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Louisiana Board of Pharmacy

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Renewal of Pharmacy Technician Certificates (06-04-242)

The Louisiana Board of Pharmacy office will begin printing renewal applications during the week of April 17, 2006. Any address changes received after April 14, 2006, will not be reflected on the renewal application. We will mail the applications during the week of April 24, 2006. If you do not receive your application by May 15, 2006, it then becomes your responsibility to obtain a renewal application. You may download a replacement application form from our Web site at www.labp.com.

For the first time this year, technicians will now be able to renew their certificates online; that portion of the Web site will be operational from May 1, 2006, through June 30, 2006. While there is a convenience fee attached to the financial transaction, the benefit is a one to two day processing time for the certificates.

All technician renewals will expire on June 30, 2006. Technicians may not practice with an expired renewal. The renewal of an expired certificate will incur a $25 penalty, as well as a $200 reinstatement fee. Applications bearing a postmark of July 1, 2006, or later must be accompanied by the additional fees, or the package will be returned unprocessed. If you need to be in possession of a renewal before July 1, 2006, we suggest you mail the properly completed application and fee on or before May 30, 2006, using the mail tracing service of your choice. If you find yourself without a renewal for the next year and it is close to the deadline, you may wish to consider the online renewal option.

Legislative and Regulatory Proposals (06-04-243)

During its February 15, 2006 meeting, the Board reviewed several proposals arising from the Regulation Revision Committee and approved the continuation of the rulemaking process. With respect to potential legislation for the Regular Session of the 2006 Louisiana Legislature, the Board reviewed measures that would alleviate a restriction on certain reciprocity candidates; technical changes associated with the recent name change by the Accreditation Council for Pharmacy Education (ACPE); clarification of notice requirements for pharmacists-in-charge (PIC) of out-of-state pharmacies; generic interchange instructions on prescriptions reimbursable by Medicare; updates to the list of drugs in Schedules II, III, and IV in the state Uniformed Controlled Substances Act; and the implementation of a prescription monitoring program for prescriptions for all controlled substances (CS). If you wish to follow the progress of these measures, we suggest you frequently review the legislative Web site at www.legis.state.la.us. The legislative session convened on March 27, 2006, and must adjourn no later than June 19, 2006.

With respect to potential regulations, the Board reviewed proposals in Chapter 3 (evidentiary standards and cease and desist orders), Chapter 5 (live continuing education with alternatives, notice requirements during state of emergency, and reporting requirements for impaired practitioners), Chapter 7 (prohibition on interns practicing in probated sites or with pharmacists on probation, and reporting requirements for impaired practitioners), Chapter 11 (restoration of a previous restriction on advertising of CS), Chapter 15 (new section for remote processing of medical orders in hospital pharmacies), Chapter 17 (inspection requirements for medications stored in drug cabinets in institutional pharmacies), Chapter 19 (technical changes related to ACPE name change), Chapter 23 (clarification of qualifications for PIC of out-of-state pharmacy), and Chapter 25 (restoration of a previous section with detailed requirements for procedures related to transfer of prescriptions). The Board approved the continuation of the rulemaking process for these proposals. On a future date, the Board will publish some or all of these regulatory proposals as a Notice of Intent in the *Louisiana State Register*, and we will then conduct a public hearing to receive comments from all interested parties. We will keep you informed on our process, as well as the progress of that process. If you wish to view or access these proposals in their current form, please visit our Web site at www.labp.com. In the interim, the current regulations on these topics are still in place, and you should comply with them.

Disciplinary Actions (06-04-244)

Although every effort is made to ensure that 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 18, 2005 administrative hearing, the Board took final action on the following matters:

David Louis Matherne (Pharmacist License No. 9961), Formal Hearing: License suspended for five years beginning January 4, 2006, with execution thereof stayed, and license placed on probation for five years, subject to certain terms; respondent also assessed $5,000 plus costs.

Dave's Village Drugs (Pharmacy Permit No. 219), Formal Hearing: Permit suspended for five years beginning January 4, 2006, with execution thereof stayed, and permit placed on probation for five years, subject to certain terms; respondent also assessed $7,500 plus costs.

