

LOUISIANA STATE BOARD OF MEDICAL EXAMINERS NEWSLETTER



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Volume 10, Number 1

September 1997

Rules and Regulations

Board Adopts Rules on Pain Management, Amends Rules on Use of Anorectic Drugs

In line with a number of other states and medical organizations which have issued rules and guidelines for the proper use of drugs in pain management, the Board has adopted final rules and regulations, effective June 20, 1997, governing the prescription, dispensation and administration of controlled substances employed in the treatment of non-cancer-related chronic or intractable pain. La. Admin. C. § 46:XLV.6915-.6923. The Board's rules are reprinted in a special insert included with this issue of the NEWSLETTER.

Effective September 20, 1997, the Board amended its rules governing the use of medications in the medical treatment of obesity, La. Admin. C. § 46:XLV.6901-.6913, to make the durational restrictions otherwise applicable to prescription of anorectic medications inapplicable to Schedule IV anorectics, such as fenfluramine, dexfenfluramine, phentermine, diethylpropion and mazindol.

Medication Warnings

Pondimin®, Redux™ Recalled; Broad-Based Use of Lincocin Inappropriate

On September 15, 1997, at the request of the U.S. Food and Drug Administration (FDA), two popular weight loss medications, Redux™ (dexfenfluramine) and Pondimin® (fenfluramine), were voluntarily withdrawn from the market by their manufacturer, Wyeth-Ayerst Laboratories. Concurrently, patients taking such medications, alone or in combination with others (such as phentermine), were advised to discontinue use of the drugs and consult their physicians.

The drug recall was implemented following the FDA's report of summary information concerning abnormal echocardiogram findings in 92 of 291 asymptomatic patients, evaluated in five centers, who had been treated with fenfluramine or dexfenfluramine for up to 24 months, most often in combination with phentermine—a combination popularly known as "fen-phen." Phentermine was unaffected by the recall.

Over the past two years "new" medications, such as dexfenfluramine, and combinations of drugs, such as fenfluramine and phentermine, had been promoted as safe and effective for long-term use in the medical treatment of obesity. By mid-1997, however, emerging scientific evidence indicated that such drugs were not without their risks of adverse effects, some serious, for a percentage of the population. The FDA report precipitating the withdrawal of Redux and Pondimin followed closely on the heels of a prior FDA alert regarding the potential dangers of fen-phen and a published review of studies on the long-term effects of fenfluramines.

■ **FDA Advisory on "Fen-Phen."** A July 1997 FDA *Summary of Reports*, the FDA advised, in part, that:

As of July 8, 1997, there have been 33 cases reported to the FDA [later revised to in excess of 80 cases] of unusual valvular morphology and regurgitation involving the mitral, aortic, and/or tricuspid valves, usually being multivalvular. About half of the women were reported to have pulmonary hypertension with their valvular disease. All 33 patients were American women with a mean age of 43.4 years (range 35-72), all of whom had received combined fenfluramine and phentermine therapy for between 1 and >16 months (mean 10) before presentation with their valvular disease. Echocardiographic confirmation of valvular disease was seen in nearly all of these patients.

The FDA encouraged all health care professionals to report any cases of cardiac valvular disease or other serious toxicities associated with the use of fenfluramine, dexfenfluramine or phentermine to the FDA's MEDWATCH program (1-800-FDA-1088; or fax 1-800-FDA-0178) or to the respective pharmaceutical manufacturers.

■ **Fenfluramines, Brain Serotonin Neurotoxicity.** Similarly, a systematic review of studies of the long-term effects of fenfluramines was reported in an August issue of the *Journal of the American Medical Association*.¹ The review confirmed association of the prolonged use of fenfluramines with the previously-recognized increased risk of primary pulmonary hypertension (PPH). Newly reported were animal-based studies demonstrating that fenfluramine and dexfenfluramine may damage brain serotonin neurons. The report concluded that "when fenfluramines are prescribed, alone or in combina-

¹U.D. McCann, M.D., L.S. Seiden, Ph.D., L.J. Rubin, M.D., G.A. Ricuarte, M.D., Ph.D., *Brain Serotonin Neurotoxicity and Primary Pulmonary Hypertension From Fenfluramine and Dexfenfluramine: A Systematic Review of the Evidence*, 278 J. AM. MED. ASS'N 666 (Aug. 27, 1997).

tion with other anorectic agents (e.g., phentermine), physicians and patients need to be vigilant for symptoms and/or signs of PPH" and should be aware of the possibility that they may cause brain serotonin neurotoxicity.

