November 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

Upcoming Board Vacancy

If you live in the Second Congressional District and are interested in serving on the South Carolina Department of Labor, Licensing, & Regulation – Board of Pharmacy, you must meet the following requirements:

- Reside in the Second Congressional District;
- Be licensed and actively practicing pharmacy in South Carolina; and
- Before December 1, 2014, submit to the Board office a biography and petition bearing signatures of at least 15 pharmacists practicing in the Second Congressional District. The term begins July 1, 2015 and ends June 30, 2021.

After receiving biographies and petitions, the Board administrator will:

- Prepare and mail ballots by January 15, 2015, to all pharmacists who have notified the Board that they reside in the Second Congressional District; and
- Certify as true and valid all ballots postmarked before February 15, 2015, and received by the Board office before February 25, 2015.

Before March 1, 2015, the Board will certify in writing to the governor the names of the three candidates receiving the most votes in the election and the name of the person who the nominee will replace on the Board. The new member, when appointed by the governor, will take office on July 1, of that year.

If you are interested in becoming a candidate for this position or have any questions, please contact the Board office.

Board Welcomes New Inspector

Alison Gratton joined the Board staff as an inspector on August 4, 2014. She holds a bachelor of science degree in pharmacy from the University of South Carolina College of Pharmacy and a bachelor of science degree in broadcasting from John Brown University. A second generation pharmacist, Gratton has practiced for 20 years in mail-order and retail pharmacy practice settings. She was also a conversion trainer for both Rite Aid and CVS/pharmacy. Prior to her pharmacy career, she worked in the banking industry. Alison lives with her husband, George, in Blythewood, SC.

Consultant Pharmacist Written Monthly Inspections

At its June 2014 meeting, the Board approved the following interpretation of South Carolina Code Annotated §40-43-86(C)(1)(f): "The consultant pharmacist of record may delegate the written monthly inspection reports to a South Carolina licensed pharmacist, the consultant pharmacist must countersign the inspection report/form and send it to the non-dispensing drug outlet site to retain in their records. It may be sent electronically."

S.C. Code Ann. §40-43-86(C)(1) states:

(C) Except for a pharmacy, wholesaler, or a permitted facility that supplies only oxygen, every holder of a permit from the Board shall designate a pharmacist duly licensed by the Board of Pharmacy as a consultant pharmacist to be responsible for the duties as stated in this chapter at the permit holder's location. The consultant pharmacist shall sign a new or renewal application along with the permit holder and agree in writing to assume the responsibilities of consultant pharmacist.

(1) The consultant pharmacist must be consistent with the accepted standards of professional conduct and practice and responsible for compliance with all applicable laws and regulations including:

(a) establishing as applicable to the permit, policies, and procedures for the procurement, storage, compounding, dispensing, and distribution of drugs;

(b) establishing and supervising the record-keeping system for the purchase, sale, possession, storage, safekeeping, and return of drugs;

(c) facilitating drug recalls and the removal of outdated and adulterated drugs;

(d) supervising all employees of the permit holder whose duties relate to the procurement, compounding, sale, distribution, and storage of drugs;

(e) acting as a drug information resource for the staff by bringing new and current drug information to their attention and being available by phone for questions;

(f) performing written monthly inspections that are readily available.

Continued on page 4

DEA Reschedules Hydrocodone Combination Products as Schedule II

Drug Enforcement Administration (DEA) has published its final rule rescheduling hydrocodone combination products from Schedule III to Schedule II in the *Federal Register.* The change imposes Schedule II regulatory controls and sanctions on anyone handling hydrocodone combination products, effective October 6, 2014. DEA first published the proposed rules in March 2014 in response to a Food and Drug Administration (FDA) recommendation. DEA received almost 600 public comments regarding the proposed rules after they were published, with a small majority of the commenters supporting the change, DEA notes in a press release, which is available at *www.justice.gov/dea/divisions/hq/2014/hq082114.shtml.*

The announcement is available on the *Federal Register* website at *https://federalregister.gov/articles/2014/08/22/2014-19922/schedules-of-controlled-substances-rescheduling-of-hydrocodone-combination-products-from-schedule.*

The mL-Only Standard for Liquid Dosing Gathers Steam

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. *E-mail: ismpinfo@ismp.org.*

ISMP first reported on the confusion of teaspoonfuls and milliliters (mL) in its newsletter in 2000, and in 2009, issued a call for practitioners to move to sole use of the metric system for measuring over-the-counter and prescription oral liquid doses, but mix-ups have continued to result in the serious injury of children and adults. Use of the metric system alone when prescribing, dispensing, and administering medications would prevent mix-ups because there would only be one method used to communicate and measure doses.

