



# Louisiana Board of Pharmacy

5615 Corporate Blvd., Suite 8E, Baton Rouge, LA 70808 Published to promote voluntary compliance of pharmacy and drug law.

## Change Creates Questions (98-07-16)

Someone once said change is what people fear most. Below are pharmacy technician questions that the Louisiana Board of Pharmacy office answers on a daily basis. The Board will continue to address your concerns as the pharmacy technician program evolves.

The start of knowledge begins with a question . . .

**Question:** *What are the Board's continuing education (CE) requirements for pharmacy technicians in 1998?*

**Answer:** The Board will not require CE hours for 1998. The Board will notify all Louisiana-certified pharmacy technicians if CE hours are required in 1999.

**Q:** *When will the next pharmacy technician examination be given by the Board?*

**A:** The Board has scheduled the next exam for August 8, 1998, at the University of New Orleans. Please note that all applications must be in the Board office 30 days before that exam date.

**Q:** *The Board told me I cannot receive my pharmacy technician certificate because I owe money for student loans.*

**A:** The Board office is required by Act 689 of 1990 to submit names of all applicants seeking issuance or renewal of certificates, licenses, or permits to the Louisiana Office of Student Financial Assistance (LOSFA) for clearance to verify that there are no defaulted student loans. If LOSFA notifies the Board office that an individual has defaulted on a student loan, the Board may not issue or renew any certificate, license, or permit unless a satisfactory arrangement between the applicant and LOSFA is made for repayment. After satisfactory arrangements are made, LOSFA notifies the Board office in writing.

**Q:** *My pharmacy technician just won the lottery and I have to hire and train a pharmacy technician candidate right away. What do I do and what is required?*

**A:** Here is a condensed version of what must be done:

1. The pharmacy technician candidate must successfully complete a Board-approved training program.
2. The pharmacy technician candidate must obtain a minimum of 200 training hours, only under the authorization of an on-site training work permit, which can be issued only after a training program has begun.
3. The pharmacist-in-charge must provide the Board with an affidavit of the training hours obtained.
4. The pharmacy technician candidate then may complete and submit to the Board an application and fee for the technician examination at least 30 days prior to the examination.
5. A minimum score of 75 must be obtained for a candidate to pass the examination.

This is a brief explanation of Chapter 8, Section 805, pages 133-134 of the Louisiana Board of Pharmacy Regulations. Please read and review the entire chapter.

**Q:** *I am a certified pharmacy technician. Why do I have to wear a name tag?*

**A:** The Board regulations specify that all pharmacy technicians shall be identified by a name badge and the "Pharmacy Technician" designation while working in the pharmacy. This is done for identification purposes and to ensure that the one-to-one pharmacist/technician ratio is complied with.

**Q:** *Now that I am a certified technician, I notice that the pharmacist-in-charge allows me to work alone in the pharmacy department while he runs errands. Is that OK?*

**A:** Positively **NO!** A pharmacy technician assists in the practice of pharmacy under the direct and immediate supervision of a Louisiana-licensed pharmacist. You are placing your certificate in serious jeopardy. If the pharmacist you work with does this again, halt all technician duties, and vacate and secure the pharmacy prescription department. The pharmacist's license is also subject to Board action.

**Q:** *We have a very busy store and I need help. Can I work alone with two technicians on duty at the same time?*

**A:** No! The ratio of no more than one pharmacy technician per supervising pharmacist on duty is the limit.

**Q:** *Can I, as a pharmacy technician, receive prescription orders over the phone?*

**A:** A pharmacy technician cannot receive an original, oral telephone prescription order. Refill information can be received by the technician, provided the refill information does not generate a new prescription order.

**Q:** *What if I do not pay my pharmacy technician renewal fee of \$50, since I just gave the Board \$100 in February?*

**A:** In February, you submitted \$100 to the Board of Pharmacy for the pharmacy technician examination in order to obtain an exemption. This exemption allowed you to waive the didactic pharmacy technician program and the on-site technician training program, which are now required. This examination fee is separate and apart from the \$50 renewal fee that you must send to the Board office with your completed, signed application for renewal. A certificate not renewed by July 15, 1998, will be null and void. You may not be employed as a technician unless you have a current certificate on display.