■ **Lincocin.** In its regular review of reports of malpractice cases and in other contexts, the Board has seen evidence that some physicians may be prescribing or administering the antibiotic Lincocin® (lincomycin hydrochloride) indiscriminately, if not routinely, for a broad array of infections. Physicians should be aware that broad-based use of this antibiotic is contraindicated and inappropriate, if not dangerous. The manufacturer's FDA-mandated warning for the drug emphasizes that, as lincomycin therapy has been associated with severe colitis which may end fatally, "it should be reserved for serious infections where less toxic antimicrobial agents are inappropriate..." More specifically, the Lincocin drug insert advises that the antibiotic is indicated for the

treatment of serious infections due to susceptible strains of streptococci, pneumococci, and staphylococci. Its use should be reserved for penicillin-allergic patients or other patients for whom, in the judgment of the physician, a penicillin is inappropriate. Because of the risk of colitis... before selecting lincomycin the physician should consider the nature of the infection and the suitability of less toxic alternatives (e.g., erythromycin).

Before using Lincocin, a physician should be thoroughly familiar with its pharmacology, warnings, indications, contraindications and precautions, as reflected in the *Physicians' Desk Reference* and *AMA Drug Evaluations*.

WARNING: The Board office has recently received several telephone calls from an individual indicating he wanted to be certain we didn't have his Social Security Number confused with his partner or with his son. When asked to provide the number in question, the caller either hung up or provided a clearly fictitious number not matching any on record in this office. When Board staff declined to give out the correct numbers on record for the physicians in question, the caller again hung up. The Board's Chief Investigator then attempted to notify both physicians of the possibility that someone was attempting to obtain confidential identifying information, possibly for illicit purposes. We learned that, unfortunately, one of the physicians had already been financially victimized. All physicians should be wary of schemes to obtain particularized personal identifying information—such as Social Security numbers and birth dates—as such information can be used to access and manipulate banking and credit card accounts or to otherwise defraud an unwitting physician.

Clinical Laboratories

Sources of Continuing Education

Pathologists and other physicians who may employ, supervise or otherwise be affiliated with licensed clinical laboratory personnel should be aware of the types and sources of continuing education programs which are approved for purposes of satisfying the minimum 12 contact hours of continuing education (1.2 continuing education units) requisite to annual renewal of CLP licensure. Under applicable Board rules and regulations, a variety of programs and activities may qualify, including coursework in laboratory science, publication in a professional journal, presentation of a program and certain laboratory sessions, as well as professional meetings, telecommunication conferences, self-study courses and training programs sponsored by "approved professional organizations."

The organizations currently recognized by the Board and its Clinical Laboratory Personnel Committee as "approved professional organizations" include:

- AMERICAN SOCIETY FOR CLINICAL LABORATORY SCIENCE
- AMERICAN MEDICAL TECHNOLOGISTS
- INTERNATIONAL SOCIETY FOR CLINICAL LABORATORY TECHNOLOGY
- AMERICAN SOCIETY OF CLINICAL PATHOLOGISTS
- AMERICAN SOCIETY OF CYTOLOGY
- AMERICAN SOCIETY FOR MICROBIOLOGY
- AMERICAN ASSOCIATION OF BLOOD BANKS
- AMERICAN ASSOCIATION OF CLINICAL CHEMISTRY
- CLINICAL LABORATORY MANAGEMENT ASSOCIATION
- ASSOCIATION OF TERRITORIAL AND PUBLIC HEALTH LABORATORY DIRECTORS
- CENTERS FOR DISEASE CONTROL
- NATIONAL ACCREDITING AGENCY FOR CLINICAL LABORATORY SCIENCES
- GAMMA BIOLOGICALS REFERRED IMMUNOHEMATOLOGY SELF-EVALUATION SYSTEM AND TUTORIAL PROGRAM FOR CONTINUING EDUCATION OF BLOOD BANKERS
- AMERICAN SOCIETY FOR CYTOTECHNOLOGY
- AMERICAN ACADEMY OF FORENSIC TESTING
- SOCIETY OF FORENSIC TESTING
- AMERICAN HEART ASSOCIATION
- COLLEGE OF AMERICAN PATHOLOGISTS

Continuing education programs not sponsored by "approved professional organizations" may nonetheless qualify as continuing education for clinical laboratory personnel if the sponsors apply to the Board, through its Clinical Laboratory Personnel Committee, for approval of single or multiple programs and meet the standards for approval prescribed by the Board's rules.

