August 2014

News

SC Department of Labor, Licensing, & Regulation – Board of Pharmacy

Published to promote compliance of pharmacy and drug law

Kingstree Bldg, 110 Centerview Dr • PO Box 11927 • Columbia, SC 29211-1927
www.llr.state.sc.us/pol/pharmacy • 803/896-4700

Board Elects Officers

At its June 2014 meeting, the South Carolina Department of Labor, Licensing, & Regulation – Board of Pharmacy elected as its chairperson Addison Livingston, PharmD, RPh, of Swansea, SC. Livingston is the pharmacist representing the Second Congressional District.

Robert Hubbard, RPh, of Clemson, SC, representing the Third Congressional District, was elected vice chairperson. Each will serve a one-year term from July 1, 2014 until June 30, 2015.

Flu Season Is Approaching: Important Legal Requirements from the Pharmacist-Administered State Influenza Protocol

The pharmacist must meet the following qualifications: (1) Currently licensed in good standing, (2) Hold current Basic Life Support Training, (3) Completion of an Accreditation Council for Pharmacy Education-approved immunization course, (4) Completion of at least one hour of approved continuing education (CE) covering influenza vaccine administration, and (5) Have liability insurance covering vaccine administration.

Under this protocol, the age restriction is 18 years and older for those receiving the vaccine. Pharmacists must follow the proper sterile technique and gloving procedures when preparing the vaccine for administration. Needles must not be recapped before they are placed in the safety container. Pharmacists who are vaccinating are required to receive a Hepatitis B vaccine series or have demonstrated proof of immunity. Pharmacists must be aware and prepared to handle adverse events on the chance that an adverse reaction to the vaccine occurs.

Pharmacies administering influenza vaccines by state protocol are required to have the following supplies and equipment on hand:

- A current copy of the *South Carolina Board of Medical Examiners Protocol for Administration of Influenza Vaccine by Pharmacists.*
- A supply of the most current federal Vaccine Information Statements for influenza vaccines or electronic access to these statements.
- Aqueous epinephrine USP (1:1000) in ampules, vials of solution, or prefilled devices (ie, EpiPen®). If an EpiPen is to be stocked, at least three adult EpiPens (delivering a single dose of 0.3 mg/0.3 mL) should be available.
- Diphenhydramine (Benadryl®) injectable solution (50 mg/mL) and oral 25 or 50 mg tablets.
- Syringes: 1 mL and 3 mL, 22g and 25g, 1-inch, 1½-inch, and 2-inch needles for epinephrine and diphenhydramine.
- Alcohol swabs and bandages.
- Blood pressure monitoring device or stethoscope and sphygmomanometer (with adult and extra-large cuffs).
- Adult-size pocket mask with one-way valve.
- Flashlight with extra batteries (for examination of mouth and throat).
- Wrist watch with ability to count seconds.
- Telephone access.
- Equipment to enable the vaccinee to sit or lie down if he or she experiences an adverse reaction to the vaccine.
- A container to safely dispose of the used needles. It must comply with standards.

In accordance with the *South Carolina Board of Medical Examiners Protocol for Administration of Influenza Vaccine By Pharmacists,* the American Heart Association Basic Life Support Certification Course for Healthcare Providers is a qualification. The boards of pharmacy and medical examiners approved, effective January 27, 2014, the American Red Cross CPR course under the requirements of Section III(b) of the protocol for qualification as Basic Life Support certification.

The protocol can be found on the Board website.

Updates and Tips from SCRIPTS

By Christie Frick, RPh, Prescription Monitoring Program Director

The South Carolina Prescription Monitoring Program (SC PMP) would like to thank all dispensers for successfully transitioning to daily reporting and the use of American Society for Automation in Pharmacy 4.2 standards. Also, on the user end, the South Carolina Department of Health and Environmental Control (SC DHEC) is excited to report that it has more than 40% of practicing pharmacists registered as authorized users of the South Carolina Reporting & Identification Prescription Tracking System (SCRIPTS).

To address a few of its frequently asked questions, the SC DHEC is providing some **do's** and **don't's** of the SC PMP.

- **Do** use the SCRIPTS report to make educated health care decisions about your patients. The information can be used to supplement a patient evaluation, to confirm a patient's drug history, or document compliance with a therapeutic regimen.
- **Do** remember that all information is unconfirmed data.
- **Do** discuss the reports with patients.
- **Do** contact the SC DHEC if you have any questions by e-mail at scripts@dhec.sc.gov or by phone at 803/896-0688.
- **Do not** share your username and/or password with anyone.
- **Do not** give your patients their report. (Have them contact the SC PMP for their own copy.)
- **Do not** query anyone except your own patients.