## Disciplinary Actions (98-07-17)

The Louisiana Board of Pharmacy held a formal administrative hearing on April 23, 1998, at the First Circuit Court of Appeals, 1600 North Third Street in Baton Rouge. Although every effort is

*Continued on page 4*



## **FDA Acts on Modernization Act of 1997**

The Food and Drug Administration (FDA) has been hard at work in response to the recent passage of the Food and Drug Administration Modernization Act of 1997 (FDAMA). Section 809 of the FDAMA exempts compounding by pharmacists and physicians from FDA regulation, under certain conditions, and also maintains that compounding is appropriately regulated at the state level by the boards of pharmacy.

### **Advisory Committee Established**

In accordance with the provisions of Section 809, the FDA has established a Pharmacy Compounding Advisory Committee "to provide advice on scientific, technical, and medical issues concerning drug compounding by licensed practitioners and to make appropriate recommendations to the Commissioner of Food and Drugs."

The March 10, 1998 announcement in the *Federal Register* states that the 15-member committee will include experts in pharmaceutical compounding, pharmacy practices specializing in compounding, general retail pharmacy practice, hospital pharmacy practice, fields of medicine in which compounding drugs or the use of compounded drugs is relatively common, pharmaceutical manufacturing, clinical toxicology, clinical pharmacology, chemistry, and related specialties.

The committee will also include a representative from the National Association of Boards of Pharmacy (NABP), the United States Pharmacopoeia (USP), a pharmacy organization, a physician organization, a consumer organization, and the pharmaceutical manufacturing industry.

### **Guidelines for Industry Available**

In the March 13, 1998 *Federal Register*, the FDA announced the availability of a guide for the pharmacy industry entitled "Implementation of Section 126, Elimination of Certain Labeling Requirements, of the Food and Drug Administration Modernization Act of 1997." The guidelines clarify FDA policy with respect to the implementation of certain FDAMA amendments to the Food, Drug and Cosmetic Act. The amendments addressed by the guidelines document include those which require that labels of prescription products, prior to dispensing, contain at a minimum the statement "Rx only" instead of "Caution: Federal law prohibits dispensing without prescription." Also addressed are those amendments that repeal the requirement that the labels of certain habit-forming drugs bear the statement "Warning - May be habit forming."

The guidelines describe the new prescription drug labeling requirements of the Food, Drug and Cosmetic Act as

amended by FDAMA and advise manufacturers, packers, and distributors of the policy that the FDA will follow in implementing the requirements of Section 126. The guidelines may be found on the Internet at <http://www.fda.gov/cder/guidance/index.htm>. Written requests may be submitted to the Drug Information Branch (HFD-210), CDER, FDA, 5600 Fishers Lane, Rockville, MD 20857. Include a self-addressed stamped envelope with each request.

## **FDA Declares OTC Quinine Misbranded**

In response to concerns about the use of over-the-counter (OTC) quinine for the treatment and/or prevention of malaria, the Food and Drug Administration (FDA) published a final rule in the March 20, 1998 *Federal Register* establishing that OTC drugs containing quinine for the treatment and/or prevention of malaria are not generally recognized as safe and are misbranded. This action reclassifies quinine as a new drug within the meaning of the Federal Food, Drug and Cosmetic Act and requires that FDA approval be obtained for marketing.

The decision to classify OTC quinine as unsafe was based on data and information examined by the FDA while it was reviewing OTC quinine for the treatment and/or prevention of nocturnal leg cramps. Quinine was removed from the market for this indication due to the lack of substantial evidence of effectiveness, along with evidence of toxicity at the doses recommended. Additionally, the FDA expressed serious safety and efficacy concerns with regard to the continued OTC availability of quinine for the self-treatment of malaria without the care and supervision of a physician.

This final rule became effective April 20, 1998. For further information, contact John D. Lipnicki, CDER (HFS-560), FDA, 5600 Fishers Lane, Rockville, MD 20857; 301/827-2222.

