

care professionals licensed by the Board whose scope of practice includes the authority to prescribe opioids e.g., podiatrists and physician assistants. The proposed rules are being promulgated in accordance with Act 76 of the 2017 Regular Session, which requires physicians and other authorized providers to access and review a patient's record in the Louisiana Prescription Monitoring Program (PMP), either individually or through a delegate, prior to initially prescribing any opioid to a patient. If opioids are prescribed for more than 90 days, the proposed rules further provide that the prescriber or his delegate shall access and review the patient's PMP record at least every 90 days. Exceptions to the need to access the PMP, which are authorized by Act 76, are incorporated into the proposed rules, which also provide that non-compliance may serve as a basis for enforcement action by the Board. The impact of the proposed rules is indeterminable because there is no information or data available concerning the number of physicians, podiatrists or physician assistants who prescribe opioids or the number that do so in a manner outside of the proposed exceptions. Furthermore, there is no data or information regarding the amount of time or associated costs related to accessing, reviewing, and reacting to PMP data. However, the proposed rules may benefit the public generally to the extent that enhanced access and review of PMP data may reduce diversion and inappropriate prescribing which, in turn, may decrease patient mortality associated with the misuse of opioids and healthcare costs related to the treatment and care of overuse and addiction.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rules will not affect competition or employment.

Vincent A. Culotta, Jr., M.D.
Executive Director
1710#073

Gregory V. Albrecht
Chief Economist
Legislative Fiscal Office

NOTICE OF INTENT

Department of Health Board of Medical Examiners

Physician Practice; Physician Collaboration with Advanced Practice Registered Nurses (LAC 46:XLV.Chapter 79)

Notice is hereby given that in accordance with the Louisiana Administrative Procedure Act, R.S. 49:950 et. seq., and pursuant to the authority of the Louisiana Medical Practice Act, R.S. 37:1270, the Louisiana State Board of Medical Examiners (board) intends to adopt rules to facilitate physician collaboration with advanced practice registered nurses (APRNs), LAC 46:XLV.7901 et seq. The proposed rules provide for: the scope of the Subchapter (§7901); applicable terms and definitions (§7903); a prohibition against collaboration other than in compliance with the rules (§7905); exceptions (§7907); due diligence (§7909); eligibility and required components of a collaborative practice agreement (§7911); required information (§7913); collaborating physician responsibilities and compensation arrangements (§7915); limitations (§7917); continuous quality improvement and Board access to documents (§7919); and the effect of violations (§7921). The proposed Rule is set forth below

Title 46 PROFESSIONAL AND OCCUPATIONAL STANDARDS

Part XLV. Medical Professions Subpart 3. Practice

Chapter 79. Physician Collaboration with Advanced Practice Registered Nurses

Subchapter A. General Provisions

§7901. Scope

A. The rules of this Chapter govern the practice of physicians in this state who engage in collaborative practice with an advanced practice registered nurse who provides acts of medical diagnosis or prescriptions.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(B)(6).

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Medical Examiners, LR 44:

§7903. Definitions

A. As used in this Chapter, the following terms shall have the meanings specified.

Act—the Louisiana Medical Practice Act or Act, R.S. 37:1261 et seq.

Advanced Practice Registered Nurse or *APRN*—a licensed registered nurse who is licensed as an advanced practice registered nurse by the Louisiana State Board of Nursing.

Alternate Collaborating Physician or *ACP*—a physician meeting the eligibility requirements of this Chapter who is designated to serve as collaborating physician, in accordance with §7911.A.5 of these rules, when the collaborating physician is unavailable.

Board—the Louisiana State Board of Medical Examiners, as constituted in the Louisiana Medical Practice Act.

Clinical Practice Guidelines—written or electronic documents, jointly agreed upon by the collaborating physician and APRN that describe a specific plan, arrangement, or sequence of orders, steps, or procedures to be followed or carried out in providing patient care in various clinical situations. These may include textbooks, reference manuals, electronic communications and Internet sources.

Collaborating Physician or *CP*—a physician with whom an APRN has been approved to collaborate by the Louisiana State Board of Nursing, who is actively engaged in clinical practice and the provision of direct patient care in Louisiana, with whom an APRN has developed and signed a collaborative practice agreement for prescriptive and distributing authority. A CP shall hold a current, medical license issued by the board, or be otherwise authorized by federal law or regulation to practice medicine in this state, have no pending disciplinary proceedings and practice in accordance with rules of the board.

Collaboration or *Collaborate*—a cooperative working relationship between a physician and APRN to jointly contribute to providing patient care and may include but not be limited to discussion of a patient's diagnosis and cooperation in the management and delivery of health care with each provider performing those activities that he or she is legally authorized to perform.