The health care industry is beginning to acknowledge the risk of confusion when using non-metric measurements, especially with oral liquid medications. The National Council for Prescription Drug Programs (NCPDP) just released a white paper entitled *NCPDP Recommendations and Guidance for Standardizing the Dosing Designations on Prescription Container Labels of Oral Liquid Medications,* which is available at *www.ismp.org/sc?id=337.* The white paper supports mL as the standard unit of liquid measure used on prescription container labels for oral liquid medications. It also calls for dosing devices with numeric graduations, and for units that correspond to the container labeling to be easily and universally available, such as including a device each time oral liquid prescription medications are dispensed. NCPDP also reiterates that dose amounts should always use leading zeroes before the decimal point for amounts less than one, and should not use trailing zeroes after a decimal point on labels for oral liquid medications.

The white paper comes as welcome news and is well-aligned with the *ISMP 2014-15 Targeted Medication Safety Best Practices for Hospitals,* Best Practice 5, which calls for organizations to use oral liquid dosing devices (oral syringes/cups/droppers) that only display the metric scale. The white paper also comes at a time when the Centers for Disease Control and Prevention, ISMP, the Consumer Healthcare Products Association, the United States FDA, the US Metric Association, and the American Academy of Pediatrics have initiatives in place that will help guide health care organizations to commit to metric measurements.

ISMP recommends the following actions to help prevent errors:

- Use only metric units, not teaspoon or other non-metric measurements, for all patient instructions, including those listed in prescribing and pharmacy computer systems. This should cover directions incorporated into computer system mnemonics, speed codes, or any defaults used to generate prescriptions and prescription labels.
- Take steps to ensure patients have an appropriate device to measure oral liquid volumes in milliliters.
- Coach patients on how to use and clean measuring devices; use the "teach back" approach and ask patients or caregivers to demonstrate their understanding.

DEA Classifies Tramadol a Controlled Substance

Under a final rule published in the *Federal Register*, the pain reliever tramadol is now classified as a Schedule IV controlled substance. As of August 18, 2014, DEA requires manufacturers to print the "C-IV" designation on all labels that contain 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl) cyclohexanol (tramadol), including its salts, isomers, and salts of isomers. The agency notes that every "DEA registrant who possesses any quantity of tramadol on the effective date of this final rule must take an inventory of all stocks of tramadol on hand as of August 18, 2014, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11 (a) and (d)." In addition, all "prescriptions for tramadol

or products containing tramadol must comply with 21 U.S.C. 829, and be issued in accordance with 21 CFR part 1306 and subpart C of 21 CFR part 1311 as of August 18, 2014."

The announcement is available on the *Federal Register* website at *www.federalregister.gov/articles/2014/07/02/2014-15548/schedules-of-controlled-substances-placement-of-tramadol-into-schedule-iv*.

FDA Lowers Recommended Starting Dose for Lunesta Due to Risk of Morning Impairment

FDA has lowered the recommended starting dose of the sleep drug Lunesta® (eszopiclone) from 2 mg to 1 mg. Patients who are currently taking 2 mg and 3 mg doses of eszopiclone should contact their health care provider to ask for instructions on how to continue to take their medication safely at a dose that is best for them, FDA advises. The dose change came after findings from a study of 91 healthy adults found that the medication was associated with impairment to driving skills, memory, and coordination for as long as 11 hours after the drug is taken, FDA notes.

More information is available in an FDA news release at *www.fda.gov/newsevents/newsroom/pressannouncements/ucm397453.htm*.

Lidocaine Should Not Be Used to Treat Teething Pain in Children, FDA Warns

FDA is recommending that prescription oral viscous lidocaine 2% solution should not be used to treat infants and children with teething pain, and is now requiring a new boxed warning to be added to the drug label to highlight this information. Oral viscous lidocaine solution is not approved to treat teething pain, and use in infants and young children can cause serious harm, including death, indicates FDA in a June 2014 Safety Announcement. FDA advises health care providers not to prescribe or recommend this product for teething pain. FDA is also requiring the "Warnings" and "Dosage and Administration" sections of the drug label to describe the risk of severe adverse events and to include additional instructions for dosing when the drug is prescribed for approved uses.

In 2014, FDA reviewed 22 case reports of serious adverse reactions, including deaths, in infants and young children who were either given lidocaine for treatment of mouth pain, or who accidentally ingested the medication.

More information is available in the safety announcement on FDA's website at *www.fda.gov/Drugs/DrugSafety/ucm402240.htm*.

FDA Reiterates Warning Against Using NuVision Pharmacy Products

Health care providers should not use or distribute compounded drugs marketed as sterile produced by Downing Labs, LLC, of Dallas, TX, also known as NuVision Pharmacy, warns FDA. Inspection results issued on July 16, 2014, indicate that FDA observed unsanitary conditions resulting in a lack of sterility assurance of sterile drug products produced by the company, which may put patients at risk, FDA notes in the safety announcement. "The inspection revealed sterility failures in 19 lots of drug products intended to be sterile, endotoxin failures in three lots of drug products, and inadequate or no investigation of these failures," states FDA in the announcement.

In 2013, the agency issued several similar warnings following NuVision's refusal to recall all sterile products. In April 2013, NuVision recalled methylcobalamin injection and lyophilized injection products, citing concerns about sterility in the wake of adverse event reports. Health care providers and consumers may report adverse events or quality problems associated with NuVision products to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Additional information is available in the safety announcement, available on FDA's website at *www.fda.gov/Drugs/DrugSafety/ucm405940.htm*.

