April 2000

Louisiana Board of Pharmacy

Published to promote voluntary compliance of pharmacy and drug law.

5615 Corporate Blvd, Suite 8E, Baton Rouge, LA 70808

New Board Members (00-04-70)

Govenor Mike Foster recently announced two new appointments to the Louisiana Board of Pharmacy. **Marty R. McKay**, from Alexandria, will complete the unexpired term of the late **Robert L. Eastin** from District 8; his term expires July 28, 2002. **Jeffrey M. Landry**, from New Iberia, has replaced **Hewitt P. Theriot**, who resigned for health reasons. As the public member of the Board, Landry's term is not fixed; he serves at the behest of the governor. The Board welcomes the two new members and salutes Theriot for nearly four years of service.

Board Meeting Dates (00-04-71)

To accommodate changing construction schedules, the Board has found it necessary to adjust its previously announced meeting schedule. The April dates have been changed. The Board will meet on April 26, and the Administrative Hearing will convene on April 27. The meeting dates for August and November have not changed, but should still be considered tentative. All meetings will be held in Baton Rouge.

Emergency Rule – Drug Returns (00-04-72)

Board regulations prohibit the return of prescription drugs to a pharmacy after they have been removed from the pharmacy where they had been originally dispensed (**LAC 46:LIII.3517**). In an effort to reduce the wastage of prescription drugs in nursing homes and certain other facilities where US Pharmacopeia (USP) storage requirements can be assured, the Board has adopted a new emergency rule. The rule allows legend drugs (except controlled substances) that were previously dispensed in unit dose or individually sealed doses to be transferred to pharmacies for the relabeling and dispensing of the drugs to the indigent, at no charge. The acceptance of previously dispensed prescription drugs is limited to provisionally permitted pharmacies; no other pharmacies may accept prescription drugs for return or exchange.

The emergency rule became effective March 1; the Board is proceeding according to the mandates of the Administrative Procedure Act to convert the rule to permanent status.

Renewal of Pharmacy Technician Certifications (00-04-73)

The Board will mail applications for renewal of pharmacy technician certifications on April 26. The properly completed renewal application and $50 fee is due in the Board office on or before May 31, 2000. The pharmacy technician annual renewal period expires June 30, 2000.

In order to renew an expired certification, the pharmacy technician must apply to and appear before the Reinstatement Committee of the Board. At least 30 days prior to the hearing, the pharmacy technician shall remit the renewal fee of $50, the reinstatement fee of $200, and the hearing fee of $250.

Procedures for Pharmacy Technician Applicants (00-04-74)

The Louisiana Board of Pharmacy regulations contain essentially three requirements of pharmacy technician applicants: education, experience, and examination. Education is obtained through a Board-approved didactic program; experience through the completion of at least 200 hours under the authority of a site-specific work permit; and the examination requirement is satisfied through the successful completion of the Pharmacy Technician Certification Board examination. Once all three elements have been completed, pharmacy technician applicants may then apply to the Board for certification.

There have been some recent changes in the pharmacy technician applicant program. The change in the vendor of the examination was reported in our previous *Newsletter*. A more recent change concerns the site-specific work permit. The work permit expires one year after the beginning date of the didactic program. The purpose of the permit is to provide a mechanism for the technician applicant to obtain 200 hours of experience. One year is ample time to obtain the 200 hours. Experience has shown that some technician applicants have applied for renewal of the work permit in order to avoid completion of the examination. During its February meeting, the Board reaffirmed the original purpose of the permit. Work permits for technician applicants will no longer be renewed.

In response to recent questions received in the office, we find it necessary to remind pharmacists, technicians, and technician applicants that there is no reciprocity for pharmacy technician certificates or pharmacy technician applicant work permits. State or national credentials obtained elsewhere are not valid in Louisiana.

