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News

Louisiana Board of Pharmacy

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Board Adopts Two Emergency Rules (15-07-490)

During its May 27 meeting, the Louisiana Board of Pharmacy approved two regulatory projects and instructed staff to initiate the formal rulemaking process. In addition, the Board approved declarations of emergency for both regulatory projects, and declared both of the regulatory projects as emergency rules, effective June 1, 2015, while the formal rulemaking process is completed.

Regulatory Project 2015-4 ~ Compounding for Office Use for Veterinarians. Following the passage of the Drug Quality and Security Act of 2013 by the United States Congress, the Board revised its compounding rules to conform to the new federal law provisions relative to compounding. Within that rule change, which became effective in January 2015, the authority for pharmacies to compound medications for office use for practitioners was removed from the Board's rules.

With the recent clarification that the federal prohibition on compounding for office use for practitioners by pharmacies was applicable only to drugs for human use, the veterinarian community approached the Board for a restoration of the authority for pharmacies to compound medications for office use for veterinarians. The Board has responded with a proposed change in its compounding rules to allow pharmacies to compound medications for office use for veterinarians, and further, to establish a limitation on the amount of such products the pharmacy may distribute: five percent of the total number of dosage units distributed and/or dispensed by the pharmacy as calculated on a monthly basis. With respect to nonresident pharmacies, the five percent calculation applies only to the pharmacy's operations directed to Louisiana. Given that some of the compounded medications required by veterinarians are used in emergent conditions, the Board authorized the adoption of the emergency rule while the formal rulemaking process is completed.

Regulatory Project 2015-5 ~ Electronic Signature on Facsimile Prescription. Subsequent to the Board's adoption of the rule change relative to prescriptions in January 2015, the Board has received additional feedback from multiple stakeholders concerning one of the requirements relative to facsimile prescriptions. The rule adopted in January limits the use of electronic signatures to electronic prescriptions, and further, requires prescriptions delivered by facsimile to a pharmacy to bear a manual signature, similar to all other prescriptions existing in written form.

Physicians using several different types of prescription generating software were of the understanding that they were electronically prescribing, and were not aware that their vendor was converting the electronic prescription to a facsimile for delivery to the pharmacy.

The Board also heard from several pharmacies that they were not yet prepared to accept electronic prescriptions. Some of the vendors pointed to the pharmacies' inability to accept electronic prescriptions as to the reason for the automatic conversion to facsimile in order to facilitate delivery to the pharmacy. However, the vendors were not able to explain why they did not alert the prescriber of that conversion, which is a requirement for the electronic prescribing of controlled substances (CS).

The Board's intent for the rule change was to harmonize federal and state requirements for all medications, whether or not they are CS. Since several types of stakeholders do not yet appear ready for that goal, the Board has suggested a delay in the implementation of that particular requirement.

The proposed amendment to the rule will acknowledge that the use of an electronic signature on a facsimile prescription for a non-CS shall be construed as a validly formatted prescription for a temporary period of time, ending on December 31, 2016. This temporary allowance is designed to give the prescribing software vendors additional time to upgrade their systems to conform

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Counterfeit Botox Found in the United States, FDA Warns

On April 16, 2015, Food and Drug Administration (FDA) alerted health care providers that a counterfeit version of Botox® was found in the United States and may have been sold to doctors' offices and clinics throughout the country. The counterfeit products may be identified by a missing lot number on the vial, missing information on the carton (next to LOT, MFG, and EXP), and a displayed active ingredient as "Botulinum Toxin Type A" instead of "OnabotulinumtoxinA." The counterfeit products were sold by an unlicensed supplier who is not authorized to ship or distribute drug products in the US, according to an FDA Drug Safety Alert. The agency advises health care providers to confirm that the distributor from which they purchase Botox is authorized by Allergan, the drug's manufacturer. No adverse events related to this product have been reported to FDA.

Medical practices that purchase and administer counterfeit, illegal, and unapproved medications from unlicensed or foreign sources are putting patients' health at risk, as patients may not be getting proper treatment, warns FDA. Wholesale drug distributors must be licensed in the states where they conduct business. Suspicious Botox products may be reported to FDA's Office of Criminal Investigations. More information is available on the FDA website at *www.fda.gov/Drugs/DrugSafety/ucm443217.htm*.