## **NABP Survey Indicates Increased Telepharmacy Regulation**

Over the past few years, a growing number of pharmacists have been providing pharmaceutical care across state boundaries, using increasingly sophisticated telecommunications technologies that allow cost-effective, rapid transmission of information over long distances. While these pharmacists provide such pharmaceutical care services as drug use evaluations and medication information, they do not dispense medications. As "telepharmacy" becomes more common, boards of pharmacy have begun to look at ways to regulate the practice.

Earlier this year, the National Association of Boards of Pharmacy (NABP) conducted a survey of the state boards

# Compliance News

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of pharmacy to discover how they were regulating telepharmacy. Although none of the 30 responding states have implemented a nonresident pharmacist registration requirement as recommended by NABP's Task Force on Telepharmacy, 10 to 13 percent appear to be applying their current laws and regulations to the practice of telepharmacy. Moreover, another 23 to 33 percent of the responding states indicated that they would be addressing the telepharmacy issue in the near future. "These regulatory efforts are significant because they recognize pharmaceutical care as a health care service provided by pharmacists," said NABP Chairman Franklin Z. Wickham. "The regulations also serve to protect patients from providers who have previously been outside the states' jurisdictional authority."

The survey results show that states applying their current laws and regulations to telepharmacy generally require full in-state pharmacist licensure for nonresident pharmacists who provide only pharmaceutical care, not pharmaceuticals, to their citizens. Another survey result, however, counters the philosophy that a pharmacist provides a service rather than just dispenses a drug product. About 23 percent of the responding states noted that their current nonresident pharmacy regulations require the locations from which these pharmacists provide services to be registered as nonresident pharmacies. This requirement would apply even though the pharmacists were not dispensing drugs into the state and even though such locations as home offices would be affected. Similarly, about 23 percent of the responding states would require locations that provide pharmaceutical care services within the state to be registered as pharmacies.

Licensure/registration was addressed by NABP's 1996-97 Task Force on Telepharmacy, which determined that a registration requirement should be established for nonresident pharmacists, as opposed to nonresident pharmacies, that provide pharmaceutical care to in-state citizens. The Task Force noted that such a registration requirement would allow states to identify those persons providing pharmaceutical care to their citizens, bring those providers under the state's jurisdiction, and ensure the providers' familiarity with the state's pharmacy practice laws.

NABP's telepharmacy survey presented the state boards with questions related to four telepharmacy practice scenarios reflecting actual questions the Association has received from pharmacists or pharmacies with regard to activities they would like to perform or are currently performing. A complete chart summary of the scenarios and the state boards' responses can be found on NABP's Web site, [www.nabp.net](http://www.nabp.net).

## ***NABP Launches Pharmacist and Pharmacy Achievement and Discipline Database on Web Site***

On June 1, 1998, the National Association of Boards of Pharmacy (NABP) launched its Pharmacist and Pharmacy Achievement and Discipline™ (PPAD™) database on the Association's Web site at [www.nabp.net](http://www.nabp.net). The database provides information regarding those disciplinary actions imposed by state boards of pharmacy that affect a pharmacist's ability to practice, and highlights the positive steps taken by pharmacists to enhance their ability to practice pharmacy.

Visitors to NABP's Web site may search the PPAD database by the pharmacist's name and state of residence or licensure. The database does not specify any additional identifying information, such as the pharmacist's address and phone number.

The following data is provided for disciplined licensees: the state or states in which the pharmacist is licensed and the license number(s), the state imposing the disciplinary action, the action imposed, and the effective date of the disciplinary action or the date NABP received notice of the disciplinary action from the board of pharmacy. The database does not disclose the reason that the board imposed the disciplinary action.

Actions reported in the disciplinary database are limited to license revocation, suspension, surrender of licensure, probation, termination of probation, and reinstatement of licensure. Minor actions, such as a censure, reprimand, fine, or monetary penalty, are not reported on the database. In the future, disciplinary information pertaining to pharmacies, interns, and technicians will be added.

NABP plans to expand the database to include information about the certification and accreditation achievements awarded individuals, such as successfully completing the Pharmacist Applied Knowledge and Judgment Assessment™ (PAKJA™), formerly known as the Pharmacist Continued Competency Assessment Mechanism™ (PCCAM™). PAKJA is a voluntary competency assessment tool scheduled for implementation in late 1999.