Beyond-Use Date Requirements Revised by USP (00-04-75)

The US Pharmacopeia (USP) has revised the beyond-use dating requirement for nonsterile solid and liquid dosage forms repackaged in single-unit and unit-dose containers in order to make them more consistent with the requirements for multi-unit containers. Effective January 1, 2000, the *First Supplement* of the *United States Pharmacopeia 24 – National Formulary 19 (USP-NF)* states the beyond-use date for these products shall be one year or less from the date of repackaging, unless the stability data or the manufacturer's labeling indicates otherwise. Previously,

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IOM Report Addresses Medical Errors

A report released in late 1999 by the Institute of Medicine (IOM) of the National Academy of Science's Committee on Quality of Health Care in America concluded that rigorous changes throughout the health care system, including mandatory reporting requirements, are necessary to reduce medical errors and create a safer health care system.

Citing recent studies that place mortality estimates from medical errors between 44,000 and 98,000 annually, the Committee outlined a plan for government, industry, consumers, and health providers to reduce medical errors; called on Congress to form a national patient safety center to develop new systems that can address persistent problems; and set as a minimum goal a 50% reduction in errors over the next five years.

"Our recommendations are intended to encourage the health care system to take the actions necessary to improve safety," said William Richardson, chief executive officer of the W.K. Kellogg Foundation, Battle Creek, Mich, and chair of the Committee. "We must have a health care system that makes it easy to do things right, and hard to do them wrong."

The report, entitled "To Err Is Human: Building a Safer Health System," is available for a fee by calling 800/624-6242. The IOM is a private, nonprofit institution that provides health policy advice under a congressional charter granted to the National Academy of Sciences.

FDA Issues Final Dietary Supplement Labeling Rules

In the January 6, 2000 *Federal Register*, the US Food and Drug Administration (FDA) published final regulations that define the types of statements that can be made concerning the effects a dietary supplement has on the structure and function of the human body pursuant to the Dietary Supplement Health and Education Act of 1994 (DSHEA). The regulations are intended to clarify the types of claims that may be made for dietary supplements without prior review by the FDA, as well as the types of claims that require prior authorization through the establishment of criteria for determining when a statement about a dietary supplement is a disease claim.

Under DSHEA, dietary supplements may, without prior FDA review, carry "structure/function" claims (ie, claims that a product may affect the structure or function of the body), but may not, without prior FDA review, carry express or implied claims that they can treat, diagnose, cure, or prevent disease (disease claims). For example, the express disease claim "prevents osteoporosis" and the implied disease claim "prevents bone fragility in postmenopausal women" would be prohibited without prior FDA review. The rule clarifies that express and implied disease claims made through the name of the product (ie, Carpaltum, CircuCure); through a statement about the formulation of a product (ie, contains aspirin); or thorough the use of pictures, vignettes, or symbols (ie, electrocardiogram tracings) can be made. It also permits claims that do not relate to disease, such as health maintenance claims ("maintains a healthy circulatory system"); other non-disease claims ("for muscle enhancement"); and claims made for common, minor symptoms associated with life stages ("for common symptoms of PMS," "for hot flashes").

Under DSHEA and existing regulations, dietary supplement manufacturers are already required to maintain documentation substantiating structure/function claims and must include a disclaimer on their labels that their products are not drugs and receive no FDA pre-market approval. They must also notify the FDA of the claims they are making within 30 days of marketing.

The final rule became effective February 7, 2000. For further information contact Ann Marlin Witt, Office of Policy, Planning, and Legislation (HF-11), FDA, 5600 Fishers Lane, Rockville, MD 20857, 301/827-0084.

Tablet-Splitting Policies Raise Concern

Some state boards of pharmacy are concerned about the cost-saving initiatives of certain health care plans that encourage or mandate the practice of dispensing higher doses of certain medications so that patients must split the tablet to obtain the appropriate dose. Targeted are those high-cost drugs that are available in similarly priced higher- and lower-dose tablets, such as Zoloft®, which has 50 mg and 100 mg dosages selling for about the same price. Medical insurance plans favoring this method of cost cutting provide pill-cutters to enrollees and instruct physicians to prescribe the higher dosage tablets.

