September 2015

Kentucky Board of Pharmacy News

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Drug Manufacturer, Home Medical Equipment Provider, and Wholesale Distributor Renewal Deadline September 30, 2015

Drug manufacturer, home medical equipment provider, and wholesale distributor permits/licenses expire on September 30, 2015. A drug manufacturer, home medical equipment provider, or wholesale distributor may renew and pay the fee online. Renewal applications will not be mailed out; however, a renewal form may be printed from the Kentucky Board of Pharmacy website at *www.pharmacy.ky.gov.* If you have any questions concerning the renewal process, please contact the Board office. A drug manufacturer, home medical equipment provider, or wholesale distributor application with only a United States Post Office Box address will **not** be accepted and will be returned. All incomplete applications will be returned. Remember, the deadline is September 30, 2015.

Board Meeting and Retreat 2015

The Seelbach Hilton Louisville hotel located in downtown Louisville, KY, will be the site of the 2015 Board meeting/retreat. The Board meeting will begin at 9 AM on Friday, October 23, 2015. The Board retreat will begin at 8 AM on Saturday, October 24, 2015.

The Board is requesting that any individual or organization submit topics concerning public safety to be considered for discussion at the Board retreat. Please submit any suggestion(s) to Steve Hart, RPh, executive director, by September 30, 2015. If you have any questions, please contact the Board office.

Legislation/Regulation

The Board filed two regulations in May 2015. The two regulations filed are:

1. 201 KAR 2:360 Naloxone Dispensing: This regulation will allow a certified pharmacist to dispense naloxone pursuant to a physician-approved protocol. A pharmacist must take a training course to become certified. This was filed as an emergency regulation and is law. (Please note: A pharmacist can still dispense naloxone pursuant to a prescription from a practitioner without being certified.)
2. 201 KAR 2:015 Continuing Education: This regulation was amended to delete the language requiring a pharmacist to complete a one-hour continuing education course of HIV/AIDS every 10 years. During the 2015 Kentucky Legislative Session, a bill was passed that repealed this requirement.

KASPER Quarterly Threshold Report

Submitted by Robert M. McCool, MS, Program Manager, Kentucky Injury Prevention and Research Center

Kentucky had the third highest age-adjusted drug overdose fatality rate in the nation in 2010, with 23.6 drug overdose fatalities per 100,000. The Kentucky drug overdose fatality rate more than quadrupled in a little more than a decade, from 4.9 deaths per 100,000 in 1999 to 23.6 deaths per 100,000 in 2010. In 2010, deaths from drug overdose surpassed motor vehicle fatalities as the leading cause of unintentional injury deaths in Kentucky. Sadly, this trend has continued. In 2012, Kentucky recorded 1,031 drug overdoses (rate of 23.9 deaths/100,000). Pharmaceutical opioids remained the leading cause of overdose deaths, accounting for at least 471 of the 1,031 drug overdose deaths.[1]

In response to the elevated prescription drug overdose (PDO) fatality numbers and rates in the state, Kentucky's General Assembly enacted a number of seminal PDO laws in 2012 and 2013 to reduce inappropriate prescribing practices and resulting deaths. As codified in KRS 218A.172, the prescription drug monitoring program (Kentucky All Schedule Prescription Electronic Reporting (KASPER)) querying mandate established the authority of medical professional licensure boards within the Commonwealth to mandate querying of the KASPER system before the initial and follow-up prescribing of controlled substances.

As part of the ongoing effort to improve KASPER and enhance its effectiveness for informing prescribing and dispensing practices, KASPER and the Kentucky Injury Prevention and Research Center developed a Quarterly KASPER Threshold Report. This report illustrates the number of prescriptions for various Schedule II-V drugs in Kentucky by age and gender. Based upon feedback from readers, future editions of the report may be modified to include additional information.

The KASPER Quarterly Threshold Report is available online at *www.safekentucky.org/index.php/menu-drug-abuse/kasper-reports.*

[1] Centers for Disease Control and Prevention National Center for Health Statistics WONDER data, *http://wonder.cdc.gov.*

Compliance Corner

Is Your Pharmacy Violating Federal Law?

Submitted by Amanda Harding, RPh, Pharmacy and Drug Inspector

Does your pharmacy sell pseudoephedrine products over-the-counter (OTC)? If so, check to see if the pharmacy's Combat Methamphetamine Epidemic Act of 2005 (CMEA) Self-Certification of Regulated Sellers of Scheduled Listed Chemicals is up to date. This self-certification with Drug Enforcement Administration (DEA) expires annually and is required to sell products containing scheduled listed chemicals ephedrine, pseudoephedrine, or phenylpropanolamine OTC.

Pharmacies must recertify annually to continue selling pseudoephedrine OTC. Failure to recertify while continuing to sell these products could result in hefty fines for every transaction and potential charges of illegal drug distribution. DEA agents within the state are following up with pharmacies that do not recertify.