LOUISIANA STATE BOARD OF MEDICAL EXAMINERS

Rules and Regulations

Medications Used in the Treatment of Non-Cancer Related Chronic or Intractable Pain

LA. ADMIN. C. §§ 46:XLV.6915-.6923

CHAPTER 69—PRESCRIPTION, DISPENSATION
AND ADMINISTRATION OF MEDICATIONS

Subchapter B—Medications Used in the
Treatment of Non-Cancer Related
Chronic or Intractable Pain

- § 6915 Scope of Subchapter
- § 6917 Definitions
- § 6919 General; Conditions/Prohibitions
- § 6921 Use of Controlled Substances, Limitations
- § 6923 Effect of Violation

§ 6915. Scope Of Subchapter

The rules of this Subchapter govern physician prescription, dispensation, administration or other use of controlled substances employed in the treatment of non-cancer related chronic or intractable pain.

§ 6917. Definitions

As used in this Subchapter, unless the content clearly states otherwise, the following terms and phrases shall have the meanings specified:

Addiction—The term “Addiction” means a compulsive disorder in which an individual becomes preoccupied with obtaining and using a substance, despite adverse social, psychological and/or physical consequences, the continued use of which results in a decreased quality of life.

Board—The term “Board” means the Louisiana State Board of Medical Examiners.

Chronic Pain—The term “Chronic Pain” means pain which persists beyond the usual course of a disease, beyond the expected time for healing from bodily trauma, or pain associated with a long-term incurable or intractable medical illness or disease.

Controlled Substance—The term “Controlled Substance” means any substance defined, enumerated or included in federal or state statute or regulations 21 C.F.R. §§ 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 and statute.

Diversion—The term “Diversion” means the conveyance of a controlled substance to a person

other than the person to whom the drug was prescribed or dispensed by a physician.

Drug Abuse—The term “Drug Abuse” means a maladaptive or inappropriate use or overuse of a medication.

Intractable Pain—The term “Intractable Pain” means a chronic pain state in which the cause of the pain cannot be eliminated or successfully treated without the use of controlled substance therapy and, which in the generally accepted course of medical practice, no cure of the cause of pain is possible or no cure has been achieved after reasonable efforts towards such cure have been attempted and documented in the patient’s medical record.

Non-Cancer Related Pain—The term “Non-Cancer Related Pain” means that pain which is not directly related to symptomatic cancer.

Physician—The term “Physician” means physicians and surgeons licensed by the Board.

Protracted Basis—The term “Protracted Basis” means utilization of any controlled substance for the treatment of non-cancer related chronic or intractable pain, for a period in excess of twelve (12) weeks during any 12 month period.

§ 6919. General Conditions/Prohibitions

The treatment of non-cancer related chronic or intractable pain with controlled substances constitutes legitimate medical therapy when provided in the usual course of professional medical practice and when fully documented in the patient’s medical record. A physician duly authorized to practice medicine in Louisiana and to prescribe controlled substances in this state shall not, however, prescribe, dispense, administer, supply, sell, give or otherwise use for the purpose of treating such pain, any controlled substance unless done in strict compliance with applicable state and federal laws and the rules enumerated in this Subchapter.

§ 6921. Use Of Controlled Substances,
Limitations

A. *Requisite Prior Conditions*. In utilizing any controlled substance for the treatment of non-cancer related chronic or intractable pain on a protracted basis, a physician shall comply with the following rules:

1. *Evaluation of the Patient*. Evaluation of the patient shall initially include a full history, including complete medical, pain, alcohol and substance abuse histories, an assessment of the impact of pain on the patient’s physical and psychological functions; a review of previous diagnostic studies, previously utilized therapies, an assessment of coexisting illnesses, diseases or conditions and a complete physical examination.

