was based upon adulteration of product or contamination of pasteurized product or cheeses with pathogenic microorganisms of human significance (in accordance with §347 of this Part);

14. manufacturing grade raw milk for pasteurization (milk for manufacturing purpose) (in accordance with §353 of this Part);

15. grade A pasteurized, ultra-pasteurized and aseptically processed milk and milk products, bulk shipped grade A pasteurized or ultra-pasteurized milk and milk products and pasteurized filled milk and filled milk products (in accordance with §355 of this Part);

16. grade A bulk shipped, heat-treated milk and milk products (in accordance with §357 of this Part);

17. grade A pasteurized, ultra-pasteurized and aseptically processed milk and milk products certified for interstate shipment (in accordance with §361 of this Part);

18. milk tank trucks (in accordance with §701 of this Part);

19. sealing and protection of milk tank trucks (in accordance with §703 of this Part);

20. labeling (in accordance with §705 of this Part);

21. general requirements (in accordance with §901 of this Part);

22. approval of plans (in accordance with §903 of this Part);

23. raw milk receiving (in accordance with §905 of this Part);

24. dairy plant receivers/samplers (in accordance with §907 of this Part);

25. receiving and handling of milk derived and non-dairy ingredients (in accordance with §909 of this Part);

26. immediate surroundings (in accordance with §911 of this Part);

27. floors (in accordance with §913 of this Part);

28. walls and ceilings (in accordance with §915 of this Part);

29. doors and windows (in accordance with §917 of this Part);

30. light and ventilation (in accordance with §919 of this Part);

31. separate rooms (in accordance with §921 of this Part);

32. toilet facilities (in accordance with §923 of this Part);

33. water supply (in accordance with §925 of this Part);

34. hand washing facilities (in accordance with §927 of this Part);

35. protection from contamination (in accordance with §929 of this Part);

36. reclaim or rework operations (in accordance with §931 of this Part);

37. sanitary piping (in accordance with §935 of this Part);

38. construction and repair of containers and equipment (in accordance with §937 of this Part);

39. thermometers (in accordance with §939 of this Part);

40. pasteurization, ultra-pasteurization and aseptic processing (in accordance with §941 of this Part);

41. cleaning and sanitizing of containers and equipment (in accordance with §943 of this Part);

42. storage of cleaned containers and equipment (in accordance with §945 of this Part);

43. storage of single service containers; utensils and materials (in accordance with §947 of this Part);

44. packing, bottling and wrapping (in accordance with §949 of this Part);

45. cooling of milk and dairy products (in accordance with §955 of this Part);

46. use of overflow, leaked, spilled or mishandled dairy products (in accordance with §957 of this Part);

47. apparatus, containers, equipment and utensils (in accordance with §967 of this Part);

48. personnel health (in accordance with §969 of this Part);

49. notification of disease (in accordance with §971 of this Part);

50. procedure when infection suspected (in accordance with §973 of this Part);

51. personal cleanliness (in accordance with §975 of this Part);

52. allergen and sensitivity producing ingredient (in accordance with §977 of this Part);

53. rat proofing (in accordance with §985 of this Part);

54. waste disposal (in accordance with §987 of this Part); and

55. vehicles (in accordance with §989 of this Part).

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

Subchapter A. Supplemental Requirements for Butter Plants

§2305. General Information

A. In addition to the requirements for dairy plants, all plants manufacturing butter and related products shall conform with the following additional requirements:

1. churn rooms in addition to proper construction and sanitation as prescribed by this Part, shall be so equipped that the air is kept free from objectionable odors, vapors or extreme temperatures by means of adequate ventilation, exhaust systems or air conditioning and heating systems; and

2. print and bulk packaging rooms shall in addition to proper construction and sanitation, as prescribed by this Part, provide an atmosphere relatively free from mold (no more than 10 mold colonies per cubic foot of air), dust or other airborne contamination and be maintained at a reasonable room temperature.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2307. Construction of Utensils and Equipment

A. All utensils and equipment used in the manufacture of butter and related products shall conform with the requirements contained in §937 of this Part. In addition, for certain other equipment, the following requirements shall be met.

1. Continuous Churns. All product contact surfaces shall be of non-corrosive materials. All non-metallic product contact surfaces shall comply with 3-A Standards for plastic, rubber, and rubber-like materials. All product contact surfaces shall be accessible for cleaning and inspection.

2. Conventional churns shall be constructed of aluminum, stainless steel or equally corrosion resistant metal, free from cracks and in good repair. All gasket material shall be non-toxic and durable. Seals around doors and covers shall be tight.

3. Bulk butter trucks, boats and packers shall be constructed of aluminum, stainless steel or equally corrosion resistant metal, free from cracks or seams and must have product contact surfaces that are smooth and easily cleanable.

4. Butter, frozen or plastic cream melting machines, shavers and shredders used for the rapid melting of butter or plastic cream shall be constructed of stainless steel or

equally corrosion resistant metal and shall be of sanitary construction and easily cleanable.

5. Printing equipment shall be designed to be easily disassembled for cleaning of product contact surfaces. All product contact surfaces shall be of aluminum, stainless steel or equally corrosion resistant metal or plastic, rubber and rubber-like materials that meet 3-A Standards.

6. The product contact surfaces of all utensils and equipment used in the manufacture of butter and related products shall be smooth and easily cleanable. The use of wood or other fibrous or porous materials on product contact surfaces shall be prohibited.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2309. Cream for the Manufacture of Butter and Butter Related Products

A. Cream for the manufacture of butter and butter related products shall be derived from Grade A raw milk for pasteurization or manufacturing grade raw milk for pasteurization from a source approved by the state health officer. The milk or cream shall be pasteurized, ultra-pasteurized or aseptically processed in the plant in which the butter or butter related products are manufactured.

B. Pasteurization or ultra-pasteurization shall be performed in accordance with the requirements contained in §941 of this Part provided that:

1. the temperature of pasteurization for cream to be processed for plastic or frozen cream shall be not less than 77°C (170°F) for not less than 30 minutes or not less than 88°C (190°F) for not less than 15 seconds;

2. The temperature of pasteurization for cream to be processed into butter and other butter related products shall be not less than 74°C (165°F) for not less than 30 minutes or not less than 85EC (185EF) for not less than 15 seconds.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2311. Composition and Wholesomeness of Ingredients Used in the Manufacture of Butter and Butter Related Products

A. The composition and wholesomeness of all ingredients used in the manufacture of butter and butter related products shall be in conformance with the requirements of the *Federal Food, Drug and Cosmetic Act*, as amended.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2313. Examination of Butter and Butter Related Products

A. Samples of butter and butter related products shall be collected and examined as often as the state health officer may require. The state health officer shall not be required to pay for such samples.

B. All sampling procedures and required laboratory examinations shall be in compliance with the *Standard Methods for the Examination of Dairy Products*.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2315. Standards of Identity for Butter

A. All butter and butter related products shall conform with the standards of identity prescribed by this Part.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2317. Bacteriological Requirements

A. All butter and butter related products shall conform with the following microbial requirements:

1. standard plate count—not to exceed 1,000 cfu per gram;

2. coliform count—not to exceed 10 per gram; and,

3. pathogens—no pathogenic microorganisms of human significance.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2319. Seizure and Condemnation of Butter and Butter Related Products

A. Butter and butter related products that do not conform with the bacteriological requirements contained in §2317 of this Part shall be subject to seizure and condemnation by the state health officer as provided in §632 of the *State Food, Drug and Cosmetic Act.*

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2321. Containers

A. Containers used for the packaging of butter and butter related products shall be containers or packaging materials from sources approved by the state health officer and satisfactorily protect the safety and quality of the contents in regular channels of trade. Caps or covers which extend over the lip of the container shall be used on all cups or tubs containing two pounds or less to protect the product from contamination.

B. Liners, wrappers and other packaging materials shall be from sources approved by the state health officer and protect the products from dust, mold and other contaminants.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2323. Printing and Packaging of Butter and Butter Related Products

A. Printing and packaging of butter and butter related products shall be performed using procedures that preclude

the contamination of product and have been approved by the state health officer.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

Chapter 25. Cheese Manufacturing Plants

§2501. Approval of Plans

A. All cheese manufacturing plants that are domiciled within the state and are hereafter constructed, reconstructed or altered shall conform in their construction and operation with the requirements of this Part. Prior to construction, reconstruction or alteration, written approval of plans and specifications shall be obtained from the state health officer.

B. Prior to installation or modification, written approval shall be obtained from the state health officer of plans and specifications for the design, construction and manner of employment for all equipment.

C. Written detailed plans describing the processing of each product shall be submitted to the state health officer for approval prior to manufacture of each product and prior to any product or process change.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2503. Basic Requirements for Cheese Manufacturing Plants

A. All dairy plants that manufacture, process, cut, slice or package cheese or cheese related products shall conform with the following general requirements for dairy plants:

1. definitions (in accordance with §101 of this Part);
2. standards of identity (in accordance with §107 of this Part);
3. permits (in accordance with §109 of this Part);
4. permits required for imported milk, milk products and frozen desserts (in accordance with §111 of this Part);
5. requirements for imported dairy products (in accordance with §113 of this Part);
6. milk records (in accordance with §115 of this Part);
7. falsification of records (in accordance with §117 of this Part);
8. labeling (in accordance with §121 of this Part);
9. delivery of samples (in accordance with §303 of this Part);
10. pasteurization equipment tests, examinations and sealing (in accordance with §313 of this Part);
11. posting inspection reports (in accordance with §317 of this Part);
12. field supervision (in accordance with §319 of this Part);
13. application for regrading, reinstatement of permit and permission to resume sale of product (in accordance with §341 of this Part);
14. regrading and reinstatement of permit when degrade or suspension was based on physical violations (in accordance with §345 of this Part);
15. reinstatement of permit when suspension was based upon adulteration of product or contamination of pasteurized product or cheeses with pathogenic microorganisms of human significance (in accordance with §347 of this Part);
16. grade A raw milk for pasteurization (in accordance with §349 of this Part);
17. grade A raw milk for pasteurization (certified for interstate milk shipment) (in accordance with §351 of this Part);
18. manufacturing grade raw milk for pasteurization (milk for manufacturing purpose) (in accordance with §353 of this Part);
19. grade A aseptically processed milk and milk products (in accordance with §359 of this Part);
20. grade A pasteurized, ultra-pasteurized and aseptically processed milk and milk products certified for interstate shipment (in accordance with §361 of this Part);
21. milk tank trucks (in accordance with §701 of this Part);
22. sealing and protection of milk tank trucks (in accordance with §703 of this Part);
23. labeling (in accordance with §705 of this Part);
24. general requirements (in accordance with §901 of this Part);
25. approval of plans (in accordance with §903 of this Part);
26. raw milk receiving (in accordance with §905 of this Part);
27. dairy plant receivers/samplers (in accordance with §907 of this Part);
28. receiving and handling of milk derived and non-dairy ingredients (in accordance with §909 of this Part);
29. immediate surroundings (in accordance with §911 of this Part);
30. floors (in accordance with §913 of this Part);
31. walls and ceilings (in accordance with §915 of this Part);
32. doors and windows (in accordance with §917 of this Part);
33. light and ventilation (in accordance with §919 of this Part);
34. separate rooms (in accordance with §921 of this Part);
35. toilet facilities (in accordance with §923 of this Part);
36. water supply (in accordance with §925 of this Part);
37. hand washing facilities (in accordance with §927 of this Part);
38. protection from contamination (in accordance with §929 of this Part);
39. reclaim or rework operations (in accordance with §931 of this Part);
40. dairy plant cleanliness (in accordance with §933 of this Part);
41. sanitary piping (in accordance with §935 of this Part);
42. construction and repair of containers and equipment (in accordance with §937 of this Part);
43. thermometers (in accordance with §939 of this Part);
44. cleaning and sanitizing of containers and equipment (in accordance with §943 of this Part);
45. storage of cleaned containers and equipment (in accordance with §945 of this Part);
46. storage of single-service containers, utensils and materials (in accordance with §947 of this Part);

47. packing, bottling and wrapping (in accordance with §949 of this Part);

48. cooling of milk and dairy products (in accordance with §955 of this Part);

49. use of overflow, leaks, spilled or mishandled dairy products (in accordance with §957 of this Part);

50. dipping or transferring dairy products (in accordance with §965 of this Part);

51. apparatus, containers, equipment and utensils (in accordance with §967 of this Part);

52. personnel health (in accordance with §969 of this Part);

53. notification of disease (in accordance with §971 of this Part);

54. procedure when infection suspected (in accordance with §973 of this Part);

55. personal cleanliness (in accordance with §975 of this Part);

56. rat proofing (in accordance with §985 of this Part);

57. waste disposal (in accordance with §987 of this Part); and

58. vehicles (in accordance with §989 of this Part).

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

Subchapter A. Supplemental Requirements for Cheese Manufacturing Plants

§2505. General Information

A. Cheese manufacturing plants that manufacture, process, cut, slice or package cheese shall conform with all of the basic requirements for cheese manufacturing plants contained in this Part and with the following additional requirements.

1. All cheese and cheese related products shall conform to the standards of identity prescribed by this Part.

2. Written, detailed plans describing the processing of each product shall be submitted to the state health officer for approval prior to manufacture of each product and prior to any product process change.

3. The words "made from unpasteurized milk" shall be prominently displayed on the principal display panel of each container of cheese and cheese related products made from milk in which each particle has not been pasteurized, ultra-pasteurized or aseptically processed in a manner that conforms with the requirements for pasteurization contained in this Part.

4. All containers and packages enclosing cheese and cheese related products shall be labeled in accordance with the applicable requirements of the Federal Food, Drug and Cosmetic Act, as amended, the State Food, Drug, and Cosmetic Law (R.S. 40:601, et seq.), the Nutrition Labeling and Education Act of 1990, as amended, and the regulations developed thereunder and the requirements for labeling contained in this Part.

5. Whey disposal or use shall conform the following:

a. adequate sanitary facilities shall be provided for the handling and disposal of whey. Necessary precautions shall be taken to minimize flies, insects and objectionable odors;

b. whey or whey products to be used for human food shall be handled in accordance with the applicable provisions of this Part; and

c. whey or whey products to be used as or in Grade A products shall be produced in a cheese manufacturing plant that complies with all applicable requirements for dairy plants that produce Grade A pasteurized, ultra-pasteurized and aseptically processed products contained in Chapter 9. All such whey shall be derived from cheese produced from Grade A raw milk for pasteurization;

6. Cooling of milk and dairy products shall conform with the following:

a. all Grade A raw milk or heat treated products shall be received at 7°C (45°F) or less and maintained at or below that temperature until processed;

b. all manufacturing grade raw milk (milk for manufacturing purposes) shall not exceed 10°C (50°F) upon delivery to the dairy plant unless it is delivered to the dairy plant in less than four hours after milking. It shall be cooled immediately upon receipt to 7°C (45°F) or below and maintained at or below that temperature until processed;

c. whey and whey products in balance (constant level) tanks or hot wells may be allowed to remain at temperatures above 7°C (45°F) and below 66°C (150°F) for a period not to exceed four hours of operation provided:

i. when foam is present on the product, the temperature of the foam shall be considered the temperature of the product;

ii. the balance tank or hot well shall be emptied, cleaned and sanitized at least once each four hours of operation; and

iii. dairy products in balance tanks or hot wells at temperatures below 7EC (45°F) or above 66°C (150°F) or above are exempt from this requirement;

d. all pasteurized dairy products, except those to be cultured, shall be cooled immediately after pasteurization in approved equipment, to a temperature of 7°C (45°F) or less and stored at a temperature of 7°C (45°F) or less;

e. the temperature of milk or dairy products in delivery vehicles shall not exceed 7°C (45°F);

f. every room or tank in which dairy products are stored shall be equipped with an approved thermometer;

g. aseptically processed dairy products to be packaged in hermetically sealed containers shall be exempt from the cooling requirement for this item; and,

h. re-circulated water which is used in coolers and exchangers, including systems in which a freezing point depressant is used shall be from a safe source and protected from contamination. Such water shall be tested at the minimum frequencies specified in §2117 of this Part and shall otherwise comply with the requirements of §2117 of this Part. Freezing point depressants, when used, shall be non toxic.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2507. Additional Requirements for Cheese Manufacturing Plants that Manufacture, Process, Package, Cut or Slice Ripened or Aged Cheese and Cheese Related Products

A. Cheese manufacturing plants that manufacture, process, package, cut or slice aged cheese and cheese related products shall conform with all of the requirements for cheese manufacturing plants contained in this Part and shall conform with the following additional requirements.

1. Milk for the manufacture of aged cheese shall be derived from Grade A raw milk for pasteurization or manufacturing grade raw milk for pasteurization from a source approved by the state health officer.

2. Milk used in the manufacture of aged cheese and cheese related products may be pasteurized, ultra-pasteurized, aseptically processed or clarified or both.

3. The pasteurization, ultra-pasteurization or aseptic processing of raw milk used in the manufacture of aged cheese and cheese related products shall be performed in accordance with the requirements for pasteurization, ultra-pasteurization or aseptic processing contained in this Part.

4. The following additional separate rooms shall be provided.

a. Starter Room. Starter rooms or areas shall be properly equipped and maintained for the propagation and handling of starter cultures. All necessary precautions shall be taken to prevent contamination of starter cultures, of the room, equipment, and the air therein.

b. Make Room. The room in which the cheese is manufactured in vats that are uncovered while product is in them. It shall be of adequate size, and the vats adequately spaced to permit movement around the vats and presses for proper cleaning and satisfactory working conditions. Adequate ventilation shall be provided. In existing installations in which the make room is an integral part of a processing room, the operation shall conform with the requirements contained in §921.A.6 of this Part.

c. Drying Room. If cheese is to be paraffined, a drying room of adequate size shall be provided to accommodate the maximum production of cheese during the flush period. Adequate sanitary shelving and air circulation shall be provided for proper drying. Suitable temperature and humidity control facilities shall be provided.

d. Paraffining Room. For rind cheese, a separate room or compartment shall be provided for paraffining and boxing the cheese. The room or compartment shall be of adequate size and the temperature maintained near the temperature of the drying room to avoid sweating of the cheese prior to paraffining.

e. Rindless Block Wrapping Area. For rindless blocks a suitable space shall be provided for proper wrapping and boxing of the cheese. The area shall be free from dust, condensation, mold or other conditions which may contaminate the surface of the cheese or contribute to an unsatisfactory packaging of the cheese.

f. Coolers or Curing Rooms. Coolers or curing rooms where cheese is held for curing or storage shall be clean and maintained at the proper uniform temperature and humidity to adequately protect the cheese. Proper circulation of air shall be maintained at all times. The rooms shall be free from rodents, insects, and pests. The shelves shall be kept clean and dry. All racks, shelves and other equipment used in this room shall conform with the requirements of equipment construction required in this Part.

g. Cutting and Packaging Rooms. When cheese is cut, sliced or wrapped, separate rooms shall be provided for the cleaning and preparation of the bulk cheese and a separate room shall be provided for the cutting, slicing or wrapping operation. The rooms shall be well lighted, ventilated, and provided with filtered air. Air movement shall be outward to minimize the entrance of unfiltered air into the cutting and packaging room.

5. Rooms in which dairy products are handled, processed or stored, or in which dairy product containers, utensils and equipment are cleaned or stored, shall not open directly into any stable, farm-stead, area in which meat, poultry or any other non-dairy foods of animal origin are handled or stored, any restaurant food preparation area or any room used for domestic purposes. All rooms shall be of sufficient size for their intended purposes.

6. Designated areas or rooms shall be provided to segregate the receiving, handling and storage of returned packaged dairy products. They shall be properly identified, kept neat, clean and maintained in such a manner as to preclude contamination of other products or equipment or the attraction of flies.