"The PPAD database was implemented to assist the state boards of pharmacy in fulfilling their responsibilities to protect the public health by providing access to crucial disciplinary information about their pharmacists," said NABP President Kevin E. Kinkade. "Pharmacy should be commended for taking the lead among the allied health care professions and making this important information available to consumers."

Continued from page 1

made to ensure disciplinary action information is correct, you should check with the Board (504/925-6496) to verify the accuracy of the listing before making any decision based on this information.

**Joel A. Fruge, #14466; Voluntary Consent Agreement:** License reprimanded and assessed \$250. *Charges:* Violating pharmacy laws and unauthorized dispensing of veterinary legend drugs.

**Robert N. Hall, #9994:** License suspended for two years effective April 15, 1997, then placed on probation for eight years and assessed \$5,000. *Charges:* Violating pharmacy laws, unauthorized dispensing of controlled drugs and forged prescriptions.

**Homer Memorial Hospital Pharmacy, #0469; Voluntary Consent Agreement:** Permit owners not to violate any pharmacy laws or regulations and assessed \$1,000. *Charges:* Operations for which the permit was issued are not being conducted in compliance with the rules and regulations of the Board and are being conducted so as to endanger the public.

**Kimberly Ann Kaiser, Technician Certificate #1647:** Action by the Interlocutory Committee to suspend certificate #1647 until ratified at the next office Board session.

**Nielsen City Drugs, Inc., #0821; Voluntary Consent Agreement:** Permit owner not to violate any pharmacy laws or regulations and assessed \$500. *Charges:* Operations for which the permit was issued are not being conducted in compliance with the rules and regulations of the Board and are being conducted so as to endanger the public.

**William W. Nielsen, Jr., #14238; Voluntary Consent Agreement:** License reprimanded and assessed \$250. *Charges:* Violating pharmacy laws and unauthorized dispensing of veterinary legend drugs.

**William W. Nielsen, Sr., #8607; Voluntary Consent Agreement:** License reprimanded and assessed \$250. *Charges:* Violating pharmacy laws and unauthorized dispensing of veterinary legend drugs.

**Karl P. Petry, #13125; Voluntary Consent Agreement:** License suspended for four months effective November 10, 1997, then placed on probation for 116 months and assessed \$5,000. *Charges:* Violating pharmacy laws, failure to maintain Schedule II invoices separately, failure to complete biennial inventory, failure to remove expired legend drugs, unauthorized dispensing of controlled and legend drugs, and probation violation.

**R. Lewis Rieger, #7077:** License suspended for six months effective June 1, 1998, then placed on probation for 114 months with special conditions and assessed \$5,000. *Charges:* Violating pharmacy laws, unauthorized dispensing of legend drugs, refilling legend drugs for more than one year without authoriza-

tion, failure to provide proper notice of store closure, and failure to maintain prescription files as required.

**H. Percy Taylor, #10923; Probation modified to allow Mr. Taylor to be pharmacist-in-charge.**

**Thibodeaux Pharmacy, Inc., #2606; Voluntary Consent Agreement:** Permit placed on probation for two years and assessed \$2,000. *Charges:* Violating pharmacy laws, operations for which the permit was issued are not being conducted in accordance with the rules and regulations of the Board or are being conducted so as to endanger the public.

**R. Blake Vidrine, #10232; Voluntary Consent Agreement:** License reprimanded and assessed \$250. *Charges:* Violating pharmacy laws and unauthorized dispensing of veterinary legend drugs.

The Board also adjudicated 11 cases in the impaired pharmacist program.

### **Board Adopts Changes in Pharmacy Rules (98-07-18)**

In April, the Board of Pharmacy promulgated several changes in the pharmacy rules. The Board mailed copies to all permitted pharmacy sites. If you would like a copy of the regulation changes, simply write to the Louisiana Board of Pharmacy and request them.

### **Lagniappe (a little extra!!) (98-07-19)**

The next time your colleagues think they have the future figured out, remind them of this famous prediction: "The telephone has too many shortcomings to be seriously considered as a means of communication. The device is inherently of no value to us." (Western Union internal memo, 1876)

### **Public Notice (98-07-20)**

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.

Page 4 - July 1998

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