

NEWSLETTER



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In this issue of the Newsletter we provide timely updates on rules that may affect your practice. For more information about all of these topics and more - visit our web site at www.lsbme.la.gov and while you are visiting subscribe to the RSS feed to keep up with the News from the Board.

We welcome your feedback on the topics that are presented and recommendations regarding future topics as well as legislative and/or rule making efforts, and board services. Please contact us at feedback@lsbme.la.gov. Thank you

Guidance

USP 797

In 2008 the United States Pharmacopeia (USP) published standards relating to the preparation of sterile compounds that apply to everyone who prepares or uses these materials. The standards which are found in Chapter 797 of the USP have the force of law. Enforcement takes place at the state level primarily by Boards of Pharmacy – who have amended their rules to require compliance and by Boards of Medicine for physician's offices. In Louisiana, all pharmacies must be in full compliance by 2010.

Presently, our rules are silent with respect to this matter. The Board intends to amend its rules this year to require compliance. More information at www.lsbme.la.gov

Prescription Monitoring Program

Act 676 of the 2006 Louisiana Legislature authorized the Louisiana Board of Pharmacy to develop, implement and operate an electronic system for the monitoring of controlled substances and other drugs of concern dispensed in the state or dispensed to an address within the state. The goal of the program is to improve the state's ability to identify and inhibit the diversion of controlled substances and other drugs of concern in an efficient and cost-effective manner and in a manner that shall not impede the appropriate utilization of these drugs for legitimate medical purposes.

The program requires dispensers (pharmacies as well as other practitioners dispensing to their patients) of controlled substances and other drugs of concern to report the essential data elements of those transactions to the program. The program houses the data in a secure database and makes that information available to authorized users –

primarily prescribers and dispensers caring for their own patients. Regulatory agencies monitoring prescribers and dispensers also have access to that information. Law enforcement agencies may also access that information, provided they have acquired the appropriate administrative warrants or other judicial documents.

The Board strongly encourages physicians to register and access the data base routinely when treating patients with chronic pain and in other cases whenever questions arise as to what controlled substances a patient may be receiving from another provider. More information at www.labp.com/

Illegal Payments

The Board is becoming increasingly concerned about the potential for financial motives influencing physician's treatment decisions. In any patient-specific instance where a physician's treatment determinations have been guided by financial motives, rather than the patient's best interest, the Board has authority under the Louisiana Medical Practice Act §§37:1261-1292 (the "Act") to take appropriate action. Similarly, if a physician is involved in an arrangement that violates state or federal laws and regulations governing proscribed kickbacks, a basis for disciplinary action also exists under the Act.

The Board has the authority and responsibility to interpret and enforce La. Rev. Stat. §37:1745 (the "anti-kickback law") as it applies to physicians licensed to practice medicine in this state. The anti-kickback law provides in pertinent part that "No health care provider shall offer, make, solicit, or receive payment, directly or indirectly, in cash or in kind, for referring or soliciting patients." Board regulations interpreting the anti-kickback law provide that "A physician shall not knowingly and willfully make or offer to make any payment, directly or indirectly, overtly or covertly, in cash or in kind, to induce another person to refer an individual to the physician for the furnishing or arranging for the furnishing of any health care item or service."

The Louisiana anti-kickback law is similar in scope to its federal counterpart. However, there are important distinctions. First, the federal anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals or items or services reimbursable by a federal health care program. Where remuneration is purposely induced or rewarded for referrals for services payable by a

federal health care program, the anti-kickback statute is violated. The federal law assigns criminal liability to parties on either side of an impermissible kickback, not just physicians. The statute has been interpreted to cover any arrangement where one purpose of the remuneration is to obtain money for the referral of services or to induce further referrals. Violation of the statute is a felony punishable by a fine of not more than \$25,000, imprisonment of up to five years, or both. Conviction will also lead to automatic exclusion from federal health care programs and the Office of the Inspector General may initiate administrative proceedings to impose civil monetary penalties under Section 1128A(a)(7).