7. Construction and repair of containers and equipment:

a. The construction of all containers and equipment used in the manufacture of aged cheeses and related products shall conform with the requirements for containers and equipment contained in §937 of this Part.

b. In addition, for certain other equipment the following requirements shall be met.

i. Starter Vats. Bulk starter vats shall be of stainless steel or equally corrosion-resistant metal and shall be in good repair, equipped with tight-fitting lids and have adequate temperature controls, such as valves, indicating and/or recording thermometers and shall conform with the applicable 3-A Standards.

ii. Cheese Vats, Tanks and Drain Tables. The vats used for making cheese shall be of metal construction with adequate jacket capacity for uniform heating. The inner liner shall be minimum 16-gage stainless steel or other equally corrosion-resistant metal, properly pitched from side to center and from rear to front for adequate drainage. The liner shall be smooth, free from excessive dents or creases and shall extend over the edge of the outer jacket. The outer jacket when metal, shall be constructed of stainless steel or other metal which can be kept clean and sanitary. The junction of the liner and outer jackets shall be constructed so as to prevent milk or cheese from entering the inner jacket. The vat, tank and drain table shall be equipped with a suitable sanitary outlet valve. Effective valves shall be provided and properly maintained to control the application of heat to the vat.

iii. Mechanical Agitators. The mechanical agitators shall be of sanitary construction. The carriage and track shall be so constructed as to prevent the dropping of dirt or grease into the vat. Metal blades, forks, or stirrers shall be constructed of stainless steel and of material approved in the 3-A Standards and shall be free from rough or sharp edges which might scratch the equipment or remove metal particles.

iv. Knives, hand rakes, shovels, scoops, paddles, strainers, and miscellaneous equipment shall be stainless steel or of material approved in the 3-A Standards. The product contact surfaces of the curd mill shall be of stainless steel. All pieces of equipment shall be so constructed that they can be kept clean and free from rough or sharp edges which might scratch the equipment or remove metal particles. The wires in the curd knives shall be stainless steel, kept tight, replaced when necessary and kept clean.

v. Hoops, Forms and Followers. The hoops, forms and followers shall be constructed of stainless steel or heavy tinned steel. If tinned, they shall be kept tinned and free from rust. All hoops, forms, and followers shall be kept in good repair. Drums or other special forms used to press and store cheese shall be clean and sanitary.

vi. Press. The cheese press shall be constructed of stainless steel and all joints welded and all surfaces, seams, and openings readily cleanable. The pressure device shall be the continuous type. Press cloths shall be maintained in good repair and in a sanitary condition. Single-service press cloths, starch circles, bandages, etc., shall be used only once.

vii. Rindless Cheese Press. The press used to heat seal the wrapper applied to rindless cheese shall have square interior corners, reasonably smooth interior surface and have controls that shall provide uniform pressure and heat equally to all surfaces.

viii. Paraffin Tanks. The metal tank shall be adequate in size, have heat controls and an indicating thermometer. The cheese wax contained in the paraffin tank shall be kept clean at all times.

ix. Automatic Curd Maker. The automatic curd making system shall be constructed of stainless steel or of material approved in the 3-A Standards. All areas shall be free from cracks and rough surfaces and constructed so that they can be easily cleaned.

x. Curd Conveying Systems. The curd conveying system, conveying lines and cyclone separator shall be constructed of stainless steel or other equally corrosion resistant metal in such manner that it can be satisfactorily cleaned. The system shall be of sufficient size to handle the volume of curd and be provided with filtered air of the quality satisfactory for the intended use. Air compressors or vacuum pumps shall not be located in the processing or packaging areas.

xi. Automatic Salter. The automatic salter shall be constructed of stainless steel or other equally corrosion resistant metal. This equipment shall be constructed to equally distribute the salt throughout the curd. It shall be designed to accurately weigh the amount of salt added. The automatic salter shall be constructed so that it can be satisfactorily cleaned. The salting system shall provide for adequate absorption of the salt in the curd. Water and steam used to moisten the curd prior to salting shall be potable water or culinary steam.

xii. Automatic Curd Filler. The automatic curd filler shall be constructed of stainless steel or other equally corrosion resistant metal. This equipment shall be of sufficient size to handle the volume of curd and constructed and controlled so as to accurately weigh the amount of curd as it fills. The curd filler shall be constructed so that it can be satisfactorily cleaned.

xiii. Hoop and Barrel Washer. The washer shall be constructed so that it can be satisfactorily cleaned. It shall also be equipped with temperature and pressure controls to ensure satisfactory cleaning of the hoops or barrels. It should be adequately vented to the outside.

xiv. Cheese Vacuumizing Chamber. The vacuum chamber shall be satisfactorily constructed and maintained so that the product is not contaminated with rust or flaking paint. An inner liner of stainless steel or other corrosion resistant material should be provided.

xv. Monorail. The monorail shall be constructed so as to prevent foreign material from falling on the cheese or cheese containers.

xvi. Conveyor for moving and draining block or barrel cheese. The conveyor shall be constructed so that it will be easily cleaned. It shall be installed so that the press drippings will not cause an environmental problem.

xvii. Rindless Cheese Wrapping Equipment. The equipment used to heat seal the wrapper applied to rindless cheese shall have square interior corners, reasonably smooth interior surfaces and have controls that shall provide uniform pressure and heat to all surfaces. The equipment used to apply shrinkable wrapping material to rindless cheese shall operate to maintain the natural intended shape of the cheese in an acceptable manner, reasonably smooth surfaces on the cheese, and tightly adhere the wrapper to the surface of the cheese.

xviii. Special Equipment. All product contact areas of speciality equipment shall be constructed of stainless steel or of material approved in the 3-A Standards and constructed following 3-A Standards principles.

xix. Washing Machine. When used, the washing machine for cheese cloths and bandages shall be of commercial quality and size; or of sufficient size to handle the applicable load. It should be equipped with temperature and water level controls.

8. Packaging, cutting, slicing, repackaging of aged cheese.

a. The packaging, cutting, slicing or repackaging of aged cheese shall be conducted under rigid sanitary conditions that preclude contamination of the product.

b. The plant shall submit detailed plans of the equipment and procedures to be used in these operations to the state health officer for written approval prior to beginning such operations.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2509. Additional Requirements for Pasteurized Process Cheese Manufacturing Plants

A. All pasteurized process cheese and cheese related products shall conform with the standards of identify contained in the Code of Federal Regulations.

B. Dairy plants that manufacture, process or package process cheese or cheese related products shall conform with all of the requirements for cheese manufacturing plants contained in this Part and shall conform with the following additional requirements:

1. Milk used in the manufacture of pasteurized process cheese and cheese related products shall be derived

from Grade A raw milk for pasteurization or manufacturing grade raw milk for pasteurization from a source approved by the state health officer

2. Milk and milk products used in the manufacture of pasteurized process cheese or cheese related products shall be pasteurized, ultra-pasteurized or aseptically processed in accordance with the requirements for pasteurization or ultra-pasteurization contained in this Part.

3. Conveyors shall be constructed of material which can be properly cleaned, will not rust, or otherwise contaminate the cheese and shall be maintained in good repair.

4. The grinders or shredders used in the preparation of the trimmed and cleaned natural cheese for the cookers shall be adequate in size. Product contact surfaces shall be of corrosion resistant material, and of such construction as to prevent contamination of the cheese and to allow thorough cleaning of all parts and product contact surfaces.

5. The cookers shall be the steam jacketed or direct steam type. They shall be constructed of stainless steel or other equally corrosion-resistant material. All product contact surfaces shall be readily accessible for cleaning. Each cooker shall be equipped with an indicating thermometer, and shall be equipped with a temperature recording device. The recording thermometer stem may be placed in the cooker. Steam check valves on direct steam type cookers shall be mounted flush with cooker wall, be constructed of stainless steel and designed to prevent the backup of product into the steam line, or the steam line shall be constructed of stainless steel pipes and fittings which can be readily cleaned. If direct steam is applied to the product only culinary steam shall be used.

6. The hoppers of all fillers shall be covered but the cover may have sight ports. If necessary, the hopper may have an agitator to prevent buildup on side walls. The filler valves and head shall be kept in good repair and capable of accurate measurements.

7. The natural cheese shall be cleaned free of all nonedible portions. Paraffin and bandages as well as rind surface, mold, or unclean areas or any other part which is unwholesome or unappetizing shall be removed.

8. Each batch of cheese within the cooker, including the optional ingredients shall be thoroughly commingled and the contents pasteurized at a temperature of at least 70°C (158°F) and held at that temperature for not less than 30 seconds. Care shall be taken to prevent the entrance of cheese particles or ingredients after the cooker batch of cheese has reached the final heating temperature. After holding for the required period of time, the hot cheese shall be emptied from the cooker as quickly as possible.

9. Containers, either lined or unlined, shall be assembled and stored in a sanitary manner to prevent contamination. The handling of containers by filler crews shall be done with extreme care and observance of personal cleanliness. Performing and assembling of pouch liners and containers shall be kept to a minimum and the supply rotated to limit the length of time exposed to possible contamination prior to filling.

10. Hot fluid cheese from the cookers may be held in hot wells or hoppers to assure a constant and even supply of processed cheese to the filler or slice former. Filler valves shall effectively measure the desired amount of product into the pouch of containers in a sanitary manner and shall cut off sharply without drip or drag of cheese across the opening. An effective system shall be used to maintain accurate and precise weight control. Damaged or unsatisfactory packages shall be removed from production, and the cheese may be salvaged into sanitary containers, added back to cookers and recooked prior to repackaging.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2511. Additional Requirements for Cheese Manufacturing Plants that Manufacture, Process or Package Unripened Cheese

A. Dairy plants that manufacture, process or package unripened cheese shall conform with all of the requirements for cheese manufacturing plants contained in this Part and shall conform with the following additional requirements.

1. Milk and milk products used in the manufacture of unripened cheese and related products shall be from a Grade A raw milk for pasteurization source approved by the state health officer.

2. All milk and milk products used in the manufacture of unripened cheese and cheese related products shall be pasteurized, ultra-pasteurized or aseptically processed in accordance with the requirements for pasteurization, ultra-pasteurization or aseptic processing contained in this Part.

3. Milk and milk products including reconstituted milk or milk product shall be pasteurized, ultra-pasteurized or aseptically processed in the plant in which the unripened cheese or cheese related products are manufactured or processed, provided that the state health officer may authorize cheese manufacturing plants that comply with the requirements of §2513 of this Part to manufacture or process unripened cheese or cheese related products from milk or milk products pasteurized, ultra-pasteurized or aseptically processed in other plants.

4. Rooms and compartments. Processing operations with open cheese vats in them shall be separated from other rooms or areas.

a. Processing and packaging rooms shall be adequately ventilated to maintain sanitary conditions, preclude the growth of mold and airborne contaminants, prevent condensation, and to minimize objectionable odors.

b. Starter rooms or areas shall be properly equipped and maintained for the propagation and handling of starter cultures.

c. Coolers shall be equipped with the facilities necessary for maintaining proper temperature and humidity, consistent with GMPs for the applicable product and to prevent contamination of the products.

5. Packaging. Packaging of unripened cheese and cheese related products shall be done in a sanitary manner with mechanical equipment that complies with applicable 3-A Sanitary Standards.

a. Packaging materials for unripened cheese or cheese related products shall provide sufficiently low permeability to air and moisture and shall be resistant to puncturing, tearing, cracking or fragmentation. Any materials used in the package or packaging that has contact with product shall conform with this requirement. Approval

of the state health officer shall be obtained for all packaging materials prior to use.

b. Upright open containers and closures shall be protected from contamination by overhead shields.

c. Single service containers and closures and other single service articles for use in contact with dairy products shall be of sanitary design and construction and from sources approved by the state health officer. They shall be stored in their original containers or in equipment designed for storage of single service articles, shall be kept therein in a clean, dry place until used and shall be handled in a sanitary manner.

d. Caps or covers which extend over the lip of the container shall be used on all cups or tubs of two pounds or less.

e. Capping or closing of containers of two pounds or less shall be done in a sanitary manner using mechanical equipment that complies with applicable 3-A Sanitary Standards. Hand capping of such containers shall be prohibited.

f. A date, code or lot number that identifies the date, run or batch from which the contents originated, shall be prominently displayed on each final container (container that will reach the final consumer) of dairy product in indelible ink (or equivalent). The date, code or batch shall be printed on the container or label in such a manner that it cannot be removed, changed or defaced.

6. The cheese manufacturing plant shall:

a. obtain a representative sample of each batch or lot of cheese or related cheese product, manufactured or processed by the plant. Normally, this shall be done by collecting a closed final container of the cheese or the cheese related product, randomly selected, and perform or have a coliform count performed on the sample;

b. perform the sampling procedures and laboratory examination in substantial compliance with the procedures contained in the *Standard Methods for the Examination of Dairy Products*;

c. record the results of each test and retain the record for a period of one year after the date that the product was produced. These records shall be made available for review by the state health officer;

d. immediately take steps to determine and eliminate the cause when the coliform count of a sample of product exceeds 10 per gm; and

e. maintain a record, for review by the state health officer, of action taken to correct the cause of each coliform count that exceeded 10 per gm. Such records that shall be retained for a period of one year after the date the product was produced.

B. Unripened cheese and cheese related products shall conform with the following bacteriological, chemical and temperature standards:

a. temperature—cooled to 7°C (45° F) or less prior to final storage and maintained thereat;

b. coliform count—not to exceed 10 per gram; and,

c. pathogens—no pathogenic microorganisms of human significance;

C. During any consecutive six months at least four samples of each type of cheese manufactured or processed by each plant shall be taken by the state health officer and tested for coliform count. The state health officer shall take appropriate regulatory action on violative sample results, as prescribed in §331 of this Part.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2513. Additional Requirements for Cheese Manufacturing Plants that Manufacture or Process Unripened Cheese or Cheese Related Products from Milk or Milk Products that were Pasteurized, Ultra-pasteurized or Aseptically Processed at Other Plants without Repasteurization

A. Cheese manufacturing plants that manufacture or process unripened cheese or cheese related products from milk or milk products that were pasteurized, ultra-pasteurized or aseptically processed at another plant without being repasteurized shall conform with all of the requirements for unripened cheese contained in this Part and with the following additional requirements.

1. All milk or milk products used in the manufacture or processing of unripened cheese or cheese related products shall be Grade A pasteurized or Grade A ultra-pasteurized or aseptically processed and obtained from a plant possessing a valid permit from the state health officer.

2. All reconstituted milk or milk products shall be pasteurized, ultra-pasteurized or aseptically processed in the dairy plant in which it was reconstituted and shall be obtained from a plant possessing a valid permit from the state health officer.

3. All milk and milk products, including reconstituted milk and milk products shall be packaged and transported in sealed containers, approved by the state health officer.

4. Cheese manufacturing plants that manufacture or process unripened cheese made from milk or milk products pasteurized or ultra-pasteurized at another plant without being re-pasteurized or ultra-pasteurized shall develop and implement a HACCP system conforming with the requirements contained in Chapter 11 of this Part.

5. The cheese manufacturing plant shall:

a. obtain a representative sample of each batch or lot of cheese or related cheese product, manufactured or processed by the plant. Normally, this shall be done by collecting a closed final container of the cheese or the cheese related product, randomly selected, and perform or have a coliform count performed on the sample;

b. perform the sampling procedures and laboratory examination in substantial compliance with the procedures contained in the *Standard Methods for the Examination of Dairy Products*;

c. record the results of each test and retain the record for a period of one year after the date that the product was produced. These records shall be made available for review by the state health officer;

d. immediately take steps to determine and eliminate the cause when the coliform count of a sample of product exceeds 10 per gm; and,

e. maintain a record, for review by the state health officer, of action taken to correct the cause of each coliform count that exceeded 10 per gm. Such records that shall be retained for a period of one year after the date the product was produced.

B. Unripened cheese and related products shall conform with the following bacteriological and temperature standards:

1. temperature—cooled to 7°C (45°F) prior to final storage and maintained thereat;

2. coliform count—not to exceed 10 per gram; and,

3. pathogens—no pathogenic microorganisms of human significance.

C. During any consecutive six months, at least four samples of pasteurized or ultra-pasteurized milk or milk products to be used in the manufacture or processing un-ripened cheese or cheese related products shall be taken by the state health officer at the cheese manufacturing plant after receipt of the milk by the plant and prior to being manufactured or processed and tested for standard plate count, coliform count, temperature. The state health officer shall take appropriate regulatory action, as prescribed in §331 of this Part, on violative sample results.

D. During any consecutive six months at least four samples of each type of cheese manufactured or processed by each plant shall be taken by the state health officer and tested for coliform count. The state health officer shall take appropriate regulatory action, as prescribed in §331 of this Part, on violative sample results.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

Chapter 27. Frozen Desserts

§2701. Approval of Plans

A. All frozen dessert manufacturing plants that are domiciled within the state and are hereafter constructed, reconstructed or altered shall conform in their construction and operation with the requirements of this Part. Prior to construction, reconstruction or alteration, written approval of plans and specifications shall be obtained from the state health officer.

B. Prior to installation or modification, written approval shall be obtained from the state health officer of plans and specifications for the design, construction and manner of employment for all equipment.

C. Written detailed plans describing the processing of each product shall be submitted to the state health officer for approval prior to the manufacture of each product and prior to any product or process change.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2703. Basic Requirements for Frozen Dessert Manufacturing Plants

A. All frozen dessert manufacturing plants that manufacture, process or freeze frozen desserts shall conform with the following general requirements for dairy plants:

1. definitions (in accordance with §101 of this Code);

2. standards of identity (in accordance with §107 of this Part);

3. permits (in accordance with §109 of this Part);

4. permits required for imported milk, milk products and frozen desserts (in accordance with , §111 of this Part);

5. requirements for imported dairy products (in accordance with §113 of this Part);

6. milk records (in accordance with §115 of this Part);

7. falsification of records (in accordance with §117 of this Part);

8. registration (in accordance with §119 of this Part);

9. labeling (in accordance with §121 of this Part);

10. delivery of samples (in accordance with §303 of this Part);

11. pasteurization equipment tests, examination and sealing (in accordance with §313 of this Part);

12. application for regrading, reinstatement of permit and permission to resume sale of product (in accordance with §341 of this Part);

13. regrading and reinstatement of permit when degrade or suspension was based on physical violations (in accordance with §345 of this Part);

14. reinstatement of permit when suspension was based upon adulteration of product or contamination of pasteurized product or cheeses with pathogenic microorganisms of human significance (in accordance with §347 of this Part);

15. milk tank trucks (in accordance with §701 of this Part);

16. sealing and protection of milk tank trucks (in accordance with §703 of this Part);

17. labeling (in accordance with §705 of this Part);

18. general requirements (in accordance with §901 of this Part);

19. approval of plans (in accordance with §903 of this Part);

20. raw milk receiving (in accordance with §905 of this Part);

21. dairy plant receivers/samplers (in accordance with §907 of this Part);

22. receiving and handling of milk derived and non-dairy ingredients (in accordance with §909 of this Part);

23. immediate surroundings (in accordance with §911 of this Part);

24. floors (in accordance with §913 of this Part);

25. walls and ceilings (in accordance with §915 of this Part);

26. doors and windows (in accordance with §917 of this Part);

27. light and ventilation (in accordance with §919 of this Part);

28. separate rooms (in accordance with §921 of this Part);

29. toilet facilities (in accordance with §923 of this Part);

30. water supply (in accordance with §925 of this Part);

31. hand washing facilities (in accordance with §927 of this Part);

32. protection from contamination (in accordance with §929 of this Part);

33. reclaim or rework operations (in accordance with §931 of this Part);

34. dairy plant cleanliness (in accordance with §933 of this Part);

35. sanitary piping (in accordance with §935 of this Part);

36. construction and repair of containers and equipment (in accordance with §937 of this Part);

37. thermometers (in accordance with §939 of this Part);

38. pasteurization, ultra pasteurization and aseptic processing (in accordance with §941 of this Part);

39. cleaning and sanitization of containers and equipment (in accordance with §943 of this Part);

40. storage of cleaned containers and equipment (in accordance with §945 of this Part);

41. storage of single-service containers, utensils and materials (in accordance with §947 of this Part);

42. packing, bottling and wrapping (in accordance with §949 of this Part);

43. capping (in accordance with §951 of this Part);

44. delivery containers (in accordance with §953 of this Part);

45. cooling of milk and dairy products (in accordance with §955 of this Part);

46. use of overflow, leaked, spilled or mishandled dairy products (in accordance with §957 of this Part);

47. dipping or transferring dairy products (in accordance with §965 of this Part);

48. apparatus, containers, equipment and utensils (in accordance with §967 of this Part);

49. personnel health (in accordance with §969 of this Part);

50. notification of disease (in accordance with §971 of this Part);

51. procedure when infection suspected (in accordance with §973 of this Part);

52. personal cleanliness (in accordance with §975 of this Part);

53. allergen and sensitivity producing ingredient (in accordance with §977 of this Part);

54. rat proofing (in accordance with §985 of this Part);

55. waste disposal (in accordance with §987 of this Part); and

56. vehicles (in accordance with §989 of this Part).

