October 1998

Louisiana Board of Pharmacy

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Retiring Board Members (98-10-21)

Thomas J. "Pete" Chambliss, of Baton Rouge, served as a Board member for District 4 from 1992 to 1998. Pete has been the secretary of the Board, and has served as chairman of the Reinstatement and the Examination Committees.

Carl J. Napoli, Sr., of Baton Rouge, served as a Board member for District 6 from 1980 to 1998. Carl has served as a past first vice president of the Board, and has served on various committees.

Allan L. Brinkhaus, of Sunset, served as a Board member for District 7A from 1984 to 1988 and from 1992 to 1998. Allan also served as a member on the demanding Violations Committee.

During their combined tenure of 34 years, these three members have participated with loyalty and dedication to the Board, their profession, and the people of the state of Louisiana. Their many sacrifices and contributions to our profession have not gone unnoticed. To these three former members of the Board, we thank you for a job well done!

New Board Members (98-10-22)

Effective July 28, 1998, Governor Mike Foster appointed the following pharmacists to the Board: District 1: reappointed Salvatore J. D'Angelo; District 2: reappointed Reuben R. Dixon; District 4: Clovis S. Burch, vice Thomas J. Chambliss; District 6: Wayne A. Camp, vice Carl J. Napoli, Sr.; District 7A: Charles D. Trahan, vice Allan L. Brinkhaus; District 7B: Theodore S. Carmichael, vice Charles D. Trahan. All terms will expire July 28, 2004, with the exception of District 7A, Charles Trahan, which will expire July 28, 2000.

To the new members, we offer congratulations and bid you welcome to the Board. We look forward to working with you.

CPE Requirements for 1999 (98-10-23)

Effective January 1, 1999, the Board of Pharmacy will require 15 hours of American Council on Pharmaceutical Education (ACPE) approved continuing pharmaceutical education (CPE). The board will not require specified ACPE-approved courses. This is not to be confused with the special CPE requirements for the current year of 1998, which require a minimum of 12 hours of ACPE-approved courses dealing with drug therapy (the last two digits "01" of the CPE number indicate drug therapy) and three hours of non-specified ACPE-approved courses.

Once again, in 1998, you will be required to obtain 12 hours of drug therapy courses. In 1999 you will be required to obtain 15 hours of CPE in any non-specified ACPE-approved courses.

Registration Renewal (98-10-24)

Folks! It's that time of year again. **All pharmacist licenses and all pharmacy permits expire December 31, and must be renewed prior to January 1. The Board will mail all pharmacist and pharmacy renewal applications on October 28.**

The Board starts printing renewal applications on or about October 15. So, pharmacists, if you have an address change and have not notified the Board office, your application will be mailed to the address we have on file at that time. Any address changes submitted to the Board office on or after October 15 will not be reflected on your renewal application.

If you do not receive a renewal application on or before November 15, it is your responsibility to obtain one. Applications have been provided to all pharmacists-in-charge for placement in the law book. Pharmacists, refer to page 336.9. Pharmacists-in-charge, page 336.10 is yours. Make a copy of the form and return the original form to the law book for future use.

Web Site Update (98-10-25)

Since fall 1997, the Board has had a presence on the World Wide Web at www.labp.com. The Board has provided the following information to better serve you:

Online Materials–Title 37, Louisiana Pharmacy Law; Title 51, Louisiana Out-of-State Pharmacy Registration Act; Title 40, Uniform Controlled Dangerous Substances Law; and Title 46, Louisiana Administrative Code, Part LIII, Pharmacists (Pharmacy Regulations).

Licensing Requirements–Brief synopses of licensing requirements for pharmacy graduates and pharmacy technicians are currently online. Soon to come will be the process required for currently licensed pharmacists who wish to obtain licensure by reciprocity, and the process for applying for an initial pharmacy permit, both in-state and out-of-state.

Online Forms–Within the next month, the Board will place under "Online Materials–Online Forms" the Application for Pharmacy Extern/Intern Registration, Application for Extern/Intern Work Permit, Preceptor's Affidavit for Extern/Intern Hours, Application for Pharmacy Tech Work Permit, Application for Pharmacy Tech Examination, Affidavit for PIC to document Pharmacy Tech Hours, Official Application for In-State Pharmacy Permit, Application for Out-of-State Pharmacy Permits, and all other forms the Board provides as a courtesy in the law book.

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Pharmacy Moves Towards National Credentialing for Disease State Management

In May 1998, a new chapter in pharmacy history began when it was announced that the Health Care Financing Administration (HCFA) had approved a Medicaid waiver that would allow Mississippi pharmacists to receive payment for providing pharmaceutical care to patients in four disease states: anticoagulation, asthma, diabetes, and dyslipidemia. Since then, a coalition of national pharmacy associations and industry representatives have been working to establish pharmacist credentialing for disease state management (DSM), both in Mississippi and across the nation.