Collaborative Practice—the joint management of the health care of a patient by an APRN performing advanced practice registered nursing and one or more consulting physicians. Except as provided in R.S. 37:930, acts of medical diagnosis and prescriptions by an APRN shall be in accordance with a collaborative practice agreement.

Collaborative Practice Agreement or CPA—a formal written statement addressing the parameters of the collaborative practice which are mutually agreed upon by an APRN and one or more physicians which shall include but not be limited to the following provisions:

- a. availability of the collaborating physician for consultation or referral, or both;
- b. methods of management of the collaborative practice which shall include clinical practice guidelines; and
- c. coverage of the health care needs of a patient during any absence of the APRN or physician.

Controlled Substance—any substance defined, enumerated, or included in federal or state statute or regulations 21 CFR 1308.11-15 or R.S. 40:964, or any substance which may hereafter be designated as a controlled substance by amendment or supplementation of such regulations or statute.

Fair Market Value or FMV—the value in arm's-length transactions, consistent with the general market value of the services provided.

LSBN—the Louisiana State Board of Nursing, as constituted in R.S. 37:911 et seq.

Physician—an individual lawfully entitled to engage in the practice of medicine in this state as evidenced by a license duly issued by the board.

Practice Site or Site—a location identified in a CPA or other documentation submitted by the APRN to the LSBN at which a CP or APRN engage in collaborative practice. A hospital and its clinics, ambulatory surgery center, nursing home, any facility or office licensed and regulated by LDH, as well as a group or solo physician practice, which have more than one physical location shall be considered a *site* for purposes of this definition.

Prescription or Prescription Drug Order—an order from a practitioner authorized by law to prescribe for a drug or device that is patient specific and is communicated by any means to a pharmacist in a permitted pharmacy, and is preserved on file as required by law or regulation.

Unpredictable, Involuntary Reasons—the death, disability, disappearance, unplanned relocation, or a similar unpredictable or involuntary reason.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(B)(6).

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Medical Examiners, LR 44:

§7905. Prohibitions

A. A physician who has signed a CPA with an APRN shall comply with the rules of this Chapter.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(B)(6).

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Medical Examiners, LR 44:

§7907. Exceptions

A. This Chapter shall not apply to physician collaboration:

1. with an APRN who does not engage in acts of medical diagnosis or prescriptions, as described in R.S.

37:913(8) and (9), or those otherwise exempt from collaborative practice pursuant to R.S. 37:930; and

2. in cases of a declared emergency or disaster, as defined by the Louisiana Health Emergency Powers Act, R.S. 29:760 et seq., or as otherwise provided in title 29 of the *Revised Statutes* of 1950, or the board's rules.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(B)(6).

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Medical Examiners, LR 44:

Subchapter B. Due Diligence; Eligibility; Requirements of Collaborative Practice Agreement and Required Information

§7909. Due Diligence

A. Before entering into a collaborative practice agreement with an APRN, a physician shall:

1. insure that he or she possesses the qualifications specified by this Chapter; and
2. have an understanding of the rules of this Chapter.

B. After signing a collaborative practice agreement with an APRN a physician shall confirm with the APRN that any required documentation concerning the collaborative practice has been submitted to the LSBN.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(B)(6).

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Medical Examiners, LR 44:

§7911. Eligibility; Required Components of Collaborative Practice Agreement

A. To be eligible to engage in collaborative practice with an APRN a physician shall:

1. be actively engaged in the provision of direct patient care in Louisiana;
2. practice in an area comparable in scope, specialty, or expertise to that of the APRN;
3. except as provided in §7911.A.5, have signed a collaborative practice agreement as described in R.S. 37:913(8) and (9) with an APRN that complies with the standards of practice prescribed by §§7915-7919 of this Chapter. In addition, a collaborating physician shall insure that the CPA includes:

- a. a plan of accountability among the parties that addresses:
 - i. prescriptive authority of the APRN and the responsibilities of the collaborating physician;
 - ii. a plan for hospital and other healthcare institution admissions and privileges which provides that a collaborating physician must have hospital privileges at an institution before an APRN receives privileges at the same hospital or institution;
 - iii. arrangements for diagnostic and laboratory testing; and
 - iv. a plan for documentation of medical records;
- b. clinical practice guidelines as required by R.S. 37:913(9)(b), documenting the types or categories or schedules of drugs available and generic substitution for prescription by the APRN and be:
 - i. mutually agreed upon by the APRN and collaborating physician;
 - ii. specific to the practice setting;
 - iii. maintained on site;
 - iv. reviewed and signed at least annually by the CP to reflect current practice;

c. availability of the collaborating physician when he or she is not physically present in the practice setting for consultation, assistance with medical emergencies, or patient referral;

d. confirming that in the event all collaborating physicians are unavailable, and there is no alternate collaborating physician(s), the APRN will not medically diagnose or prescribe;

e. documentation that patients are informed about how to access care when both the APRN and/or the collaborating physician are absent from the practice setting;

f. an acknowledgment of the mutual obligation and responsibility of the APRN and collaborating physician to insure that all acts of prescriptive authority are properly documented;