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

Subchapter A. Supplemental Requirements for Dairy Plants that Manufacture Frozen Desserts

§2705. General Information

A. Dairy plants that manufacture frozen desserts including frozen dessert mixes shall conform with the basic requirements for frozen dessert manufacturing plants in §2703 of this Part and with the following additional requirements.

1. If the powdered or dry frozen dessert mix contains any dairy product, egg ingredient or other potentially hazardous food ingredient, the mix shall be pasteurized, ultra pasteurized or aseptically processed following reconstitution using pasteurization, ultra pasteurization or aseptic processing methods specified in this Part.

2. Optional dairy ingredients shall be derived from Grade A raw milk for pasteurization or manufacturing grade raw milk for pasteurization (milk for manufacturing purposes) obtained from sources that are in substantial compliance with the requirements of this Part and are approved by the state health officer.

3. Dry dairy products used in the manufacture of frozen desserts for which grades and grading criteria are specified in this Part shall be Grade A or extra grade. Products of a lower grade shall not be used.

4. Non-milk derived ingredients used in the manufacture of frozen desserts shall have been determined by the FDA to be GRAS for use in frozen desserts.

5. All dairy ingredients used in the manufacture of frozen desserts shall be produced, packed, held and shipped in a manner consistent with the requirements of this Part.

6. All non-milk derived ingredients shall be purchased only from suppliers which certify or guarantee that their product has been produced and handled in a manner that will assure a safe and wholesome ingredient which will not adulterate the finished product. Records of such verification or guarantee shall be available for review by the state health officer.

7. A safety and quality inspection of all incoming non-milk derived ingredients shall be performed. Records of the results of these inspections, corrective actions taken when problems are identified and the date and initials of the person performing the inspection shall be maintained and made available to the state health officer. The inspection shall include an evaluation for conditions related to:

a. product identity and labeling;

b. package condition and integrity;

c. bulging;

d. leaking;

e. dirt/grime;

f. insect infestation;

g. rodent damage; and

h. off-odors and non-food materials (especially toxic compounds) or residues of such materials in the truck or other conveyance.

8. All ingredients used in the manufacture of frozen desserts shall be stored and handled in such a manner as to preclude their contamination. Particular attention shall be given to closing or resealing of containers that have been opened and the contents of which have been partially used.

9. Dusty raw ingredient blending or liquification operations which create powdery conditions shall not be conducted in areas where pasteurized products are handled or stored.

10. Mix preparation operations in which ingredients are exposed shall be conducted in processing areas. Except when ingredients are being added, all openings into vessels and lines containing product shall be covered. The outer box or wrapper of powdered ingredients shall be removed prior to dumping into mixing vessels.

11. All liquid ingredients which will support bacterial growth shall be kept or immediately cooled to 7°C (45°F) or below.

12. Pasteurization, ultra- pasteurization and aseptic processing shall be performed on the following products.

a. All frozen dessert mixes, dairy and non-dairy shall be pasteurized, ultra-pasteurized or aseptically processed, provided that the state health officer may exempt some specific frozen dessert mixes that do not contain dairy ingredients and do not support the growth of pathogenic microorganisms of human significance from this requirement dependent upon their ingredients and manner of processing.

b. Pasteurization, ultra-pasteurization and aseptic processing of frozen dessert mixes shall be performed in equipment and using procedures that conform with the requirements of the *PMO* for pasteurization and with current applicable 3-A sanitary standards as approved by the state health officer.

c. Frozen desserts to be sold or distributed to retail outlets shall be frozen and packaged at the plant in which the frozen dessert mix was made and pasteurized provided that the state health officer may authorize dairy plants that have implemented HACCP systems that comply with the requirements of this Part to freeze, partially freeze or package frozen desserts from mixes that were pasteurized, ultra-pasteurized or aseptically processed in other plants.

i. The following minimum times and temperatures shall apply to pasteurization of frozen dessert mixes:

(a). 68°C (155°F) for 30 minutes;
(b). 79°C (175°F) for 25 seconds;
(c). 82°C (180°F) for 15 seconds;
(d). 88°C (191°F) for 1.0 second;
(e). 90°C (194°F) for 0.5 second;
(f). 93°C (201°F) for 0.1 second;
(g). 95°C (204°F) for 0.05 second; and,
(h). 100°C (212°F) for 0.01 second.

d. Should scientific evidence indicate that the above temperatures or times are not adequate to destroy pathogenic microorganisms of human significance or for any other reason, may not be adequate to protect the public's health, the state health officer may, with the concurrence of the FDA, immediately require that all pasteurized dairy products sold in the state be pasteurized at temperatures or times recommended to be adequate by the FDA. Should the FDA hereafter determine that any of the requirements for pasteurization or ultra-pasteurization contained in the PMO are not adequate to protect the public's health and require a change in any of the aforesaid requirements, the state health officer shall immediately require that all pasteurization or ultra-pasteurized products sold in the state conform with the new FDA requirements for pasteurization or ultra-pasteurization. Nothing shall be construed as barring any other pasteurization process, which has been recognized by the FDA to be equally efficient and which is approved by the state health officer.

13. The only ingredients that shall be added after pasteurization, ultra-pasteurization or aseptic processing are the following flavoring and coloring ingredients:

a. those subjected to prior heat treatment sufficient to destroy pathogenic microorganisms;
b. those of 0.85 percent water activity or less;
c. those with a pH of less than 4.7;
d. roasted nuts (added at freezer);
e. those that contain high alcohol content;
f. bacterial cultures; and
g. those that have been subjected to any other process which will assure that the ingredient is free of pathogenic microorganisms of human significance.

14. Reclaim or Rework Operations. Reclaim or rework operations are all activities associated with the recovery, handling, and storage of processed or partially processed products for use as an ingredient in products to be used for human consumption.

a. Product that has entered the distribution channels or has been temperature-abused, tampered with or exposed to chemical or biological contamination shall not be reclaimed or reworked for use as an ingredient in other products for human consumption.

b. Reclaimed or reworked products and reclaim or rework operations shall conform with the following requirements.

i. Reclaim areas and equipment shall be constructed, maintained and protected in a manner that is in substantial compliance with the requirements for production and processing areas contained in this Part.

ii. Products that have left the premises of the plant in which it was packaged shall not be reclaimed or reworked.

iii. All products to be reclaimed shall be maintained at 7°C (45°F) or below. Product salvaged from defoamers and tank or line rinsing shall be immediately cooled to 7°C (45°F) or below.

iv. Packages of products to be reclaimed or reworked shall be clean and free of contamination. Products from leaking or badly damaged containers shall not be reclaimed or reworked.

v. Packaged products shall be opened in such a manner as to minimize the potential for contamination. Containers shall not be opened by slashing, smashing or breaking.

vi. Woven wire strainers shall not be used in reclaim or rework operations.

vii. Reclaim or rework dump stations and tanks shall be covered except when products are actually being dumped through the openings.

viii. Reclaim or rework storage tanks shall be equipped with adequate thermometers.

ix. Reclaimed or reworked products shall be handled as a raw dairy ingredient.

x. Cleaning and sanitizing requirements shall be the same as those for other raw ingredient handling equipment.

xi. It is recommended that higher than minimum temperatures and times be used in the pasteurization of product containing reclaimed or reworked ingredients.

xii. The dairy plant shall take appropriate steps to preclude the contamination of products or equipment with allergenic and sensitivity producing reclaim or reworked ingredients or substances that will not be appropriately declared in the labeling of the final container of product.

15. Allergen and Sensitive Producing Ingredients Control

a. Due to the large number of allergens and sensitivity producing ingredients usually present in frozen dessert operations, each plant shall have a trained individual study each ingredient used in the plant and the processing steps and sequence used in the manufacture of each product. He shall determine where, how and when potentials exist for an allergen to inadvertently enter products.

b. The plant shall take appropriate steps to preclude the contamination of all products with allergens and sensitive producing ingredients that will not be declared in the labeling of the final container of each product.

16. Packaging of Frozen Desserts. Frozen dessert products shall be packaged in unused single service

containers, obtained from a source approved by the state health officer, which protects the contents from contamination and after packaging shall be stored in a sanitary manner.

a. Packaging and closing or capping of all containers of half-gallon or less shall be performed in a sanitary manner in mechanical equipment that conforms with the applicable 3-A Sanitary Standards. Hand capping of such containers is prohibited.

b. Upright open containers and all closures shall be protected from contamination by overhead shields.

c. Caps or covers shall extend over the lip of the container on all cups, tubs or containers of can-type configuration.

d. A date, code or lot number that identifies the date, run or batch from which the contents originated, shall be prominently displayed on each final container (container that will reach the final consumer) of dairy product in indelible ink (or equivalent). The date, code or batch shall be printed on the container or label in such a manner that it cannot be removed, changed or defaced.

17. All frozen desserts including frozen dessert mixes shall conform with the standards of identity prescribed by this Part.

18. Frozen desserts, including frozen dessert mixes shall conform with the following temperature and bacteriological standards:

a. cooled to 7°C (45°F) or less and maintained thereat;

b. bacteriological limits—not to exceed 50,000 cfu per gm (Cultured products are exempt from this requirement);

c. coliform count limits—not to exceed 10 per gram, except that the coliform count of those frozen desserts which contain fruit, nuts, chocolate or other bulky flavors shall not exceed 20 per gram; and,

d. pathogens—no pathogenic microorganisms of human significance.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2707. Additional Requirements for Frozen Dessert Manufacturing Plants that Have Been Authorized by the State Health Officer to Freeze or Partially Freeze and Package Frozen Desserts Made from Frozen Dessert Mixes that were Pasteurized, Ultra-pasteurized or Aseptically Processed at Another Plant

A. The plant shall implement a HACCP system, approved by the state health officer, that conform with the requirements contained in Chapter11 of this Part.

B. Frozen dessert manufacturing plants that have been authorized by the state health officer to freeze or partially freeze and package frozen desserts made from frozen dessert mixes that were pasteurized, ultra-pasteurized or aseptically processed at another plant without being repasteurized or ultra-pasteurized again shall conform with all of the requirements for frozen dessert manufacturing plants contained in this Part and shall conform with the following additional requirements.

1. All frozen dessert mixes shall have been manufactured in dairy plants possessing a valid permit from the state health officer.

2. All reconstituted mixes shall be pasteurized, ultra-pasteurized or aseptically processed in the plant in which it was reconstituted.

3. All frozen dessert mixes shall be packaged and transported in sealed containers which have been approved by the state health officer.

4. Each plant shall develop and implement a HACCP system conforming with the HACCP requirements contained in this Part and shall be approved by the state health officer.

5. The frozen dessert manufacturing plant shall:

a. obtain a representative sample of each batch of frozen desserts packaged by the plant. Normally, this shall be done by collecting a closed final container of product, randomly selected, and perform or have a standard plate count and a coliform count performed on the sample;

b. perform the sampling procedures and laboratory examination in compliance with the procedures contained in the *Standard Methods for the Examination of Dairy Products*;

c. record the results of each test and retain the record for a period of one year after the date that the product, from which the sample was collected, was packaged. These records shall be made available for review by the state health officer;

d. immediately take steps to determine and eliminate the cause when the coliform count of a sample of product exceeds 10 per gram or the standard plate count exceeds 50,000 cfu per gram (unless a cultured product); and,

e. maintain a record, for review by the state health officer, of action taken to correct the cause of each elevated coliform count or elevated standard plate count. Such records that shall be retained for a period of one year after the date the product was packaged.

C. During any consecutive six months, at least four samples of pasteurized or ultra-pasteurized frozen dessert mix to be used in the manufacture of frozen desserts shall be taken by the state health officer at the frozen dessert manufacturing plant. The container in which it was packaged by the plant shall be opened and the frozen dessert mix tested for standard plate count and coliform count. The state health officer shall take appropriate regulatory action based on violative sample results as prescribed in §331 of this Part.

D. During any consecutive six months at least four samples of each flavor and fat level of product packaged by the plant shall be taken by the state health officer and tested for standard plate count and coliform count. The state health officer shall take appropriate regulatory action on violative sample results as prescribed in §331 of this Part.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

Subchapter B. Frozen Dessert Retail Requirements

§2709. Counter Freezers [formerly paragraph 8:013]

A. The processing, handling, and distribution of milk and milk products in the manufacture of frozen desserts shall

conform to the minimum requirements for Grade A milk as prescribed in this Part. All milk and milk products shall be of quality approved by the state health officer. Counter freezer operations which freeze mixes and sell only at retail on the premises shall comply with the following requirements:

1. only mixes that have been processed and packaged in an approved plant shall be allowed;

2. counter freezers used for freezing mixes which contain milk solids, milk fat, or vegetable fat shall be located only in premises which meet the minimum requirements for retail food establishments as prescribed in Part XXIII of this Code;

3. the frozen dessert operator shall be a food handler other than the cashier of a grocery or convenience store;

4. ice cream, ice milk and other frozen desserts shall be offered to consumers who serve themselves only when dispensed from approved dispensing machines designed expressly for that purpose;

5. the dipping and/or packaging of firmly frozen frozen desserts by consumers who serve themselves is prohibited.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4.A.(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2711. Mobile Frozen Dessert Units [formerly paragraph 8:021]

A. All milk and milk products used in the manufacture of frozen desserts shall be of a quality approved by the state health officer. The processing, handling and distribution of milk and milk products as well as the building, equipment, and other entities used in the manufacture of frozen desserts shall conform to the requirements for Grade A milk in this Part. In addition, mobile frozen dessert units shall comply with the following requirements.

1. Each operator of a mobile frozen dessert unit shall obtain a permit to operate from the state health officer.

2. Truck interior shall be completely enclosed with the exception of serving windows and shall be of sufficient size with equipment and fixtures conveniently located so as to render efficient and sanitary operation.

3. Serving openings shall not be larger than 18 inches wide and 28 inches high, and there shall not be more than two serving openings to each mobile unit. The serving openings shall be closed at all times that the operator of the mobile unit is not actually dispensing frozen desserts.

4. A potable water supply tank, minimum capacity of 40 gallons, heated electrically or otherwise, and tilted toward a capped drain cock, shall be provided. Water inlet pipe shall be of removable flexible copper or other tubing approved by the state health officer, with nozzle for hose connection capped when not being used. The tank shall be provided with permanent vacuum breaker properly mounted (6 inches above top of tank). Tank shall be vented and screened with copper, brass or bronze screen. Hose and rack for connection to potable water supply shall be provided. An approved gauge shall be provided to determine content levels.

5. A three-compartment seamless sink supplied with running hot and cold water, equipped with a swivel faucet, shall be provided. Each compartment shall be large enough to accommodate the largest piece of equipment to be cleansed therein. Said sink shall be trapped and vented.

6. A hand sink, seamless, with running hot and cold water, soap and single service or individual towels, shall be provided. The sink shall be trapped and vented.

7. A suitable waste tank with capacity of at least 15 percent larger than the water supply tank, shall be provided, tilted toward a drain cock with an adequate method of gauging the contents. It shall be emptied and flushed as often as necessary in a sanitary manner. All connections on the vehicle for servicing the waste tank shall be of different size or shape than those used for supplying potable water. The waste connection shall be located lower than the water inlet connection to preclude contamination of the potable water system. An approved gauge shall be provided to determine content levels.

8. A refrigerator box, constructed of stainless steel or other noncorrosive material and equipped with an indicating thermometer shall be provided. Metal racks or platforms shall be provided to store all ingredients.

9. Floors of the mobile unit shall be of material approved by the state health officer. Junctures of floors, wall and adjoining fixtures shall be watertight and covered. The floors shall be kept clean and dry at all times during the operation of the mobile unit.

10. Only mixes that have been processed and packaged in a plant approved by the state health officer shall be allowed, and mixes which require reconstitution are not allowed.

11. A covered waste can or container of sufficient size shall be provided for daily needs, constructed, designed and placed for ready cleaning. An easily accessible covered waste can or container shall be provided for customer's use. It shall be readily cleanable and kept clean, so located as not to create a nuisance, and so labeled that the public will be informed.

12. The truck interior shall be provided with artificial light sufficient to provide 15 foot-candles of light in all areas.

13. Separation of partition (self-closing doors accepted) shall be made between driver's seat and manufacturing unit unless vehicle is air-conditioned.

14. Persons preparing and handling frozen desserts shall wear clean, washable clothing, and effective, clean hair restraints.

15. The original frozen dessert permit to operate shall be displayed on each vehicle with photostat posted in operator's depot.

16. Each mobile unit shall display a sign advising the public of the type of frozen dessert being sold (e.g., ice milk, ice cream, etc.). The sign shall be printed in letters at least 8 inches in height.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4.a.(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2713. Depots for Mobile Frozen Dessert Units [formerly paragraph 8:022]

A. All mobile units shall operate from depots and shall report to their respective depot for cleaning and sanitizing at least once each day. All depots shall comply with the following requirements.

1. All plans and specifications for depots shall be approved by the state health officer prior to construction of

same in accordance with §1701.A of this Part. Structurally the building shall comply with the provisions of §1703 of this Part.

2. For washing purposes there shall be at least three large sinks, each of which shall be large enough to accommodate the largest piece of equipment to be washed. Sinks are to be provided with drainboards of impervious material.

3. A metal pipe drying rack for utensils shall be provided.

4. Clothes lockers and garbage cans shall be provided.

5. Adequate storage for perishable materials shall be provided.

6. A separate room shall be provided for the storage of all non-perishable food and paper products.

7. Adequate facilities shall be provided for the washing of vehicles.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4.A(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

Chapter 29. Standards for the Fabrication of Single Service Containers and Closures for Milk and Milk Products Including Fabricating Plants Producing Component Parts, Films and Closures

§2901. General Requirements

A. The following criteria pertains to manufactures of preforms and bottles preformed at one plant and molded at a second plant:

1. The preforming plant must be IMS listed, but sampling of the pre-form is not required at this plant.

2. If the first preforming plant is also molding the containers into their final form, this plant must be IMS listed and the containers must be sampled at this plant.

3. If the second plant, where containers are molded into their final form, is a single-service manufacturer, this plant must be IMS listed and the containers must be sampled at this plant.

4. If the second plant is a milk plant where containers are molded into their final form, for use only in that milk plant, the milk plant listing is sufficient, but the containers shall be sampled at this plant.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2903. Approval of Plans

A. All plants domiciled within the state, in which single service milk containers or closures are manufactured, shall conform in their construction to the requirements of these regulations. Equipment and installation of all equipment used in single service milk container or closure manufacturing plants shall conform in design, construction and manner in which it is installed and used, to the requirements of these regulations. Written approval of plans for construction, reconstruction or alteration shall be obtained from the state health officer prior to construction, reconstruction or alteration. Written approval of plans for the design, construction, installation and employment for all equipment used in the single service milk container or closure manufacturing plant shall be obtained from the state health officer prior to the installation or modification of the equipment.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2905. Bacterial Standards and Examination of Single Service Containers and Closures

A. Paper stock shall meet the bacteriological standard of not more than 250 cfu per gram as determined by the disintegration test. The supplier of the paper stock shall certify that his/her paper stock was manufactured in compliance with this standard. This applies only to the paper stock prior to lamination.

B. Where a rinse test can be used, the residual microbial count shall not exceed 50 cfu per container, except that in containers less than 100 ml., the count shall not exceed 10 cfu, or not over 50 cfu per eight square inches (one cfu per square centimeter) of product contact surface when the swab test is used, in three out of four samples taken at random on a given day. All single service containers and closures shall be free of coliform bacteria.

C. During any consecutive six months, at least four sample sets shall be collected in at least four separate months, except when three months show a month containing two sampling dates separated by at least 20 days, and analyzed at a laboratory approved by the state health officer.

D. When a single service container or closure is made from one or more component parts as defined in this document, only those final assembled products which may have product contact surface(s) must be sampled and tested for compliance.

E. All sampling procedures and required laboratory examinations shall be conducted in laboratories approved by the state health officer and shall be made in substantial compliance with the methods contained in the *Standard Methods for the Examination of Dairy Products.*

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§2907. Single Service Milk Container or Closure Manufacturing Plant Standards

A. Floors. The floor of all fabricating areas shall be smooth, impervious and maintained in a state of good repair. The floor of storage rooms may be constructed of tightly joined wood.

