October 2006

NEWS

Louisiana Board of Pharmacy

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License and Permit Renewals for 2007 (06-10-253)

The Louisiana Board of Pharmacy office will begin printing pharmacist license and pharmacy permit renewal applications on October 16, 2006. Any address changes submitted to the office after October 13, 2006, will not be reflected on your renewal applications. We will mail the renewal applications during the week of October 23, 2006. If you do not receive your renewal application by November 15, 2006, it is **your** responsibility to obtain a renewal application. You may retrieve a blank renewal application form from the Board's Web site at www.labp.com, or by contacting the office.

The option for online renewal for pharmacist licenses and pharmacy permits will be available again this year. That feature of the Web site will only be accessible from November 1, 2006 through December 31, 2006. We have removed the convenience fee for online renewal transactions; therefore, the renewal fee will be the same for both paper and electronic applications.

Pharmacist License Renewal

- Licenses expire December 31, 2006; there is no grace period, and a pharmacist shall not practice with an expired license.
- If you elect to use a paper application and you need a current renewal on or before January 1, 2007, we suggest you submit your completed application and $100 fee to the Board office on or before December 1, 2006. Do not forget to date and sign the application, and answer the questions at the bottom of the application – if they are not all answered, or if there is no supporting information with positive responses, the application will be returned to you as an incomplete application.
- The renewal of an expired license will incur a 50% penalty as well as a lapsed license reinstatement fee, resulting in a total charge of $350.
- If it is important for you to know when your application is received at the Board office, we suggest you use a mailing service with tracking options (United States Postal Service, United Parcel Service, FedEx, etc)

Pharmacy Permit Renewal

- Pharmacy permits expire December 31, 2006; there is no grace period, and a pharmacy shall not operate with an expired permit.
- If you elect to use a paper application and you need a current renewal on or before January 1, 2007, we suggest you submit your completed application and appropriate fee to the Board office on or before December 1, 2006. Do not forget to answer all questions and sign the application; incomplete applications will be returned to you unprocessed.
- The renewal of an expired pharmacy permit will incur a 50% penalty as well as a lapsed permit reinstatement fee, resulting in a total charge of $387.50.
- The renewal of an expired controlled dangerous substance (CDS) permit will incur a 50% penalty as well as a lapsed reinstatement fee, resulting in a total charge of $237.50.
- If it is important for you to know when your application is received at the Board office; we suggest you use a mailing service with tracking options.

Pharmacists, Interns, Technicians, and Technician Candidates (06-10-254)

If you are a pharmacist-in-charge, you must – at all times – ensure that all personnel allowed to perform professional functions in your prescription department are properly licensed, registered, or certified. If you are a staff pharmacist or relief pharmacist, it is your responsibility to ensure that the employees assisting you in the prescription dispensing process are properly credentialed to perform their duties during your presence. If a compliance officer discovers persons performing professional functions without the necessary credentials, you will be identified as the responsible person in the investigative report filed by the compliance officer.

Legislative Update (06-10-255)

During the recently completed legislative session, several bills were adopted that impact pharmacy practice.

- Act 676 (House Bill [HB] 153) authorized the Board of Pharmacy to develop, implement, and operate a Prescription Monitoring Program (PMP). The PMP will collect relevant data concerning all prescriptions for all controlled substances (CS) dispensed to all Louisiana residents by all pharmacies and other dispensing practitioners. The data will be available for authorized inquiries by prescribers, dispensers, and regulatory agencies for prescribers and dispensers. The Board will first need to promulgate rules for the program before it can begin. We will keep you posted on the progress of the project.
- Act 54 (HB 211) revised Schedules I, II, III, and V of the state CS list to make it identical to the federal list of CS.
- Act 56 (HB 216) revised Schedule IV of the state CS list to make it identical to the federal list of CS.
- Act 164 (HB 261) made technical corrections to four sections of the Pharmacy Practice Act; it also revised one of the qualifications for licensure by reciprocity.
- Act 834 (HB 693) transferred the authority for the issuance of all CDS licenses from the Department of Health and Hospitals to the Board of Pharmacy.
- Act 797 (HB 1235) and Act 643 (Senate Bill [SB] 19) made changes to the provision allowing donations of certain unused prescription drugs.
- Act 600 (SB 467) required pharmacies issuing prescriptions for CS to require the patient or patient's agent purchasing or receiv-

