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Louisiana Board of Pharmacy

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Renewal of Pharmacy Technician Certificates (07-04-267)

The Louisiana Board of Pharmacy office will begin printing renewal applications during the week of April 16, 2007. Any address changes received after April 13, 2007, will not be reflected on the renewal application. We will mail the renewal applications during the week of April 23, 2007. If you do not receive your application by May 15, 2007, it becomes your responsibility to obtain a renewal application. You may download a replacement renewal application form from our Web site at *www.labp.com*.

For the second year in a row, technicians will be able to renew their certificates online; that portion of the Web site will be operational from May 1, 2007 through June 30, 2007. We have removed the convenience fee for online renewal transactions, so the renewal fee will be the same for both paper and electronic applications. The difference will be the processing time. We mail renewals from online transactions within one to two days, but it will take substantially longer with paper transactions.

All technician renewals will expire on June 30, 2007, regardless of the date of issue. Technicians may not practice with an expired renewal. The renewal of an expired certificate will incur an additional $25 penalty, as well as an additional $200 reinstatement fee. Applications bearing a postmark from the mail service of July 1, 2007, or later must be accompanied by the additional fees, or the package will be returned to the sender unprocessed, causing additional delays. If you need to be in possession of a current renewal before July 1, 2007, we suggest that you mail the properly completed application and fee on or before May 30, 2007, using the mail tracking service of your choice. If you find yourself without a current renewal for the 2007-2008 year and it is close to the deadline, you may wish to consider the online renewal option.

Revised Procedures for Applications for New Pharmacy Permits (07-04-268)

The 2003 Louisiana Legislature passed Act 1052 authorizing the Board to require criminal history record checks for applicants of credentials issued by the Board. You may recall we initiated these procedures for all persons (pharmacists, interns, technicians, and technician candidates) in January 2004. During the December 2006 meeting, the Board voted to complete the implementation of the law by requiring criminal history record checks for applicants of new pharmacy permits.

Since applications for new pharmacy permits require the signature of the owner's managing officer and the pharmacist-in-charge, the criminal history record check will be required for both persons signing the application. Applicants who have previously submitted a criminal history record check for the Board will not be required to repeat that process.

Disciplinary Actions (07-04-269)

Although every effort is made to ensure the information is correct, you should call the Board office at 225/925-6496 to verify the accuracy of any listing before making any decision based on this information.

During its August 17, 2006 administrative hearing, the Board took final action in the following matters:

Jared Paul Latiolais (Technician Certificate No. 1889), Formal Hearing: Certificate revoked; further, respondent assessed $5,000 plus investigative, administrative, and hearing costs. *Charges*: five counts, including theft of controlled substances from employer pharmacy.

Downtown Drugs, Inc (Pharmacy Permit Applicant), Formal Hearing: Permit application denied, and further, respondent assessed administrative and hearing costs. *Charges*: three counts, including attempted acquisition of permit by fraud or misrepresentation.

The Medicine Shoppe (Pharmacy Permit No. 2662), Formal Hearing: Permit suspended for five years with execution thereof stayed, and then placed on probation for five years beginning September 21, 2006, and further, permit holder was assessed a fine of $108,777 (*in solido* with Steve Patrick Michel), plus investigative, administrative, and hearing costs. *Charges*: six counts, including dispensation of prescription drugs based solely on results of electronic questionnaires and failure to conform to minimal standards of acceptable and prevailing pharmacy practice.

Steve Patrick Michel (Pharmacist License No. 11199), Formal Hearing: License suspended for five years, beginning September 21, 2006, with execution of all but the first six months stayed, and then the license was placed on probation for the remainder of the original five-year suspensive period beginning on March 21, 2007, and further, respondent was assessed a fine of $108,777 (*in solido* with MPI, Inc d/b/a The Medicine Shoppe), plus investigative, administrative, and hearing costs. *Charges*: seven, including dispensation of prescription drugs based solely on results of electronic questionnaires, failure to verify authenticity of prescriptions, and failure to conform to minimal standards of acceptable and prevailing pharmacy practice.

During its December 7, 2006 administrative hearing, the Board took final action in the following matters:

Lewis Duane Roe, Jr (Technician Candidate Registration No. 10182). Formal Hearing: Registration revoked; further, respondent assessed $500 plus investigative, administrative, and hearing costs. *Charges*: five counts, including unlawful practice for approximately nine months with an expired registration.