1. The joints between the walls and floor shall be tight, impervious and shall have coved or sealed joints.

2. Where floor drains are provided, they shall be properly trapped and floors sloped to drain.

B. Walls and Ceilings. Walls and ceilings of fabricating areas shall have a smooth, cleanable, light colored surface.

1. Walls and ceilings in fabricating and storage areas shall be kept in good repair.

C. Doors and Windows. All outside openings shall be effectively protected against entry of insects, dust and airborne contamination.

1. All outer doors shall be tight and self closing.

D. Lighting and Ventilation. All rooms shall be adequately lighted by either natural light, artificial light or both. A minimum of 20-foot candles shall be maintained in fabricating areas and 5-foot candles should be maintained in storage areas. Packaging, sealing, wrapping, labeling and similar procedures are considered part of the fabricating area.

1. Ventilation shall be sufficient to prevent excessive odors and the formation of excessive water condensation.

2. The intake of all pressure ventilation systems in fabricating areas, whether they are positive or exhaust, shall be properly filtered.

E. Separate Rooms. All fabricating areas shall be separate from non fabricating areas to protect against contamination, provided, that if the entire plant meets all sanitation requirements and no source of cross contamination exists, separation between areas is not required.

1. All re-grinding of plastic and the shredding, packaging or baling of paper trim shall be conducted in rooms separate from the fabricating room except that they may be conducted within the fabricating room provided such operations are kept clean and free of dust.

F. Toilet Facilities-Sewage Disposal. Disposal of sewage and other wastes shall be in a public sewerage system, if available. If a public sewerage system is not available, the disposal of sewage and other wastes shall be done in a manner which is in compliance with Part XIII of this Code.

1. All plumbing shall comply with Part XIV of this Code and any stricter local plumbing regulations.

2. Toilet rooms shall have solid, tight-fitting doors that are self-closing.

3. The toilet room and fixtures shall be maintained in a clean and sanitary condition and in good repair.

4. Each toilet room shall be well lighted and adequately ventilated by mechanical means. Air ventilation ducts from toilet facilities shall directly vent to the outside atmosphere.

5. Proper hand washing facilities with hot and cold running water under pressure delivered through a mixing faucet shall be provided in toilet rooms.

6. All windows shall be effectively screened when open.

7. Signs shall be posted in all toilet rooms informing the employees that they shall wash their hands before returning to work.

8. Eating or storage of food is prohibited in toilet rooms.

9. A covered trash container shall be provided.

G. Water Supply. The water supply shall comply with Part XII of this Code.

1. There shall be no cross-connection between the potable water supply and any unsafe or questionable water supply or any source of pollution through which the potable water supply might become contaminated.

2. Samples for bacteriological testing of private water supplies are taken upon the initial approval of the physical structure, each 12 months thereafter, and when any repair or alteration of the water supply system has been made. The examination of the sample shall be conducted by a laboratory which has been certified by the state health officer for the examination of potable water for bacteriological contaminants.

H. Hand Washing Facilities. Hot and cold or warm running water delivered under pressure through a mixing faucet, soap, air dryer or individual sanitary towels shall be convenient to all fabricating areas, provided that solvent or soft soap dispensers containing sanitizers may be used if water is not available. When individual sanitary towels are used, covered trash containers shall be provided.

1. Hand washing facilities shall be kept clean.

I. Plant Cleanliness. The floors, walls, ceilings, overhead beams, fixtures, pipes and ducts of production, storage, re-grind, baling and compacting rooms shall be clean.

1. All production areas, warehouse, toilet, lunch and locker rooms shall be free of evidence of insects, rodents and birds.

2. Machines and appurtenances shall be kept clean. Provided, that minor accumulations of paper, plastic or metal dust and other production soils incidental to normal fabricating operations do not violate this requirement.

J. Locker and Lunch Rooms. Locker and lunch rooms shall be separate from plant operations and be equipped with self closing doors.

1. Eating or storage of food is prohibited in fabricating and storage areas.

2. Locker and lunch rooms shall be kept in a clean and sanitary condition.

3. Cleanable refuse containers, properly labeled, shall be provided which are covered, impervious, leak-proof and readily accessible.

4. Proper hand washing facilities shall be convenient to locker and lunch rooms.

5. Signs shall be posted informing employees that they shall wash their hands before returning to work.

K. Storage and Disposal of Wastes. All waste disposal shall be handled in accordance with Part XXVII of this Code.

1. All refuse and garbage shall be stored in covered, impervious and leak-proof containers. This requirement does not pertain to production scrap.

2. All waste containers shall be clearly labeled for their intended purpose and contents.

3. Where possible, garbage and assorted rubbish should be stored outside the building in covered, impervious, cleanable containers. If stored inside the building, it must be contained in similar receptacles, but in an area separate from fabricating areas.

L. Personal Cleanliness. Hands shall be thoroughly washed before commencing plant functions and as often as may be required to remove soil and contamination, and before returning to work after visiting the toilet room or lunch room.

1. All personnel shall wear clean outer garments and shall wear effective hair restraints, hair nets or caps. Shorts shall not be worn as outer garments.

2. No person affected with any disease in a communicable form or while a carrier of such disease, and no person with an infected cut or lesion shall work in any processing area in any capacity where there is a likelihood of such person contaminating product or product contact surfaces with pathogenic microorganisms.

3. The use of tobacco products is prohibited in fabricating, re-grind and storage areas.

M. Protection from Contamination. All product-contact surfaces of containers, closures and all materials in process are covered or otherwise protected to prevent the access of insects, dust, condensation and other contamination.

1. The manufacture of single service containers and closures for milk and milk products shall be conducted in such a manner that there will be no cross contamination of raw material or re-grind with non-food grade materials.

2. Whenever air under pressure is directed at resin. regrind, colorants and similar materials, it shall be free of oil, dust, rust, excessive moisture, extraneous materials and odor and shall otherwise comply with the applicable requirements of Appendix H of the *PMO*.

3. Air that is directed at product contact surfaces by fans or blowers shall be filtered and shall otherwise comply with the applicable requirements of Appendix H of the *PMO*.

4. Only pesticides approved for use in food plants and registered with the U.S. Environmental Protection Agency shall be used for insect and rodent control.

5. Pesticides shall be used in accordance with the manufacturer's directions and used so as to preclude the contamination of containers or closures.

N. Storage of Materials and Finished Product. Blanks, roll stock and all other single service containers, closures and articles shall be stored off the floor by use of pallets, slip sheets or other methods and away from any wall a sufficient distance to facilitate inspection, cleaning and pest control activities. Any roll stock having dirty or soiled outer turns or edges shall have sufficient turns discarded prior to use and edges trimmed to provide protection from contamination.

1. Single service articles in process shall be protected from contamination by use of single service cover sheet or other protective device. This includes chip board, dividers, separators, bags and other items that can become contact surfaces.

2. Appropriate clean, dry storage facilities shall be provided for single service containers, closures, paper for wrapping, adhesives, blanks and other production material to provide protection from splash, insects, dust and other contamination.

3. Where containers and closures are preformed in plants other than the original fabricating facility:

a. containers, blanks and closures shall be stored in the original cartons and sealed until used;

b. partially used cartons of containers, blanks and closures shall be resealed until used.

4. Containers used for storage of resin and other raw materials, re-grind, broke and trim, intended for use in the process, shall be covered, clean, impervious and properly identified. Reuse of storage containers, such as gaylords, is permitted provided single-use plastic liners are used.

5. In process storage bins that touch the product contact surface of containers or closures shall be constructed of cleanable, nonabsorbent material and kept clean.

O. Fabricating, Processing and Packaging Equipment. The requirements of this Subsection pertain to all equipment and processes used in the fabrication of containers and closures irrespective of the materials used and whether or not mentioned herein. Some of this equipment includes grinders, rollers, reamers and cutters, molders and fittings, extruders, silos, resin bins and hoppers, printing equipment, blanking equipment and sealing equipment.

1. Rolls, dies, belts, tables, mandrels, transfer tubing and all other contact surfaces shall be kept clean, sanitary and reasonably free of accumulation of paper, plastic or metal dust and other production soils. Equipment designed for dairy plant use which is utilized for preforming containers shall be clean and sanitized prior to operation.

2. All materials in process for containers and closures shall be protected from contamination by condensate or drippage from overhead pipes or equipment components.

3. Makeshift devices such as tape, rope, twine, paperboards, etc., shall not be used. All fasteners, guides, hangers, supports and baffles shall be constructed of impervious, cleanable materials and kept in good repair.

4. Take off tables and other container contact surfaces shall be constructed of cleanable material, kept clean and in good repair.

5. All grinders, shredders and similar equipment used for re-grinding shall be installed above the floor or installed in such a manner that they are protected, so that floor sweepings and other contaminants cannot enter the grinder or shredder.

6. Storage tanks, silos, gaylords or bins used for plastic resin shall be so constructed to protect the resin from contamination. All air vents shall be filtered to prevent the entrance of dust or insects. Air tubes used to conduct resin shall be supported above ground to prevent their becoming submerged in water. Air tubes used to convey resin shall have end caps, attached by a chain or cable that prevent contamination. This Paragraph also applies to all raw materials handled in like manner.

7. Storage tanks, silos, etc., located outside of buildings shall have all outer openings locked or sealed at all times when not being filled, repaired or cleaned.

P. Equipment and Materials for Construction of Containers and Closures. Single service containers and closures for milk and milk products shall not be fabricated on equipment used for the manufacture of products made of non-food grade materials unless such equipment has been thoroughly cleaned and purged of all non-food grade material by a process that will not contaminate the food grade material.

1. Only plastic sheeting and extrusions, plastic laminated paper, metal and paperboard blanks, or combination thereof from a manufacturing or fabricating plant conforming with these standards shall be used. Fabricating plants listed in the current IMS publication of *Certified Manufacturers of Single Service Containers and Closures for Milk and Milk Products* shall be considered in compliance with this item.

2. Only sanitary, nontoxic lubricants shall be used on container closure contact surfaces. Excess lubricant shall be removed from surfaces close to shafts, rollers bearing sleeves and mandrels. These lubricants shall be handled and stored in a manner that will prevent cross contamination with non food grade lubricants. Such storage areas shall be clean and adequately ventilated.

3. Containers, resin and flashing on the floor and floor sweepings of production materials are prohibited from being reused. This shall not preclude the use of these materials

when it complies with a protocol which has been reviewed and accepted by the FDA.

Q. Waxes, Adhesives, Sealants and Inks. Waxes, adhesives, sealants and inks used for containers and closures shall be handled and stored in a manner that will prevent cross contamination with similar non-food grade materials. Such storage areas shall be clean and adequately ventilated.

1. Waxing shall be performed so as to assure that containers or closures are completely coated and the wax shall be kept at temperature of 60°C (140°F) or higher.

2. Unused materials shall be covered and properly stored.

3. Waxes, adhesives, sealants and inks shall not impart odor or taste to the milk or milk products and shall not contaminate the product with microorganisms or toxic or injurious substances. All materials that are applied to the product contact surface shall comply with the requirements of Parts 175 through 178 of Title 21 of the CFR.

4. Transfer containers shall be kept clean and shall be properly identified and covered.

R. Handling of Containers and Equipment. Handling of containers and closure contact surfaces shall be kept to a minimum.

S. Wrapping and Shipping. Blanks, closures, halves, nested or preformed containers and parts such as valves, hoses, tubes and other fittings shall be properly packaged or containerized prior to shipping.

1. The outer package or containerized units shall protect the contents from dust and other contamination.

2. Transportation vehicles used to ship finished materials from the single service container and closure plant or within the plant shall be clean and in good repair and shall not have been used for the transportation of garbage, waste or toxic materials.

3. Paperboard containers, wrappers and dividers that contact the surface of the container or closure shall not be reused for this purpose.

4. All packaging materials that contact the product contact surface of the container or closure shall comply with the requirements of *Parts 175* through *178 of Title 21 of the CFR* and the bacteriological standards of *§2905*, but the material does not have to be manufactured at a listed single service plant. Some outer packaging material such as corrugated cardboard boxes used for the packaging of milk carton flats, are exempt from this bacteriological standard. The edges of these flats are subject to heat during the forming and sealing of the container.

T. Identification and Records. Outer wrappings shall be identified with the name and city of the plant where the contents are fabricated, except those manufactured in, and which are only for use in the same facility. In the cases where several plants are operated by one firm, the common firm name may be utilized, provided that the location of the plant at which the contents were fabricated is also shown either directly or by the FIPS numerical code on the outer wrapper.

1. Records of all required bacteriological tests of containers and closures shall be maintained at the plant of manufacture for two years and results shall be in compliance with §2905.

2. The fabricating plant shall have on file information from suppliers of raw materials, waxes, adhesives, sealants, coating and inks indicating that the material complies with the requirements of Parts 175 through 178 of Title 21 of the *CFR*.

3. The fabricating plant shall have on file information from the suppliers of packaging materials specified in Paragraph 3 of this Subsection indicating that the material complies with the bacteriological standards of *§2905*. There are no specifications for sampling frequency. The state health officer may choose to collect samples of packaging materials to determine compliance with bacteriological standards of this Part.

4. Multi plant corporations may have all required information at a central location as long as it can be transmitted to the site upon request.

U. Surroundings. Exterior surroundings shall be neat and clean and free from conditions which might attract or harbor flies, other insects and rodents.

1. Driveways, lanes and areas serving the plant vehicular traffic are graded, drained and free from pools of standing water.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

Part VIII. Frozen Desserts

§101. Definitions and Standards of Identity [formerly paragraph 8:001]

Repealed.

AUTHORITY NOTE: The first source of authority for promulgation of the sanitary code is R.S. 36:258.B, with more particular provisions found in Chapters 1 and 4 of Title 40. This part is promulgated in accordance with the specific provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1283 (June 2002), repealed LR 37:

§103. Sweetening Ingredients Permitted [formerly paragraph 8:002]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1285 (June 2002), repealed LR 37:

§105. Use of Alcohol Prohibited [formerly paragraph 8:003]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1285 (June 2002), repealed LR 37:

§107. Milk and Milk Products Permitted [formerly paragraph 8:004]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1285 (June 2002), repealed LR 37:

§109. Flavoring Ingredients Permitted

[formerly paragraph 8:005]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1286 (June 2002), repealed LR 37:

§111. Vegetable and Animal Fats Permitted [formerly paragraph 8:006]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1286 (June 2002), repealed LR 37:

§113. Filler Prohibited [formerly paragraph 8:007]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1286 (June 2002), repealed LR 37:

§115. Stabilizers Permitted [formerly paragraph 8:008]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1286 (June 2002), repealed LR 37:

§117. Ingredients Prohibited [formerly paragraph 8:009]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1286 (June 2002), repealed LR 37:

§119. Method of Analysis [formerly paragraph 8:010]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1286 (June 2002), repealed LR 37:

§121. Labeling of Frozen Desserts [formerly paragraph 8:011]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1286 (June 2002), repealed LR 37:

§123. Processing, Packing and Distribution [formerly paragraph 8:012]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1286 (June 2002), repealed LR 37:

§125. General Requirements [formerly paragraph 8:013]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1287 (June 2002), repealed LR 37:

§127. Plans [formerly paragraph 8:014]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1287 (June 2002), repealed LR 37:

§129. Pasteurization [formerly paragraph 8:015]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1287 (June 2002), repealed LR 37:

§131. Bacterial Count [formerly paragraph 8:016]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1287 (June 2002), repealed LR 37:

§133. Permits [formerly paragraph 8:017]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1287 (June 2002), repealed LR 37:

§135. Standards [formerly paragraph 8:019]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1287 (June 2002), repealed LR 37:

§137. Records and Reports [formerly paragraph 8:020]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1287 (June 2002), repealed LR 37:

§139. Mobile Frozen Dessert Units [formerly paragraph 8:021]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1287 (June 2002), repealed LR 37:

§141. Depots for Mobile Frozen Dessert Units [formerly paragraph 8:022]

Repealed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a). Also see R.S. 40:5(15).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1288 (June 2002), repealed LR 37:

Part XXI. Day Care Centers and Residential Facilities

Chapter 1. General Requirements

§105. General [formerly paragraph 21:002-1]

A. - I. …

J. [Formerly paragraph 21:009] The serving and/or use of milk or milk products shall conform with the following.

1. Only Grade A pasteurized milk shall be served and dispensed at day care centers and residential facilities. The milk shall be dispensed from a bulk milk container dispensing device that conforms with 3-A Standards. In lieu thereof, milk may be served by providing a commercially filled container of one pint capacity or less to each child, and/or client.

EXCEPTION: In facilities licensed for 30 or less children or clients, the state health officer may allow milk to be served from commercially filled containers with a capacity of not greater than one gallon.

2. The serving of reconstituted milk is prohibited except in making instant desserts, whipped products, or for cooking and baking purposes, as stated in Part XXIII, §1707.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a), R.S. 40:4(A)(10), R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1399 (June 2002), amended LR 37:

Part XXIII. Retail Food Establishments

Chapter 11. Food Supplies

§1115. Milk [formerly paragraph 22:08-7]

A. …

B. All pasteurized, ultra-pasteurized and aseptically processed milk and dairy products shall be placed in their final delivery containers in the plant in which they are pasteurized, ultra-pasteurized or aseptically processed. It shall be unlawful for hotels, soda fountains, restaurants, grocery stores, markets and similar establishments to sell or serve any milk or milk products except in the original containers received from the plant in which it was pasteurized, ultra-pasteurized or aseptically processed or from a bulk container dispensing device that conforms with 3-A Standards. Packaging of milk and milk products from such dispensers is prohibited. This requirement shall not apply to cream consumed on the premises or milk and milk products in portions less than 1/2 pint used in mixed drinks, cereals, desserts or other foods. In these instances, pouring from a commercially filled container of not more than one gallon capacity is acceptable. (see LAC 51:VII.953.A)

C. Food establishments having counter freezers which freeze frozen dessert or non-dairy frozen dessert mixes shall comply with the requirements of Part VII of this code, as applicable, particularly LAC 51:VII.2709.A.1-4.

D. The dipping and/or packaging of firmly frozen frozen desserts by consumers who serve themselves is prohibited. Ice cream, ice milk and other frozen desserts shall be offered to consumers who serve themselves only when dispensed from approved dispensing machines designed expressly for that purpose.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a), R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:319 (February 2002), amended LR 28:1413 (June 2002), LR 37:

Chapter 45. Mobile Food Establishments, Mobile Retail Food Stores/Markets and Pushcarts [formerly paragraph 22:34-3]

§4525. Mobile Frozen Dessert Units

A. Mobile frozen dessert units shall comply with LAC 51:VII.2711.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a), R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

§4527. Depots for Mobile Frozen Dessert Units

A. Depots for mobile frozen dessert units shall comply with LAC 51:VII.2713.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(1)(a), R.S. 40:5(2)(3)(5)(7)(15)(17) and R.S. 40:922.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 37:

Family Impact Statement

1. The Effect on the Stability of the Family. The goal of this Rule is to prevent disease and illnesses due to food-borne disease agents which may find their way into finished milk and dairy products. Therefore, a lower disease and illness rate of family members will result and will contribute to family stability.

2. The Effect on the Authority and Rights of Parents Regarding the Education and Supervision of their Children. No effect on the authority and rights of parents regarding the education and supervision of their children is anticipated as a result of this proposed rulemaking.

3. The Effect on the Functioning of the Family. Lowering the disease and illness rate of family members because of this Rule should help the family to function better than it may should a family member become ill if such a Rule did not exist.

4. The Effect on the Family Earnings and Family Budget. It is expected that family members would remain healthier with the adoption of this Rule. Therefore, the family earnings and budget may be protected from additional costs should a family member become ill.

5. The Effect on the Behavior and Personal Responsibility of Children. No effect on the behavior and personal responsibility of children is anticipated as a result of this proposed Rule.

6. The Ability of the Family or Local Government to Perform the Function as Contained in the Proposed Rule. The family or local governments have no function to perform under this Rule. Therefore the family or local government's ability to perform the function under this Rule is not an issue.

Public Comments

In addition, all interested persons are invited to submit written comments on the proposed rule. Such comments must be received no later than Friday, July 29, 2011 at COB, 4:30 pm, and should be addressed to Gary Cazaubon, Administrator, Milk and Dairy Program, Sanitarian Services, Center for Environmental Health Services, Office of Public Health, CEHS Mail Bin # 12, P.O. Box 4489, Baton Rouge, LA 70821-4489, or faxed to (225) 342-7552. If comments are to be shipped or hand-delivered, please deliver to the Bienville Building, 628 N. Fourth Street - Room 162, Baton Rouge, LA 70802.