4. if the APRN has been granted prescriptive authority by the Louisiana State Board of Nursing that includes controlled substances; possess a current, unrestricted Louisiana controlled dangerous substance permit and a current, unrestricted registration to prescribe controlled substances issued by the United States Drug Enforcement Administration; and

5. in the event all CPs at a practice site are unavailable, the CP may designate an alternate collaborating physician at the practice site to be available for consultation and collaboration provided the following conditions are met:

a. there is a formal, documented, approved and enforceable organizational policy that allows and provides for designation of an alternate collaborating physician;

b. the organizational policy establishes and provides for documenting such designation and such documentation shall be made available to board representatives when requested, including the dates of the designation and name of the alternate collaborating physician(s);

c. the alternate collaborating physician agrees to the provisions of the collaborative practice agreement previously signed by the collaborating physician(s);

d. the collaborating physician and APRN are responsible for insuring that the documented organization policy is established and that such policy and any ACP meet the requirements of this Chapter; and

e. the ACP is designated to collaborate with the APRN only at the same practice site as the designating CP.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(B)(6).

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Medical Examiners, LR 44:

§7913. Required Information

A. Each physician shall report to the board annually, as a condition to the issuance or renewal of medical licensure, whether or not he or she is engaged in collaborative practice with an APRN, along with such other information as the board may request.

B. The information required by this Section shall be reported in a format prepared by the board, which shall be made part of or accompany each physician's renewal application for medical licensure.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(B)(6).

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Medical Examiners, LR 44:

Subchapter C. Standards of Practice

§7915. Responsibilities, Compensation Arrangements

A. A collaborating physician shall insure that the identity, contact information and availability of the collaborating physician(s) and APRN are available to patients of the collaborative practice.

B. When serving as the sole CP for an APRN at a practice site, the CP:

1. shall give no less than 30-days notice to the APRN when ending a collaborative practice agreement for predictable, voluntary reasons in order to provide for continuity of care of patients; and

2. work with the APRN to identify and enlist a physician to serve as alternate collaborating physician for unpredictable, involuntary reasons. A physician serving as alternate collaborating physician for unpredictable or involuntary reasons:

a. shall insure that the APRN notifies the LSBN within two business days of the commencement of service as an ACP;

b. may serve in such capacity for at least 30, but no more than 120, days to provide for continuity of care while the APRN secures another CP; and

c. may be excused from the requirements §7911.A.2 (e.g., practice in an area comparable in scope, specialty, or expertise of the APRN, unless following notification pursuant to §7915.B.2.a of this Section, the APRN advises the ACP that the collaborative practice has not been approved by LSBN).

C. In structuring any compensation arrangement or other financial relationship with an APRN, a collaborating physician shall be mindful that a CPA is not an option for an APRN; rather, it is a requirement of state law. Any attempt to exploit such requirement by way of compensation arrangements for performing no professional services, merely serving as a CP under a CPA, or for an amount that is not consistent with the FMV of the services provided to an APRN under a CPA shall be viewed as unprofessional conduct.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(B)(6).

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Medical Examiners, LR 44:

§7917. Limitations

A. A physician shall not collaborate with an APRN:

1. except in compliance with all applicable state and federal laws and regulations;

2. when the APRN and collaborating physician, or in the physician's absence an alternate collaborating physician, do not have the capability to be in contact with each other face-to-face, by telephone or other means of direct telecommunication;

3. who treats and/or utilizes controlled substances in the treatment of:

a. non-cancer-related chronic or intractable pain, as set forth in §§6915-6923 of the board's rules;

b. obesity, as set forth in §§6901-6913 of the board's rules;

c. one's self, spouse, child or any other family member; or

4. who distributes medication, other than free or gratuitous non-controlled substances.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(B)(6).

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Medical Examiners, LR 44:

§7919. Continuous Quality Improvement; Board Access to Documents

A. A collaborating physician shall insure that copies of the collaborative practice agreement, clinical practice guidelines, organization policy and required designation documentation for an alternate collaborating physician are available at the practice site for examination, inspection and copying upon request by the board or its designated employees or agents.