One way pharmacies can be assured of the legitimacy of a wholesale distributor is to look for the National Association of Boards of Pharmacy® (NABP®) Verified-Accredited Wholesale Distributors® (VAWD®) Seal. Wholesale distributors that achieve VAWD accreditation are in compliance with state and federal laws, as well as NABP's VAWD criteria. Wholesale distributors that display the VAWD Seal as part of their accreditation have undergone a criteria compliance review, including a rigorous review of their operating policies and procedures, licensure verification, survey of facility and operations, background checks, and screening through the NABP Clearinghouse. Accredited facilities are reviewed annually and undergo an on-site survey every three years. Created in 2004, the accreditation program plays a pivotal role in preventing counterfeit drugs from entering the US drug supply.

Seven Persistent Safety Gaffes in Community/Ambulatory Settings That Need to Be Resolved!

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization 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 provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Errors Reporting Program Report online at* www.ismp.org. *Email: ismpinfo@ismp.org.*

ISMP has been reflecting on the strength and resolve of many across the nation who have demonstrated an unparalleled commitment to keeping patients safe. Despite the many safety accomplishments in 2014, ISMP cannot help but mull over persistent medication safety gaffes that continue to be unresolved. ISMP would like to share seven persistent safety gaffes of 2014, in three parts, with NABP *National Pharmacy Compliance News* readers with the hope that they will join ISMP in bringing attention to these crucial issues and the compelling need for their resolution. Part one of the three-part series is below.

1) Patient Counseling: Still Only a Veiled "Offer" in Many States

The effectiveness of patient counseling in a community pharmacy to detect and prevent medication errors, and its link to improved medication adherence and positive clinical outcomes have been well documented in the literature. Yet, studies have placed patient counseling rates at only eight percent to 42%. An increase in the frequency and quality of patient counseling has been linked to state-specific regulations that require patient counseling for new prescriptions coupled with strict enforcement surveillance. States that require an "offer" to counsel have very low patient counseling rates. Patients often fail to recognize an offer to counsel when simply asked, "Do you have any questions?" or told to "Please sign here." They may not even know what to ask. This means that, with few exceptions, pharmacies in states that require only an offer to counsel will likely dispense a powerful opioid such as fentanyl transdermal patches and allow the patient or caregiver to walk out of the pharmacy without even a brief discussion about safe use and disposal. ISMP has long promoted mandatory patient counseling in community pharmacies for prescriptions for targeted high-alert medications.

For a list of high alert community medications, please visit *www.ismp.org/communityRx/tools/ambulatoryhighalert.asp.* ISMP hopes you will use this list to determine which medications require mandatory patient education in order to reduce the risk of errors and minimize harm.

2) Patients Impacted by Dispensing Errors: Callous Response From Pharmacists

When patients report dispensing errors to ISMP, they are usually more upset about the response they received when contacting the pharmacist or pharmacy manager than the actual error itself. All too often, consumers tell ISMP that pharmacy staff have responded in a callous manner when confronted with the possibility of a dispensing error, demonstrating a lack of empathy and concern for the adverse effects the patient might have experienced. While pharmacy staff may want to be more responsive to patients who report errors, they are often following corporate policies that are focused on legal concerns. As patients are continually encouraged to be active participants in their health care, they want and deserve honest disclosure of errors, and knowledge that there is an action plan to reduce the risk of it happening again.

Flurbiprofen-Containing Topical Medication May Be Dangerous to Pets, Cautions FDA

People who use topical medications containing flurbiprofen, a nonsteroidal anti-inflammatory drug (NSAID), should take care to prevent their pets from being exposed to the drug, recommended FDA in an April 2015 Safety Alert. The warning is in response to reports of cats in two separate households that became ill or died after their owners used topical medications containing flurbiprofen to treat

muscle, joint, or other pain. Two cats in one household developed kidney failure and recovered with veterinary care. Two cats in a second household developed symptoms that included reluctance to eat, lethargy, vomiting, melena, anemia, and dilute urine, and subsequently died despite veterinary care. A third cat in the second household also died after the owner stopped using the medication. Necropsies on the three cats found evidence that were consistent with NSAID toxicity. The pet owners had applied the drug to their own neck or feet, and not directly to the pet, and it is not known exactly how the cats became exposed to the medication, the Safety Alert notes.