To certify or recertify, pharmacies should visit the DEA's Office of Diversion Control website at *www.deadiversion.usdoj.gov* and select CMEA Required Training & Self-Certification under the Registration tab. In submitting for self-certification, the pharmacy confirms:

- Employees have been trained;
- Records of training are maintained;

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*.

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

KENTUCKY BOARD OF PHARMACY

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Continued from page 1

- Products are properly stored;
- Sales limits are enforced; and
- Electronic or paper logbook of sales are kept.

Reminder: Only pharmacists, pharmacy interns, and pharmacy technicians may sell OTC ephedrine, pseudoephedrine, or phenylpropanolamine products in a pharmacy. Customers are limited to 7.2 grams of active ingredient within a 30-day period and 24 grams within a year. The year is a rolling period, so purchases made in October will count toward the annual total until the following October. Denied customers may check their purchasing history via the Kentucky Office of Drug Control Policy website, *www.odcp.ky.gov*. They will need the denied transaction number from MethCheck.

Many pharmacies continue to see suspicious and questionable behavior and buying practices from customers. Under KRS 315.121, it is considered unprofessional or unethical conduct to sell a chemical or drug found in illegal traffic when the pharmacist, pharmacy intern, or pharmacy technician knows or should have known of its intended use in illegal activities.

Board Website

The Board office has recently updated the frequently asked questions (FAQs) on its website. There are sections for consumers, pharmacists, businesses, and compounding. The Pharmacist FAQs section includes the following subsections: general, controlled substances, KASPER, record keeping, and buprenorphine. Most answers include a link to the related law reference. By consulting the website, it may be possible to get an answer more quickly. If further clarification is needed, contact the inspector for your area, who may be found on the County Breakdown by Inspector map under Pharmacist FAQs. The contact information for the inspectors is available in the Board Information section of the website under Board Staff. Inspectors are frequently in the field performing inspections and may not be immediately accessible. In addition, the past *Newsletters* are archived on the home page of the website. The *Newsletter* is considered the official method of notification to pharmacists, pharmacist interns, pharmacies, wholesalers, and manufacturers credentialed by the Board. **These *Newsletters* will be used in administrative hearings as proof of notification.**

Sterile Compounding

Submitted by Katie Busroe, RPh, Pharmacy and Drug Inspector

The Board's pharmacy and drug inspectors are conducting more intensive sterile compounding inspections this year. The new sterile compounding inspection form is multiple pages and may take several hours to complete. The inspectors may be contacting the pharmacists-in-charge (PICs) to schedule the inspections. Depending on the operation, multiple inspectors may be assisting with the inspection. If this is the case, it will be communicated to the PICs at the time of scheduling. This will be a learning process for both the Board and the pharmacies. The Board inspectors will be gathering information on the types of compounding occurring in Kentucky and verifying compliance with United States Pharmacopeia Chapter <797>. Pharmacies will learn where the gaps in sterile compounding are occurring and practices to improve compliance. Some of the items the inspectors will be reviewing include policies and procedures; documentation on training, cleaning, and environmental monitoring; and observing compounding procedures.

For policies and procedures, the inspectors will be reviewing the application of the policies and procedures to the actual practice. For example, veterinary pharmacies should have policies and procedures addressing animal compounding, not human compounding. Pharmacies using a barrier isolator need policies and procedures addressing compounding within a barrier isolator and not a cleanroom.

There must be documentation of initial training of all compounding personnel, which includes hand hygiene and garbing, cleaning and disinfecting, and aseptic technique. The training shall be didactic in nature with written examinations, as well as practical with garbing and aseptic technique practices observed. For low- and medium-risk compounding, the training is conducted annually. For high-risk compounding, the training is conducted semiannually. The inspectors will be randomly reviewing training documentation on compounding personnel.

Cleaning documentation includes daily and monthly cleaning activities for cleanrooms. It is permissible for pharmacy personnel or environmental services to clean the cleanroom. The same training documentation is required regardless of who performs the cleaning, environmental services or pharmacy personnel. Cleaning of the primary engineering control(s) (the hoods and/or isolators) will also be reviewed.

At a minimum, documentation of environmental monitoring to be reviewed includes particle count sampling, viable air sampling, surface sampling, temperature monitoring, and pressure differential monitoring as applicable to the pharmacy compounding practices. Parts of the environmental monitoring may be performed by an outside certifier. The environmental monitoring documentation may be manual or electronic, but must be retrievable.

If possible, the inspectors will be observing garbing and hand hygiene and aseptic technique. This may require the inspectors to garb and enter the cleanroom. All inspectors have completed a week-long sterile compounding training with periodic refreshers. The inspectors will be reviewing the compounding processes including, but not limited to, the review of the physical aspects of the cleanroom, final preparation checks, and any testing required.

As the Board progresses through these inspections, updates with more detailed information will be provided in the *Newsletter*. The Board inspectors appreciate the time and patience of the pharmacists and technicians in working through the new inspection process.

The *Kentucky Board of Pharmacy News* is published by the Kentucky 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.

B. Steven Hart, RPh - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Deborah Zak - Communications Manager