Brandi Denise Chapman (Technician Candidate Registration No. 2899), Formal Hearing: Registration revoked; respondent also assessed $1,000 plus costs; any future application for reinstatement conditioned upon payment of all assessments.

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

Glenda Renee Cobb (Technician Certificate No. 5750), Voluntary Consent Agreement: Certificate revoked, with permanent prohibition on any future application.

Advanced Pharmacy (Pharmacy Permit No. 5565), Voluntary Consent Agreement: Permit revoked, with permanent prohibition on any future application.

Continued on page 4

FDA Cautions Consumers About Filling US Prescriptions Abroad

Food and Drug Administration (FDA) issued a warning to health care professionals and consumers that filling their prescriptions abroad may have adverse health consequences due to the confusion with drug brand names that could inadvertently lead consumers to take the wrong medication for their condition. In an investigation, FDA has found that many foreign medications, although marketed under the same or similar-sounding brand names as those in the United States, contain different active ingredients than in the US. Taking a different active ingredient could potentially harm the user.

FDA found 105 US brand names that have foreign counterparts that look or sound so similar that consumers who fill such prescriptions abroad may receive a drug with the wrong active ingredient. For example, in the United Kingdom, Amyben®, a brand name for a drug product containing amiodarone, used to treat abnormal heart rhythms, could be mistaken for Ambien®, a US brand name for a sedative. Using Amyben instead of Ambien could have a serious adverse outcome. For more information on this topic visit www.fda.gov/oc/opacom/reports/confusingnames.html.

Safety Can Not be Sacrificed For Speed

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.

Problem: Typically, pharmacies have developed well-established methods for monitoring the accuracy of the dispensing process. But today, pharmacy work is increasingly stressful and these checks and balances can easily be strained beyond capacity. With an increasing number of prescriptions and a shortage of qualified pharmacists, conditions are ripe for potentially unsafe working conditions – long hours without breaks; multitasking between answering phones, overseeing other pharmacy staff, dispensing prescriptions, and counseling patients; and ever-increasing time spent attending to insurance issues. Inevitably, these conditions can increase the chance for dispensing errors.

One pharmacy knows this all too well after a five-year-old boy died as a result of an order entry and medication compounding error that was not caught by the usual verification process. In this case, imipramine was dispensed in a concentration five times greater than prescribed. Imipramine is a tricyclic antidepressant used to treat adults, but it is also used to treat childhood enuresis. An extemporaneous solution was to be prepared at this pharmacy that specialized in compounded prescriptions since a liquid formulation was not commercially available. A pharmacy technician incorrectly entered the concentration of the prescribed solution into the computer as **50 mg/mL** instead of **50 mg/5 mL**, along with the prescribed directions to give 2 tsp at bedtime. He then proceeded to prepare the solution using the incorrect concentration on the label rather than the concentration indicated on the prescription. When the compound was completed, the technician placed it in a holding area to await a pharmacist's verification. At this time, one of the two pharmacists on duty was at lunch and the high workload of the pharmacy made it difficult for the pharmacist to check the prescription right away. When the child's mother returned to pick up the prescription, the cash register clerk retrieved the prescription from the holding area without telling a pharmacist, and gave it to the mother, unaware that it had not yet been checked. At bedtime, the mother administered 2 tsp of the drug (500 mg instead of the intended 100 mg) to the child. When she went to wake him the next morning, the child was dead. An autopsy confirmed imipramine poisoning.

There are many factors that contributed to this error including inaccurate order entry and issues related to high workload. However, a critical breakdown in safety processes occurred when the cash register clerk took the prescription from the pharmacy holding area (to prevent the mother from waiting any longer for the prescription), thereby circumventing the usual pharmacist verification process.

While this error underscores a growing problem in health care, the problem was clearly evident to this pharmacy owner – even a year before the error occurred. When interviewed for an article that appeared in a national publication, he vented his frustrations about the scant attention paid in our society to pharmacist workload difficulties faced in today's health care environment. On the day of the interview, 49 prescriptions were in the process of being prepared and about a dozen patients were standing in line or wandering around the store waiting for prescriptions. Yet this was a slow day. The owner also said that, while managed care had reduced profits considerably over the past several years, prescription volume had increased 50% (at the time of the error, the pharmacy was dispensing about 10,000 prescriptions per month versus 7,000 per month during the prior year, without an increase in staff) and medication regimens and drug interactions were more complex. To overcome these barriers, the owner added private consultation areas for patient counseling; installed a $175,000 robot that accurately dispenses the 200 most common drugs; and diversified sales to offset full-time pharmacists' salaries. But these efforts could not have prevented this tragic fatal error that circumvented the normal safety processes.