Another distinction is that federal law regulates activities, arrangements and transactions intended to induce referrals for goods or services paid for in whole or in part by *governmental* payers, while Louisiana law is applicable to *all* payers—private and governmental alike. In applying the Louisiana anti-kickback law, the Board recognizes that physicians owe a fiduciary duty to patients to exercise their professional judgment in providing, furnishing, prescribing, recommending or referring patients for health care items and services without regard to personal financial recompense. Accordingly, the expressed purpose of the anti-kickback law is to prevent payments by or to a physician as a financial incentive for the referral of patients to other physicians or health care providers for diagnostic or therapeutic services or items. A physician who violates the Louisiana anti-kickback law is subject to disciplinary action by the Board.

Dispensing – Physician requirements

The “practice of pharmacy” is defined in pertinent part by the Louisiana Pharmacy Practice Act (“the Pharmacy Law”) as the “compounding, filling, dispensing, exchanging, giving, offering for sale or selling, drugs, medicines, or poisons, pursuant to prescriptions or orders of physicians, dentists, veterinarians, or other licensed practitioners...” The Pharmacy Law limits the compounding, filling and dispensing of medication to pharmacists and pharmacy technicians. Pharmacy technicians comprise a category of health care practitioner created by the Louisiana Legislature to assist a pharmacist in the practice of pharmacy. Pharmacy technicians must be certified by the Board of Pharmacy and practice under the direct and immediate supervision of a pharmacist.

In addition to pharmacists and pharmacy technicians the Pharmacy Law, as re-enacted and amended, exempts from the necessity for licensure by the Board of Pharmacy, physicians and other “Licensed practitioners authorized under the laws of this state to compound and dispense drugs to their patients in the course of their respective professions.” All others are prohibited from dispensing medication or otherwise engaging or assisting in the practice of pharmacy.

Pharmacy technicians are not authorized by the Pharmacy Law or applicable rules to assist a physician dispense medication. The Legislature did not create an equivalent category of licensed practitioner to assist a physician dispense medication.

The Board takes cognizance of a provision in the Pharmacy law that “[A]fter the pharmacist or pharmacy technician has complied with all duties imposed upon him by law regarding a prescription,” and provided the pharmacist or pharmacy technician is physically present in the prescription department, a cashier or other clerical person may lawfully deliver a drug and collect payment. By virtue of the

inclusion of this authority in the Pharmacy Law the Board is of the opinion that clerical or medical staff of a dispensing physician is likewise permitted to follow a similar protocol, provided the Dispensing Physician is physically present and has complied with all requirements imposed upon pharmacists by the Pharmacy Law. (Go to Board website for citations). Citations at www.lsbme.la.gov

Delegation

It has long been the position of the Board that the practice of medicine as defined by the Louisiana Medical Practice Act, La. Rev. Stat. §37:1262(1) may only be undertaken or performed in this state by a Louisiana licensed physician or an unlicensed individual who functions solely under a licensed physician’s direction and immediate personal supervision—i.e., where the physician is physically present in the office or suite where the procedure is being performed at all times that the unlicensed assistant is on duty (irrespective of the employee’s level of training or experience) and retains full responsibility to the patients for the training, delivery and results of all services rendered.

An individual filling such a position could not—and may not be permitted to under any circumstances—act independently of a licensed physician or to exercise independent medical judgment in starting, selecting or implementing modalities of treatment. If an unlicensed person acts beyond this scope he or she would be in violation of the Louisiana Medical Practice Act. A physician enabling such activity would be in violation of the Act as well. Citations at www.lsbme.la.gov

Orders by Out of State Physicians

It has long been the Board’s formally-stated position that any diagnosis, prescription, recommendation or administration of treatment, so as to effect the diagnosis or treatment for or with respect to an individual who is a resident of and located in Louisiana, constitutes the “practice of medicine” in this state, as defined by the Louisiana Medical Practice Act. As matter of law, to be valid, effective and lawful, each prescription or order for diagnostic testing or treatment must be issued or given by an authorized practitioner (i.e., a Louisiana licensed physician) with respect to an individually identified patient, based on the practitioner’s examination and diagnosis of the patient. This is necessarily so because the Medical Practice Act restricts the practice of medicine to persons possessing a license issued by the Board.

