August 2015

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 2015 meeting, the South Carolina Department of Labor, Licensing, & Regulation – Board of Pharmacy elected Robert C. Hubbard, RPh, of Clemson, SC, as its chairperson. Hubbard is the pharmacist representing the Third Congressional District.

Carole S. Russell, RPh, of Charleston, SC, representing the First Congressional District, was elected vice chairperson. Each will serve a one-year term from July 1, 2015, until June 30, 2016.

Board Welcomes New Member

The Board congratulates Eric J. Strauss, PharmD, RPh, of Greenville, SC, on his recent appointment to the Board by Governor Nikki Haley.

Strauss' term expires on June 30, 2020. He represents the Fourth Congressional District and replaces David Banks, RPh. Strauss is currently employed by Walgreens and will provide valuable experience in chain pharmacy practice.

The Board welcomes its new member and offers sincere appreciation to Banks for his dedicated service to the citizens of South Carolina and to the profession of pharmacy.

Board Welcomes New Part-Time Inspector

Regina Erving, RPh, joined the Board staff as a part-time pharmacist inspector on April 2, 2015. She earned a bachelor of science degree in pharmacy from the Medical University of South Carolina in 1978. Erving was the previous director of the South Carolina Department of Health and Environmental Control Bureau of Drug Control and retired in June 2014. She has extensive regulatory and long-term care pharmacy experience, as well as retail, hospital, and pharmaceutical sales. Erving has practiced pharmacy in Virginia, Ohio, and South Carolina. The Board and staff look forward to working with Erving in her new role.

Optometrists May Prescribe Rescheduled HCPs

Effective May 7, 2015, Section 40-43-290 of the 1976 Code of Laws was amended as follows:

Section 40-37-290. Notwithstanding any other provision of law, an optometrist may purchase, possess, administer, supply, and prescribe pharmaceutical agents, including oral and topically applied medications other than Schedule I and II controlled substances as defined in Section 44-53-110 except controlled substances that have been reclassified from Schedule III to Schedule II effective on or after October 6, 2014, may continue to be purchased, possessed, administered, supplied, and prescribed by an optometrist, for diagnostic and therapeutic purposes in the practice of optometry, except that:

(1) when prescribing oral and topically applied medications, an optometrist is limited to these oral pharmaceutical agents: antihistamines, antimicrobial, antiglaucoma, over-the-counter drugs, and analgesics for the treatment of ocular and ocular adnexal eye disease. An optometrist may only prescribe these medications for the treatment of ocular and ocular adnexal eye disease;

(2) when prescribing medications for the treatment of ocular and ocular adnexal disease, documentation in the patient's chart and appropriate consultations and referrals must be in accordance with the standard of care provided for in Section 40-37-310(E);

(3) when prescribing analgesics, the prescription must be limited to a seven-day supply;

(4) when prescribing topical steroids, if after twenty-one days of treatment it is necessary to continue this medication, the optometrist shall

Continued on page 4

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*.

Continued from page 1

communicate and collaborate with an ophthalmologist;

(5) no medications may be given by injection or intravenously.

As a reminder, effective October 6, 2014, Drug Enforcement Administration rescheduled hydrocodone combination products (HCPs) from Schedule III to Schedule II controlled substances.

Revisions Made to Vaccine Law

Section 40-43-190 of the 1976 Code, as added by Act 224 of 2010, is amended to read:

Section 40-43-190.

(A)(1) Upon recommendation of the Joint Pharmacist Administered Vaccines Committee, the Board of Medical Examiners shall determine whether a specific vaccine is appropriate for administration by a pharmacist without a written order or prescription of a practitioner pursuant to this section. If a vaccine is approved, the Board of Medical Examiners shall issue a written protocol for the administration of vaccines by pharmacists without an order or prescription of a practitioner.

(2) The administration of vaccines as authorized in this section must not be to a person under the age of eighteen years; provided, however, that:

(a) the influenza vaccine may be administered to a person twelve years of age or older pursuant to protocol issued by the Board of Medical Examiners; and

(b) a pharmacist who has completed the training described in subsection (B)(1) may administer a vaccine approved by the Centers for Disease Control to a person of any age pursuant to a written order or prescription of a practitioner for a specific patient of that practitioner.

(3) The written protocol must further authorize pharmacists to administer without an order or prescription of a practitioner those medications necessary in the treatment of adverse events. These medications must be used only in the treatment of adverse events and must be limited to those delineated within the written protocol.

(4) The Board of Medical Examiners must issue the written protocol upon its approval of the vaccine for administration pursuant to this section.

(5) A pharmacist who has completed the training described in subsection (B)(1) may administer a vaccine approved by the Centers for Disease Control pursuant to written order or prescription of a practitioner for a specific patient of that practitioner.

(B) The written protocol must provide that:

(1) A pharmacist seeking authorization to administer a vaccine approved pursuant to this section shall successfully complete a course of training accredited by the Accreditation Council for Pharmacy Education or a similar health authority or professional body approved by the Board of Pharmacy and the Board of Medical Examiners. Training must comply with current Centers for Disease Control guidelines and must include study materials, hands-on training, and techniques for administering vaccines and must provide instruction and experiential training in the following content areas:

(a) mechanisms of action for vaccines, contraindications, drug interactions, and monitoring after vaccine administration;

(b) standards for adult vaccination practices;

(c) basic immunology and vaccine protection;

(d) vaccine-preventable diseases;

(e) recommended vaccination schedules;

(f) vaccine storage management;

(g) biohazard waste disposal and sterile techniques;

(h) informed consent;

(i) physiology and techniques for vaccine administration;

(j) prevaccine and postvaccine assessment and counseling;

(k) vaccination record management;

(l) management of adverse events, including identification, appropriate response, emergency procedures, documentation, and reporting;

(m) understanding of vaccine coverage by federal, state, and local entities;

(n) needle stick management.