Safe Practice Recommendations: The environment and demands placed on health professionals significantly affect their ability to provide safe health care services. While technology such as robots can help, overstressed professionals cannot consistently perform at the maximum level of safety. Therefore, it is important that the public and health care leadership understand this problem so they can be more open to tradeoffs, such as working

with one patient at a time and incurring longer turnaround times, which are necessary to enhance patient safety. With a shortage of qualified professionals, we need to demand more rapid adoption of computerized prescribing to reduce time spent with prescription transcription. We should identify the biggest distractions that occur in our workplaces and eliminate or reduce the source by batching common interruptions and reorganizing work areas. Staff members need to be properly trained to understand safety procedures that are in place and know the limits of their specific duties. Fail-safe processes to ensure an independent double check before dispensing medications and performing other critical processes are a must. The pharmacy where this error occurred now requires two pharmacists to check every prescription. Unfortunately, this level of vigilance is typical after a patient has been harmed from an error. In other pharmacies, especially where there is only one pharmacist on duty, technicians may be involved in the double-check process.

A few other strategies can be used to prevent similar errors:

- Have one person perform order entry and a different person prepare the prescription, if possible, to add an independent validation of the order entry process.
- Do not prepare prescriptions using only the computer-generated label, as order entry may have been incorrect.
- Ensure that the original prescription, computer-generated label, prepared product, and manufacturer's product(s) remain together throughout the preparation process.
- Verify dispensing accuracy by comparing the original prescription with the labeled patient product and the manufacturer's product(s) used.

NIH Develops Community Drug Alert Bulletin

The National Institute on Drug Abuse, as part of the National Institutes of Health (NIH), has developed a new Community Drug Alert Bulletin that addresses the latest scientific research on the non-medical use of prescription drugs of abuse and addiction.

This bulletin is geared toward parents, teachers, counselors, school nurses, and health professionals who are associated with those at risk from prescription drug abuse for non-medical purposes. It summarizes the growing problem in the US and the trend of non-medical use of prescription drugs. For more information on this bulletin visit www.nida.nih.gov/PrescripAlert/index.html.

Implementation of the Anabolic Steroid Control Act of 2004

According to the December 16, 2005 *Federal Register*, effective January 20, 2005, the Anabolic Steroid Control Act of 2004 amended the Controlled Substances Act (CSA) and replaced the existing definition of "anabolic steroid" with a new definition. This new definition changed the basis for all future administrative scheduling actions relating to the control of the anabolic steroids as Schedule III controlled substances (CS) by eliminating the requirement to prove muscle growth. Also, the Act lists 59 substances as being anabolic steroids; these substances and their salts, esters, and ethers are Schedule III CS. The Act also revised the language of the CSA requiring exclusion of certain over-the-counter products from regulation as CS.

According to the House Report, the purpose of the Act is "to prevent the abuse of steroids by professional athletes. It will also address the widespread use of steroids and steroid precursors by college, high school, and even middle school students."

The changes to the definition include the following:

- Correction of the listing of steroid names resulting from the passage of the Anabolic Steroid Control Act of 1990.
- Replacement of the list of 23 steroids with a list of 59 steroids, including both intrinsically active steroids as well as steroid metabolic precursors.
- Automatic scheduling of the salts, esters, and ethers of Schedule III anabolic steroids without the need to prove that these salts, esters, or ethers promote muscle growth.
- Removal of the automatic scheduling of isomers of steroids listed as Schedule III anabolic steroids.
- Addition of dehydroepiandrosterone to the list of excluded substances.

FDA Unveils New Package Insert Format

On January 18, 2006, FDA unveiled a major revision to the format of prescription drug information, commonly called the package insert, which will give health care professionals clear and concise prescribing information. This new format was developed in order to manage the risks of medication use and reduce medical errors; the new package insert will provide the most up-to-date information in an easy-to-read format. This new format will also make prescription information more accessible for use with electronic prescribing tools and other electronic information resources.