Public Hearing

DHH-OPH will conduct a public hearing at 10 am on Tuesday, July 26, 2011, in Room 173 of the Bienville Building, 628 North Fourth Street, Baton Rouge, LA. Persons attending the hearing may have their parking ticket validated when one parks in the 7-story Galvez Parking Garage which is located between N. Sixth and N. Fifth/North and Main Sts. (catercorner and across the street from the Bienville Building). All interested persons are invited to attend and present data, views, comments, or arguments, orally or in writing.

Bruce D. Greenstein
Secretary

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES
RULE TITLE: Milk Code

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

The proposed rule amends Part VII (Milk, Milk Products, and Manufactured Milk Products), Part VIII (Frozen Desserts), Part XXI (Day Care Centers and Residential Facilities) and Part XXIII (Retail Food Establishments) of the State Sanitary Code (LAC 51). The purpose of this rule is update and incorporate changes from the U.S. Public Health Service/Food and Drug Administration's (FDA) "Pasteurized Milk Ordinance" (PMO), which governs the sale of all Grade "A" milk in interstate commerce, that have not been comprehensively revised since 1984. There is no anticipated cost or savings as these rule changes put the state sanitary code in compliance with federal regulations.

The first proposed rule in Section 101 revises the section title, removes verbiage and adds definitions to reflect products now being offered to the consumer and updates the standards for compliance. The second proposed rule in Sections 107-111 revises section titles and adds verbiage to clarify the standard of identify for milk and dairy products and obtain a permit to operate from the state health officer prior to beginning operation. The third proposed rule in Section 311 revises the section title and adds verbiage to require the program to regulate the industry according to Hazard Analysis Critical Control Point (HACCP) requirements and to conduct performance based inspections. The fourth proposed rule in Section 323 adds language that will prohibit individuals who consume raw milk from obtaining the milk by subterfuge. This is the practice of "cow share" or purchasing raw milk for animal food which has been used in other states to obtain the milk. The fifth proposed rule change in Chapter 27 clarifies existing language to encompass other products in commerce that at one time were not covered. These products include but are not limited to gelato, frozen yogurt drinks and novelties. The sixth proposed rule in Chapter 29 incorporates language that will allow the regulation of Single Service Containers (SSC) facilities that are not a part of a milk manufacturing facility.

Additional changes including provisions adopted in the 2009 United States Food and Drug Administration (USFDA) Pasteurized Milk Ordinance (PMO) that governs the sale of Grade "A" Milk and Milk Products in interstate commerce have also been incorporated throughout the document wherever appropriate. Also, changes relative to the retail food regulations of how milk and dairy products (including frozen desserts) are handled and dispensed are planned to be made to Part XXI (Day Care Centers and Residential Facilities) and to Part XXIII (Retail Food Establishments). The changes to Part XXI and Part XXIII are intended to comport with the changes being made into the proposed new Part VII.

The proposed rule changes will result in an estimated cost of $29,479 (FY 10-11: $14,801 and FY 11-12: $14,678) to publish the notice of intent and the final rule in the Louisiana Register. This is a one-time cost that is included in the agency's budget. No additional staff will be needed to implement the rule because this rule simply revises existing sanitary code to comply with federal regulations that does not increase staff workload. Also, it is not anticipated that the proposed rule will have any significant impact on local government units.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

There is no anticipated effect on revenue collections of state or local governmental units as a result of promulgation of this regulation.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS (Summary)

There is no anticipated cost to non-governmental groups that own or operate the following facilities; dairy farm, milk tank truck shipping company, milk or dairy manufacturing plant, cheese plant, frozen dessert manufacturing plant, single service container and closure manufacturing plant (for milk and milk products including fabricating plants producing component parts, films and closures), receiving station, transfer station, finished dairy product depot and transfer point, milk tank truck cleaning facility, dry milk plant, butter plant, day care center, residential facility, or retail food establishment. Owners of these facilities are already in compliance with the proposed rules and they are not expected to incur additional costs to comply with these rule changes.

The goal of this rule is to prevent disease and illnesses due to food-borne disease agents, which may find their way into finished milk and dairy products. A lower disease and illness rate of the general population should translate into an economic benefit relative to the health care savings realized due to the preventive nature of this rule; however the amount of this cost savings cannot be determine.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

There is no anticipated effect on competition and employment as a result of promulgation of this regulation.

Clayton Williams	H. Gordon Monk
Assistant Secretary	Legislative Fiscal Officer
1106#047	Legislative Fiscal Office

NOTICE OF INTENT

Department of Natural Resources
Office of Conservation

Surface Mining—Statewide Order 29-O-1
(LAC 43:XV.Chapters 1, 23, 29, 31, 35, 54, 65, and 85)

Under the authority of the Louisiana Surface Mining and Reclamation Act, particularly R.S. 30:901 et seq., and in accordance with the provisions of the Administrative Procedure Act, R.S. 49:950 et seq., notice is hereby given that the Office of Conservation proposes to amend LAC 43:XV, (Statewide Order 29-O-1) the Louisiana Surface Mining Regulations, governing permit application information, ownership and control information for the permit applicant and the applicant's operator, transfer, assignment or sale of permit rights, permit eligibility, and remining.

The Department of the Interior, Office of Surface Mining Reclamation and Enforcement, under the provisions of 30 CFR 732.17(d), has notified the Louisiana Office of Conservation, Injection and Mining Division of changes in Public Law 95-87, the Surface Mining Control and Reclamation Act of 1977, as amended, (SMCRA) and the federal regulations promulgated pursuant to SMCRA which make it necessary for Louisiana to modify its Surface Mining Regulatory Program to remain consistent with all federal regulations. The director of the Office of Surface Mining Reclamation and Enforcement approved the proposed rules in *Federal Register*, vol. 76, no. 46, March 9, 2011, pp. 12852-12857.

Copies of the proposed Rules may be obtained or viewed at the Office of the State Register, 1201 North Third Street, Baton Rouge, LA 70802, phone (225) 342-5015 or through the Department of Natural Resources, Office of Conservation, 617 North Third Street, Baton Rouge, LA 70802, phone (225) 342-5586.

Title 43

NATURAL RESOURCES

Part XV. Office of Conservation—Surface Mining

Subpart 1. General Information

Chapter 1. General

§105. Definitions.

A. As used in these regulations, the following terms have the specified meaning, except where otherwise indicated.

* * *

Applicant/Violator System or *AVS*—an automated information system of applicant, permittee, operator, violation and related data the Office of Surface Mining maintains to assist in implementing the Surface Mining Control and Reclamation Act, as amended.

* * *

Control or *Controller* (when used in Chapters 23, 31 and 35)—

a. a permittee of a surface coal mining operation;

b. an operator of a surface coal mining operation; or

c. any person who has the ability to determine the manner in which a surface coal mining operation is conducted.

* * *

Knowing or *Knowingly*—a person who authorized, ordered, or carried out an act or omission knew or had reason to know that the act or omission would result in either a violation or a failure to abate or correct a violation.

* * *

Own, *Owner*, or *Ownership* (as used in Chapters 23, 31 and 35) (except when used in the context of ownership of real property)—being a sole proprietor or owning of record in excess of 50 percent of the voting securities or other instruments of ownership of an entity.

* * *

Transfer, Assignment or *Sale of Rights*—a change of a permittee.

* * *

Violation (when used in the context of the permit application information or permit eligibility requirements of §§907 and 910.C of the Act and related regulations)—

a. a failure to comply with an applicable provision of a federal or state law or regulation pertaining to air or water environmental protection, as evidenced by a written notification from a governmental entity to the responsible person; or

b. a noncompliance for which the Office of Surface Mining has provided one or more of the following types of notice or the office has provided equivalent notice under corresponding provisions of these regulations:

i. a notice of violation under §6503;

ii. a cessation order under §6501;

iii. a final order, bill, or demand letter pertaining to a delinquent civil penalty assessed under Chapters 69 or 71;

iv. a bill or demand letter pertaining to delinquent reclamation fees owed under §906 of the Act; or

v. a notice of bond forfeiture under Chapter 47 when:

(a). one or more violations upon which the forfeiture was based have not been abated or corrected; or

(b). the amount forfeited and collected is insufficient for full reclamation under §4703.D.1, the office orders reimbursement for additional reclamation costs, and the person has not complied with the reimbursement order.

* * *

Willful or *Willfully*—a person who authorized, ordered or carried out an act or omission that resulted in either a violation or the failure to abate or correct a violation acted:

a. intentionally, voluntarily, or consciously; and

b. with intentional disregard or plain indifference to legal requirements.

* * *

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:901-932.

HISTORICAL NOTE: Promulgated by the Department of Natural Resources, Office of Conservation, LR 5:395 (December 1979), amended LR 6:177 (May 1980), LR 14:441, (July 1988), LR 20:447 (April 1994), LR 24:2283 (December 1998), LR 29:1492 (August 2003), LR 37:

Subpart 3. Surface Coal Mining and Reclamation Operations Permits and Coal Exploration and Development Procedures Systems

Chapter 23. Surface Mining Permit Applications: Minimum Requirements for Legal, Financial, Compliance and Related Information

§2304. Certifying and Updating Existing Permit Application Information

A. If the applicant has previously applied for a permit and the required information is already in AVS, then the applicant may update the information as shown in the following table.

If…	then the applicant…
(1) all or part of the information already in AVS is accurate and complete	may certify to the office by swearing or affirming, under oath and in writing, that the relevant information in AVS is accurate, complete, and up to date.
(2) part of the information in AVS is missing or incorrect	must submit to the office the necessary information or corrections and swear or affirm, under oath and in writing, that the information submitted is accurate and complete.
(3) the applicant can neither certify that the data in AVS is accurate and complete nor make needed corrections	must include in the permit application the required information.

B. The applicant must swear or affirm, under oath and in writing, that all information provided in an application is accurate and complete.

C. The office may establish a central file to house identity information, rather than place duplicate information in each permit application file. The office will make the information available to the public upon request.

D. After the office approves an application, but before issuing a permit, the applicant must update, correct, or indicate that no change has occurred in the information previously submitted under this section and §§2305-2307.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:901-932.

HISTORICAL NOTE: Promulgated by the Department of Natural Resources, Office of Conservation, LR 37:

§2305. Identification of Interests

A. …

1. a statement as to whether the applicant and the applicant's operator are corporations, partnerships, single proprietorships, associations or other business entities;

2. - 2.a. …

b. applicant's resident agent;

c. any operator, if different from the applicant;

d. each business entity in the applicant's and operator's organizational structure, up to and including the ultimate parent entity of the applicant and operator. For every such business entity, the applicant must also provide the required information for every president, chief executive officer, and director (or persons in similar positions), and every person who owns, of record, 10 percent or more of the entity; and

e. for the applicant and applicant's operator, the information required by §2305.A.2.d must be provided for every officer, partner, member, director, person performing a function similar to a director and person who owns, of record, 10 percent or more of the applicant or operator;

3. for each person identified in §2305.A:

a. - e. …

4. for any surface coal mining operation owned or controlled by either the applicant, the applicant's operator, or by any person who owns or controls the applicant under the definition of owned or controlled and owns or controls in §105, the operation's:

4.a. - 10. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:901-932.

HISTORICAL NOTE: Promulgated by the Department of Natural Resources, Office of Conservation, LR 5:395 (December 1979), amended LR 14:441 (July 1988), LR 20:447 (April 1994), LR 37:

§2307. Compliance Information

A. …

1. a statement of whether the applicant, applicant's operator, any subsidiary, affiliate or persons controlled by or under common control with the applicant or applicant's operator has had a federal or state mining permit suspended or revoked in the last five years; or forfeited a mining bond or similar security deposited in lieu of bond;

2. - 2.e. …

3. for any violation of a provision of the Act, or of any law, rule or regulation of the United States, or of any state law, rule or regulation enacted pursuant to federal law, rule or regulation pertaining to air or water environmental protection incurred in connection with any surface coal mining operation, a list of all violation notices received by the applicant or the applicant's operator during the three year period preceding the application date, and a list of all unabated cessation orders and unabated air and water quality violation notices received prior to the date of the application by any surface coal mining and reclamation operation owned or controlled by either the applicant, the applicant's operator, or by any person who owns or controls the applicant. For each violation notice or cessation order reported, the lists shall include the following information, as applicable:

3.a - .4. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:901-932.

HISTORICAL NOTE: Promulgated by the Department of Natural Resources, Office of Conservation, LR 5:395 (December 1979), amended LR 14:441 (July 1988), LR 20:447 (April 1994), LR 24:2283 (December 1998), LR37:

Chapter 29. Requirements for Permits for Special Categories of Mining

§2913. Lands Eligible for Remining

A. This Section contains permitting requirements to implement §3113.H. Any person who submits a permit application to conduct a surface coal mining operation on lands eligible for remining must comply with this Section.

B. An application for a permit under this Section shall be made according to all requirements of Subpart 3 of the regulations applicable to surface coal mining and reclamation operations. In addition, the application shall:

1. to the extent not otherwise addressed in the permit application, identify potential environmental and safety problems related to prior mining activity at the site and that could be reasonably anticipated to occur. This identification shall be based on a due diligence investigation which shall include visual observations at the site, a record review of past mining at the site, and environmental sampling tailored to current site conditions; and

2. with regard to potential environmental and safety problems referred to in §2913.B.1, describe the mitigative measures that will be taken to ensure that the applicable reclamation requirements of the regulatory program can be met.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:901-932.

HISTORICAL NOTE: Promulgated by the Department of Natural Resources, Office of Conservation, LR 37:

Chapter 31. Public Participation, Approval of Permit Applications and Permit Terms and Conditions

§3113. Review of Permit Applications

A. - B. …

C. Entry of Information Into AVS

1. Based on an administratively complete application, the office must undertake the reviews required under Subsections D-F of this Section.

2. The office will submit to the federal office, which will then enter into AVS:

a. the information required under §2305; and

b. the information submitted under §2307 pertaining to violations which are unabated or uncorrected after the abatement or correction period has expired.

3. The office will update the information referred to in Paragraph C.2 of this Section upon verification of any

additional information submitted or discovered during permit application review.

D. Review of Applicant, Operator, and Ownership and Control Information. The office will rely upon the information required under §2305, information from AVS, and any other available information, to review the applicant's and operator's organizational structure and ownership or control relationships. This review will be conducted before making a permit eligibility determination under Subsection G of this Section.

E. Review of Permit History

1. The office will rely upon the permit history information submitted under §2305, information from AVS, and any other available information to review the applicant's and operator's permit histories. This review will be conducted before making a permit eligibility determination under Subsection G of this Section.

2. The office will determine whether the applicant or operator have previous mining experience.

3. If the applicant or operator do not have any previous mining experience, the office may conduct an additional review under §3521. The purpose of this review will be to determine if someone else with mining experience controls the surface coal mining and reclamation operation.

F. Review of Compliance History. The office will rely upon the violation information submitted under §2307, a report from AVS, and any other available information to review histories of compliance with the Act or these regulations, and any other applicable air or water quality laws, for the applicant, the operator, and surface coal mining and reclamation operations which the applicant or operator own or control. This review will be conducted before making a permit eligibility determination under Subsection G of this Section.

G. Permit Eligibility Determination. Based on the reviews required under Subsections D-F of this Section, the office will determine whether the applicant is eligible for a permit under section 910.C of the Act.

1. Except as provided in §§3113 and 3114, the applicant is not eligible for a permit if the office finds that any surface coal mining and reclamation operation that:

a. the applicant directly owns or controls has an unabated or uncorrected violation; or

b. the applicant or operator indirectly control has an unabated or uncorrected violation and the control was established or the violation was cited after November 2, 1988.

2. The office will not issue a permit if the applicant or operator are permanently ineligible to receive a permit under §3521.C.

3. After permit approval under §3115, the office will not issue the permit until the applicant complies with the information update and certification requirement of §2304.D. After the applicant completes that requirement, the office will again request a compliance history report from AVS to determine if there are any unabated or uncorrected violations which affect the applicant's permit eligibility under Paragraphs G.1 and 2 of this Section. The office will request this report no more than five business days before permit issuance under §3119.

4. If the applicant is ineligible for a permit under this Section, the office will send written notification of the decision setting forth the reasons for this decision and including notice of appeal rights under Chapter 33.

H. Unanticipated Events or Conditions at Remining Sites

1. The applicant is eligible for a permit under Subsection G of this Section if an unabated violation:

a. occurred after October 24, 1992; and

b. resulted from an unanticipated event or condition at a surface coal mining and reclamation operation on lands that are eligible for remining under a permit that was held by the person applying for the new permit.

2. For permits issued under §2913, an event or condition is presumed to be unanticipated for the purpose of this Section if it:

a. arose after permit issuance;

b. was related to prior mining; and

c. was not identified in the permit application.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:901-932.

HISTORICAL NOTE: Promulgated by the Department of Natural Resources, Office of Conservation, LR 5:395 (December 1979), amended LR 6:177 (May 1980), LR 14:441 (July 1988), LR 20:447 (April 1994), LR 37:

§3114. Eligibility for Provisionally Issued Permits

A. This Section applies to an applicant who owns or controls a surface coal mining and reclamation operation with:

1. a notice of violation issued under §6503 for which the abatement period has not yet expired; or

2. a violation that is unabated or uncorrected beyond the abatement or correction period.

B. The office will find an applicant eligible for a provisionally issued permit under this Section if he or she demonstrates that one or more of the following circumstances exists with respect to all violations listed in Subsection A of this Section:

1. for violations meeting the criteria of Subsection A of this Section, the applicant certifies that the violation is being abated to the satisfaction of the office, and there is no evidence to the contrary;

2. as applicable, the applicant, the applicant's operator, and operations that the applicant or the applicant's operator own or control are in compliance with the terms of any abatement plan (or, for delinquent fees or penalties, a payment schedule) approved by the agency with jurisdiction over the violation;

3. the applicant is pursuing a good faith:

a. challenge to all pertinent ownership or control listings or findings under §§3131-3135; or

b. administrative or judicial appeal of all pertinent ownership or control listings or findings, unless there is an initial judicial decision affirming the listing or finding and that decision remains in force.

4. the violation is the subject of a good faith administrative or judicial appeal contesting the validity of the violation, unless there is an initial judicial decision affirming the violation and that decision remains in force.

C. The office will consider a provisionally issued permit to be improvidently issued, and must immediately initiate procedures under §§3127 and 3129 to suspend or rescind that permit, if:

1. violations included in Paragraph B.1 of this Section are not abated within the specified abatement period;

2. the applicant, the applicant's operator, or operations that the applicant or the applicant's operator own or control do not comply with the terms of an abatement plan or payment schedule mentioned in Paragraph B.2 of this Section;

3. in the absence of a request for judicial review, the disposition of a challenge and any subsequent administrative review referenced in Paragraphs B.3 or 4 affirms the validity of the violation or the ownership or control listing or finding; or

4. the initial judicial review decision referenced in Subparagraphs B.3.b or B.4 affirms the validity of the violation or the ownership or control listing or finding.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:901-932.

HISTORICAL NOTE: Promulgated by the Department of Natural Resources, Office of Conservation, LR 37:

§3115. Criteria for Permit Approval or Denial

A. - A.16. …

17. for a proposed remining operation where the applicant intends to reclaim in accordance with the requirements of §5414, the site of the operation is a previously mined area as defined in §105;

18. for permits to be issued under §2913, the permit application must contain:

a. lands eligible for remining;

b. an identification of the potential environmental and safety problems related to prior mining activity which could reasonably be anticipated to occur at the site; and

c. mitigation plans to sufficiently address these potential environmental and safety problems so that reclamation as required by the applicable requirements of the regulatory program can be accomplished;

19. the applicant is eligible to receive a permit, based on the reviews under §§3113-3114.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:901-932.

HISTORICAL NOTE: Promulgated by the Department of Natural Resources, Office of Conservation, LR 5:395 (December 1979), amended LR 6:177 (May 1980), LR 14:441 (July 1988), LR 20:447 (April 1994), LR 29:1497 (August 2003), LR 37:

§3127. Improvidently Issued Permits: General Procedures

A. When the office has reason to believe that it improvidently issued a surface coal mining and reclamation permit, it shall review the circumstances under which the permit was issued. The office will make a preliminary finding that the permit was improvidently issued if, under the permit eligibility criteria section 910.C of the Act in effect at the time of permit issuance, the permit should not have been issued because the applicant or the applicant's operator owned or controlled a surface coal mining and reclamation operation with an unabated or uncorrected violation.