JCPP Releases New Patient-Care Document to Promote Consistency

The Joint Commission of Pharmacy Practitioners (JCPP) has released a resource document aimed at promoting consistency in the pharmacists' process of patient care service delivery. "Pharmacists' Patient Care Process" was developed by examining key source documents on pharmaceutical care and medication therapy management. The document describes the process in five parts: collect, assess, plan, implement, and follow-up.

JCPP brings together the chief executive officers and elected officers of national pharmacy associations, including the National Association of Boards of Pharmacy®, to create a forum for discussion and opportunity for collaborative work on issues and priorities of pharmacy practice.

The document can be downloaded online at *www.pharmacist.com/sites/default/files/JCPP_Pharmacists_Patient_Care_Process.pdf*.

CPE Credit Offered for FDA Course on Misleading Prescription Drug Promotion

To raise awareness about the risks associated with false or misleading prescription medication marketing, FDA, in partnership with Medscape, is offering an online, one-hour continuing education course through its Bad Ad Program. Pharmacists may receive continuing pharmacy education (CPE) credit by taking this course. Learning objectives, faculty information, and other information is available on the course's website at *www.sigmatech.com/BadAd*. There is no registration fee for the course. Upon completion, pharmacists will receive one Accreditation Council for Pharmacy Education-accredited CPE hour (0.1 continuing education unit).

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

The intent of this interpretation was to provide clarification regarding coverage of consultant pharmacist duties when the consultant pharmacist is not available. S.C. Code Ann. §40-43-86(C)(1)(a-e) shall be performed by the consultant pharmacist. Also, the monthly inspections, as required by §40-43-86(C)(1)(f), **should be performed by the consultant pharmacist.** However, should the consultant pharmacist be unavailable, another South Carolina licensed pharmacist may cover the inspection. The pharmacist actually performing the inspection **must document the inspection by signing his or her name on the inspection form. The inspection is not delegable to a state certified technician or a registered pharmacy technician.** The consultant pharmacist must review, sign, and date the inspection form in a timely manner.

If you are a consultant pharmacist, please be aware that you are responsible for any violations found under the non-dispensing pharmacy permit, regardless of whether you or another pharmacist performs the monthly inspection. Additionally, if another pharmacist covers the monthly inspection for the consultant pharmacist, the pharmacist actually performing the inspection will also be liable for any violations from the inspection covered. Under S.C. Code Ann. §40-1-110(k), the Board has the authority to fine, cancel, revoke, or restrict the authorization to practice of the individual for any violation of the practice act or regulations.

Please be mindful of your obligations as a consultant pharmacist. **As a consultant pharmacist, the best practice is to cover all duties required of you under §40-43-86(C)(1).** However, the Board recognizes the practical need for coverage when a consultant pharmacist is unavailable. If you cover for a consultant pharmacist, you should also be mindful that you **must** document the inspection by signing your name to the inspection report, and know that you also must ensure that the South Carolina Pharmacy Practice Act and regulations of the Board are followed. Failure to do so may result in disciplinary action against your license and the permit.

Tax Credit for State Certification Apprenticeship, Opportunities for South Carolina Pharmacies

By Candice Geiger, pharmacy technician program director, Midlands Technical College, and Brad Neese, director, Apprenticeship Carolina

Apprenticeship Carolina, in conjunction with your local technical college or other accredited pharmacy technician training programs, can aid in getting your pharmacy technician employees state certified. Regardless of company size, you can develop a registered apprenticeship program and receive a $1,000 state tax credit per apprentice (pharmacy technician trainee/employee) per year (up to four years). Apprenticeships are a combination of structured on-the-job training and job-related education. Often this is a less formal process, but Apprenticeship Carolina can help formalize and structure the training process free of charge to the participating South Carolina pharmacies. Pharmacies are not required to develop a structured education program, and can utilize American Society of Health-System Pharmacists (ASHP)-accredited programs that are currently offered. Pharmacy technician certificate programs offered at nine different technical colleges across the state allow a pharmacy technician who is currently working to complete his or her formal education leading to state certification. If you are interested in pursuing a registered apprenticeship program, the Board encourages you to contact Apprenticeship Carolina at 803/896-5376 or visit them online at *www.apprenticeshipcarolina.com* to contact the consultant in your area, and contact an ASHP-accredited program in your area regarding its pharmacy technician certificate program *(http://accred.ashp.org/aps/pages/directory/technicianProgramDirectory.aspx)*.

Rescheduling of HCPs as Schedule II CS by DEA

Effective October 6, 2014, Drug Enforcement Administration (DEA) has rescheduled hydrocodone combination products (HCPs) from Schedule III to Schedule II controlled substances (CS). Communication from the South Carolina Department of Health and Environmental Control, Bureau of Drug Control indicates that South Carolina will follow all of DEA's guidelines regarding the rescheduling of these products.

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