B. A collaborating physician or alternate collaborating physician shall comply with and respond to requests by the board for personal appearances and information relative to his or her collaborative practice;

C. Employees or agents of the board may perform an on-site review of a collaborating physician or alternate collaborating physician's practice at any reasonable time, without the necessity of prior notice, to determine compliance with the requirements of these rules.

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(B)(6).

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Medical Examiners, LR 44:

Subchapter D. Sanctions

§7921. Effect of Violation

A. Any violation or failure to comply with the provisions of this Chapter shall be deemed unprofessional conduct and conduct in contravention of the board's rules, in violation of R.S. 37:1285(A)(13) and (30), respectively, as well as violation of any other applicable provision of R.S. 37:1285(A).

AUTHORITY NOTE: Promulgated in accordance with R.S. 37:1270(B)(6).

HISTORICAL NOTE: Promulgated by the Department of Health, Board of Medical Examiners, LR 44:

Family Impact Statement

In compliance with Act 1183 of the 1999 Regular Session of the Louisiana Legislature, the impact of the proposed Rule on the family has been considered. It is not anticipated that the proposed Rule will have any impact on family, formation, stability or autonomy, as described in R.S. 49:972.

Poverty Impact Statement

In compliance with Act 854 of the 2012 Regular Session of the Louisiana Legislature, the impact of the proposed Rule on those that may be living at or below 100 percent of the federal poverty line has been considered. It is not anticipated that the proposed rules will have any impact on child, individual or family poverty in relation to individual or community asset development, as described in R.S. 49:973.

Provider Impact Statement

In compliance with HCR 170 of the 2014 Regular Session of the Louisiana Legislature, the impact of the proposed Rule on organizations that provide services for individuals with developmental disabilities has been considered. It is not anticipated that the proposed Rule will have any impact on

the staffing, costs or overall ability of such organizations to provide the same level of services, as described in HCR 170.

Public Comments

Interested persons may submit written data, views, arguments, information or comments on the proposed rules to Rita Arceneaux, Confidential Executive Assistant, Louisiana State Board of Medical Examiners, 630 Camp Street, New Orleans, LA 70130, (504) 568-6820, Ex. 242. She is responsible for responding to inquiries. Written comments will be accepted until 4 p.m., November 20, 2017.

Public Hearing

A request pursuant to R.S. 49:953(A)(2) for a public hearing must be made in writing and received by the board within 20 days of the date of this notice. If a public hearing is requested to provide data, views, arguments, information or comments orally in accordance with the Louisiana Administrative Procedure Act, the hearing will be held on Monday, November 27, 2017 at 9 a.m. at the office of the Louisiana State Board of Medical Examiners, 630 Camp Street, New Orleans, LA 70130. Any person wishing to attend should call to confirm that a hearing is being held.

Vincent A. Culotta, Jr., M.D.
Executive Director

**FISCAL AND ECONOMIC IMPACT STATEMENT
FOR ADMINISTRATIVE RULES**

**RULE TITLE: Physician Practice; Physician
Collaboration with Advanced Practice Registered Nurses**

**I. ESTIMATED IMPLEMENTATION COSTS (SAVINGS) TO
STATE OR LOCAL GOVERNMENT UNITS (Summary)**

The proposed rules will result in a one-time publication cost of \$1,016 in FY 18 for the LA State Board of Medical Examiners. Other than the cost of publication, the proposed rules will not result in any additional costs or savings to the Board or other state or local governmental units. Under the proposed rules, physicians will annually report if they are engaged in a collaborative practice with an advanced practice registered nurse (APRN). The Board anticipates devoting nominal administrative resources to processing that portion of its annual renewal applications for physicians who serve as a collaborating physician (CP) for an APRN. While the number of CPs is unknown, because the information will be included in and processed with existing systems for annual medical license renewals, the Board believes it can absorb any increases in administrative workload with existing personnel and resources.

**II. ESTIMATED EFFECT ON REVENUE COLLECTIONS OF STATE
OR LOCAL GOVERNMENTAL UNITS (Summary)**

The proposed rules will not affect revenue collections of state or local governmental units.

**III. ESTIMATED COSTS AND/OR ECONOMIC BENEFITS TO
DIRECTLY AFFECTED PERSONS OR NONGOVERNMENTAL
GROUPS (Summary)**

The proposed rules will impact physicians who are or wish to serve as a collaborating physician (CP) for an APRN. These rules are complementary to regulations developed by the Louisiana State Board of Nursing governing APRNs. This set of proposed rules accommodates CPs who wish to provide for continuity of care during absences from the practice site, and expand the existing pool of physicians eligible to serve as a CP.

