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State Health Department Requests Pharmacist and Technician Volunteers (14-07-465)

The Center for Community Preparedness in the Office of Public Health at the Louisiana Department of Health and Hospitals is requesting your help as a volunteer. In the event of a public health emergency that requires mass prophylaxis for citizens in any part of the state, the first persons to receive medical countermeasures will be first responders, which includes (but is not limited to) law enforcement, emergency medical services, firefighters, as well as those who support various sectors of critical infrastructure. The State of Louisiana maintains assets for immediate response activities that are designated for prophylaxis for first responders. These medical countermeasures may be shipped in bulk containers and will require repackaging into individual antibiotic regimens. The oversight of repackaging activities is the responsibility of the Department of Health and Hospital's Office of Public Health (DHH-OPH) Pharmacy Services.

There is a current need to strengthen the existing repackaging response plans and increase the pool of professional volunteers dedicated to ensuring the timely preparation of individual antibiotic regimens for our first responders. It is for this purpose that DHH-OPH is soliciting for pharmacist and technician volunteers. DHH-OPH will assume all responsibility for providing volunteers with the information and training necessary for responding should the need ever arise. In the event you are interested, DHH-OPH requests pharmacists and technicians to enroll in the Louisiana Volunteers in Action Registry. Those professionals willing to support this effort will only be asked to serve within their respective DHH-OPH region should their services ever be required. To affiliate with the registry, interested pharmacists and technicians should visit the registry's website at *www.lava.dhh.louisiana.gov.* When you decide to complete the enrollment process, kindly reserve about 20 minutes and have your professional credentials and driver's license with you. In the event you have questions during the registration process, you may call 225/354-3517.

Note: This article was written by DHH-OPH personnel; the Louisiana Board of Pharmacy is pleased to collaborate with that agency to distribute this article to all of its licensed pharmacists and certified technicians.

Disciplinary Actions (14-07-466)

During its February 2014 meeting, the Board took final action in the following matter:

Harvey Lee Smith, Jr (PST.020467): Board approved application for pharmacist licensure by reciprocity, authorized issuance of the license, suspended the newly issued license for five years and suspended the execution of the suspension, then placed the license on probation for five years, effective February 13, 2014, subject to certain terms enumerated in the consent agreement; for two counts, including failure to disclose prior history on application for license.

During its May 7, 2014 meeting, the Board took final action in the following matters:

Joann Harris (PTC Applicant): For an extensive prior criminal history, the Board denied the application and refused to issue the registration.

Breanna Michelle Williamson (PTC.021390): In consideration of prior criminal history, the Board approved the application and authorized the issuance of the registration, then suspended it for two years and suspended the execution of the suspension, then placed it on probation for two years, effective May 8, 2014, subject to certain terms enumerated in the consent agreement.

Ashley Kristen Simon (PTC.021391): In consideration of prior criminal history, the Board approved the application and authorized the issuance of the registration, then suspended it for one year and suspended the execution of the suspension, then placed it on probation for one year, effective May 8, 2014, subject to certain terms enumerated in the consent agreement.

Tiffanie Lakayma Lebby (PTC.021392): In consideration of her failure to disclose an extensive prior criminal history, the Board approved the application and authorized the issuance of the registration, then suspended it for two years and suspended the execution of the suspension, then placed it on probation for two years, effective May 7, 2014, subject to certain terms enumerated in the consent agreement.

Orthofix, Inc, dba Orthofix (DME.000217): For its admission to a guilty plea to one count of obstruction of a 2008 Medicare audit, the Board suspended the permit for a period of time ending December 14, 2017, and suspended the execution of the suspension, then placed the permit on probation for a period of time ending December 14, 2017, and further, assessed a fine of $5,000 plus administrative costs.

Sentry Drugs of Louisiana, Inc, dba Sentry Drugs (PHY.001670): For its failure to obtain a new permit following a change of ownership and continuing to operate after the change, the Board assessed a fine of $15,000 plus administrative and investigative costs.