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FDA Launches Consumer Educational Program on the Safe Use of OTCs

The United States Food and Drug Administration's (FDA) Center for Drug Evaluation and Research, in cooperation with the National Council on Patient Information and Education and Maryland's Montgomery County Public Schools, has launched "Medicines in My Home," an interactive educational program aimed at informing middle school students about the safe and effective use of over-the-counter (OTC) medicines. Key concepts students will learn from the program are:

- the Drug Facts label tells you what a medicine treats, if it is right for you and your problem, and how to use the medicine;
- read the label and follow the directions carefully and correctly;
- two medicines with the same active ingredient should not be used at the same time; and
- measure medicines correctly with measuring tools made for medicines.

The program emphasizes that medicines should be used only with permission from an adult and that if there are questions about medicine use, ask a pharmacist or doctor. Materials are provided to encourage students to share what they learn with their families so that all family members can learn to use OTC medicines more safely. Program information can be found at www.fda.gov/medsinmyhome.

HHS Warns Public of Heroin and Fentanyl Deadly Combo

In efforts to warn the public and health care professional communities regarding a recent rash of drug-related deaths due to an illicit street drug combination consisting of the prescription medication fentanyl and either heroin or cocaine, the Department of Health and Human Services (HHS) released a fact sheet containing specific information with the goal of saving lives.

A letter from H. Westley Clark, director of HHS Center for Substance Abuse Treatment, to health care professionals warned that in "just one week, an estimated 33 individuals in the Detroit, MI area are reported to have died after using this fatal mix of drugs; the same drug combination may have been responsible for more than 100 deaths in the same region last September [2005]." Philadelphia, PA; Chicago, IL; St Louis, MO; and Camden, NJ have also recently experienced similar clusters of drug-related deaths.

Fentanyl, an injectable Schedule II prescription opioid analgesic, is roughly 50 to 80 times more potent than morphine but can also be produced in clandestine laboratories in powder form and then mixed with or substituted for heroin. Fentanyl-related overdoses can result in sudden death through respiratory arrest, cardiac arrest, severe respiratory depression, cardiovascular collapse, or severe anaphylactic reaction. In some cases, heroin or cocaine users are aware they are purchasing this dangerous combination of drugs and in other cases, they are not. Because the potency of street-sold heroin or cocaine is amplified markedly by fentanyl and because the inclusion of fentanyl may not be disclosed, any use, even a reduced dose, can result in overdose or death. The fact sheet advises that suspected overdoses should be treated rapidly with a naloxone injection, 0.4 to 2 mg intravenously, subcutaneously, or intramuscularly every two to three minutes, which should rapidly reverse symptoms related to a narcotic overdose; if there is no response after 10 minutes, then a different diagnosis should be considered.

For additional information, contact Kenneth Hoffman at the Substance Abuse and Mental Health Services Administration at 240/276-2701 or via e-mail at Kenneth.Hoffman@samhsa.hhs.gov.

Pharmacy Technicians and Medication Error Prevention

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.

In an October 2005 article in the *American Journal of Health-System Pharmacists*, the results of a random nationwide survey of more than 800 pharmacy technicians' views about their medication errors was published (Desselle SP. Certified pharmacy technicians' views of their medication preparation errors and educational needs. *Am J Health-Syst Pharm.* October 1, 2005; 62:1992-97). Most of the technicians worked in community pharmacies, but more than a quarter (27%) were employed in hospitals.

As one might expect in both settings, interruptions and inadequate staffing were among the most frequent factors perceived to contribute to technician medication preparation errors. Inadequate staffing was perceived as especially problematic in chain pharmacies, while inadequate supervision by pharmacists was cited as a factor more frequently by hospital technicians. It also may come as no surprise that the pharmacists' most frequently cited response to an error that was caught during the checking process was to make the technician aware of the error and require him or her to correct it. However, only about 17% of the technicians reported that the pharmacist had used the error as an opportunity to provide instructions on how to avoid the same or similar errors in the future.