CPs and the patients served by collaborative practice between CPs and APRNs would be favorably impacted by the proposed rules. The proposed rules provide that a CP may designate an alternate collaborating physician (ACP) to serve

as CP when all CPs at a practice site are unavailable. The eligibility requirements also make it clear that physicians with a medical license on probationary terms and conditions, which do not restrict the ability to collaborate with an APRN, would be eligible to serve as a CP. Under current practices, these opportunities are unavailable to CPs.

The proposed rules also place certain administrative obligations on collaborating physicians to: insure eligibility to serve as a CP, have an understanding of the applicable law/rules governing such practice and confirm with the APRN that any required documentation concerning collaborative practice has been submitted to the Board of Nursing; report the fact that he or she is engaged in a collaborative practice with an APRN to the Board annually as part of their medical license renewal process; when serving as a sole CP at a practice site, provide no less than thirty days' notice to an APRN when ending a collaborative practice agreement for predictable, voluntary reasons, and work with an APRN to identify and enlist a physician to serve as an ACP in the event of involuntary or unpredictable reasons e.g., death, disability or unplanned absence.

Finally, the proposed rules also prohibit compensation arrangements for performing no professional services and merely serving as a CP, or for an amount that is not consistent with the fair market value of the services provided to an APRN. While it is not possible to estimate the degree of the impact the proposed rules will have, there is no anticipated material effect on the costs, workload, paperwork, receipts or income of affected physicians.

IV. ESTIMATED EFFECT ON COMPETITION AND EMPLOYMENT (Summary)

The proposed rules will not affect competition or employment.

Vincent A. Culotta, Jr., M.D.
Executive Director
1710#045

John D. Carpenter
Legislative Fiscal Officer
Legislative Fiscal Office

NOTICE OF INTENT

Department of Health Bureau of Health Services Financing

Home Health Program Home Health Encounters and Services (LAC 50:XIII.Chapters 1-5)

The Department of Health, Bureau of Health Services Financing proposes to amend LAC 50:XIII.Chapters 1-5 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 compliance with Act 299 of the 2011 Regular Session of the Louisiana Legislature, the Department of Health, Bureau of Health Services Financing amended the provisions governing home health services in order to adopt provisions establishing mandatory cost reporting requirements for providers of home health services (*Louisiana Register*, Volume 39, Number 3). The department now proposes to amend the provisions governing home health services in order to comply with U.S. Department of Health and Human Services, Centers for Medicare and Medicaid Services (CMS) regulations requiring face-to-face encounters, to clarify the provisions

governing home health services settings, and to remove the visit limit for adult recipients in order to align services with those received by the Medicaid expansion population.

Title 50

PUBLIC HEALTH—MEDICAL ASSISTANCE

Part XIII. Home Health Program

Subpart 1. Home Health Services

Chapter 1. General Provisions

§101. Definitions

[Formerly LAC 50:XIX.101]

A. The following words and terms, when used in this Subpart 1, shall have the following meanings, unless the context clearly indicates otherwise:

Home Health Services—patient care services provided in the patient's residential setting or any setting in which normal life activities take place under the order of a physician that are necessary for the diagnosis and treatment of the patient's illness or injury, including one or more of the following services:

a. - e. ...

f. medical supplies, equipment and appliances suitable for use in any setting in which normal life activities take place.

NOTE: Medical supplies, equipment and appliances for home health are reimbursed through the Durable Medical Equipment Program and must be prior authorized.

Occupational Therapy Services—medically prescribed treatment to improve, maintain or restore a function which has been impaired by illness or injury or, when the function has been permanently lost or reduced by illness or injury, to improve the individual's ability to perform those tasks required for independent functioning

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 30:431 (March 2004), amended by the Department of Health, Bureau of Health Services Financing, LR 44:

§103. Requirements for Home Health Services

[Formerly LAC 50:XIX.103]

A. Home health services shall be based on an expectation that the care and services are medically reasonable and appropriate for the treatment of an illness or injury, and that the services can be performed adequately by the agency in the recipient's residential setting or any setting in which normal life activities take place. For initial ordering of home health services, the physician or authorized non-physician provider (NPP) must document a face-to-face encounter that is related to the primary reason the recipient requires home health services. This face-to-face encounter must occur no more than 90 days before or 30 days after the start of services. For the initial ordering of medical supplies, equipment and appliances, the physician must document that a face-to-face encounter that is related to the primary reason the recipient requires medical equipment occurred no more than six months prior to the start of services. A written plan of care for services shall be evaluated and signed by the physician every 60 days. This plan of care shall be maintained in the recipient's medical records by the home health agency.