The Mississippi State Board of Pharmacy, the University of Mississippi School of Pharmacy, the National Association of Boards of Pharmacy (NABP), and other interested pharmacy groups worked cooperatively to develop a credentialing process for disease state management by HCFA's July 1, 1998 deadline. The result was a process adopted by the Mississippi Board that requires pharmacists to pass a disease state specific examination and participate in a Board-approved, one-day performance skills workshop. The first DSM credentialing examinations for asthma, diabetes, and dyslipidemia were successfully administered to Mississippi-licensed pharmacists on July 8 and 9, 1998.

In a move towards establishing a national credentialing examination, NABP, the National Association of Chain Drug Stores (NACDS), and the National Community Pharmacists Association (NCPA) cooperatively formed the National Institute for Standards in Pharmacist Credentialing (NISPC), whose purpose is to coordinate the development of standards for DSM examination programs. Credentialing development includes setting the standards and guidelines for the DSM examination programs, establishing the skill and knowledge competency expectations for the respective DSM exam programs, and developing the evaluation instruments to assure that each pharmacist who completes the various DSM exam programs possesses the adopted competencies.

"The efforts of our three organizations and other interested members of the pharmacy community have encouraged the development of a quality credentialing program that is objective and defensible," said Carmen A. Catizone, NABP's executive director/secretary. "The program will provide the public with unprecedented access to pharmacists credentialed in disease state management, and will assist pharmacists in pursuing credentialing through a practical, valid, and economical process."

NABP and NISPC have created DSM credentialing examinations for asthma, diabetes, and dyslipidemia. These examinations, along with a fourth exam for anticoagulation therapy, will be offered in cooperation with the state boards of pharmacy, beginning with the first nationwide test administration on October 28 and 29, 1998. Examination programs for other disease states will be developed as required.

The national credentialing model relies on NABP's examinations as the universally recognized "standardizing" credential for disease state management. However, the model also encourages pharmacists to participate in educational programs that they feel best meet their individual needs.

The standards for each of the DSM exams have been made available to organizations that develop educational and experiential programs for pharmacists, such as NCPA's National Institute for Pharmacist Care Outcomes (NIPCO). Release of this information helps ensure that the programs preparing pharmacists for patient care are consistent with the competencies of NABP's examinations.

NABP will also maintain a national database of pharmacists who pass the DSM examinations. The database will be part of NABP's searchable Pharmacist and Pharmacy Achievement and Discipline™ (PPAD™) database, which is available through the Association's Web site at www.nabp.net.

More information about NABP's DSM examinations may be obtained from NABP's Web site or by calling the Association at 847/698-6227. For information about the status of disease state management credentialing in an individual state, contact the state board of pharmacy office.

DEA Clarifies Schedule II Faxing Rule for Hospice Patients

The Drug Enforcement Administration (DEA) recently responded to a request from NABP to clarify the provisions of Title 21, Code of Federal Regulations, Section 1306.11 (g), which permits the facsimile transmission of a Schedule II prescription by a practitioner or his/her agent "...for a patient *residing* in a hospice certified by Medicare under Title XVIII or licensed by the state..."

Clarification from the DEA was necessary because of confusion among various state agencies that were incorrectly interpreting the rule to mean that only those patients who reside in a long-term care facility could benefit from necessary prompt adjustments to their pain relief medications. In a letter to NABP, Patricia M. Good, chief of the Liaison and Policy Section of the DEA's Office of Diversion Control, emphasized the rule "was never intended to be 'venue' specific."

"The qualification of Title XVIII certification or state licensure was deemed to be sufficiently broad enough to encompass all circumstances which terminally ill patients would

encounter, including those circumstances in which the hospice patient continues to reside in his/her residence," Good explained. "The 'venue specific' interpretation of this regulation, which requires the patient to reside in a location (such as a long-term care facility), clearly is a restriction not placed by, nor intended by, the regulation."

FDA Approves Thalidomide Use, Distribution System

On July 16, 1998, the Food and Drug Administration (FDA) announced that it had approved the drug thalidomide in treating erythema nodosum leprosum (ENL), a serious inflammatory condition in patients with leprosy, along with a restricted system of distribution intended to prevent fetal exposure to the drug. Originally used in the 1950s and 1960s outside the United States as a sedative and as a treatment for morning sickness during pregnancy, thalidomide use by pregnant women resulted in major fetal abnormalities, including amelia (absence of limbs), phocomelia (short limbs), hypoplasticity of the bones, absence of bones, external ear abnormalities, facial palsy, eye abnormalities, and congenital heart defects.

To prevent fetal exposure to thalidomide, the drug's manufacturer, Celgene, has developed a program titled System for Thalidomide Education and Prescribing Safety (STEPS). Only physicians and pharmacists registered in the STEPS program and trained in the risk of teratogenicity may prescribe and dispense thalidomide to patients. Additionally, all patients, both female and male, must comply with mandatory contraceptive measures, patient registration, and patient surveys.

The STEPS program requires that pharmacies dispensing thalidomide agree to several conditions. For example, at the time of first dispensing, the pharmacy must register the patient with the STEPS program, and must obtain and keep on file a signed patient consent form. The pharmacy may only dispense thalidomide based on a prescription that is no more than seven days old and may dispense no more than a one-month supply.