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FD&C Act Holds Manufacturers Accountable for Availability of Medication Guides

Under the Federal Food, Drug, and Cosmetic (FD&C) Act, Food and Drug Administration (FDA) requires that Medication Guides be dispensed with products the agency deems a serious and significant public health concern. Medication Guides provide consumers with information about the risks and benefits of these drugs and are necessary for patients to use these products safely and effectively.

FDA is interested in receiving reports about all instances in which manufacturers, distributors, or packers are not complying with the Medication Guide distribution requirements as set forth in Title 21, Code of Federal Regulations (CFR), section 208.24, Distributing and dispensing a Medication Guide.

The regulation requires manufacturers, distributors, or packers to provide authorized dispensers with Medication Guides – or the means to produce Medication Guides – in sufficient numbers to provide one to each patient who receives the drug. The manufacturer is responsible for ensuring that pharmacists have the Medication Guides they need when dispensing these drugs to consumers.

Problems related to the availability of Medication Guides are a labeling concern to FDA, and pharmacists are often the first to become aware of these problems. Voluntary reporting by pharmacists of these instances would assist FDA in ensuring manufacturer, distributor, and packer compliance with the Medication Guide regulatory requirement.

In addition to reporting to FDA, the agency advises pharmacies to contact the manufacturers directly to discuss problems associated with the availability of Medication Guides.

More information is available at *www.fda.gov/medwatch/report/hcp.htm*. Reports can also be made by phone at 1-800/FDA-1088.

Infant Deaths Attributed to Cough and Cold Medications

The Centers for Disease Control and Prevention (CDC) issued a Morbidity and Mortality Weekly Report article describing three deaths of infants ranging in age from one to six months associated with cough and cold medications. These medications were determined by medical examiners or coroners to be the underlying cause of death.

According to the report, the three infants – two boys and one girl – had what appeared to be high levels (4,743 ng/mL to 7,100 ng/mL) of pseudoephedrine in postmortem blood samples. One infant had received both a prescription and an over-the-counter (OTC) cough and cold combination medication at the same time; both medications contained pseudoephedrine.

During 2004-2005, an estimated 1,519 children younger than two years were treated in emergency departments in the United States for adverse events, including overdoses, associated with cough and cold medications.

Because of the risks, parents and caregivers should consult a health care provider before administering cough and cold medications to children in this age group. Clinicians should use caution when prescribing cough and cold medications to children younger than two years. In addition, clinicians and pharmacists should always ask caregivers about their use of OTC combination medications to avoid overdose from multiple medications containing the same ingredient.

The complete article is available at *www.cdc.gov/mmwr/preview/mmwrhtml/mm5601a1.htm.*

Changes in Medication Appearance Should Prompt Investigation

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that works closely with United States Pharmacopeia (USP) and FDA in analyzing medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, then publishes its recommendations. If you would like to report a problem confidentially to these organizations, go to the ISMP Web site (www.ismp.org) for links with USP, ISMP, and FDA. Or call 1-800/23-ERROR to report directly to the USP-ISMP Medication Errors Reporting Program. ISMP address: 1800 Byberry Rd, Huntingdon Valley, PA 19006. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.

As the number of generic products continues to increase, it seems that both patients and practitioners have become desensitized to changes in medication appearance. So much so that patients may not question a change or, when they do, practitioners may simply reassure them that it was due to a change in manufacturer without actively investigating the reason. It is not uncommon for ISMP to receive reports from both practitioners and consumers where a change in medication appearance was not fully investigated and subsequently contributed to an error.

In one case, a man shared an account of what his 86-year-old father experienced over the course of nine days after his prescription for minoxidil was mistakenly refilled with another medication. He had been taking minoxidil 2.5 mg for years at a dose of 5 mg (2 tablets) twice daily. Due to failing vision, he did not realize that his minoxidil tablets looked different. His daughter noticed the change, but was unconcerned since the tablets had previously changed appearance. Within a few days of taking the medication, his appetite began to fade, he complained of a sore throat, and felt like he was coming down with a cold. Soon after, he developed a red rash on his face, had trouble maintaining his balance, needed assistance with his daily activities, and wished to remain in bed. When a family friend (a nurse) came to see him, she noticed a very red, raised rash on his abdomen that looked like a medication rash. She asked his daughter if he was taking any new medications and was informed that there were no new medications, but the minoxidil tablets looked different than before. The pharmacy was contacted about the change and a staff member explained that it was a different generic for minoxidil, and that the pills could be exchanged for those that he usually received. There was no mention of a mistake being made when the medication was exchanged. He was taken to the hospital the following day, when he could barely walk.