Inaccuracies in tablet splitting, the lack of testing on the effectiveness of split pills, and the potential for overdosing are the primary issues of concern. "As a cost-saving measure, tablet splitting may be considered in certain situations; however, health care insurers should not mandate such practices for financial gain without regard to patient safety," says NABP President Dyke F. Anderson. "The pharmacist is ultimately responsible for providing adequate patient counseling, and for assuring that tablet-splitting is safe and appropriate for the patient."

FDA Targets Illegal Internet Prescription Sales

The US Food and Drug Administration (FDA) is furthering its efforts to combat illegal Internet prescription drug and device sales. The agency recently announced that it has issued, via the Internet, warning letters to a dozen foreign-based Internet

Compliance News

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Web site operators suspected of illegally offering to sell prescription drugs. This is the first time the FDA has used the Internet as a means for reaching those suspected of violating the Federal Food, Drug, and Cosmetic Act. In each case, the agency sent electronic letters to the domain holders of sites suspected of engaging in illegal prescription dispensing activities. The "cyber" warnings outlined the nature of the alleged violations and requested a formal response. They also explained the statutory provisions that govern interstate commerce of drugs in the US and warned that future shipments of products into this country might automatically be detained and refused entry. To date, the FDA has received one response indicating that the operator will cease its illegal activities. The FDA has indicated that it may use this approach in its efforts to crack down on domestic Web sites conducting illegal activities.

On another front, as part of its attempt to increase public awareness about the health, economic, and legal risks of online sales of prescription drugs and medical products, the agency recently established a Web site to provide consumers with information about buying such products online. The site provides information on FDA enforcement efforts, how to spot health care fraud, and how to protect oneself from dangerous online practices. It also has an electronic complaint form for consumers to report suspect sites. The FDA Web site may be accessed at www.fda.gov.

DEA Issues Guidelines to Avert Drug Abuser Scams

The US Drug Enforcement Administration has posted on its Web site guidelines for health care practitioners to avoid being scammed by drug abusers. The guidelines describe common characteristics of drug abusers (ie, assertiveness, unusual knowledge of controlled substances) and modus operandi often used in their efforts to obtain drugs (ie, seeks services after normal business hours, pressures practitioners by eliciting sympathy or guilt). The guidelines also summarize "do's" and "don'ts" for practitioners.

Entitled "Don't Be Scammed By A Drug Abuser," this publication can be found at www.usdoj.gov/dea/programs/diversion/divpub/pub120799.htm.

Pharmacist Impairment

A number of state boards of pharmacy report a growing concern with pharmacists procuring and using prescription medications for their own use. Besides constituting an illegal activity, these activities place the patient and pharmacist in a potentially dangerous situation. In situations where the pharmacist has become impaired and has not sought assistance through a state board-recognized impairment program, disciplinary actions have often resulted. The state boards of pharmacy are encouraging pharmacists to seek assistance if they believe they are suffering from impairment and to avoid disciplinary actions and dangerous situations. Most programs ensure the confidentiality of those who call for assistance.

NABP Announces Internet Licensure and Renewal Program

As early as this spring, if your state board of pharmacy participates in NABP's Internet License and Renewal Program, pharmacists will be able to renew their licenses via the Internet.

The system, which is being developed in conjunction with eGovnet, a provider of Web-based solutions for online transactions, is being pilot tested. NABP plans on having the program fully operational by late spring or early summer. Once activated, pharmacists will be able to renew their license in a matter of minutes using the Internet and a credit or debit card. The system will also allow for the licensing and renewal of pharmacy licenses/registrations and any other entity under the jurisdiction of the state boards of pharmacy.

Computerized NISPC DSM Program Available this Spring

Beginning in May 2000, the National Institute for Standards in Pharmacist Credentialing (NISPC) disease state management (DSM) program will offer pharmacists a new, computerized format of NABP's DSM examinations in anticoagulation, asthma, diabetes, and dyslipidemia.

NABP, owner, developer, and administrator of the DSM exams will utilize LaserGrade, Vancouver, Wash, to administer the examinations. According to NABP Competency Assessment and Support Programs Director Ron Hanchar, LaserGrade has more than 200 testing sites nationwide.