Health care providers who prescribe or dispense topical pain medications containing flurbiprofen should advise patients with pets to take steps to prevent exposure of the pets to the medication. Additional information is available in the FDA Safety Alert available at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm443386.htm*.

New FDA Drug Info Rounds Videos Available

FDA Drug Info Rounds, a series of online videos, provides important and timely drug information to practicing clinical and community pharmacists so they can help patients make better decisions. The latest Drug Info Rounds videos are as follows.

- In "NDC Directory," pharmacists demonstrate how to use this quick, easy, online resource.
- In "FAERS," pharmacists discuss the FDA Adverse Event Reporting System (FAERS) and review three ways FAERS data is made available to the public.

Drug Info Rounds is developed with contributions from pharmacists in FDA's Center for Drug Evaluation and Research, Office of Communications, Division of Drug Information. These videos and previous Drug Info Rounds resources are available on the FDA website at *www.fda.gov/Drugs/ResourcesForYou/HealthProfessionals/ucm211957.htm*.

Mucinex Cold, Sinus, and Flu Medications Recalled Due to Possible Labeling Error

In April 2015, RB (formerly Reckitt Benckiser) of Parsippany, NJ, issued a voluntary recall of certain lots of liquid Mucinex® due to a potential error involving the over-the-counter medications' drug facts labels. While the front label of the recalled lots correctly lists the name of the product as well as the active ingredients, some bottles may not have the correct corresponding drug facts label on the back. The recall was initiated after a confirmed report from a retailer. The recalled medications include:

- MUCINEX FAST-MAX Night-Time Cold & Flu;
- MUCINEX FAST-MAX Cold & Sinus;
- MUCINEX FAST-MAX Severe Congestion & Cough; and
- MUCINEX FAST-MAX Cold, Flu & Sore Throat.

If mislabeled, consumers who purchase these products may be unaware of the side effects and potential risks associated with active ingredients such as acetaminophen, dextromethorphan, guaifenesin, phenylephrine, and/or diphenhydramine. RB is recalling these products as a precautionary measure to ensure consumers have all relevant facts and warnings; the company asks consumers to dispose of any unused product.

Additional information about the recall, including the lot numbers and expiration dates for the recalled medications and guidelines for safe disposal, is available on the FDA website at *www.fda.gov/Safety/Recalls/ucm444028.htm*.

Pharmacists Are Performing More Patient Care Activities, National Survey Indicates

Pharmacists are performing more patient care activities in a variety of health care settings and are spending less time in traditional dispensing roles, indicates the *2014 National Pharmacist Workforce Survey*. Specifically, the report found that 60% of pharmacists provided medication therapy management, and 53% performed immunizations in 2014, indicates a press release from the American Association of Colleges of Pharmacy (AACP). The survey was created using a random sample of 5,200 individuals selected from a list of 7,000 licensed pharmacists in the US. Response rate to the survey was 48%.

Additional details, including the full results of the survey and an executive summary, are available through the Resources section of the AACP website, *www.aacp.org*.

Potentially Lethal Drug Sold Globally as Diet Supplement, Warns INTERPOL

INTERPOL has issued a global alert for a drug known as 2.4-dinitrophenol (DNP), an illicit and potentially lethal drug sold as a dieting and body building aid. The "Orange Notice" warning about DNP was published in May 2015, following the death of a woman in the United Kingdom and the serious illness of a man in France. In the 1930s, DNP was used to boost metabolism and encourage weight loss, but it was taken out of circulation due to several deaths. Sold as a plain yellow powder, capsules, or cream, DNP is often illegally manufactured and sold via the Internet; unsafe manufacturing of the drug and potential contamination may be magnifying the dangers of taking the drug, notes INTERPOL.

Additional information is available on the INTERPOL website at *www.interpol.int/News-and-media/News/2015/N2015-050*.