After this incident was explained to hospital staff, they contacted the pharmacy. It was then revealed that he was given methotrexate by mistake because the bottles were stored next to each other. By this time, the man had taken 36 methotrexate 2.5 mg tablets, his white blood cell and platelet counts were extremely low, and he was in critical condition. We later learned that he passed away during that hospital visit.

In another case, a breast cancer patient went to her pharmacy to pick up a refill for **Femara**® (letrozole) but instead received the estrogen replacement product **femhrt**® (norethindrone and ethinyl estradiol). The patient recognized that the tablets were different, but after she read the label on the prescription bottle, which indicated Femara, she proceeded to use the tablets thinking the pharmacy used another manufacturer's product. After some time, she began to experience bloating, low back pain, and menstrual spotting. The error was discovered when she visited the clinic and the practitioner asked to see her medication. It is believed that disease progression had occurred secondary to the estrogen exposure, as evidenced by increased tumor markers. As a result of the error, chemotherapy was restarted.

The nature of these errors (wrong product dispensed on a refilled prescription despite a correct interpretation of the prescription) reinforces the need for the prescription verification process to be standardized. Verification should include comparisons of the pharmacy label with the selected manufacturer's product and the original prescription (whenever possible). In addition, the national drug code (NDC) number on the manufacturer's product should be compared to the NDC number in the pharmacy computer system. Pharmacies that utilize drug-imaging technology or bar code scanners as part of their verification process experience fewer of these errors.

Patients should be made aware of what their medication will look like and be educated to always question any change in its appearance. Pharmacies could consider software that allows a description of the medication's appearance to be printed on either the pharmacy label or receipt. Staff and patients should then be educated about proper use of this method. Ideally, pharmacists should proactively communicate with patients about the appearance of their medication by showing the medication to them during counseling and alerting them whenever a change occurs. Pharmacists should thoroughly investigate questions raised by patients or caregivers. Consider making it mandatory for pharmacists to investigate all inquiries related to changes in medication appearance. Although an auxiliary label can be placed on the medication container or the pharmacy receipt to alert the patient or caregiver that a change in appearance has occurred, the label may go unnoticed.

FDA Launches CDERLearn Educational Tutorial on MedWatch

FDA's Center for Drug Evaluation and Research (CDER) has launched its new Web-based self-learning tutorial, FDA MedWatch and Patient Safety, available at *www.connectlive.com/events/fdamedwatch*. This tutorial is intended to teach students in the health care professions and practicing health care professionals about FDA's Safety Information and Adverse Event Reporting Program, known as MedWatch.

The module explains how MedWatch provides important and timely clinical safety information on medical products, including prescription and OTC drugs, biologics, medical and radiation-emitting devices, and special nutritional products (eg, medical foods, dietary supplements, and infant formulas). It also describes how the reporting of serious adverse events, product quality problems, and product use errors to MedWatch is essential to FDA's safety monitoring process and to improving patients' safe use of medical products. The module consists of a 30-minute video and PowerPoint program with optional quiz and certificate of completion.

Three additional free programs for health professionals are available on the CDERLearn site, on the topics of the drug development and review process, the generic drug review process, and osteoporosis. Continuing education credit for these three programs may be awarded after completion of a quiz and evaluation form.

More information is available at *www.fda.gov/cder/learn/CDERLearn/default.htm*.

ONDCPRA Increases Patient Limit for Physicians Authorized under DATA 2000

The Office of National Drug Control Policy Reauthorization Act of 2006 (ONDCPRA) has modified the restriction on the number of patients a physician authorized under the Drug Addiction Treatment Act of 2000 (DATA 2000) may treat.

Under DATA 2000, physicians were restricted to treating no more than 30 patients at any one time. Under ONDCPRA, which became effective on December 29, 2006, physicians meeting certain criteria may notify the Secretary of Health and Human Services of their need and intent to treat up to 100 patients at any one time.

To be eligible for the increased patient limit: (1) the physician must currently be qualified under DATA 2000; (2) at least one year must have elapsed since the physician submitted the initial notification for authorization; (3) the physician must certify his or her capacity to refer patients for appropriate counseling and other appropriate ancillary services; and (4) the physician must certify that the total number of patients at any one time will not exceed the applicable number.

DATA 2000 allows qualified physicians to dispense or prescribe specifically approved Schedule III, IV, and V narcotic medications for the treatment of opioid addiction in treatment settings other than the traditional opioid treatment program (ie, methadone clinics). In addition, DATA 2000 allows qualified physicians who practice opioid addiction therapy to apply for and receive waivers of the registration requirements defined in the Controlled Substances Act.