Robert Blake Vidrine dba Blake's Family Pharmacy (PHY.000077 and CDS.038544-PHY): For allowing the owner (whose pharmacist license was previously suspended) to receive verbal prescription orders for dispensing in the pharmacy while the pharmacy permit was on previously imposed probation, and

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New Educational Video for Pharmacists Addresses Prescription Drug Abuse

The National Association of Boards of Pharmacy® (NABP®) and the Anti-Diversion Industry Working Group (ADIWG), a consortium of pharmaceutical manufacturers and distributors of controlled substances (CS), have released an educational video for pharmacists to help them identify the warning signs of prescription drug abuse and diversion when dispensing CS prescriptions. The video, entitled "Red Flags," encourages pharmacists to help combat this national problem by exercising their professional judgment to ensure that the prescriptions they dispense were written for a legitimate medical purpose, and to act upon any unusual behavior they observe.

Drug Enforcement Administration and various state pharmacy boards have described "red flags" as circumstances surrounding the presentation of a CS prescription that should raise reasonable suspicion about the validity of that prescription. The video highlights a number of these potential warning signs, some of which are not easy to spot, by weaving personal narratives with interactions between pharmacists and customers.

The video is available in the Pharmacists section of the AWAR$_X$E® Prescription Drug Safety website at *www.AWARERX.ORG/pharmacists*.

Root Causes: A Roadmap to Action

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 Error Reporting Program Report online at* www.ismp.org. *E-mail: ismpinfo@ismp.org.*

Errors are almost never caused by the failure of a **single** element in the system. More often, there are **multiple** underlying system failures that lead to an error, many of which can be identified when the involved health care providers take the time to uncover them.

Consider the following error: A doctor sent a hand-written order for car**bam**azepine 400 mg twice daily for an adult patient with a history of seizures.

The pharmacist entered the medication into the profile of a four-year-old child with the same last name as the adult patient for whom the medication had been prescribed.

The pharmacist failed to notice that the patient was a child, as age was not in a prominent location on the order entry screen. The nurse failed to recognize that the dose was too high and administered 400 mg of car**bam**azepine to the child. She also never thought to question why the pharmacy would send oral tablets for a four-year-old child, considering that the drug is available in chewable tablets and as a liquid suspension.

The nurse **assumed** that the child was receiving the medication because he had a history of seizures. However, the nurse did not check the patient's medical record. In fact, the child did **not** have a history of seizures.

The parents had a very limited understanding of English, so they were unable to intervene to correct the erroneous seizure history.

The error was finally detected after the child became lethargic and developed nausea and vomiting. At the time of discovery, the child's car**bam**azepine level was 18 mcg/mL; levels greater than 12 in pediatric patients are supratherapeutic.[i]

It may be discouraging to see how many things go wrong when a medication error reaches a patient. However, a thorough root cause analysis (RCA) can uncover the latent failures and produce an action plan to avoid future errors.

ISMP, through a generous grant from the National Association of Boards of Pharmacy Foundation™, has developed the *Root Cause Analysis Workbook for Community/Ambulatory Pharmacy.* The workbook is designed to assist community pharmacy personnel in completing RCA for a sentinel event that may have occurred in their pharmacy. The RCA workbook uses a specific set of steps and associated tools to identify the primary causes of the **sentinel event.**

The goal of the RCA is to create an action plan framework, including risk-reduction strategies, communication and implementation strategies, and measurement of effectiveness.

RCA for **sentinel events** is required in the Center for Pharmacy Practice Accreditation's standards developed by NABP, American Pharmacists Association, and American Society of Health-System Pharmacists Association, as well as by several boards of pharmacy in conjunction with their continuous quality improvement regulations.

This ISMP RCA workbook is suitable for use in community pharmacy, mail-order pharmacy, or other ambulatory pharmacy practice settings that need to investigate a **sentinel event.** For more information and to access the **free** workbook, visit *www.ismp.org/tools/rca/.*

[i] *http://pediatrics.aappublications.org/content/113/2/406.abstract*

FDA Withdraws Approval of Some High Dose Acetaminophen Products

Food and Drug Administration (FDA) is withdrawing approval of 108 abbreviated new drug applications (ANDAs) for prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit. For the 108 ANDAs, the manufacturers asked to withdraw their applications, as announced in the March 27, 2014 *Federal Register* notice. A second *Federal Register* notice addresses the applications of six manufacturers who have discontinued marketing their products, but who have not withdrawn their applications. The notice also announces FDA's intention to begin the process of withdrawing approval of those applications.