Continued on page 4

National Pharmacy

(Applicability of the contents of articles in the National Pharmacy Comp
and can only be ascertained by examini

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 were accepted until July 31, 2014.

National Association of Boards of Pharmacy Foundation
1600 Feehanville Drive
Mount Prospect, IL 60056

SOUTH CAROLINA DEPARTMENT OF LABOR,
LICENSING, & REGULATION – BOARD OF PHARMACY

Presorted Standard
U.S. Postage
PAID
Chicago, Illinois
Permit No. 5744

Continued from page 1

Your Voices Have Been Heard!

On June 6, 2014, Governor Nikki R. Haley signed legislation to allow the registration of delegates for the SC PMP. An "authorized delegate" means an individual who is approved as having access to the SC PMP and who is directly supervised by an authorized practitioner or pharmacist. The SC DHEC anticipates delegate registration will begin later this year.

DEA Places Tramadol into Schedule IV; Final Rule Effective August 18, 2014

On Wednesday, July 2, 2014, Drug Enforcement Administration (DEA) published in the *Federal Register* the final rule placing tramadol into Schedule IV of the Controlled Substances Act. **This rule will become effective 45 days after publication, or Monday, August 18, 2014.** All regulatory requirements applicable to Schedule IV controlled substances (CS) will apply to tramadol beginning August 18, 2014. The final rule was available for public inspection on Tuesday, July 1, 2014, at *www.archives.gov/federal-register/public-inspection.* The final rule is posted on the DEA website and is also available at *www.regulations.gov.*

Tramadol is a centrally-acting opioid analgesic that produces its primary opioid-like action through an active metabolite, referred to as the "M1" metabolite (O-desmethyltramadol). Tramadol was first approved for use in the United States by the US Food and Drug Administration (FDA) in 1995, under the trade name ULTRAM®. Subsequently, FDA approved generic, combination, and extended release tramadol products. Tramadol is manufactured and distributed in various forms that include tablets, capsules, and liquid.

The abuse of tramadol products has increased over the last several years and it is used as a substitute for other opioids such as hydrocodone. The final rule imposes the regulatory controls and administrative, civil, and criminal sanctions applicable to Schedule IV CS on persons who handle (manufacture, distribute, dispense, import, export, engage in research, conduct instructional activities with, or possess) or propose to handle tramadol beginning August 18, 2014.

When the status of a non-CS is changed to that of a CS, each registrant who possesses that substance must take an inventory of all stocks of the substance on hand. The inventory date for a newly scheduled CS is on the effective date of the rule. Thereafter, such substance shall be included in each inventory made by the registrant.

Board Meeting Calendar

The Board welcomes all interested individuals to attend committee meetings held throughout the year at the Board office in Columbia, SC. Board meeting dates are listed below. For more information, please contact the Board office.

- September 17-18, 2014
- November 19, 2014
- January 14-15, 2015
- November 18, 2015
- March 18, 2015
- June 17-18, 2015
- September 16-17, 2015

The Board also has many special committees that meet periodically throughout the year to address specific concerns for the pharmacy community. These meetings are held at the discretion of the committee chairperson.

- Compounding – Carole Russell, RPh, chairperson
- Legislative – Addison Livingston, PharmD, RPh, chairperson
- Pharmacy Practice and Technology – Robert Hubbard, RPh, chairperson
- Scope of Practice – Robert Hubbard, RPh, chairperson
- Pharmacy Technician – Rebecca Gillespie, PharmD, RPh, chairperson
- Medication Integrity – David Banks, RPh, chairperson
- Nuclear – Spencer Morris, PharmD, RPh, BCPS, chairperson
- Recovering Professionals Program – Leo Richardson, PhD
- Non-Resident Application Review – Addison Livingston, PharmD, RPh, chairperson

For more information, or if you would like to be added to the agenda distribution list for Board or committee meetings, please contact the Board office.

CE Audits

According to §40-43-130 of the South Carolina Pharmacy Practice Act, the Board shall conduct an audit of CE credits of 10% of its licensees, randomly selected, of the total number of active pharmacists and pharmacy technicians renewing. Staff will be sending out notices to the individuals selected for the random audit. Pharmacist CE audit notices were sent in July, and pharmacy technician audit notices will be sent in August. If you are selected for the audit, you must submit copies of certificates of CE programs you have completed for the 2014-2015 renewal period. CE certificates will be accepted from January 1, 2012, until the date you submitted your 2014 renewal application. Failure to comply with the CE audit may result in disciplinary action.

The *South Carolina Board of Pharmacy News* is published by the South Carolina 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.

Lee Ann F. Bundrick, RPh, Administrator - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Deborah Zak - Communications Manager