Developed to access the competencies of practicing pharmacists in disease state management, the NISPC DSM program should not be considered "entry-level." NISPC recommends that pharmacists have at least two years of practice experience prior to sitting for the exams.

Pharmacists will have the option of taking one, two, three, or all four of the examinations by appointment. The fee for each examination is $135, which includes the NISPC credential. Pharmacists registering for two or more exams on the same registration form will pay $135 for the first exam and $110 for the others.

For more information about the availability of the NISPC DSM examinations in your state, call NABP at 847/698-6227, or visit NABP's Web site at www.nabp.net.

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the beyond-use date for these products was six months, or 25% of the remaining time provided by the manufacturer's label, whichever was less.

Essentially, the new beyond-use date provides patients with a longer period of time to use the medication. To use the longer beyond-use date, the dispenser repackaging a product into single-unit or unit-dose containers must maintain controlled room temperature in the facility where the repackaging occurs and where the repackaged product is stored. In addition, the plastic material used for repackaging must provide better protection against moisture permeation than polyvinyl chloride.

Disciplinary Actions (00-04-76)

During its February 10, 2000 meeting, the Board took final action on the following cases. Although every effort is made to ensure the information is correct, you should call the Board at 225/925-6496 to verify the accuracy of the listing before making any decision based on this information.

Kristine O. Barz, Technician Certificate No. 3416. Voluntary Consent Agreement: The certificate was revoked. *Charges:* Unprofessional conduct or conduct endangering the public, violating or attempting to violate pharmacy laws, rules, or regulations, dispensing or distributing or possessing with intent to dispense or distribute a controlled dangerous substance in Schedule III without a valid prescription.

Bloom Drug Co., Permit No. 2110. The Board accepted the voluntary surrender of the permit. *Charges:* Unprofessional conduct or conduct endangering the public health, violating or attempting to violate pharmacy laws or other federal or state laws pertaining to the practice of pharmacy, dispensing medications with improper labeling, and dispensing misbranded medications.

Gary M. Gunn, License No. 11151. Voluntary Consent Agreement: License was suspended indefinitely, assessed $5,000, and prohibited from applying for reinstatement before January 1, 2003. *Charges:* Unprofessional conduct or conduct endangering the public health, violating or attempting to violate pharmacy laws or other federal or state laws pertaining to the practice of pharmacy, dispensing medications with improper labeling, and dispensing misbranded medications.

Petmed Express, Inc., Permit No. 3667. Voluntary Consent Agreement: Permit owner assessed $3,000. *Charges:* Failure to verify a prescription prior to dispensing Heartgard.

Kathleen R. Williams, Technician Certificate No. 3576. The Board accepted the voluntary surrender of the certificate, and ordered an indefinite suspension, effective December 26, 1999. *Charges:* Unprofessional conduct or conduct endangering the public, violating or attempting to violate pharmacy laws, rules, or regulations, dispensing a Schedule II controlled substance with no valid prescription, and obtaining possession of a controlled substance by forgery.

Steve L. Wilson, Jr., License No. 15952. The Board accepted the voluntary surrender of the license, and ordered an indefinite suspension, effective January 30, 2000. *Charges:* Practiced pharmacy in violation of pharmacy laws, rules, or regulations, departed from or failed to conform to the minimal standards of acceptable and prevailing pharmacy practice, whether or not actual injury to a patient has occurred.

In addition, the Board accepted the voluntary surrender of two licenses from impaired pharmacists, approved two requests for modification of probation, approved one request for reinstatement on probation, approved one petition for initiation of the reinstatement process, and denied one request for removal of probation.

Lagniappe (00-04-77)

If you can imagine it, you can achieve it. If you can dream it, you can become it.

Special Note (00-04-78)

The *Louisiana Board of Pharmacy News* is considered an official method of notification to pharmacists and certified pharmacy technicians licensed by the Louisiana Board of Pharmacy. **These *Newsletters* will be used in hearings as proof of notification.** Please read them carefully and keep them for future reference.

The *Louisiana Board of Pharmacy News* is published by the Louisiana Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc., to promote voluntary compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

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