In light of these announcements, and to protect patients from inadvertent acetaminophen overdose, NABP advises that pharmacies no longer dispense combination drugs containing more than 325 mg of acetaminophen per dosage unit. NABP also advises that pharmacists consult with prescribers to discuss alternative products with lower acetaminophen doses.

FDA asked manufacturers to voluntarily withdraw these products from the market to reduce the risk of severe liver injury from inadvertent acetaminophen overdose. In January 2014, FDA recommended that providers consider prescribing acetaminophen products containing 325 mg or less per dose. The original announcement may be found in the Drug Safety and Availability section of FDA's website at *www.fda.gov/Drugs/DrugSafety*.

NCPDP Recommends Standardized Metric Measurements on Oral Liquid Medication Labels

The National Council for Prescription Drug Programs (NCPDP) has issued new recommendations and guidance for standardizing the dosing designation used on prescription container labels of oral liquid medications dispensed by community pharmacies in order to reduce dosing errors. NCPDP notes that such errors have been "a source of concern for many years," and that dosing errors involving young children are of particular concern because they may be more susceptible to harm from measurement errors and overdoses. The paper outlines the following recommendations for the dosing designation on prescription container labels for oral liquid medications:

- The millimeter (mL) should be used as a standard unit of measurement.
- Dose amounts should always use leading zeros before decimal points for amounts less than one and should not use trailing zeros after a decimal point.
- Dosing devices with numeric graduations and units corresponding to the container label should be made easily and universally available. For example, a device should be included with each dispensed medication.

The white paper was developed following a meeting with stakeholders representing 27 participants, including NABP. In addition to its general recommendations, the white paper also issued calls to action for relevant stakeholders, including government agencies, standards organizations, pharmacists and pharmacy technicians, pharmacy leadership, and health care associations. The white paper, *NCPDP Recommendations and Guidance for Standardizing the Dosing Designations on Prescription Container Labels of Oral Liquid Medications,* is available for download from the NCPDP website at *http://ncpdp.org/Education/Whitepaper*.

USP Proposes New General Chapter Addressing Compounding of Hazardous Drugs

In an effort to protect health care providers and personnel who handle hazardous drugs, United States Pharmacopeial Convention (USP) has proposed new General Chapter <800> Hazardous Drugs–Handling in Healthcare Settings. The new proposed chapter addresses standards that apply to all personnel who compound hazardous drug preparations and all places where hazardous drugs are prepared, stored, transported, and administered. The new chapter also covers standards for receiving, storing, compounding, dispensing, administering, and disposing of nonsterile and sterile products and preparations. The proposed chapter applies to all personnel who are involved in handling hazardous drugs, including health care providers and staff, occupational health and safety specialists, and human resources. General Chapter <800> was published in the May/June issue of *Pharmacopeial Forum,* and may currently be viewed on the USP website at *www.usp.org/usp-nf*. Comments will be accepted until July 31, 2014.

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for operating the pharmacy without a pharmacist-in-charge (PIC) for an extended period of time, the Board revoked the previously imposed probation, suspended the pharmacy permit and controlled dangerous substances (CDS) license for 10 years and suspended the execution of the suspension, then placed the pharmacy permit and CDS license on probation for 10 years, effective May 7, 2014, subject to certain terms enumerated in the consent agreement, and further, assessed a fine of $10,000 plus administrative and investigative costs.

Louisiana CVS Pharmacy, LLC, dba CVS Pharmacy No. 5327 (PHY.005835): For operating the pharmacy without a PIC for approximately two months while the pharmacy permit was on previously imposed probation, the Board added two additional years of probation, effective July 1, 2014, and further, assessed a fine of $25,000 plus administrative and investigative costs.

Jewella Avenue Pharmacy, LLC, dba Jewella Avenue Pharmacy (PHY.006603): For its failure to properly close, the Board revoked the pharmacy permit.

Kawanda McCarty Williams (PST.017842): For her failure as owner and PIC to properly close Jewella Avenue Pharmacy, the Board assessed a fine of $1,000 plus administrative and investigative costs, and further, issued a lifetime restriction prohibiting her from having any ownership interest in any pharmacy licensed by the Board.