While many of these respondents attributed this responsibility to the organization as a whole, not necessarily the individual pharmacist who detects an error, it appears technicians may not be receiving guidance about system and process changes that can help avert errors. After an

error is corrected, the checking pharmacist should find time that same day (or the next day, if necessary) to review the error with the technician and suggest ways to avoid it, including safer behavioral choices if applicable. Later, during pharmacy staff meetings or other forms of intradepartmental communication, errors, their causes, and ways to prevent them should be shared with all staff in a way that does not embarrass those who were possibly involved in the errors.

One or Both Nostrils?

Submitted by ISMP

Although many nasal sprays are intended for administration in each nostril for a single dose, there are notable exceptions. For example, some medications are meant to be delivered via the nasal passage but **not** sprayed into each nostril. Calcitonin salmon (**Fortical®, Micalcin®**) is a prime example. Patients should administer a single spray (200 international units) into one nostril daily, using alternate nostrils each day. Other examples in metered-dose or unit-dose nasal spray containers include butorphanol, desmopressin (**DDAVP®**), sumatriptan (**Imitrex®**), and zolmitriptan (**Zomig®**).

Some pharmacy and/or physician electronic prescribing systems have been preprogrammed to print directions that default to "spray in each nostril" when nasal sprays are selected. For the previously mentioned drugs, this would result in the administration of a double dose of medication. One health care facility recently reported that about 50 patients, who had been prescribed medications intended to be given into one nostril, had prescription container labels that instructed the patients to administer the spray into both nostrils. Some physicians might anticipate patients' confusion and write the prescription for "half" doses in each nostril. Even if instructed to use the spray in one nostril, patients who administer other nasal medications in both nostrils may spray these medications into both nostrils without thinking.

Explicit verbal directions and written instructions that emphasize administration via one nostril only are critical to avoid an overdose.

FDA/ISMP National Campaign to Help Eliminate Ambiguous Medical Abbreviations

FDA and the ISMP have launched a national education campaign that focuses on eliminating the use of potentially harmful abbreviations by health care professionals, medical students, medical writers, and the pharmaceutical industry. The campaign addresses the use of error-prone abbreviations in all forms of medical communication, including written medication orders, computer-generated labels, medication administration records, pharmacy or prescriber computer order entry screens, and commercial medication labeling, packaging, and advertising. For more information visit www.fda.gov/cder/drug/MedErrors.

DEA Provides Retail Training Materials

Drug Enforcement Administration (DEA) recently announced the availability of training materials regarding self-certification training for regulated retail sellers of non-prescription drug products containing ephedrine, pseudoephedrine, and phenylpropanolamine as required by the Combat Methamphetamine Epidemic Act of 2005 (Title VII of Public Law 109-177).

Two sets of training materials have been developed: one for regulated persons who are mobile retail vendors, and one for regulated persons who are not mobile retail vendors. Both sets of training materials may be found on the Diversion Control Program Web site, www.deadiversion.usdoj.gov, under "Combat Methamphetamine Epidemic Act of 2005."

DEA notes that regulated sellers must use the content of these training materials in the training of their employees who sell scheduled listed chemical products. A regulated seller may utilize additional content in its training program, but DEA's posted material must be included.

DEA is continuing to work to promulgate regulations to implement the Combat Methamphetamine Epidemic Act of 2005.

FDA Announces Release of Guidance on Useful Written Consumer Medication Information

In the July 18, 2006 *Federal Register,* FDA announced the availability of a guidance entitled "Useful Written Consumer Medication Information (CMI)." This guidance is intended to assist individuals or organizations (eg, pharmacies, private vendors, health care associations) in developing useful written consumer medication information to comply with Public Law 104-180. CMI is written information about prescription drugs developed by organizations or individuals, other than a drug's manufacturer, that is intended for distribution to consumers at the time of dispensing. Since neither FDA nor the drug's manufacturer reviews or approves CMI, FDA recommends that the developers of written medication information use the factors discussed in this guidance to help ensure that their CMI is useful to consumers.