B. The office will make a finding under §3127.A only if the applicant or the applicant's operator:

1. continue to own or control the operation with the unabated or uncorrected violation;

2. the violation remains unabated or uncorrected; and

3. the violation would cause the applicant to be ineligible under the permit eligibility criteria in the current regulations.

C. When the office makes a preliminary finding under §3127.A, it must serve the applicant with a written notice of the preliminary finding, which must be based on evidence sufficient to establish a prima facie case that the permit was improvidently issued.

D. Within 30 days of receiving a notice under §3127.C, the applicant may challenge the preliminary finding by providing the office with evidence as to why the permit was not improvidently issued under the criteria in §3127.A and B.

E. The provisions of §§3131-3135 apply when a challenge under §3127.D concerns a preliminary finding under §3127.A and B.1 that the applicant or the applicant's operator currently own or control, or owned or controlled, a surface coal mining operation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:901-932.

HISTORICAL NOTE: Promulgated by the Department of Natural Resources, Office of Conservation, LR 20:447 (April 1994), LR 37:

§3129. Improvidently Issued Permits: Suspension or Rescission Procedures

A. The office must suspend or rescind the permit upon expiration of the time specified in §3129.A.1.

1. Automatic Suspension and Rescission. After a specified period of time not to exceed 90 days the permit automatically will become suspended, and not to exceed 90 days thereafter rescinded, unless within those periods the applicant submits proof, and the office finds, that:

a. the finding of the office under §3127.B was erroneous;

b. the applicant or the applicant's operator has abated the violation on which the finding was based, or paid the penalty or fee, to the satisfaction of the responsible agency;

c. the violation, penalty or fee is the subject of a good faith appeal, or of an abatement plan or payment schedule with which the applicant or applicant's operator is complying to the satisfaction of the responsible agency; or

d. since the finding was made, the applicant or applicant's operator has severed any ownership or control link with the person responsible for, and does not continue to be responsible for, the violation, penalty or fee.

2. Cessation of Operations. After permit suspension or rescission, the office shall issue written notice that the applicant shall cease all surface coal mining and reclamation operations under the permit, except for violation abatement and for reclamation and other environmental protection measures as required by the office.

3. The office shall post the notice at the conservation office closest to the permit area.

4. Right to Appeal. The applicant may obtain administrative and judicial review of the notice under §§3301 and 3303.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:901-932.

HISTORICAL NOTE: Promulgated by the Department of Natural Resources, Office of Conservation, LR 20:447 (April 1994), LR 37

§3131. Challenges to Ownership or Control Listings and Findings

A. The applicant may challenge a listing or finding of ownership or control using the provisions under §§3133 and 3135 if he or she is:

1. listed in a permit application or AVS as an owner or controller of an entire surface coal mining operation, or any portion or aspect thereof;

2. found to be an owner or controller of an entire surface coal mining operation, or any portion or aspect thereof, under §§3127 or 3521.G; or

3. an applicant or permittee affected by an ownership or control listing or finding.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:901-932.

HISTORICAL NOTE: Promulgated by the Department of Natural Resources, Office of Conservation, LR 37:

§3133. Challenging an Ownership or Control Listing or Finding

A. To challenge an ownership or control listing or finding, the applicant must submit a written explanation of the basis for the challenge, along with any evidence or explanatory materials he or she wishes to provide under §3135.B, to the regulatory authority, as identified in the following table.

If the challenge concerns…	Then submit a written explanation to…
(1) a pending state or federal permit application	the regulatory authority with jurisdiction over the application.
(2) applicant's ownership or control of a surface coal mining operation, and he or she is not currently seeking a permit	the regulatory authority with jurisdiction over the surface coal mining operation.

B. The provisions of this Section and of §§3135 and 3137 apply only to challenges to ownership or control listings or findings. The applicant may not use these provisions to challenge liability or responsibility under any other provision of the Act or these regulations.

C. When the challenge concerns a violation under the jurisdiction of a different regulatory authority, the regulatory authority with jurisdiction over the permit application or permit must consult the regulatory authority with jurisdiction over the violation and the AVS office to obtain additional information.

D. A regulatory authority responsible for deciding a challenge under §3133.A may request an investigation by the AVS Office.

E. At any time, the applicant, a person listed in AVS as an owner or controller of a surface coal mining operation, may request an informal explanation from the AVS office as to the reason he or she is shown in AVS in an ownership or control capacity. Within 14 days of the request, the AVS Office will provide a response describing why the applicant is listed in AVS.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:901-932.

HISTORICAL NOTE: Promulgated by the Department of Natural Resources, Office of Conservation, LR 37:

§3135. Burden of Proof for Ownership or Control Challenges

A. When the applicant challenges a listing of ownership or control, or a finding of ownership or control made under §3521.G, the applicant must prove by a preponderance of the evidence that he or she either:

1. does not own or control the entire surface coal mining operation or relevant portion or aspect thereof; or

2. did not own or control the entire surface coal mining operation or relevant portion or aspect thereof during the relevant time period.

B. In meeting the burden of proof, the applicant must present reliable, credible, and substantial evidence and any explanatory materials to the office. The materials presented in connection with the challenge will become part of the permit file, an investigation file, or another public file. If the applicant requests, the office will hold as confidential any information submitted under this paragraph which is not required to be made available to the public under §6311.

C. Materials the applicant may submit in response to the requirements of §3135.B include, but are not limited to:

1. notarized affidavits containing specific facts concerning the duties that the applicant performed for the relevant operation, the beginning and ending dates of ownership or control of the operation, and the nature and details of any transaction creating or severing ownership or control of the operation;

2. certified copies of corporate minutes, stock ledgers, contracts, purchase and sale agreements, leases, correspondence, or other relevant company records;

3. certified copies of documents filed with or issued by any state, municipal, or federal governmental agency;

4. an opinion of counsel, when supported by:

a. evidentiary materials;

b. a statement by counsel that he or she is qualified to render the opinion; and

c. a statement that counsel has personally and diligently investigated the facts of the matter.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:901-932.

HISTORICAL NOTE: Promulgated by the Department of Natural Resources, Office of Conservation, LR 37:

§3137. Written Decision on Challenges to Ownership or Control Listings or Findings

A. Within 60 days of receipt of the challenge under §3133.A, the regulatory authority identified under §3133.A, will review and investigate the evidence and explanatory materials submitted and any other reasonably available information bearing on the challenge and issue a written decision. The decision must state whether the applicant owns or controls the relevant surface coal mining operation, or owned or controlled the operation, during the relevant time period.

B. The office will promptly provide the applicant with a copy of this decision by either:

1. certified mail, return receipt requested; or

2. any means consistent with the rules governing service of a summons and complaint under Rule 4 of the Federal Rules of Civil Procedure, or its state regulatory program counterparts.

C. Service of the decision on the applicant is complete upon delivery and is not incomplete if delivery is refused.

D. The office will post all decisions made under this Section on AVS.

E. Any person who receives a written decision under this Section, and who wishes to appeal that decision, must

exhaust administrative remedies under Chapter 33 before seeking judicial review.

F. Following the written decision or any decision by a reviewing administrative or judicial tribunal, the office must review the information in AVS to determine if it is consistent with the decision. If it is not, the office must promptly revise the information in AVS to reflect the decision.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:901-932.

HISTORICAL NOTE: Promulgated by the Department of Natural Resources, Office of Conservation, LR 37:

Chapter 35. Permit Reviews and Renewals; Transfer, Sale and Assignment of Rights Granted under Permits; Post-Permit Issuance Requirements; and Other Actions Based on Ownership, Control and Violation Information

§3517. Transfer, Assignment or Sale of Permit Rights: Obtaining Approval

A. - C. …

1. the applicant is eligible to receive a permit in accordance with §§3113.G and 3115;

C.2. - D.2. …

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:901-932.

HISTORICAL NOTE: Promulgated by the Department of Natural Resources, Office of Conservation, LR 5:395 (December 1979), amended LR 14:441 (July 1988), LR 20:447 (April 1994), LR 37:

§3521. Post-Permit Issuance Requirements for Regulatory Authorities and Other Actions Based on Ownership, Control, and Violation Information

A. For the purposes of future permit eligibility determinations and enforcement actions, the office must enter into AVS the data shown in the following table:

Enter into AVS all…	Within 30 days after…
(1) permit records	the permit issued or subsequent changes made.
(2) unabated or uncorrected violations	the abatement or correction period for a violation expires.
(3) changes to information initially required to be provided by an applicant under 30 CFR 778.11	receiving notice of a change.
(4) changes in violation status	abatement, correction, or termination of a violation, or a decision from an administrative or judicial tribunal.

B. If, at any time, the office discovers that any person owns or controls an operation with an unabated or uncorrected violation, the office will determine whether enforcement action is appropriate under §§6501 or 6503. The office must enter the results of each enforcement action, including administrative and judicial decisions, into AVS.

C. The office must serve a preliminary finding of permanent permit ineligibility under section 910.C of the Act on the applicant or operator if the criteria in §3521.C.1 and C.2 are met. In making a finding under this Paragraph, the office will only consider control relationships and violations which would make, or would have made, the applicant ineligible for a permit under §3113.G.1 and G.2. The office must make a preliminary finding of permanent permit ineligibility if it finds that:

1. the applicant controls or has controlled surface coal mining and reclamation operations with a demonstrated pattern of willful violations under section 910.C of the Act; and

2. the violations are of such nature and duration with such resulting irreparable damage to the environment as to indicate the applicant's intent not to comply with the Act, these regulations, the regulatory program, or the permit.

D. The applicant may request a hearing on a preliminary finding of permanent permit ineligibility under Chapter 33.

E. Entry into AVS.

1. If the applicant does not request a hearing, and the time for seeking a hearing has expired, the office will enter our finding into AVS.

2. If the applicant requests a hearing, the office will enter it's finding into AVS only if that finding is upheld on administrative appeal.

F. At any time, the office may identify any person who owns or controls an entire surface coal mining operation or any relevant portion or aspect thereof. If such a person is identified, the office must issue a written preliminary finding to the person and the applicant or permittee describing the nature and extent of ownership or control. The written preliminary finding must be based on evidence sufficient to establish a prima facie case of ownership or control.

G. After the office issues a written preliminary finding under §3521.F, the office will allow the person subject to the preliminary finding, 30 days in which to submit any information tending to demonstrate his or her lack of ownership or control. If, after reviewing any information submitted, the office is persuaded that the person is not an owner or controller, the will serve the person a written notice to that effect. If, after reviewing any information submitted, the office still finds that the person is an owner or controller, or if no information is submitted within the 30-day period, we will issue a written finding and enter our finding into AVS.

H. If we identify the applicant as an owner or controller under paragraph (g) of this Section, the applicant may challenge the finding using the provisions of §§3131-3137.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:901-932.

HISTORICAL NOTE: Promulgated by the Department of Natural Resources, Office of Conservation, LR 37:

§3523. Post-Permit Issuance Information Requirements for Permittees

A. Within 30 days after the issuance of a cessation order under §6501, the permittee must provide or update all the information required under §2305.

B. The permittee does not have to submit information under §3523.A if a court of competent jurisdiction grants a stay of the cessation order and the stay remains in effect.

C. Within 60 days of any addition, departure, or change in position of any person identified in §2305.C, the permittee must provide:

1 the information required under §2305.D; and

2. the date of any departure.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:901-932.

HISTORICAL NOTE: Promulgated by the Department of Natural Resources, Office of Conservation, LR 37:

Subpart 5. Permanent Program Performance Standards

Chapter 53. Permanent Program Performance Standards: Surface Mining Activities

§5414. Backfilling and Grading: Previously Mined Areas

A. Remining operations on previously mined areas that contain a preexisting highwall shall comply with the requirements of §§5405-5413 and 5703, except as provided in this section.

B. The requirements of §5405.B.1 requiring the elimination of highwalls shall not apply to remining operations where the volume of all reasonably available spoil is demonstrated in writing to the office to be insufficient to completely backfill the reaffected or enlarged highwall. The highwall shall be eliminated to the maximum extent technically practical in accordance with the following criteria:

1. all spoil generated by the remining operation and any other reasonably available spoil shall be used to backfill the area. Reasonably available spoil in the immediate vicinity of the remining operation shall be included within the permit area;

2. the backfill shall be graded to a slope which is compatible with the approved postmining land use and which provides adequate drainage and long-term stability;

3. any highwall remnant shall be stable and not pose a hazard to the public health and safety or to the environment. The operator shall demonstrate, to the satisfaction of the office, that the highwall remnant is stable; and

4. spoil placed on the outslope during previous mining operations shall not be disturbed if such disturbances will cause instability of the remaining spoil or otherwise increase the hazard to the public health and safety or to the environment.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:901-932.

HISTORICAL NOTE: Promulgated by the Department of Natural Resources, Office of Conservation, LR 37:

Chapter 65. Enforcement

§6501. Cessation Orders

A. - F. …

G. Within 60 days after issuing a cessation order, the office shall notify in writing the permittee, the operator, and any person who has been identified under §§3123.A.6 and 2305.A.3-4 as an owner or controller of the surface coal mining and reclamation operation.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:901-932.

HISTORICAL NOTE: Promulgated by the Department of Natural Resources, Office of Conservation, LR 5:395 (December 1979), amended LR 14:441 (July 1988), LR 20:447 (April 1994), LR 37:

Subpart 6. Abandoned Mine Lands

Chapter 85. General Reclamation Requirements

§8509. Contractor Eligibility

A. To receive moneys from the Fund or Treasury funds provided to uncertified States and Indian tribes under 30 CFR §872.29 or to certified States or Indian tribes for coal AML reclamation as required to maintain certification under §411(a) of the federal Act, every successful bidder for an AML contract must be eligible under §§3113.G, 3113.H and 3114 at the time of contract award to receive a permit or be provisionally issued a permit to conduct surface coal mining operations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 30:901-932.

HISTORICAL NOTE: Promulgated by the Department of Natural Resources, Office of Conservation, LR 37:

Family Impact Statement

In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature, the impact of the proposed Rules on the family has been considered. It is anticipated that this proposed Rules will have no impact on family functioning, stability, and autonomy as described in R.S. 49:972.

Public Comments

All interested persons may submit written comments no later than 5 p.m., July 10, 2011 on the proposed Rules to Joseph S. Ball, Jr., Injection and Mining Division, Office of Conservation, P.O. Box 94275, Baton Rouge, LA 70804-9275.

James H. Welsh
Commissioner

FISCAL AND ECONOMIC IMPACT STATEMENT FOR ADMINISTRATIVE RULES
RULE TITLE: Statewide Order 29-O-1

I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO STATE OR LOCAL GOVERNMENT UNITS (Summary)

The proposed rule amendment will have no impact on state or local governmental unit expenditures. The amended sections of LAC 43:XV will make the Louisiana rules consistent with federal requirements.

II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE OR LOCAL GOVERNMENTAL UNITS (Summary)

The proposed rule amendment will have no effect on state or local governmental unit revenues.

III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL GROUPS (Summary)

Surface coal mine applicants will be required to submit additional information concerning the organizational structure of both the applicant and the applicant's mine operator. Benefits will be realized by persons in the vicinity of the surface coal mining operations, due to the reclamation of surface mining property according to state and federal standards.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rule amendment will have no effect on competition and employment in the public and private sectors.

James H. Welsh	Evan Brasseaux
Commissioner	Staff Director
1106#025	Legislative Fiscal Office

Potpourri

POTPOURRI

Department of Health and Hospitals
Bureau of Health Services Financing

Professional Services Program—Optometry Services

The Department of Health and Hospitals, Bureau of Health Services Financing currently provides coverage and reimbursement for optometry services rendered to Medicaid recipients. Optometrists enrolled in the Louisiana Medicaid Program are considered part of the Professional Services Program. Optometrists who perform eye care services that are within their scope of practice will receive Medicaid reimbursement to the same extent, and according to the same standards, as physicians who perform the same eye care services.

Bruce D. Greenstein
Secretary

1106#081

POTPOURRI

Department of Health and Hospitals
Office of Public Health
Maternal and Child Health Section

Public Notice of MCH Block Grant

The Department of Health and Hospitals (DHH) intends to apply for Maternal and Child (MCH) Block Grant Federal Funding for FY 2011-2012 in accordance with Public Law 97-35 and the Omnibus Budget Reconciliation Act of 1981. The Office of Public Health, Maternal and Child Health Section, is responsible for program administration of the grant.

The block grant application describes in detail the goals and planned activities of the state Maternal and Child Health Program for the next year. Program priorities are based on the results of a statewide needs assessment conducted in 2010, which is updated annually based on relevant data collection.

Interested persons may request copies of the application from:

State of Louisiana
DHH - Office of Public Health
Maternal and Child Health Section
628 North Fourth Street
Baton Rouge, LA 70821

Or view a summary of the application at: http://www.dhh.louisiana.gov/offices/publications.asp?ID=267&Detail=1065

Additional information may be gathered by contacting Tracy Hubbard at (225) 342-7805.

Clayton Williams
Assistant Secretary

1106#015

POTPOURRI

Department of Natural Resources
Office of Conservation

Orphaned Oilfield Sites

Office of Conservation records indicate that the oilfield sites listed in the table below have met the requirements as set forth by Section 91 of Act 404, R.S. 30:80 et seq., and as such are being declared Orphaned Oilfield Sites.

Operator	Field	District	Well Name	Well Number	Serial Number
S.W. Richardson	Cheneyville	L	Beasley	001	23917

James H. Welsh
Commissioner

1106#024

POTPOURRI

Department of Natural Resources
Office of Conservation

Public Hearing—Docket No. ENV 2011-08

Notice is hereby given that the Commissioner of Conservation will conduct a hearing at 6 p.m., Wednesday, July 27, 2011, at the Minden City Hall located at 520 Broadway, Minden, Louisiana.

At such hearing, the commissioner, or his designated representative, will hear testimony relative to the application of State Line Vacuum Services, LLC, 10450 Highway 79, Haynesville, LA. The applicant requests approval from the Office of Conservation to construct and operate a commercial deep well injection waste disposal facility for disposal of exploration and production waste (E and P Waste) fluids located in Township 20 North, Range 10 West, Section 10 in Webster Parish.

The application is available for inspection by contacting Mr. Daryl Williams, Office of Conservation, Environmental Division, eighth floor of the LaSalle office building, 617 North Third Street, Baton Rouge, Louisiana. Copies of the application will be available for review at the Webster Parish Police Jury in Minden, Louisiana, the Webster Parish Main Branch Library in Minden, Louisiana and the Cotton Valley Branch Library in Cotton Valley, Louisiana no later than 30 days prior to the hearing date. Verbal information may be received by calling Mr. Williams at (225) 342-7286.

All interested persons will be afforded an opportunity to present data, views or arguments, orally or in writing, at said public hearing. Written comments which will not be presented at the hearing must be received no later than 4:30

p.m., Wednesday, August 3, 2011, at the Baton Rouge office. Comments should be directed to:

Office of Conservation
Environmental Division
P.O. Box 94275
Baton Rouge, LA 70804
Re: Docket No. ENV 2011-08
Commercial Facility Well Application
Webster Parish

James H. Welsh
Commissioner

1106#046

POTPOURRI

Department of Natural Resources
Office of the Secretary
Fishermen's Gear Compensation Fund

Loran Coordinates

In accordance with the provisions of R.S. 56:700.1 et seq., notice is given that 3 claims in the amount of $11,986.55 were received for payment during the period May 1, 2011-May 31, 2011.

There were 3 paid and 0 denied.

Latitude/Longitude coordinates of reported underwater obstructions are:

2915.576	8956.402	Jefferson
2943.868	8941.903	St. Bernard
3002.346	8942.446	St. Bernard

A list of claimants and amounts paid can be obtained from Gwendolyn Thomas, Administrator, Fishermen's Gear Compensation Fund, P.O. Box 44277, Baton Rouge, LA 70804 or you can call (225) 342-0122.

Scott A. Angelle
Secretary

1106#020

POTPOURRI

Department of Public Safety and Corrections
Board of Private Investigator Examiners

Little Lake Crude Oil Discharge Draft
Settlement Agreement

Action: Notice of availability of a draft settlement agreement (draft SA) with a 30-day public review and comment period on the draft SA document and the draft Damage Assessment and Preliminary Restoration Plan (draft DAPRP) for LOSCO NRDA case file #LA2002-0406-1000 (Little Lake 2002]).