Donald Kermit Fellows, Jr, dba Central Rexall Drugs (PHY.000151): For its operation of a "call center" in a location not licensed by the Board, and for allowing pharmacy technicians to perform professional functions in that call center in the absence of direct and immediate supervision, the Board assessed a fine of $5,000 plus administrative and investigative costs.

Starns Pharmacy, LLC, dba Starns Pharmacy (PHY.006581): For allowing the illegal sale of pseudoephedrine products and for the improper record keeping of such transactions, the Board suspended the pharmacy permit for five years and suspended the execution of the suspension, then placed the pharmacy permit on probation for five years, effective May 7, 2014, subject to certain terms enumerated in the consent agreement.

Karl Lindell Starns, III (PST.011259): For the illegal sale of pseudoephedrine products and for the improper record keeping of such transactions, the Board suspended the license for five years and suspended the execution of the suspension, then placed the license on probation for five years, effective May 7, 2014, subject to certain terms enumerated in the consent agreement.

Donald Wayne Crawley (PST.010199): Board accepted the voluntary surrender, resulting in the suspension of the license for an indefinite period of time, effective March 31, 2014.

Tiffany Cathleen Luse Upshaw (PST.018936): Board accepted the voluntary surrender, resulting in the suspension of the license for an indefinite period of time, effective April 21, 2014.

Kasey Leah Hart (CPT.011051): Board accepted the voluntary surrender, resulting in the suspension of the certificate for an indefinite period of time, effective May 1, 2014.

Randy Wayne Owers (PST.018354): Board granted request for reinstatement of the previously suspended license, converted the duration of the suspensive period from an indefinite term to a term of five years and suspended the execution of the suspension, then placed the license on probation for five years, effective May 7, 2014, subject to certain terms enumerated in the consent agreement.

Scott Nolan Gewin (PST.017104): Board granted request for reinstatement of the previously suspended license, converted the duration of the suspensive period from an indefinite term to a term of five years and suspended the execution of the suspension, then placed the license on probation for five years, effective May 7, 2014, subject to certain terms enumerated in the consent agreement.

Jeremy Christopher Powell (PST.016108): Board granted request for modification of previously imposed probationary terms by removing all probationary restrictions and restoring the license to active and unrestricted status, effective May 7, 2014.

Wanda Jean Tamplin (CPT.002283): For the alleged diversion of hydrocodone from her employer pharmacy, the Board revoked the certificate, effective April 4, 2014, and further, prohibited the acceptance of any future application for the reinstatement of the certificate or for any other credential issued by the Board.

Alexandra Nicole McCrory (PTC.020116): For the alleged diversion of alprazolam and diazepam from her employer pharmacy, the Board revoked the registration, effective February 20, 2014, and further, prohibited the acceptance of any future application for the reinstatement of the registration or for any other credential issued by the Board.

Saundra Avis Zeringue (CPT.003936): For the alleged diversion of controlled substances from her employer pharmacy, the Board revoked the certificate, effective April 7, 2014, and further, prohibited the acceptance of any future application for the reinstatement of the certificate or for any other credential issued by the Board.

Jessica Rose Murnane (CPT.010353): For the alleged diversion of approximately 3,300 tablets of various strengths of hydrocodone from her employer pharmacy, the Board revoked the certificate, effective April 21, 2014, and further, prohibited the acceptance of any future application for the reinstatement of the certificate or for any other credential issued by the Board.

During the same meeting, the Board granted conditional approval for the reinstatement of an expired certificate for one technician, pending satisfaction of certain terms enumerated in the consent agreement. The Board also issued a letter of reprimand to one pharmacist, and further, it issued letters of warning to one pharmacist as well as the owners of five pharmacy permits. Finally, the Board suspended the CDS licenses for three physicians whose medical licenses were suspended by the Louisiana State Board of Medical Examiners, for another physician who surrendered his federal Drug Enforcement Administration registration, and for one nurse practitioner whose nursing license was suspended by the Louisiana State Board of Nursing.

Calendar Notes (14-07-467)

The next Board meeting and administrative hearing will be held on November 13-14, 2014, at the Board office. The office will be closed September 1, in observance of Labor Day, and November 11, in observance of Veterans Day.

Special Note (14-07-468)

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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