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Louisiana Board of Pharmacy News

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Board Adopts New Rules (12-07-412)

The following rule changes became effective on May 20, 2012; additional information is available on the Louisiana Board of Pharmacy Web site: *www.pharmacy.la.gov → Library → Public Notices*:

- *Pharmacist-in-Charge (PIC) Requirements:* Amends §1105 of the Board's rules. To qualify for a PIC privilege, the pharmacist shall hold an active license, shall have accumulated at least two years of licensed practice as a pharmacist, and shall complete the required affidavit form. The PIC shall be present and practicing in that pharmacy at least 20 hours per week during the pharmacy's ordinary course of business, or in the alternative, at least 50% of the pharmacy's normal business hours of operation. For those pharmacists with less than two years of accumulated practice who were serving as the PIC of a pharmacy on May 20, 2012, the Board has allowed those PIC appointments to continue.
- *Cognitive Services:* Creates a new section (§525) in the Board's rules. The new rule defines and itemizes cognitive services and further, requires all pharmacists providing such services to Louisiana residents from a location other than a pharmacy permitted by the Board to be licensed by the Board.
- *Hospital Pharmacy:* Creates a new section (§1512) in the Board's rules, relative to the labeling requirements for medications prepackaged in a hospital pharmacy, and further, amends §1513 relative to the labeling of sterile preparations compounded in hospital pharmacies.
- *Remote Processing of Medical Orders:* The effect of the amendments to the rules is to remove the restriction that limited hospital pharmacies engaging in such activities when one of the pharmacies was closed, so that such activities may now occur at any time in all pharmacies.
- *Penal Pharmacy:* Creates a new chapter of rules (Chapter 18) and new classification of pharmacy permit for those pharmacies operating within penal institutions owned by government organizations or in private pharmacies providing products and services to offenders in government owned penal institutions under contract. This new rule will allow penal pharmacies to recycle unused prescription drugs it dispenses to its own offenders, subject to prevailing professional practice standards, instead of the previous requirement to destroy all such drugs.

Disciplinary Actions (12-07-413)

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

During its February 1, 2012 meeting, the Board took final action in the following matter:

Diane Nicole Drollinger (PST.019749): Application for licensure by reciprocity approved; newly issued license suspended for three years with execution thereof stayed, and license placed on probation for three years, effective February 1, 2012, subject to certain terms enumerated in the consent agreement.

During its May 2-3, 2012 Board meeting and administrative hearing, the Board took final action in the following matters:

Gaynell P. Perniciaro (CPT.001548): Accepted voluntary surrender of the credential, resulting in suspension of the certificate for an indefinite period of time, effective March 7, 2012.

Robert Mark McGee (PST.015107): Suspended license for six months, effective April 1, 2012, and then placed license on probation for four years and six months, effective October 1, 2012, subject to certain terms enumerated in the consent agreement; further, assessed a fine of $7,500 plus administrative costs; and further, imposed a lifetime prohibition on any ownership interest in any pharmacy permitted by the Board; for 20 counts, including failure to exercise professional judgment and corresponding responsibility in dispensing prescriptions for controlled substances.

Fred's Pharmacy No. 2991 (PHY.004101): Assessed a fine of $7,500 plus investigative and administrative costs; for 12 counts, including failure to secure controlled substances and subsequent diversion of over 33,000 tablets of hydrocodone/acetaminophen within a seven-month period of time.

Kerry Michael Finney (PST.013535): Assessed a fine of $1,000 plus administrative costs; and further, imposed an additional restriction to his existing list of probationary terms to prohibit the acceptance of an appointment as the PIC of any pharmacy permitted by the Board; for 13 counts, including failure to secure controlled substances while serving as PIC of Fred's Pharmacy No. 2991 and subsequent diversion of over 33,000 tablets of hydrocodone within a seven-month period of time.

Dawnelle Devonn Alexander (CPT.007465): Suspended the certificate for an indefinite period of time, effective March 17, 2012, and further, prohibited any future application for reinstatement of the certificate until April 1, 2017; for 12 counts, including diversion of over 33,000 tablets of hydrocodone within seven months at Fred's Pharmacy No. 2991.

Kerry Michael Finney (PST.013535): For violation of probationary terms, revoked probationary status, and suspended the license for an indefinite period of time, effective April 6, 2012.

Scott Taylor Lovitt (PST.017931): Accepted voluntary surrender of credential, resulting in suspension of the license for an indefinite period of time, effective February 24, 2012.

Edwin Paul Domingue, Jr (PST.010459): Granted request for reinstatement of the previously suspended license, converted the suspensive period from an indefinite term to a term of five years and stayed the execution of the suspension, and then placed the license on probation for five years, effective May 2, 2012, subject to certain terms enumerated in the consent agreement.