In certain limited situations the Board by way of exercising its authority to apply the Medical Practice Act has held that a physician who holds an unrestricted license to practice medicine in another state may order non-invasive, routine diagnostic tests where (1) the patient is a non-Louisiana resident who is visiting, traveling through, or temporarily residing in this state for a brief period of time, (2) the non-resident patient has an established physician-patient relationship with the physician ordering the testing, and (3) the test results are provided directly to the ordering out-of-state physician.

Chelation therapy – AHA Statement

According to the American Heart Association there is no scientific evidence to demonstrate any benefit from this form of chelation therapy for coronary artery disease. A large multi center prospective study was undertaken in 2002 by the NIH to find out if EDTA chelation therapy is safe and effective for the treatment of this condition. The study is due to be completed this year. More information is available on the American Heart Association web site.

Hydrogen peroxide therapy – FDA warning

FDA has warned consumers not to purchase or to use high-strength hydrogen peroxide products, including a product marketed as "35 Percent Food Grade Hydrogen Peroxide," for medicinal purposes because they can cause serious harm or death when ingested. FDA recommends that consumers who are currently using high-strength hydrogen peroxide stop immediately and consult their health care provider.

FDA has never approved high-strength hydrogen peroxide to be taken internally and considers hydrogen peroxide at 35 percent strength dangerous, even if handled according to the manufacturer's directions. High-strength hydrogen peroxide -- more than 10 times stronger than the solution used in over-the-counter drugs to disinfect minor cuts -- is highly corrosive. Ingesting hydrogen peroxide can cause gastrointestinal irritation or ulceration. Intravenous (IV) administration of hydrogen peroxide can cause inflammation of the blood vessel at the injection site, gas embolisms (bubbles in blood vessels), and potentially life-threatening allergic reactions. More information is available on the FDA web site.

Increase in Fatal Poisonings Involving Opioid Analgesics

According to the National Center for Health Statistics in a report published in September 2009, poisoning is the second leading cause of injury death overall, and the leading cause of injury death for people aged 35–54 years, surpassing both firearm-related and motor vehicle-related deaths in this age group. From 1999 through 2006, the number of fatal poisonings involving opioid analgesics more than tripled from 4,000 to 13,800 deaths. Opioid analgesics were involved in almost 40% of all poisoning deaths in 2006. In about one-half of the deaths involving opioid analgesics, more than one type of drug was specified as contributing to the death, with benzodiazepines specified with opioid most frequently.

"Bioidentical hormones" - ACOG Statement

In response to recent media attention being given to so-called bioidentical hormones, The American College of Obstetricians and Gynecologists (ACOG) reiterates its position that there is no scientific evidence supporting the safety or efficacy of compounded bioidentical hormones. More information is available on the ACOG web site

In the News

Retirement

Dr Linda Gage-White has retired from the Board. She served the Board with great distinction as a representative of the Louisiana State Medical Society since her appointment by Governor Foster in 2002. Dr White served as Secretary, Vice President and at the time of her retirement as President of the Board. The Board is deeply indebted to her for her years of dedicated service and leadership.

Appointments

Governor Jindal has reappointed Dr Mel Bourgeois to the Board. Dr Bourgeois represents the Louisiana Academy of Family Physicians and has served on the Board since his appointment to the Board by Governor Foster in 2000

The Governor has appointed Dr J Michael Burdine to replace Dr. Gage-White. Dr Burdine is one of four members of the Board representing the Louisiana State Medical Society

On line renewal

All licensees will be required to renew online starting with licensees due to renew in March 2010. The information that licensees enter will carry forward from year to year. Each year you will be asked to update the information. More effort will be required the first go around.

If you are renewing through your office, select pay-by-check and send a copy of the receipt to our office. This will enable us to post the payment to the correct account when payment is made. Your office may pay for more than one physician as long as we receive the receipts with the check.

Board Offices

The Board moved its offices in March 2010 so as to accommodate renovations of its offices at 630 Camp Street in New Orleans. We expect to return to Camp St in the fall of 2011. The address for the temporary office is 1515 Poydras Street, Suite 2700, New Orleans, LA 70112- 1279. Our telephone numbers will not change.



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