Prescriptions for female patients will not be filled without a physician's written report of a negative pregnancy test conducted within 24 hours of starting therapy. Pregnancy testing will continue to be required weekly during the first month of use, then monthly in women with regular menstrual cycles or every two weeks if cycles are irregular.

Although the number of patients being treated for leprosy in the United States is low (about 2,000 patients), the FDA and Celgene anticipate that thalidomide will be prescribed "off-label" for patients with certain dermatological conditions related to cancer and AIDS.

For further information, contact the FDA at 1-800/532-4440 or log onto the FDA Web site at www.fda.gov. Information may also be obtained from Celgene by calling 1-800/890-4619, ext. 4083.

New "Rx Only" Symbol Causing Confusion

New prescription product labeling requirements established by the Food and Drug Administration Modernization Act of 1997 (FDAMA) for pharmaceutical manufacturers may be causing some confusion among pharmacists and pharmacy staff, according to an article published in the July 1998 issue of *Pharmacy Today*.

Under the FDAMA, manufacturers' prescription packaging must carry, at a minimum, the symbol "Rx only," instead of the statement, "Caution: Federal law prohibits dispensing without prescription." This change was implemented to simplify drug labels and to reduce the incidence of medication errors caused by overcrowded labels.

Some pharmacists and pharmacy personnel, however, appear to be unaware of the new symbol. The article cites a letter to the American Pharmaceutical Association (APhA) from a prescription drug manufacturer that had received reports of pharmacy staff "putting some prescription medications out with the OTC products in error because of the lack of the [federal legend] statement."

Manufacturers must comply with the new labeling requirements by February 19, 2003.

NABP/State Boards Introduce Multistate Pharmacy Jurisprudence Examination

On November 2, 1998, the National Association of Boards of Pharmacy (NABP) begins to administer its new Multistate Pharmacy Jurisprudence Examination™ (MPJE™), a computer-based examination that assists participating state boards of pharmacy in assessing licensure candidates' knowledge of the jurisprudence requirements to practice pharmacy. The MPJE, which replaces the paper-and-pencil Federal Drug Law Examination™ (FDLE®) and many individual state law exams, will assess knowledge of both federal and state pharmacy jurisprudence requirements.

The computerized exam will be administered Monday through Friday, excluding holidays, on a year-round testing schedule through the Cogent Testing Network℠. In addition to the test administration for pharmacist licensure candidates, the examination may be used by participating boards of pharmacy as a requirement for licensure transfer between states.

Contact the individual state boards of pharmacy for more information about whether a state requires the MPJE.

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Newsletters–January 1997, January 1998, April 1998, and July 1998 are presently online.

Board Meeting Minutes–Minutes of the Board meetings of January 1998 and April 1998 are online.

Consumer Information–Timely consumer information will soon be provided.

Progress At Your Board Office (98-10-26)

The Louisiana Board of Pharmacy is making changes to better serve you!!

In order to serve the public, pharmacists, pharmacy students, and pharmacy technicians to the best of the Board's ability, it was felt that a new automated phone system was one solution to help the office become more efficient.

The new phone system will provide pre-recorded, up-to-date information that will save you time. The staff will continue to address your questions and give you the personal attention that you have come to expect.

Ms. Jo Ellen Prather joined the Board staff in July 1998. Ms. Prather's responsibilities will be focused on the pharmacy technician program. We welcome her on board and wish her continued success.

Veterinary Legend Drugs (98-10-27)

A question that frequently arises is the following: What is the difference between the labeling *"Federal law restricts this drug to use by or on the order of a licensed Veterinarian"* and *"For veterinary use only"*?

Drugs intended for use on animals may be labeled by the manufacturer in two ways:

1. *"Federal law restricts this drug to use by or on the order of a licensed Veterinarian."*
   Any drug with this caution label must only be dispensed by a pharmacist on a valid prescription order from a licensed veterinarian. These drugs must be kept in the prescription department and proper records kept of their distribution.
2. *"For veterinary use only."*
   Any drug with this caution label may be sold over-the-counter (OTC) and could be stocked with other OTC medications for use by customers on their pet animals.

Pharmacists-Students-Technicians (98-10-28)

If you are a pharmacist-in-charge, you must, at all times, ensure that all personnel you allow to function in your prescription department are properly licensed, certified, or possess a valid work permit. (Student pharmacists or technicians-in-training need a valid work permit for your store.) The only exception would be student pharmacists in the pharmacy school's training program, in conjunction with the pharmacy curriculum.

If you are a staff or relief pharmacist, it is your responsibility to ensure that the employees assisting you in the prescription dispensing process are legally able to perform their duties during your shift. If an inspection or investigation occurs while you are on duty and unqualified persons are performing duties under your supervision, then you will be responsible to the Board in the investigative report filed by the Inspector.

Lagniappe (a little extra!!) (98-10-29)

The best way to cheer yourself up is to cheer someone else up.
—Mark Twain

Special Note

The *Louisiana Board of Pharmacy News* is considered an official method of notification to pharmacists 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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