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FDA Warned Medical Practices About Counterfeits in US and Risks to Patients

In April 2012, Food and Drug Administration (FDA) sent letters to medical practices in several states requesting that they stop administering drugs purchased from any foreign or unlicensed source. FDA's letters were sent in response to the discovery that the medical practices purchased medications from foreign or unlicensed suppliers that sold illegal prescription medications. FDA has advised that these medical practices are putting patients at risk of exposure to medications that may be counterfeit, contaminated, improperly stored and transported, ineffective, and dangerous.

In an FDA statement, the agency urges the health care community "to examine their purchasing practices to ensure that they buy directly from the manufacturer or from licensed wholesale drug distributors in the United States." Further, FDA reminds health care providers, pharmacies, and wholesalers/distributors that they are valuable partners in protecting consumers from the threat of unsafe or ineffective products that may be stolen, counterfeit, contaminated, or improperly stored and transported. FDA advises that the receipt of suspicious or unsolicited offers from unknown suppliers should be questioned, and extra caution should be taken when considering such offers.

FDA notes that the "Verify Wholesale Drug Distributor Licenses" FDA Web page, available at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm281446.htm,* may be used to verify that a wholesale drug distributor is licensed in the state(s) where it is conducting business.

The FDA warning letters were sent following two incidences of counterfeit injectable cancer drugs found in US medical practices, one in February 2012, involving counterfeit Avastin® 400 mg/16 mL, and another in April 2012, involving a counterfeit version of Roche's Altuzan® 400 mg/16 ml (bevacizumab).

More information and a list of the medical practices that were sent warning letters are available on the FDA Web site at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/ucm299920.htm.*

Rethink the Vial

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency that analyzes 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, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. *ISMP is a federally certified patient safety organization, providing legal protection and confidentiality for submitted patient safety data and error reports. ISMP is also an FDA MedWatch partner. Call 1-800/FAIL-SAF(E) to report medication errors to the ISMP Medication Errors Reporting Program or report online at* www.ismp.org. *ISMP address: 200 Lakeside Dr, Suite 200, Horsham, PA 19044. Phone: 215/947-7797. E-mail: ismpinfo@ismp.org.*

Recently, ISMP has been receiving many reports from consumers who report the pharmacy "shorted them" on a variety of opioid prescriptions. They report that when they call the pharmacy to complain about the missing number of tablets or capsules the pharmacy staff insists the proper quantity was dispensed. ISMP also receives reports from pharmacists reporting this same situation. The concern is that pharmacy personnel may be diverting the medication, the patient may be seeking more medication than what was prescribed, or some of the medication may be taken by someone else in the patient's home.

In the US, we dispense almost all oral solid drugs as loose tablets or capsules in a plastic vial that is labeled for the patient. This manner of dispensing makes diversion of a few tablets or capsules relatively easy. However, in many other countries, unit-dose and unit-of-use packaging is widely used.

It seems to reason that if unit-of-use, manufacturer-sealed containers or individual unit-dose packages of medications were used in the US for these drugs, diversion and/or speculation of diversion could be reduced. Manufacturers could produce unit-dose or unit-of-use packages, in numbered strips for ease of inventory and dispensing. Patients could be asked to sign for and agree to the amount dispensed at the point-of-sale. The numbered packaging would also help patients at home know if they had taken their medication or possibly alert them to diversion within their home. Of course, prescribers would need to prescribe quantities available in patient compliance packs or in multiples of that packaging, and insurance companies would have to pay for this specialized packaging.

Unit-of-use packs would provide other safety benefits. For example, patients would be able to verify the drug name on the label for each dose, which would add a redundancy in checking the pharmacy label to what was actually dispensed. Also, the manufacturer could print and attach the patient information sheet and/or medication guide to the package the patient receives, eliminating extra work in the pharmacy to print and supply these mandated education sheets to the patient.