HHS Announces New Interactive Training on Safe Opioid Use

The Department of Health and Human Services (HHS) has announced a new, interactive training course that teaches health care providers how to talk to patients about safely using opioids to manage chronic pain. The course, "Pathways to Safer Opioid Use," also teaches implementation strategies for meeting the opioid-related recommendations from the National Action Plan for Adverse Drug Event Prevention. Adverse drug events (ADEs) are the largest contributor to hospital-related complications and account for more than 3.5 million physician office visits each year, according to HHS. The training, which is offered at no cost, includes self-guided interactive videos with decision points to help users learn how to apply health literacy strategies to help patients understand and act on information to prevent opioid-related ADEs; identify individual risk factors, opioid medications, and interactions that place individuals with chronic pain at increased risk for opioid-related ADEs; recognize the importance of a multidisciplinary team-based approach to treating patients with chronic pain; and demonstrate the ability to combine the principles of the Health Literate Care Model and the biopsychosocial model.

Additional information, including a link to the National Action Plan for Adverse Drug Event Prevention, is available on the course website at *http://health.gov/hcq/training.asp#pathways*.

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with the federal standard, and will also provide additional time for pharmacies to upgrade their information systems to accept and process electronic prescriptions. Given the impact on patient care from inadvertently invalid prescription formats, the Board authorized the adoption of the emergency rule while the formal rule-making process is completed.

Do You Have Any Debts Owed to the State of Louisiana? (15-07-491)

Act 399 of the 2013 Louisiana State Legislature established the Office of Debt Recovery within the Louisiana Department of Revenue, and then gave that office significant powers with its mission to collect debts owed to the state. Among those powers is the authority to request the denial, suspension, or revocation of any professional license issued by the state. The Board is required to cooperate with the Office of Debt Recovery, and the Board will be following procedures very similar to those it already follows with respect to defaulted student loans and defaulted child support court judgments. Please, take care of your business.

Disciplinary Actions (15-07-492)

During its February 2015 meeting, the Board took final action in the following matters.

Shalana Necole Cartwright (CPT.011395): *Formal Hearing* – For her failure to provide information requested by the Board relative to an arrest for unlawful possession of CS, the Board revoked the certificate, and further, assessed administrative, investigative, and hearing costs.

Winfield Gregory Woodruff (CPT.008650): *Formal Hearing* – For his failure to disclose criminal history information on his renewal application, and for his failure to provide information requested by the Board relative to that matter, the Board revoked his certificate, and further, assessed administrative, investigative, and hearing costs.

Jasmine O'Neal (PTC.021416): *Formal Hearing* – For her failure to provide information requested by the Board relative to a positive drug screen, the Board revoked the registration, and further, assessed administrative, investigative, and hearing costs.

During its May 2015 meeting, the Board took final action in the following matters.

Chandra Demetria Norman (PTC Applicant): For her failure to disclose her entire criminal history, the Board denied the application and refused to issue the registration.

John Wesley Hill III (PTC Applicant): For his failure to disclose his entire criminal history, the Board denied the application and refused to issue the registration.

Wal-Mart Louisiana, LLC, dba Wal-Mart Pharmacy No. 10-1109 (PHY.004768): For its dispensing of over 22,000 dosage units of CS from September 2013 through October 2014 pursuant to 285 prescriptions forged by a pharmacy technician working within the pharmacy, the Board assessed administrative and investigative costs.

Riche-Gebbie, Inc, dba Bradley's Pharmacy (PHY.000093): For its failure to acquire a new pharmacy permit when the ownership changed in January 2008, and for the continued operation of a pharmacy without a valid pharmacy permit, the Board assessed a fine of $30,000 plus administrative and investigative costs.

Loye's Pharmacy, Inc, dba Loye's Pharmacy (PHY.000683): For its failure to acquire a new pharmacy permit when the ownership changed in December 2010, and for the continued operation of a pharmacy without a valid pharmacy permit, the Board assessed a fine of $15,000 plus administrative and investigative costs.

Megan Nichole Beech (CPT.010807): For her diversion of approximately 150 dosage units of hydrocodone from her employer pharmacy, the Board suspended the certificate for five years and stayed the execution of the suspension, then placed the certificate on probation for five years, effective May 27, 2015, subject to certain terms enumerated in the consent agreement, and further, assessed administrative costs.