Revised for the first time in more than 25 years, the new format requires that the prescription information for new and recently approved products meet specific graphical requirements and includes the reorganization of critical information so physicians can find the information they need quickly. Some of the more important changes include:

- A new section called *Highlights* to provide immediate access to the most important prescribing information about benefits and risks.
- A table of contents for easy reference to detailed safety and efficacy information.
- The date of initial product approval, making it easier to determine how long a product has been on the market.
- A toll-free number and Internet reporting information for suspected adverse events to encourage more widespread reporting of suspected side effects.

This new format will be integrated into FDA's other e-Health initiatives and standards-settings through a variety of ongoing initiatives at FDA. For more information please visit www.fda.gov/cder/regulatory/physLabel/default.htm.

Continued from page 1

Jenny Ann Newman, RN (Technician Candidate Registration Applicant), Voluntary Consent Agreement: Application denied, with permanent prohibition on any future application.

Chad Eric Dennis (Technician Certificate No. 4137), Voluntary Consent Agreement: Certificate revoked, with permanent prohibition on any future application.

Gina Chamberlain Whittlesey (Pharmacist License No. 17644), Voluntary Consent Agreement: License suspended for five years beginning October 28, 2005, with execution thereof stayed, and license placed on probation for five years, subject to certain terms.

Tiffany Skye Harker (Technician Certificate No. 4973), Voluntary Consent Agreement: Certificate revoked, with permanent prohibition on any future application.

Chad Stuart Herlyn (Pharmacist License No. 17530), Voluntary Consent Agreement: License suspended for two years beginning July 19, 2005, with execution thereof stayed, and license placed on probation for two years, subject to certain terms.

Thomas James Lemoine (Pharmacist License No. 14604), Accepted voluntary surrender, resulting in the indefinite suspension of the license, effective November 12, 2005.

Sandy B. Decoux (Technician Certificate No. 2242), Accepted voluntary surrender, resulting in the indefinite suspension of the certificate, effective November 21, 2005.

The Medicine Shoppe of Covington (Pharmacy Permit No. 4416), Accepted voluntary surrender, resulting in the indefinite suspension of the permit, effective January 24, 2006.

C. Shantelle Williams (Pharmacist License No. 15233), Accepted voluntary surrender, resulting in the indefinite suspension of the license, effective January 24, 2006.

Advanced Healthcare Pharmacy (Pharmacy Permit No. 5301), Accepted voluntary surrender, resulting in the indefinite suspension of the permit, effective January 12, 2006.

Andre LaDawn Collins (Technician Candidate Registration No. 10571), Accepted voluntary surrender, resulting in the indefinite suspension of the registration, effective January 24, 2006.

Jessica Faye Fontenot (Technician Certificate No. 6581), Accepted voluntary surrender, resulting in the indefinite suspension of the certificate, effective February 15, 2006.

The Board also issued Letters of Warning to four pharmacy permit holders and one pharmacist, as well as Letters of Reprimand to three pharmacy permit holders, two pharmacists, and one technician. With respect to the reinstatement of lapsed credentials, the Board granted requests from four pharmacists, as well as a petition from one pharmacist for modification of a prior conditional reinstatement order; they also denied a request for the reinstatement of a controlled dangerous substance permit by a pharmacy permit holder. With respect to impaired practitioners, the Board accepted the voluntary surrender of license from one pharmacist, granted a petition for probation modification from one pharmacist, placed one pharmacist in the Practitioner Recovery Program, and ordered medical evaluations for impairment for two pharmacists.

Did You Know? (06-04-245)

As of February 15, 2006, we have issued active credentials to the following numbers of practitioners located inside and outside of the state:

	Inside	Outside	Total
Pharmacists	4,444	1,854	6,298
Interns	1,020	139	1,159
Technicians	4,527	97	4,624
Technician Candidates	743	20	763
Pharmacies	1,319	206	1,525

Calendar Notes (06-04-246)

The next Board meeting and administrative hearing will be held May 16-18, 2006, at the Board office. The office will be closed April 14, 2006, for Good Friday.

Special Note (06-04-247)

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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