It is evident that further steps must be taken to reduce and minimize abuse of prescription drugs. It is critical that education be provided to patients, caregivers, and health care providers to increase awareness about the dangers of prescription drug abuse and about ways to appropriately prescribe, dispense, store, and dispose of prescription medications. Development and deployment of consumer-friendly and environmentally responsible prescription drug disposal programs may also help to limit diversion (as well as reduce the risk of accidental ingestion) of drugs by family members and friends. FDA must continue its efforts to require new concepts for risk evaluation and mitigation strategies and provider education for opioid drugs. For more information on understanding prescription drug abuse, and to request *Parents' Guide to Understanding Prescription Drug Abuse* brochures for distribution to your patients, visit *www.SafeguardMyMeds.org.*

Counterfeit Vicodin ES Sold Via Rogue Internet Drug Outlet, Abbott Reports

In March 2012, Abbott warned consumers and health care providers about counterfeit Vicodin® ES purchased via the Internet. Abbott reports that the counterfeit product drug and package do not match that of Abbott's FDA-approved Vicodin ES (hydrocodone bitartrate and acetaminophen). Descriptions and images of the counterfeit product and authentic Vicodin ES are shown in a consumer alert posted on the Abbott Web site at *www.abbott.com/vicodin-consumer-alert.htm.* Abbott advises that anyone who has the counterfeit ver-

sion should stop taking the product. Further, consumers who suspect a product to be counterfeit or have questions about the legitimacy of Vicodin ES are encouraged to make a report to FDA Office of Criminal Investigations (OCI) by calling 800/551-3989 or by completing the online form on the OCI Web site at *www.accessdata.fda.gov/scripts/email/oc/oci/contact.cfm.*

PSM LEADER's Guide Offers Tips for Protecting Patients from Counterfeits

The Partnership for Safe Medicines (PSM) released a guide to assist health care providers in protecting patients from counterfeit drugs and recognizing the signs that may indicate use of counterfeits. Three versions of the *LEADER's Guide* – including one for nurses, one for doctors, and another specific to pharmacists – are available for download from the PSM Web site at *www.safemedicines.org/resources-for-healthcare-professionals.html*. Each guide provides tips specific to these health care provider roles and includes guidance for safe sourcing of medications, evaluating suspect medications, educating patients about counterfeit drugs and the risks of ordering drugs online, and reporting suspected counterfeit drugs.

FDA Urges Providers to Help Prevent Children's Accidental Exposure to Fentanyl Patches

FDA issued a safety alert reminding patients, caregivers, and health care providers to appropriately store, use, and dispose of fentanyl patches to prevent children's accidental exposure to the medication, which is potentially life-threatening. FDA recently evaluated a series of 26 cases of pediatric accidental exposures to fentanyl patches reported over the past 15 years, and determined that 10 of the cases resulted in death, and 12 in hospitalization. In addition, 16 of the 26 cases occurred in children two years old or younger.

FDA warns that young children may be at risk for accidental exposure when fentanyl patches are discarded in trash receptacles, or when children find lost or improperly stored patches. Young children can be harmed when they place the patches in their mouths or stick the patches to their skin. In addition, young children are at risk of exposure when being held by someone wearing a partially detached patch that can then transfer to the child. Exposure of young children to a fentanyl patch can lead to serious adverse events and even death, due to the amount of fentanyl present in the patches. FDA stresses that harm can even occur with used patches because they may still contain a considerable amount of fentanyl.

To prevent accidental exposure, FDA advises that patients securely store needed fentanyl patches out of children's reach and sight. When applying a patch, FDA also recommends that patients consider covering the fentanyl patch with an adhesive film to make sure the patch does not come off. Finally, FDA recommends checking throughout the day to make sure that the patch is still in place.

Further, FDA advises that used or unneeded patches are properly disposed. FDA recommends that the adhesive side of the patch should be folded together and then the patch should be flushed down the toilet. FDA notes that the agency "recognizes that there are environmental concerns about flushing medicines down the toilet. However, FDA believes that the risk associated with accidental exposure to this strong narcotic medicine outweighs any potential risk associated with disposal by flushing. When the patches are no longer needed, disposing by flushing completely eliminates the risk of harm to people in the home."

FDA urges health care providers to educate patients and their caregivers about the appropriate use and disposal of fentanyl patches. FDA's consumer Web page provides detailed information for patients and caregivers and is available at *www.fda.gov/ForConsumers/ConsumerUpdates/ucm300803.htm.* Providers, patients, and caregivers are also encouraged to review the fentanyl patch product label for instructions. The FDA safety alert is available at *www.fda.gov/Drugs/DrugSafety/ucm300747.htm.* Additional consumer information about safe medication use and storage, and the importance of proper disposal of unneeded medications, is available on the AWAR$_X$E® Web site at *www.awarerx.org/informedSiteMap.php.*

Providers Asked to Advise Patients of Acetaminophen Safe Use Steps

With a world of conditions and hundreds of medicines, the Acetaminophen Awareness Coalition asks pharmacists and other health care providers to educate patients and caregivers about the proper use of medications containing acetaminophen. As the most common drug ingredient in America, acetaminophen can be found in over 600 medicines, including many prescription and over-the-counter medicines. The coalition notes that when used as directed, acetaminophen is safe and effective. The coalition asks providers to advise patients that there is a daily dosage limit for acetaminophen and that taking more than directed is an overdose and can lead to liver damage.