2. *Medical Diagnosis*. A medical diagnosis shall be established and fully documented in the patient’s medical record, which indicates not only

the presence of non-cancer related chronic or intractable pain, but also the nature of the underlying disease and pain mechanism if such are determinable.

3. *Treatment Plan.* An individualized treatment plan shall be formulated and documented in the patient's medical record, which includes medical justification for controlled substance therapy. Such plan shall include documentation that other medically reasonable alternative treatments for relief of the patient's non-cancer related chronic or intractable pain have been offered or attempted without adequate or reasonable success. Such plan shall specify the intended role of controlled substance therapy within the overall plan, which therapy shall be tailored to the individual medical needs of each patient.

4. *Informed Consent.* A physician shall ensure that the patient and/or his guardian is informed of the benefits and risks of protracted controlled substance therapy.

B. *Controlled Substance Therapy.* Upon completion and satisfaction of the conditions prescribed in Paragraph A of this Subchapter, and upon a physician's judgment that the prescription, dispensation or administration of a controlled substance is medically warranted, a physician shall adhere to the following rules:

1. *Assessment of Treatment Efficacy and Monitoring.* Patients shall be seen by the physician at appropriate regular and frequent intervals, of no more than twelve (12) weeks, to assess the efficacy of treatment, assure that controlled substance therapy remains indicated, evaluate the patient's progress toward treatment objectives and any adverse drug effects. During each visit, attention shall be given to the possibility of decreased function or quality of life as a result of controlled substance usage, as well as indications of possible addiction, drug abuse or diversion.

2. *Drug Screen.* If a physician reasonably believes that the patient is suffering from addiction or drug abuse or that he is diverting controlled substances, the physician shall obtain a drug screen on the patient. It is within the physician's discretion to decide the nature of the screen and which type of drug(s) to be screened.

3. *Responsibility for Treatment.* A physician shall take primary responsibility for the controlled substance therapy employed by him in the treatment of a patient's non-cancer related chronic or intractable pain.

4. *Consultation.* Consultation with specialists may be warranted depending on the expertise of a physician and the complexity of the presenting prob-

lem. If the patient is maintained on controlled substance therapy on a protracted basis, the physician should either consult with one or more specialists for additional evaluation and/or treatment in order to achieve treatment objectives, or he shall document in the patient's medical record the reason he has not obtained such consultation. It is within the discretion of the physician to decide the level and type of consultation which is believed to be medically warranted.

5. *Medications Employed.* A physician shall document in the patient's medical record the medical necessity for the use of more than one type or schedule of controlled substance employed in the management of a patient's non-cancer related chronic or intractable pain.

6. *Treatment Records.* A physician shall document and maintain in the patient's medical record, accurate and complete records of all history, physical and other examinations and evaluations, consultations, laboratory and diagnostic reports, treatment plans and objectives, controlled substance and other medication therapy, informed consents, periodic assessments and reviews and the results of all other attempts at analgesia which he has employed alternative to controlled substance therapy.

7. *Documentation of Controlled Substance Therapy.* At a minimum, a physician shall document in the patient's medical record the date, quantity, dosage, route, frequency of administration, the number of controlled substance refills authorized, as well as the frequency of visits to obtain refills.

C. *Termination of Controlled Substance Therapy.* Evidence or behavioral indications of addiction, drug abuse or diversion of controlled substances, shall be followed by tapering and discontinuation of controlled substance therapy. Such therapy shall be reinitiated only after referral to, and written concurrence of the medical necessity of continued controlled substance therapy by an addiction medicine specialist, a pain management specialist, a psychiatrist, or other substance abuse specialist, based upon his physical examination of the patient and a review of the referring physician's medical record of the patient.

§ 6923. Effect Of Violation

Any violation of or failure of compliance with the provisions of this Subchapter, §§ 6915-6923, shall be deemed a violation of R. S. 37:1285(A)(6) and (14), providing cause for the Board to suspend or revoke, refuse to issue, or impose probationary or other restrictions on any license held or applied for by a physician to practice medicine in the state of Louisiana culpable of such violation.