This guidance can be accessed at www.fda.gov/cder/guidance/7139fnl.htm.

2007 Survey of Pharmacy Law Available Soon

NABP's 2007 *Survey of Pharmacy Law* CD-ROM will be available in early December 2006. New topics include whether or not licensure for wholesale distributors of non-prescription drugs is required and the recognition of Verified-Accredited Wholesale Distributors™ accreditation.

The *Survey* consists of four sections: organizational law, licensing law, drug law, and census data. The *Survey* can be obtained for $20 from NABP by downloading the publication order form from www.nabp.net and mailing in the form and a money order to NABP. The CD-ROM is provided free of charge to all final-year pharmacy students through a grant from AstraZeneca Pharmaceuticals. If you do not have Web access or would like more information on the *Survey,* please contact NABP at 847/391-4406 or via e-mail at custserv@nabp.net.

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ing the prescription to produce a photo identification, unless the patient or patient's agent is known to the pharmacist.

Disciplinary Actions (06-10-256)

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 May 18, 2006 administrative hearing, the Board took final action in the following matters:

Nicholas Michael Schiro (Pharmacist License No. 14563), Formal Hearing: License revoked. Respondent assessed $5,000 plus investigative, administrative, and hearing costs. *Charges:* (1) obtained a license by fraud or misrepresentation, and (2) failure to report adverse action taken by another law enforcement agency.

Brishea J. Lee (Technician Certificate No. 3510), Formal Hearing: Certificate revoked. Respondent assessed investigative, administrative, and hearing costs. *Charge:* failure to furnish information legally requested by the Board.

During its August 16, 2006 administrative hearing, the Board took final action in the following matters:

Yolanda Marie Brown (Technician Candidate Registration No. 11555), Voluntary Consent Agreement: Registration revoked, with permanent prohibition on any future application. *Charges:* (1) unlawful acquisition of a CDS, and (2) unlawful possession of Schedule III CDS.

Rosa Maria Jarrell (Technician Certificate No. 7457), Voluntary Consent Agreement: Certificate revoked, with permanent prohibition on any future application. *Charge:* has committed fraud in connection with the practice of pharmacy.

Andrea Nicole Harris (Technician Certificate No. 7291), Voluntary Consent Agreement: Certificate revoked, with permanent prohibition on any future application. *Charges:* (1) unlawful acquisition of a CDS, and (2) unlawful possession of a Schedule II CDS.

Angela Marie Johnson (Technician Certificate No. 3101), Voluntary Consent Agreement: Certificate revoked, with permanent prohibition on any future application. *Charge:* unlawful acquisition of a CDS.

Rodney Joseph Krumm, Jr (Pharmacist License No. 16050), Voluntary Surrender: License suspended for an indefinite period of time, beginning June 8, 2006.

Kerry Layne Nelson (Pharmacist License No. 16539), Voluntary Consent Agreement: License reinstated, then suspended for remainder of original suspensive period with execution thereof stayed, then placed on probation until September 15, 2014, subject to certain terms as enumerated in the agreement.

Stephanie Ann Richards (Pharmacist License No. 15339), Voluntary Consent Agreement: Probation revoked; license suspended for five years, beginning June 15, 2006.

The Board also issued Letters of Warning to three pharmacy permit holders. With respect to the reinstatement of lapsed credentials, the Board granted a request from one pharmacist. With respect to impaired practitioners, the Board accepted the voluntary surrender of credentials from one pharmacist, one intern, and one technician, and then granted petitions for reinstatement from one pharmacist and one technician candidate.

Calendar Notes (06-10-257)

The next Board meeting and administrative hearings will be held December 5-7, 2006, at the Board office. **Please note this represents a change from previously published dates.** The office will be closed November 7, 2006, for Election Day, November 10, 2006, for Veterans Day, November 23-24, 2006, for Thanksgiving Day, December 25, 2006, for Christmas Day, and January 1, 2007, for New Year's Day.

Special Note (06-10-258)

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.

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