The coalition calls on health care providers to participate in the Know Your Dose campaign, by reminding all patients and caregivers to (1) always read and follow the labels on their medicines; (2) know if a medicine contains acetaminophen; and (3) never take or administer two medicines that contain acetaminophen at the same time. Additional medication safety tips for consumers and more information about the Know Your Dose campaign are available on the "OTC Medication Use" page of the AWAR$_X$E Web site at *www.awarerx.org/OTCMedUse.php.* The AWAR$_X$E consumer protection program and the National Association of Boards of Pharmacy® (NABP®) are part of the Acetaminophen Awareness Coalition.

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Barney Joseph Fusilier, Jr (PST.013323): Granted request for reinstatement of the previously suspended license, converted the suspensive period from an indefinite term to a term of five years and stayed the execution of the suspension, and then placed the license on probation for five years, effective May 2, 2012, subject to certain terms enumerated in the consent agreement.

LaShunda Renee Williams (CPT.006933): Granted request for reinstatement of the previously suspended certificate, converted the suspensive period from an indefinite term to a term of two years and stayed the execution of the suspension, and then placed the certificate on probation for two years, effective May 2, 2012, subject to certain terms enumerated in the consent agreement.

Shawn Adrienne Mouton (PTC.016780): Denied request for reinstatement of the previously suspended registration.

Bryant Paul Pierce, Jr (CPT.001594): Granted request for reinstatement of the expired certificate, conditioned upon the satisfactory completion of certain requirements identified in the consent agreement; further, ordered the probationary status of any credential issued to respondent, with such probation to terminate on May 2, 2013.

Chelsie Marie Chouest (CPT.009954): Revoked certificate, effective February 2, 2012; and further, prohibited any future application for reinstatement of the certificate; for five counts, including the diversion of controlled substances from her employer pharmacy.

Barry Kent Powers (PST.016002): Suspended license for five years and stayed the execution thereof, and then placed the license on probation for five years, effective September 7, 2011, subject to certain terms enumerated in the consent agreement; for one count, to mirror action taken by the Texas State Board of Pharmacy on his pharmacist license in that state.

Alicia Dupre Marcel (CPT.006682): Revoked certificate, effective February 9, 2012; and further, prohibited any future application for reinstatement of the certificate; for five counts, including the diversion of controlled substances from her employer pharmacy.

Larissa Elizabeth Walraven (CPT.010243): Revoked certificate, effective February 6, 2012; and further, prohibited any future application for reinstatement of the certificate; for five counts, including the diversion of controlled substances from her employer pharmacy.

Lindsay Alexandra Pantalion (CPT.007361): Revoked certificate, effective February 14, 2012; and further, prohibited any future application for reinstatement of the certificate; for five counts, including the diversion of controlled substances from her employer pharmacy.

Truong Van Tran (PNT.046139): Revoked intern registration, effective February 16, 2012; and further, prohibited any future application for reinstatement of the registration; for five counts, including the diversion of controlled substances from his employer pharmacy.

Anika Shantell Barnes (CPT.010701): Revoked certificate, effective March 27, 2012; and further, prohibited any future application for reinstatement of the certificate; for four counts, including the diversion of controlled substances from her employer pharmacy.

Lori Nickole Cicero (CPT.007583): Accepted voluntary surrender of the credential, resulting in suspension of the certificate for an indefinite period of time, effective March 5, 2012.

Tyler John Sylve (PNT.045809): Accepted voluntary surrender of the credential, resulting in suspension of the registration for an indefinite period of time, effective March 30, 2012.

Village Pharmacy of Port Vincent (PHY.006278): Accepted voluntary surrender of the credential, resulting in suspension of the pharmacy permit for an indefinite period of time; and further, pharmacy ordered to close permanently no later than May 4, 2012.

Kirkland Daniel Jeane (PST.018892): Accepted voluntary surrender of the credential, resulting in suspension of the license for an indefinite period of time, effective April 30, 2012.

At the same meeting in May, the Board also issued letters of reprimand to two pharmacists and three technicians as well as a letter of warning to one pharmacy. In addition, they granted requests from two pharmacists to modify previously imposed probationary terms, and further, granted requests from two technicians to reinstate expired certificates, conditioned upon the completion of certain requirements identified in their consent agreements.

Calendar Notes (12-07-414)

The next Board meeting and administrative hearing will be August 22-23, 2012, at the Board office. The office will be closed July 4, in observance of Independence Day and September 3, in observance of Labor Day.

Special Note (12-07-415)

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. The Board encourages 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 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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