Agencies: Louisiana Oil Spill Coordinator's Office, Department of Public Safety and Corrections (LOSCO); Louisiana Department of Environmental Quality (LDEQ); Louisiana Department of Natural Resources (LDNR); and Louisiana Department of Wildlife and Fisheries (LDWF).

Authorities: The Oil Pollution Act of 1990 (OPA) (33 USC 2701 et seq.) and the Louisiana Oil Spill Prevention and Response Act of 1991 (OSPRA) (La. Rev. Stat. 30:2451 et seq.) are the principal federal and state statutes, respectively, authorizing federal and state agencies and tribal officials to act as natural resource trustees for the recovery of damages for injuries to trust resources and services resulting from oil spill incidents in Louisiana. In accordance with OPA and OSPRA, the agencies listed above (referred to herein as the "trustees") have conducted a Natural Resource Damage Assessment (NRDA) for the April 6, 2002 unauthorized discharge of crude oil into the coastal waters of Little Lake, Lafourche Parish, Louisiana, in which BP Oil Pipeline Company (BP) was identified by the trustees as the responsible party.

Summary: Pursuant to LAC 43:XXIX.Chapter 1, notice is hereby given that a document entitled "Draft Settlement Agreement Little Lake 2002" will become available for public review and comment on June 20, 2011. The draft SA was negotiated by the Trustees and BP to recover damages for injuries to natural resources and services resulting from the incident. The draft SA is a binding agreement in which BP agrees to pay the trustees for their response costs, past assessment costs, future trustee costs, and future restoration project implementation costs associated with a trustee-implemented compensatory restoration project, as described in the draft DAPRP (Attachment 1 of the draft SA). The draft SA document and draft DAPRP are available to the public for a 30-day comment period, which will begin on the date of this public notice announcing availability of the documents for public review. The trustees invite the public to review these documents and submit comments to the address listed below. The trustees will consider comments received during the public comment period on the draft SA document and draft DAPRP before finalizing the settlement agreement. Execution of the final settlement agreement by the trustees and BP shall provide the basis for compensating the public for injuries to natural resources and services resulting from the incident. Public review of the draft SA and draft DAPRP is consistent with all State laws and regulations that apply to the NRDA process, including \section 2480 of the Louisiana Oil Spill Prevention and Response Act (OSPRA), R.S. 30:2451 et seq.; and the regulations for NRDA under OSPRA, LAC 43:XXIX.Chapter 1.

Interested members of the public are invited to view the draft SA document and draft DAPRP via the internet at http://www.losco.state.la.us (look under News Flash for Little Lake 2002 Oil Spill) or by requesting a copy of the documents from Gina Muhs Saizan at the address provided below:

Gina Muhs Saizan
Louisiana Oil Spill Coordinator's Office
Department of Public Safety and Corrections
P.O. Box 66614
Baton Rouge, LA 70896
(225) 925-6606
Gina.Saizan@la.gov

Comment Submittals: Comments must be submitted in writing or digitally to Gina Muhs Saizan on or before the end of the 30-day comment period.

For Further Information: Contact Gina Muhs Saizan at (225) 925-6606 or by email at gina.saizan@la.gov.

Supplementary Information: On November 20, 2002, the trustees published a Notice of Intent in the *Louisiana Register* (Vol. 28, No. 11, pp. 2450-2452) to conduct restoration planning for the incident in order to develop restoration alternatives that will restore, replace, rehabilitate, or acquire the equivalent of natural resources injured and/or natural resource services lost as a result of the incident. In May 2011, BP decided to settle their NRDA liability for cash, in lieu of implementing a project. As a result, the trustees compiled the draft DAPRP to: 1) identify a preferred restoration alternative, which will be implemented by the Trustees, as a basis for the cash settlement; 2) provide an analysis using the HEA method for scaling the preferred restoration alternative to the injured resources; and 3) identify the methodology used for estimating the costs of implementing the preferred restoration alternative.

Roland Guidry
Oil Spill Coordinator

1106#037

POTPOURRI

Department of Revenue
Policy Services Division

Natural Gas Severance Tax Rate

The natural gas severance tax rate effective July 1, 2011, through June 30, 2012, has been set at 16.4 cents per thousand cubic feet (MCF) measured at a base pressure of 15.025 pounds per square inch absolute and at the temperature base of 60 degrees Fahrenheit.

This tax rate is set each year by multiplying the natural gas severance tax base rate of 7 cents per MCF by the "gas base rate adjustment" determined by the secretary of the Department of Natural Resources in accordance with R.S. 47:633(9)(d)(i). The "gas base rate adjustment" is a fraction, of which the numerator is the average of the New York Mercantile Exchange (NYMEX) Henry Hub settled price on the last trading day for the month, as reported in the Wall Street Journal for the previous 12-month period ending on March 31, and the denominator is the average of the monthly average spot market prices of gas fuels delivered into the pipelines in Louisiana as reported by the Natural Gas Clearing House for the 12-month period ending March 31, 1990 (1.7446 $/MMBTU).

Based on this computation, the secretary of the Department of Natural Resources has determined the natural gas severance "gas base rate adjustment" for April 1, 2010, through March 31, 2011, to be 234.68 percent. Applying this gas base rate adjustment to the base tax rate of 7 cents per MCF produces a tax rate of 16.4 cents per MCF effective July 1, 2011, through June 30, 2012. The reduced natural gas severance tax rates provided for in R.S. 47:633(9)(b) and (c) remain the same.

The "gas base rate adjustment" and the "gas tax rate" are being published as required by R.S. 47:633(9)(d)(i). Questions concerning the natural gas severance tax rate should be directed to the Department of Revenue at (225) 219-7656.

Cynthia Bridges
Secretary

1106#082

POTPOURRI

Senate Committee on Health and Welfare

Legislative Oversight Review—Physical Therapy
(LAC 46:LIV.Chapters 1-5)

Editor's Note: The referenced Notice of Intent was published in its entirety in the December 20, 2010 *Louisiana Register* on pages 2975-3007.

This letter is to inform the Office of the State Register that on June 1, 2011, the Senate Committee on Health and Welfare held a legislative oversight meeting for the purpose of reviewing a proposed Notice of Intent promulgated by the Louisiana Physical Therapy Board captioned "Department of Health and Hospitals Physical Therapy Board-Physical Therapy (LAC 46:LIV. Chapters 1-5)." The Notice of Intent was originally published in the *Louisiana Register* on December 20, 2010, and was amended and republished in the *Louisiana Register* on March 20, 2011. The committee did not take official action but respectfully requested that the Louisiana Physical Therapy Board withdraw their final report and amend the proposed Notice of Intent to address the concerns which were raised by the committee. The Louisiana Physical Therapy Board agreed to this action and this is evidenced by a letter received by the committee from the board on June 2, 2011. The letter has been duly incorporated as part of the committee record.

I would respectfully request that a copy of this letter be published at the next available date in the *Louisiana Register* in order for the public to be properly noticed of the actions of the committee.

Senator Willie L. Mount
Chairperson

1106#007

POTPOURRI

Department of Transportation and Development
Professional Engineering and Land Surveying Board

Public Hearing—Substantive Changes to Proposed Rules—General Provisions
(LAC 46:LXI.Chapters 7, 9, 13, 15, 17, 23, 29 and 31)

The board published a Notice of Intent to amend its rules in the March 20, 2011 edition of the *Louisiana Register*. The notice solicited written comments. As a result of its analysis of the written comments received, the board proposes to amend certain portions of the proposed Rules, specifically §2901, §2909 and §2911, to read as follows.

Title 46
PROFESSIONAL AND OCCUPATIONAL STANDARDS
Part LXI. Professional Engineers and Land Surveyors
Chapter 29. Minimum Standards for Property Boundary Surveys

§2901. Scope and Purpose

A. The following standards of practice for boundary surveying in the state of Louisiana have been adopted to help ensure that boundary surveys are performed in accordance with acceptable procedures.

B. The purpose of these standards is to safeguard life, health and property, and to promote the public welfare, by establishing technical standards of practice for every boundary survey performed in the state of Louisiana so that professional performance can be evaluated for but not limited to research, field work, monuments, descriptions, plats and maps. If higher standards are required by clients, or by local, state and federal jurisdictions, then those standards shall govern. When a boundary survey involves certain corners or lines that are covered under the appropriate edition of the *Manual of Instructions for the Survey of the Public Lands of the United States*, then the Manual's rules or instructions for these particular surveys shall apply. Every professional land surveyor performing a boundary survey in the state of Louisiana is required to follow these standards.

C. A boundary survey in this state shall only be performed by a professional land surveyor, licensed pursuant to the laws of this state, or persons under his/her responsible charge. The professional land surveyor shall at all times comply with the provisions of the licensure law and the rules of the board.

D. It is intended that these standards of practice not be relied upon by the professional land surveyor as a substitute for the exercise of proper individual skill, professional discretion, and professional judgment in fulfilling the contractual requirements of any boundary survey. This also does not absolve the professional land surveyor from his/her obligation to use due diligence in the practice of land surveying and from complying with all applicable laws and rules pertaining to the practice of land surveying.

E. When in the professional land surveyor's opinion, special conditions exist that effectively prevent the boundary survey from meeting these standards of practice, the special conditions and any necessary deviation from these standards shall be noted upon the drawing. It shall be a violation of this Chapter to use special conditions to circumvent the intent and purpose of these standards of practice.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:688.

HISTORICAL NOTE: Promulgated by the Department of Transportation and Development, Board of Registration for Professional Engineers and Land Surveyors, LR 16:1064 (December 1990), amended LR 22:713 (August 1996), amended by the Department of Transportation and Development, Professional Engineering and Land Surveying Board, LR 27:1042 (July 2001), LR 30:1725 (August 2004), LR 37:

§2909. Route Survey

A. Definition

Route Survey—a survey for determining the route of a proposed pipeline, power line, cable, road or other linear facilities in order to acquire a right-of-way, servitude or easement from the property owner being crossed.

B. Scope and Product. A route survey shall, as a minimum, consist of the following elements.

1. The professional land surveyor shall utilize sufficient title information and research as needed to define the tract boundaries.

2. The professional land surveyor shall locate sufficient evidence, on the ground, to determine the location of all boundary lines that will be crossed by the proposed right-of-way, servitude or easement. Installation of new monuments is not required when defining the limits of the right-of-way, servitude or easement to be acquired.

3. The professional land surveyor shall prepare a plat(s) or map(s) for those tracts being crossed, showing the alignment of the proposed route and the length of the proposed right-of-way, servitude or easement across the tract. These plats or maps shall be prepared in compliance with those requirements for property boundary survey plats or maps that are specifically contained in §2907.G.1, 2, 6, 7 and 14. Final plats or maps issued to the client shall contain a statement by the professional land surveyor certifying its authenticity (that it represents his/her survey) and stating that the route survey complies with the applicable standards of practice as stipulated in this Chapter. Sufficient information to re-establish the right-of-way, servitude or easement, including any found monuments, must be shown at a suitable scale or in a separate detail on each plat or map.

4. If requested by the client, the professional land surveyor shall prepare a legal description of the proposed right-of-way, servitude or easement for each tract crossed by the proposed facility. The description shall describe the alignment and length of the proposed right-of-way, servitude or easement and shall comply with those requirements for legal descriptions for property boundary surveys that are specifically contained in §2907.H.6 through 11.

5. The accuracy standards that are required for route surveys shall be based on property classification D, as presented in §2913.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:688.

HISTORICAL NOTE: Promulgated by the Department of Transportation and Development, Professional Engineering and Land Surveying Board, LR 37:

§2911. Mineral Unitization Survey

A. Definition

Mineral Unitization Survey—a survey performed to define subsurface mineral tracts for the specific purpose of allocating mineral rights within a mineral unit.

B. Scope and Product. A mineral unitization survey shall, as a minimum, consist of the following elements.

1. The professional land surveyor shall utilize sufficient title information, as provided by the client, needed to define the mineral tracts, in conjunction with adequate information to define the unit boundary.

2. The professional land surveyor shall determine, on the ground, the location of the unit well and the location of sufficient tract lines in order to determine the subsurface mineral tracts located inside the unit boundaries. Geologically significant wells, as identified by the Louisiana Department of Natural Resources, Office of Conservation field order or the client, will be located with respect to the unit boundaries. Installation of new monuments defining the limits of the unit, or of the tracts which comprise the unit, is not required.

3. The professional land surveyor shall prepare a unitization plat or map (Louisiana Department of Natural Resources, Office of Conservation field order unit, voluntary unit or declared unit) showing the mineral participant(s) and limits of the tracts (or portions of tracts) which are included in the proposed mineral unit. These plats or maps shall be prepared in compliance with those requirements for property boundary survey plats or maps that are specifically contained in §2907.G.1, 2, 6, 7 and 14. These plats or maps shall contain bearings and distances around the perimeter of the unit boundary, but are not required to depict or list such calls for the individual tracts which comprise the unit. Final plats or maps issued to the client shall contain a statement by the professional land surveyor certifying its authenticity (that it represents his/her survey) and stating that the mineral unitization survey complies with the applicable standards of practice as stipulated in this Chapter. In addition, the plats or maps, when applicable, shall be in compliance with the Louisiana Department of Natural Resources, Office of Conservation's requirements governing unit plats and survey plats (LAC 43:XIX.Chapter 41).

4. The accuracy standards that are required for mineral unitization surveys shall be based on property classification D, as presented in §2913.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:688.

HISTORICAL NOTE: Promulgated by the Department of Transportation and Development, Professional Engineering and Land Surveying Board, LR 37:

In accordance with R.S. 49:968(H)(2), a public hearing will be held on July 21, 2011 at 9 a.m. at the Louisiana Professional Engineering and Land Surveying Board, 9643 Brookline Avenue, Suite 121, Baton Rouge, LA 70809-1433.

Donna D. Sentell
Executive Director

1106#026

CUMULATIVE INDEX
(Volume 37, Number 6)

2011	
Pages	**Issue**
1-437	January
438-759	February
760-1069	March
1070-1324	April
1325-1476	May
1477-2044	June

EO—Executive Order
PPM—Policy and Procedure Memoranda
ER—Emergency Rule
R—Rule
N—Notice of Intent
CR—Committee Report
GR—Governor's Report
L—Legislation
P—Potpourri

ADMINISTRATIVE CODE UPDATE

Cumulative
January 2010-December 2010, 428
January 2011-March 2011, 1301

AGRICULTURE AND FORESTRY

Agricultural Commodities Commission
Aflatoxin, 441ER
Agricultural commodity dealer and warehouse law, 494R
Giant salvinia, 269R, 809R
Labeling of coated seeds, 269R
Landscape architect registration exam, 751P
Louisiana strawberries, 270R
Structural pest control commission, 272R

Agriculture and Environmental Sciences
Annual quarantine listing for 2011, 1304P
Quarantine rescissions for formosan termites, Hurricanes Katrina and Rita, 1060P

Seed Commission, Office of
Agriculture chemistry lab fees, 809R
Cotton acreage reporting and collection of assessments, 923N
Laboratory testing and seed sampling fees, 356N, 1373R

Commissioner, Office of
Aflatoxin, 441ER

Feed, Fertilizer, and Agriculture Commission
Definition of small package, 809R

Horticulture Commission
Landscape architect registration exam, 432P

CHILDREN AND FAMILY SERVICES
Formerly Department of Social Services.

Child Welfare Section
Annual progress and services report, 1305P
Daycare services—residential licensing, 513R
Social services block grant intended use report, 1306P

Division of Programs
Child care assistance program
Employment and training (E and T) hours, 605N, 1373R
Child support enforcement
Securing and enforcing medical support obligation, 810R
Exempt earned income tax credit (EITC) payments, 1071ER, 1421N
Portability of criminal history, religious exemption, and sex offender rule, 441ER, 811R

Economic Stability and Self-Sufficiency Section
Daycare services—residential licensing, 513R
TANF caseload reduction report, 432P

Licensing Section
Child placing agencies, 816R
Class "A" regulations, 607N

CIVIL SERVICE

Civil Service Commission
Temporary suspension of merit increase authority, 924n

Ethics, Board of
Local government lobbying, 1374R
Statements filed pursuant to section 1111(e) of the code of governmental ethics, 357N, 1376R

ECONOMIC DEVELOPMENT

Business Development, Office of
Enterprise zone program, 296R
Industrial ad valorem tax exemption program, 304R
Louisiana filmmakers grant fund program, 515R
Motion picture investor tax credit program, 514R
Retention and modernization act, 514R
Sound recording production and infrastructure tax credit programs, 309R

Entertainment Industry Development, Office of
Louisiana filmmakers grant fund program, 515R
Motion picture investor tax credit program, 514R
Sound recording production and infrastructure tax credit programs, 309R

Louisiana Economic Development Corporation
Retention and modernization act, 514R

EDUCATION

Elementary and Secondary Education, Board of
Bulletin 103—Louisiana Health Education Content Standards, 1178N
Bulletin 105—Louisiana Content Standards for Programs Serving Four-Year Old Children, 518R
Bulletin 111—The Louisiana School, District, and State Accountability System, 639N, 1122R, 1202N, 1864N
9-12 Transition from 2010 to 2012, 857R
Bulletin 118—Statewide Assessment Standards and Practices, 858R, 1123R

EDUCATION (continued)
Bulletin 119—Louisiana School Transportation Specifications and Procedures, 1205
Bulletin 125—Standards for Educational Leaders in Louisiana, 861R
Bulletin 126—Charter Schools, 867R, 1124R, 1422N
Board of director composition, 641N, 1376R
Bulletin 129—The Recovery School District, 310R, 642N, 876R, 1125R, 1377R
Bulletin 131—Alternative Education Schools/Programs Standards, 925N
Bulletin 741—Louisiana Handbook for School Administrators, 645N
Approval for alternative schools/programs, 933N
Assignment and transfer of students, 1125R
Attendance, 1126R
Building and maintenance, 1128R
Carnegie credit for middle school students, 929N
Classroom management training, 646N, 1380R
College and career diploma; career diploma, 1210N
Compulsory attendance, 931N
Connections process, 932N
Curriculum instruction, 547R, 1128R, 1212N
Disciplinary regulations, 1132R, 1133R
Dropout prevention and recovery, 879R
Electronic telecommunication devices, 1134R
Elementary program of studies, 1134R
Eligibility to participate in high school interscholastic athletics, 1135R
Family and consumer sciences education, 880R
General powers of local educational governing authorities, 1136R
High schools, 1137R
Home study program, 1137R
Immunizations, 934N
Physical abuse of teachers and school employees by students, 1138R
Red tape reduction waiver and local empowerment program, 1866N
Religious studies, 935N
Staff misconduct, 1138R
Student biometric information, 1139R
Teachers' retirement system, part-time, seasonal or temporary classroom teacher, 1140R
Textbooks, 1141R
Uniform grading policy, 936N
Written policies and procedures, 936N, 1141R, 1380R
Nonpublic Bulletin 741—Louisiana Handbook for Nonpublic School Administrators, 940N, 1218N, 1869N
School approval, 1221N
Bulletin 746—Louisiana Standards for State Certification of School Personnel, 549R
Alternate teacher preparation programs, 556R
Certificate endorsements, 647N, 1381R
Early interventionist, 648N, 1381R
Elementary mathematics specialist, 1214N
Louisiana teacher assistance and assessment program (LaTAAP)
Mental health professional counselor, 880R
Middle school specialty area endorsements, 881R
Out-of-state (OS) certificate, 882R
Out-of-state principal level 2 (OSP2), 882R
Overview, 1215N
Requirements to add early childhood, 883R, 1561R
School nurse, 883R
School therapists, 884R
Supervisor of student teaching, 1216N
Bulletin 996—Standards for Approval of Teacher and/or Educational Leader Preparation Programs
Bulletin 1179—Driver Education, Traffic Safety, and Administrative Guide for Louisiana Schools
Driver education; required, 1217N
Bulletin 1196—Louisiana Food and Nutrition Programs, Policies of Operation, 566R, 927N, 1141R
Bulletin 1929—Louisiana Accounting and Uniform Governmental Handbook, 649N
Bulletin 1530—Louisiana's IEP Handbook for Students with Exceptionalities, 885R
Bulletin 1706—Regulations for Implementation of the Children with Exceptionalities Act
Regulations for students with disabilities, 937N
Bulletin 1929—Louisiana Accounting and Uniform Governmental Handbook, 1382R
Membership Foundation Program, student membership, 1142R
Organization, Operations, 941N
State superintendent, 886R
Student Financial Assistance Commission
Student Financial Assistance, Office of
Bylaws of the advisory committee to the student financial assistance commission, 1081ER, 1430N
Scholarship/grant programs
Academic year, 2ER, 654N, 1561R
Applications, federal grant aid and ACT test, 588R
Award amount, 358N, 1386R
Establishing eligibility, 1327ER
GO grant summer billing, 1388R
John R. Justice grant program, 359N, 1387R
LASFAC committees, 1871N
Student financial assistance commission bylaws, 1328ER
TOPS equivalent courses, 1872N
Tuition, 3ER, 655N, 1562R
Tuition Trust Authority
Student Financial Assistance, Office of
LATTA committees, 1873N
Tuition trust authority bylaws, 1329ER