More information is available by phone at 866/287-2728, via e-mail at info@buprenorphine.samhsa.gov, or online at *www.buprenorphine.samhsa.gov*.

Deadline Approaches for Pharmacists to Use NPI Numbers

The Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) require pharmacists to begin using the National Provider Identifier (NPI) by May 23, 2007. These provisions are intended to improve the efficiency and effectiveness of the electronic transmission of health information. Pharmacists can apply online or print an application for an NPI at *https://nppes.cms.hhs.gov*.

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CVS Pharmacy No. 5326 (Pharmacy Permit No. 5406), Voluntary Consent Agreement: Permit holder assessed $15,000 plus investigative and administrative costs. *Charges*: six counts, including aiding and abetting a technician candidate to practice with an expired registration for approximately nine months.

Janel Stelly King (Technician Certificate No. 2223), Formal Hearing: Certificate revoked; further, respondent assessed $500 plus investigative, administrative, and hearing costs. *Charges*: five counts, including unlawful practice for approximately one year with an expired certificate.

CVS Pharmacy No. 5614 (Pharmacy Permit No. 5433), Voluntary Consent Agreement: Permit holder assessed $20,000 plus investigative and administrative costs. *Charges*: six counts, including aiding and abetting a technician to practice with an expired certificate for approximately one year.

Louis Oliver Lenfant, Jr (Pharmacist License No. 10793), Voluntary Consent Agreement: Reinstated the surrendered license, and then suspended it for ten years, beginning May 12, 2005; and further, conditioned the acceptance of any future application for reinstatement upon certain terms: (1) active suspension for no less than twenty months; (2) payment of $50,000 fine plus investigative and administrative costs; and (3) other terms as enumerated in the agreement. *Charges*: five counts, including a felony conviction in federal court for diversion and illegal wholesale distribution of prescription drugs.

Bishoy Samir Ramzy (Intern Registration No. 42209), Voluntary Consent Agreement: Registration suspended for two years, with execution thereof stayed, and then placed on probation for two years beginning October 15, 2006; and further, respondent required to complete 500 hours of practice in a charitable pharmacy; and further, respondent assessed investigative and administrative costs. *Charges*: four counts, including the commission of fraud in employer pharmacy.

Batiste Drugs (Pharmacy Permit No. 2134), Voluntary Consent Agreement: Permit revoked; and further, permit holder is permanently barred from seeking reinstatement of this permit; and further, permit holder is permanently barred from holding any ownership or officer position in any other pharmacy in Louisiana. *Charges*: seven counts, including diversion of controlled substances and other prescription drugs.

Jamie Danielle Brady (Technician Certificate No. 7420), Voluntary Consent Agreement: Certificate revoked; and further, respondent is permanently barred from seeking reinstatement of this credential or making application for any other credential. *Charges*: four counts, including improper use of controlled substances.

Sandra Gail Fontenot (Technician Certificate No. 4316). The Board accepted the voluntary surrender of the certificate, resulting in the suspension of the certificate for an indefinite period of time beginning November 20, 2006.

Carlton Ireneaus Isidore Charles (Pharmacist License No. 11135), Voluntary Consent Agreement: License revoked, and further, respondent is permanently barred from seeking reinstatement of this credential. *Charge*: one count – the practice of pharmacy without a license or permit or any other designation deemed necessary to engage in the practice of pharmacy.

The Board also issued a Letter of Warning to one permit holder and a Letter of Reprimand to one pharmacist. With respect to the reinstatement of expired credentials, the Board granted one request from a technician, and then issued two conditional reinstatement orders for one technician and one pharmacist. With respect to impaired practitioners, the Board accepted the voluntary surrender of one pharmacist license, granted requests for probated reinstatement to three pharmacists, and denied a reinstatement request from one pharmacy intern.

Calendar Notes (07-04-270)

The next Board meeting and administrative hearing will be May 9-10, 2007, at the Board office. The office will be closed April 6 in observance of Good Friday, as well as July 4 in observance of Independence Day.

Special Note (07-04-271)

The *Louisiana Board of Pharmacy Newsletter* is considered an official method of notification to pharmacies, pharmacists, pharmacy interns, pharmacy technicians, and pharmacy technician candidates credentialed by the Board. **These *Newsletters* will be used in administrative hearings as proof of notification.** Please read them carefully. We encourage you to keep them in the back of the *Louisiana Pharmacy Law Book* 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.

Malcolm J. Broussard, RPh - State News Editor
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LOUISIANA BOARD OF PHARMACY

National Association of Boards of Pharmacy Foundation, Inc
1600 Feehanville Drive
Mount Prospect, IL 60056

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