Brittaney Nicole Sanford (CPT.011833): The Board accepted the voluntary surrender of the credential, resulting in the active suspension of the certificate for an indefinite period of time, effective March 4, 2015.

Diamondback Drugs, LLC, dba Diamondback Drugs (PHY.006003): For its failure to acquire a new pharmacy permit when the ownership changed in January 2013, and for its continued operation of a pharmacy without a valid pharmacy permit, and for its continued dispensing of approximately 500 prescriptions into Louisiana while its permit had expired during the month of January 2015, the Board assessed a fine of $30,000 plus administrative and investigative costs.

Doddi Vidrine Alexander (PST.016007): For her practice of pharmacy with an expired license during calendar year 2013, the Board granted her request for the reinstatement of the lapsed license, suspended the license and stayed the execution of the suspension, then placed the license on probation for 10 years, effective May 27, 2015, subject to certain terms enumerated in the consent agreement, and further, assessed a fine of $5,000 plus administrative costs.

Richard Jeffrey Gaude (PST.015640): The Board granted his request for the reinstatement of the previously suspended license, converted the duration of the suspensive period from an indefinite term to a term of five years and stayed the execution of the suspension, then placed the license on probation for five years, effective May 27, 2015, subject to certain terms enumerated in the consent agreement.

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Alex Anthony Capace (PST.013422): The Board granted his request for the reinstatement of the previously suspended license, converted the duration of the suspensive period from an indefinite term to a term of five years and stayed the execution of the suspension, then placed the license on probation for five years, effective May 27, 2015, subject to certain terms enumerated in the consent agreement.

Edwin Paul Domingue, Jr (PST.010459): The Board denied his request for the removal of all probationary restrictions.

Robert Mark McGee (PST.015107): The Board granted his request for the removal of all probationary terms, originally scheduled to conclude in May 2017, and then restored his license to active and unrestricted status.

James Robert Lang (PST.010884): The Board granted his request for the removal of all probationary terms, originally scheduled to conclude in May 2020, and then restored his license to active and unrestricted status.

Isabelle Huey Robinson (CPT.003165): For her diversion of approximately 1,000 dosage units of hydrocodone, 500 dosage units of alprazolam, and four pints of promethazine syrup from her employer pharmacy, the Board revoked the certificate, and further, permanently prohibited the acceptance of any future application for the reinstatement of the certificate or for any other credential issued by the Board.

Celeste Ann Trahan (CPT.006620): For her diversion of CS from her employer pharmacy, the Board revoked the certificate, and further, permanently prohibited the acceptance of any future application for the reinstatement of the certificate or for any other credential issued by the Board.

Elizabeth Ann Marie Freeman (PTC.021790): For her admission to the routine use of an illicit substance, the Board revoked the registration, and further, permanently prohibited the acceptance of any future application for the reinstatement of the registration or for any other credential issued by the Board.

Tamia Anjani Cornish (PTC.020491): For her admission to approving her own prescriptions without prescriber authorization at her employer pharmacy, the Board revoked her registration, and further, permanently prohibited the acceptance of any future application for the reinstatement of the registration or for any other credential issued by the Board.

During the same meeting, the Board granted (1) conditional approval for the reinstatement of expired credentials for four technicians and one pharmacist, pending satisfaction of certain requirements identified in their consent agreements, and (2) one request for the return of an inactive pharmacist license to active status, conditioned upon the satisfaction of certain requirements identified in his or her consent agreement. The Board also issued a letter of warning to one pharmacy permit, as well as letters of reprimand to three pharmacists and one pharmacy permit. Finally, the Board suspended the controlled dangerous substances (CDS) license for six physicians whose medical licenses were suspended by the Louisiana State Board of Medical Examiners, as well as another physician who renewed his CDS license with a fraudulent payment.

Calendar Notes (15-07-493)

The Board office will be closed on July 3, in observance of Independence Day; September 7, in observance of Labor Day; and November 11, in observance of Veterans Day.

Special Note (15-07-494)

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™ (NABPF™) 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 NABPF or the Board unless expressly so stated.

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