ENVIRONMENTAL QUALITY
Environmental Protection Agency
Secretary, Office of
Legal Affairs Division
Control of emissions of smoke, 1143R
Emergency response for solid waste facilities, 1563R
Greenhouse gases, 361N, 1144R, 1147R, 1389R
Louisiana engineering review activity form, 1307P
Non-road engines, 656N, 1391R
Organic solvents; emissions, 365N, 1150R
Pm2.5 NSR implementation, 658N, 1568R
Pollutant discharge elimination system exclusions, pesticide application, 1307P
Removal of pesticide application exemption from

LPDES permitting requirements, 588R
Solid waste, 944N
Standards for the use or disposal of sewage sludge and biosolids, 751N, 1223N
Toxic air pollutant emission control program, 1222N
Waste expedited permitting, 972N

EXECUTIVE ORDERS

BJ 10-20 Gulf Opportunity Zone Advance Refunding Bond Allocation—Louisiana Local Government Environmental Facilities and community Development Authority, 1EO
BJ 11-01 Carry Forward Bond Allocation 2010, 438EO
BJ 11-02 Bond Allocation—Local Government Environmental Facilities and Community Development Authority, 439EO
BJ 11-03 Bond Allocation—Local Government Environmental Facilities and Community Development Authority, 439EO
BJ 11-04 State of Emergency—Extension of Qualifying in the Parish of Union, 440EO
BJ 11-05 Coordinated System of Care Governance Board, 760EO
BJ 11-06 Executive Branch—Personal Services Expenditure Freeze, 1070EO
BJ 11-07 Executive Branch—Expenditure Freeze, 1325EO
BJ 11-08 Executive Branch—DOTD Guidelines for Vehicles, Trucks and Loads which haul Hay from Louisiana to Texas, 1477EO
BJ 11-09 Merit Increase Freeze—Merit Increase Freeze, 1477EO
BJ 11-10 Flags at Half Staff—Flags at Half Staff, 1478EO

FIREFIGHTERS PENSIONAND RELIEF FUND

Firefighters' Pension and Relief Fund for the City of New Orleans and Vicinity
Tax qualification provisions, 662N, 1392R

GOVERNOR

Administration, Division of
Cosmetology, Board of
Exam ineligibility and alternative hair design, 366N, 1150R
Facility Planning and Control
Louisiana building code, 1228N
Racing Commission
Corrupt and prohibited practices, 1393R
Mandatory health screening, 3ER, 1393R
Tax Commission
Ad valorem taxation, 1071ER, 1394R
Public hearing, substantive changes to proposed rule oil and gas properties, 1308P
Architectural Examiners, Board of
Titles, firm names, and assumed names, 663N
Auctioneers Licensing Board
Public hearing, substantive change to proposed rules, 1308P
Coastal Protection and Restoration Authority
2012 draft annual plan hearing, 432P
Prohibition of activities on levees and flood control structures, 1479ER
Crime Victims Reparations Board
Compensation to victims, 976N, 1605R
Elderly Affairs, Office of
State plan on aging, 319R
Financial Institutions, Office of
Broker-Dealer and investment adviser recordkeeping requirements, 666N
Residential mortgage lending program, 589R
Supervision of salesmen and investment adviser representatives, 983N
Home Inspectors, Board of
Licensing, education, standards of practice and code of ethics, 973N
Law Enforcement and Administration of Criminal Justice, Commission on
Peace officer training, 319R, 976N, 1606R
Public Defender Board
Trial court performance standards for attorneys representing parents in child in need of care and termination of parental rights cases, 321R
Trial court performance standards for attorneys representing children in delinquency, 984N, 1445N
Real Estate Appraisers Board
Appraisers, 332R
Appraisal management companies, 368N
Shorthand Reporters, Board of Examiners
General requirements for certified digital reporters, 317R
State Uniform Payroll, Office of
403(b) tax shelter annuity program, 366N, 1404R
Used Motor Vehicle Commission
Licensure and established place of business, 1405R, 1612R
Veterans Affairs, Department of
Military family assistance program, 978N, 1606R

HEALTH AND HOSPITALS

Adult Protective Services, Division of
Definition of abuse and sexual abuse, 904R
Aging and Adult Services, Office of
All inclusive care for the elderly, reimbursement rate reduction, 761ER, 1003N, 1082ER, 1572R
Definition of abuse and sexual abuse, 904R
Home and community-based services waivers
Adult day health care, 1334ER, 1883N
Reimbursement rate reduction 765ER, 1095ER, 1232N
Elderly and disabled adults
Personal assistance services, 899R
Reimbursement rate reduction, 766ER, 1235N

HEALTH AND HOSPITALS (continued)
Louisiana physician order for scope of treatment, 709N, 1603R
Nursing facilities
Standards for payment level of care determinations, 341R
Personal care services—long-term, reimbursement rate reduction, 806ER, 1112ER, 1116ER
Chiropractic Examiners, Board of
Specialty advertising, unethical conduct, code of ethics, 1875N
Certified Social Worker Examiners, Board of
Social work, 1431N
Citizens with Developmental Disabilities, Office of
Home and community-based services waivers
Children's choice, service cap and reimbursement rate reduction, 1233N
New opportunities waiver, reimbursement rate reduction, 774ER, 1244N
Residential options waiver, 775ER, 1337ER
Supports waiver, reimbursement rate reduction 790ER, 1245N
Dentistry, Board of
Administration of nitrous oxide inhalation analgesia, 1082ER
Advertising; license renewal fees; anesthesia/analgesia administration; continuing education; and dental hygienists examination, 1229N
Automated external defibrillator; botox and dermal fillers; licensure; portable and mobile dentistry; nitrous oxide; sanctions; examination of dentist, hygienists, 667N, 1405R
Licenses; authorized duties; nitrous oxide inhalation, 590R
Dietetics and Nutrition, Board of Examiners in
Registered dietitians, 372N
Emergency Response Network Board
Interregional transfer protocol, 751N
LERN entry criteria: trauma, LERN destination protocol: trauma, 1466P
Health Services Financing, Bureau of
Adult day health care (ADHC)
Minimum licensing standards, 1106ER
All inclusive care for the elderly, reimbursement rate reduction, 4ER, 761ER, 1003N, 1082ER, 1572R
Ambulatory surgical centers, reimbursement rate reduction, 5ER, 761ER, 1004N, 1083ER, 1572R
CommunityCARE program
Primary care providers
Referral exemptions, 338R
Program redesign, 6ER, 1084ER
Coordinated care network, 680N, 1573R
Coordinated system of care, behavioral health services, 1060P
Direct service worker registry, 1088ER
Disproportionate share hospitals payments, 1481ER
Low income and needy care collaborations, 10ER, 1090ER
Non-Rural Community Hospitals, 446ER
EPSDT
Dental program
Covered services and reimbursement rate reduction, 762ER, 1005N, 1598R
Reimbursement rate reduction, 12ER, 1092ER
Health services, EarlySteps reimbursement rate reduction, 13ER, 1007N, 1094ER, 1599R
Substance abuse services, 1330ER
End stage renal disease facilities, reimbursement rate reduction, 14ER, 763ER, 1008N, 1094ER, 1599R
Estate recovery, 339R
Family planning clinics, reimbursement rate reduction, 764ER, 1010N, 1600R
Family planning waiver, reimbursement rate reduction, 765ER, 1231N
Federally qualified health centers diabetes self-management training, 448ER, 1483ER, 1880N
Forensic supervised transitional residential and aftercare facilities, minimum licensing standards, 380N, 1154R
Greater New Orleans community health connection waiver, 15ER, 1331ER
Home and community-based service providers
Minimum licensing standards, 1500ER
Home and community-based service providers
Minimum licensing standards, 1888N
Home and community-based services waivers
Adult day health care, 1334ER, 1485ER, 1883N
Reimbursement rate reduction 765ER, 1095ER, 1232N
Children's choice,
Allocation of waiver opportunities, 1336ER
Service cap and reimbursement rate reduction, 1096ER, 1233N
Elderly and disabled adults,
Personal assistance services, 18ER, 899R
Reimbursement rate reduction, 766ER, 1235N
Elderly and disabled adult waiver
Emergency opportunities and reimbursement methodology, 1490ER
New opportunities waiver
Reimbursement rate reduction, 774ER, 1244N
Supports waiver, reimbursement rate reduction, 1245N
Residential options waiver, 775ER, 1337ER
Supports waiver, reimbursement rate reduction 790ER
Home health program
Durable medical equipment, provider accreditation, 1246N
Extended nursing services, reimbursement rate reduction, 21ER, 1097ER, 1247N
Inpatient hospital services
Low income and needy care collaboration, supplemental payments, 1308P
Major teaching hospitals,
Qualifying criteria, 449ER, 1533ER
Supplemental payments, 1532ER
Neonatal and pediatric intensive care units and outlier payment methodologies, 790ER, 1535ER
Non-rural, non-state hospitals
Children's specialty hospitals, 597R
Low income and needy care collaboration, 22ER, 1098ER
Major teaching hospitals, 1099ER
Outlier payment methodology, 23ER, 452ER
Reimbursement rate reduction, 24ER, 1100ER

HEALTH AND HOSPITALS (continued)
Non-rural, non-state public hospitals, reimbursement methodology, 1352ER
Pre-admission certification, 25ER, 1353ER
Reimbursement methodology, 793ER, 1248N
Small rural hospitals upper payment limit, 796ER
State hospitals, supplemental payments, 452ER, 1353ER
Intermediate care facilities for persons with developmental disabilities
Non-state facilities
Reimbursement methodology, 797ER
Public facilities
Reimbursement methodology, 797ER, 1538ER
Reimbursement rate reduction, 1101ER
Laboratory and radiology services, reimbursement rate reduction, 26ER, 799ER, 1102ER
Medicaid program
Reimbursement rate and prescription limit reductions, 453ER
Medical necessity criteria, 341R
Medical transportation program
Emergency ambulance services, reimbursement rate reduction, 27ER, 1103ER
Supplemental payments, 1539ER
Non-emergency ambulance services, reimbursement rate reduction, 28ER, 1104ER
Non-emergency medical transportation, reimbursement rate reduction, 29ER, 800ER, 1105ER
Mental health rehabilitation program,
Provider participation requirements. 399N, 1173R
Reimbursement rate reduction, 29ER, 1105ER
Termination of parent/family intervention (intensive) services and continued treatment clarifications, 800ER
Multi-systemic therapy
reimbursement rate reduction, 30ER, 802ER, 1108ER
Nursing facilities
Minimum licensing standards
Approval of facility plans, 1541ER, 1921N
Per diem rate reduction, 401N, 1174R
Reimbursement methodology
Direct care multiplier and fair rental value component, 1011N, 1541ER, 1922N
Minimum data set assessments, 31ER, 1354ER
Reimbursement rate reduction, 34ER, 902R
Standards for payment, level of care determinations, 341R
Transition of state-owned or operated nursing facility, 903R
Outpatient hospital services
Diabetes self-management training, 454ER, 1542ER
Duration of outpatient status, 1012N, 1600R
Non-rural, non-state hospitals and children's specialty hospitals, reimbursement rate reduction, 35ER, 803ER, 1109ER
Non-rural, non-state hospitals, major teaching hospitals, 1111ER
Small rural hospitals, upper payment limit, 805ER
Personal care services—long-term, reimbursement rate reduction, 37ER, 806ER, 1112ER, 1116ER
Pharmacy benefits management program
Maximum allowable costs, 1357ER
Medication administration, influenza vaccinations, 1117ER
Minimum allowable costs, 38ER
Prescription limit reduction, 455ER, 1358ER
Pregnant women extended services
Dental services, reimbursement rate reduction, 39ER, 807ER, 1117ER
Substance abuse screening and intervention services, 1119ER
Professional services program
Diabetes self-management training, 456ER, 1543ER
Physician services
Obstetrics rate increase, 904R
Reimbursement methodology, supplemental payments, 457ER, 1544ER
Prosthetics and orthotics
Osteogenic bone growth stimulators, 1013N, 1600R
Rural health clinics
Diabetes self-management training, 458ER, 1546ER, 1924N
Licensed Professional Counselors, Board of Examiners
License of title for marriage and family therapy, 706N, 1601R
Professional assistance program, 344R
Medical Examiners, Board of
Clinical laboratory personnel, licensure and certification, 596R, 1439N
Enforcement terms; unprofessional conduct, 336R
Licensure and certification; reciprocity, 337R
Medical psychologists, general, licensure, certification and practice, 888R, 1150R
Physician consultation or collaboration with medical psychologists, 897R
Nursing, Board of
Administration of anesthetic agents, 898R
Alternative to disciplinary proceedings, 1877N
Paperless licensing revisions, 1878N
Nursing Facility Administrators, Board of Examiners
Nursing facility administrators, 590R, 887R
Physical Therapy Board
Public hearing, substantive changes to proposed rules, comprehensive revision, 1060P
Public Health, Office of
Added controlled dangerous substances, 41ER, 1015N, 1359ER
Maternal and child health section
Public notice of MCH block grant, 2033P
Milk code, 1930N
Preventive health and health services block grant hearing, 433P
Public buildings, schools and other institutions, 1252N, 1440N
Tuberculosis control program
Inmate health, 597R
Mandatory testing, 598R
Secretary, Office of
Community and family support system—flexible family fund, 1926N
Speech-Language Pathology and Audiology, Board of Examiners for
Speech pathology and audiology, 671N

HEALTH AND HOSPITALS (continued)

Veterinary Medicine, Board of
Continuing veterinary medicine education, 377N, 1152R
Prescribing and dispensing drugs
Preceptorship program, 1001N, 1571R

Wholesale Drug Distributors, Board of
Exemptions, 899R

INSURANCE

Commissioner, Office of
Rule number 9—prelicensing education, 1257N
Rule number 10—continuing education, 1262N
Regulation number 47—actuarial opinion and memorandum regulation, 598R

Health, Office of
Annual HIPPAA assessment rate, 1468P

LEGISLATION

House Committee on Ways and Means
Ad valorem taxation, 1303CR

Senate Committee On Health And Welfare
Legislative oversight review, physical therapy, 2035P

NATURAL RESOURCES

Conservation, Office of
Advanced notice of rulemaking and solicitation of comments on water well registration, construction and closure, 1313P
Hearing notice, CCS Midstream Services, LLC (Docket No. Env 2011-04), 1061P
Legal notice, docket no. ENV 2011-05, 1317P
Orphaned oilfield sites, 433P, 755P, 1062P, 2033P
Public hearing, docket No. ENV 2011-08, 2033P
Statewide order no. 29-B—general provisions, 1268N
Statewide orders no. 29-B and 29-B-a, 460ER, 1547ER
Surface Mining—Statewide Order 29-O-1, 2025N
Vanguard Environmental, LLC public hearing, 433P
Water well notification requirements, 711N
Water wells, 905R

Environmental Division
Public hearing—application of Heckmann water resources corporation (Docket ENV 2011-07), 1538P

Secretary, office of

Fishermen's Gear Compensation Fund
Loran Coordinates, 755P, 1064P, 1317P, 1318P, 1469P, 2034P

PUBLIC SAFETY AND CORRECTIONS

Corrections Services
Disaster remediation program, 403N, 1174R
Judicial agency residential referral facilities, 41ER, 712N, 1360ER, 1408R
Non-Medical furloughs, 720N, 1415R
Offender visitation, 1269N
Special agents, 1276N
Supervised release of sex offenders upon expiration of sentence, 404N, 1176R
Telephone use and policy on monitoring of calls, 599R

Gaming Control Board
Casino gaming payment interception, 406N, 1415R
Definition of Louisiana business, 1462N

Liquefied Petroleum Gas Commission
Storage and handling of liquefied petroleum gases, 913R

Private Investigators, Board of
Little Lake crude oil discharge draft settlement agreement, 2034P

State Fire Marshal, Office of the
Commercial building energy conservation code, 1279N
Property protection licensing, 408N
State uniform construction code, 601R

State Police, Office of
Applicability of regulations, 1278N
Breath and blood alcohol analysis methods and techniques, 720N, 721N, 1416R, 1417R
Collection, submission, receipt, identification, storage and disposal of DNA samples, 471ER, 722N, 1417R
Federal motor carrier regulations, 1016N, 1613R

State Uniform Construction Code Council
State uniform construction code, 913R

REVENUE

Policy Services Division
Electronic filing mandate for reports and returns related to the sports facility assistance fund, 914R
Electronic filing requirements for oil or gas severance tax, 474ER, 1017N, 1613R
Natural gas severance tax rate, 2035P
New markets tax credit, 914R
Advanced notice of proposed rulemaking and solicitation of comments on mandatory electronic filing of corporate and individual income tax extensions and extension payments, 1469P

TRANSPORTATION AND DEVELOPMENT

Highway Construction
Access connection permits and driveway permits, 347R

Outdoor Advertising
Outdoor advertising, 916R
Tourist oriented directional signs, 920R

Professional Engineering and Land Surveying Board
General provisions, 1019N
Public hearing—substantive changes to proposed rules—general provisions, 2035P

Transportation Research Center
LTRC transportation training and education fund, 354R

TREASURY

Deferred Compensation Commission
Public employees deferred compensation plan, 723N, 1617R

Treasurer, Office of
Permissible investments, 1367ER

Trustees of the Louisiana State Employees' Retirement System, Board of
Election to the board of trustees, 1029N, 1614R

WILDLIFE AND FISHERIES

Wildlife and Fisheries Commission
2011-2012 commercial king mackerel season, 48ER
Alligator regulations, 1281N
Assignment of HINs to undocumented vessels manufactured in Louisiana, 922R
Calcasieu lake public oyster area closure, 1120ER
Civil fish and wildlife values, threatened and endangered species, 1294N
Coastal sharks commercial fishery opening, 49ER
Commercial fisheries opening, 1367ER
Crab trap closure and derelict crab trap clean-up, 475ER
Deer management assistance program, 1033N
Fall inshore shrimp season extension in Breton and Chandeleur Sounds, 1120ER
Fall inshore shrimp season extension in portions of zone 1, 49ER
General and wildlife management area hunting rules and regulations, 728N
Greater amberjack commercial season closure, 1368ER
Greater amberjack recreational season closure, 1368ER
King mackerel commercial season, 476ER
Methods of payment for commercial licenses and oyster tags, 745N, 1622R
Oyster Bedding Season—CSA 1, 1560ER
Oyster leases, 1622R
Public seed grounds east of the Mississippi river and oyster lease relocation, 424N, 1624R
Recreational and commercial fisheries closure, 1369ER
Recreational and commercial fisheries opening, 1369ER
Red snapper recreational season closure, 1370ER
Reef fish—harvest regulations, 2011-2012 commercial reef fish season, 50ER
Reef fish—harvest regulations, 2011-2012 recreational reef fish season, 50ER
Reef fish—harvest regulations, gag grouper recreational season closure, 51ER
Resident game hunting season, 746N
Shrimp season closure—Zone 1, 476ER
Special shrimp season in portion of state inside waters, 1371ER
Spring inshore shrimp season opening dates, 1371ER
Spotted seatrout management measures, 354R
State outside waters
Partial opening of shrimp season, 1120ER
Texas border waters, reciprocal agreement and black bass regulations, 1035N
Wildlife rehabilitation program, 602R
Use of yo-yo's and trotlines in Lake Lafourche, 355R

Secretary, Office of
Atchafalaya Basin closure continuation, 1559ER
Atchafalaya Basin flooding closure, 1559ER

WORKFORCE COMMISSION

State Plumbing Board
Continuing professional education programs, 905R, 1463N

Workers' Compensation, Office of
Hearing rules, 1053N, 1625R
Medical guidelines, 51ER, 426N, 477ER

Workforce Development
Apprenticeship law, 1037N
Hearing notice and comment period revision labor and employment, apprenticeship law, 1318P