(2) A pharmacist administering vaccinations without an order or prescription of a practitioner pursuant to this section shall:

(a) obtain the signed written consent of the person being vaccinated or that person's guardian;

(b) maintain a copy of the vaccine administration in that person's record and provide a copy to the person or the person's guardian;

Continued on page 5

Continued from page 4

(c) notify that person's designated physician or primary care provider of a vaccine administered;

(d) report administration of all vaccinations to the South Carolina Immunization Registry in compliance with regulations established by the Department of Health and Environmental Control as the department may require; provided, however, that the phase-in schedule provided in Regulation 61-120 for reporting vaccinations does not apply to vaccinations administered pursuant to this section;

(e) maintain a current copy of the written protocol at each location at which a vaccination is administered pursuant to this section.

(3) A pharmacist may not delegate the administration of vaccines to a pharmacy technician or certified pharmacy technician.

(4) A pharmacy intern may administer vaccinations under the direct supervision, as defined in Section 40-43-84(C), of a pharmacist who has completed vaccination training as required by item (1) if the pharmacy intern:

(a) is certified through a basic life support or CPR provider-level course that is jointly approved by the Board of Medical Examiners and the Board of Pharmacy; and

(b) completes this course of training described in item (1).

(5) A pharmacist administering vaccinations shall, as part of the current continuing education requirements pursuant to Section 40-43-130, complete no less than one hour of continuing education each license year regarding administration of vaccinations.

(C) Informed consent must be documented in accordance with the written protocol for vaccine administration issued pursuant to this section.

(D) All records required by this section must be maintained in the pharmacy for a period of at least ten years from the date of the last vaccination for adults and at least thirteen years from the date of the last vaccination for minors.

(E) All documentation, records, and copies required by this section may be stored electronically.

Joint Pharmacist Administered Vaccines Committee Recommendations and Duties Are Defined

SECTION 2. Section 40-43-200 of the 1976 Code, as added by Act 224 of 2010, is amended to read:

Section 40-43-200.

(A) There is created a Joint Pharmacist Administered Vaccines Committee as a committee to the Board of Medical Examiners which consists of seven members with experience regarding vaccines. The committee is comprised of two physicians selected by the Board of Medical Examiners, two pharmacists selected by the Board of Pharmacy, and two advanced practice nurse practitioners selected by the Board of Nursing. One member of the Department of Health and Environmental Control designated by the director of the department also shall serve on the committee. Members of the committee may not be compensated for their service on the board and may not receive mileage, per diem, and subsistence as otherwise authorized by law for members of state boards, committees, and commissions.

(B) The committee shall meet at least once annually and at other times as may be necessary. Five members constitute a quorum for all meetings. At its initial meeting, and at the beginning of each year thereafter, the committee shall elect from its membership a chairperson to serve for a one year term.

(C) The committee shall assist and advise the Board of Medical Examiners in determining whether a specific vaccine is appropriate for administration by a pharmacist without a written order or prescription of a practitioner pursuant to Section 40-43-190. For a specific vaccine recommended by the committee to the Board of Medical Examiners, the committee also must submit a proposed written protocol for the purpose of authorizing pharmacists to administer the vaccine as authorized by Section 40-43-190. The committee must submit its initial recommendations to the board no later than four months after the passage of this act, and periodically thereafter as determined by the committee.

The Board selected Terry Blackmon, RPh, and Brandon Bookstaver, PharmD, RPh, to represent the Board on the Joint Pharmacist Administered Vaccines Committee. The Board will update you on any new protocols and/or changes to the current state influenza protocol.

Flu Season Is Approaching

Please review the current *Protocol for Administration of Influenza Vaccine by Pharmacists* and appendixes on the Board website, *www.llr.state.sc.us/pol/pharmacy,* to familiarize yourself with the qualifications to administer the vaccine and the requirements of supplies and

Continued on page 6

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 5

equipment to have on hand. Pharmacist inspectors will be inspecting to monitor compliance with the protocol.

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.

CE Audits Are on the Horizon

According to §40-43-130 of the South Carolina Pharmacy Practice Act, the Board shall conduct an audit of continuing education (CE) credits of 10% of the 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 CE 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 2015-2016 renewal period. CE certificates will be accepted from January 1, 2013, until the date you submitted your 2015 renewal application. Failure to comply with the CE audit may result in disciplinary action.

Board Updates Meeting Calendar

The Board welcomes all interested individuals to its committee meetings held throughout the year at the Board office in Columbia, SC. Board meeting dates are listed below.

- September 16-17, 2015
- November 18, 2015
- January 13-14, 2016
- March 16, 2016
- June 15-16, 2016
- September 14-15, 2016
- November 16, 2016

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 – Terry Blackmon, RPh, chairperson
- Pharmacy Technician – Rebecca Gillespie, PharmD, RPh, chairperson
- Medication Integrity – Addison Livingston, PharmD, RPh, chairperson
- Nuclear – Spencer Morris, PharmD, RPh, BCPS, chairperson
- Recovering Professionals Program (RPP) – Leo Richardson, PhD
- Non-Resident Application Review

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.

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