December 2016

Kentucky Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Happy Holidays!!!!
From
Kentucky Board of Pharmacy
Board Members and Staff

2017 Pharmacist License Renewals

Pharmacist licenses expire on February 28, 2017. The Kentucky Board of Pharmacy will send out a **postcard** the first week of January 2017 as a reminder (in addition, an email reminder will be sent to all pharmacists with a valid email address on file with the Board). This year the Board encourages you to renew your license online. **Renewal applications will not be mailed out; however, a renewal application may be printed from the Board's website at *www.pharmacy.ky.gov.***

Continuing Education Reminder

A pharmacist shall complete a minimum of one and five-tenths (1.5) CEUs (15 contact hours) annually between **January 1 through December 31,** pursuant to 201 KAR 2:015, Section 5(1). A pharmacist first licensed by the Board within 12 months immediately preceding the annual renewal date shall be exempt from the continuing pharmacy education provisions.

2017 Pharmacy Technician Registration Renewals

Pharmacy technician registrations expire on March 31, 2017. The Board will send out a **postcard** the first week of February 2017 as a reminder (in addition, an email reminder will be sent to all pharmacy technicians with a valid email address on file with the Board). The Board encourages you to renew your registration online. **Renewal applications will not be mailed out; however, a renewal application may be printed from the Board's website at *www.pharmacy.ky.gov.***

Board Meeting Dates and Locations 2017

At its September 7, 2016 meeting, the Board approved the following dates and locations of the Board meetings in 2017:

- Wednesday, January 18, 2017 – Board Office
- Wednesday, March 8, 2017 – Sullivan University College of Pharmacy
- Wednesday, May 10, 2017 – Board Office
- Wednesday, July 12, 2017 – Board Office
- Wednesday, September 13, 2017 – University of Kentucky College of Pharmacy
- Friday, November 3, 2017 – Site to be determined
- Wednesday, December 13, 2017 – Board Office

The Board Retreat will be held November 4, 2017.

2017 CAPTASA Conference

The 2017 Clinical Applications of the Principles in Treatment of Addictions and Substance Abuse (CAPTASA) Conference will be held Friday and Saturday, January 27-28, 2017, at the Embassy Suites in Lexington, KY. For information on this conference, please visit *www.CAPTASA.org* or contact Sandy Patrick at sandyp@kyrecovery.org.

KPhA Emergency Preparedness Volunteer Program

Submitted by Leah Tolliver, RPh, KPhA Director of Pharmacy Emergency Preparedness

Pharmacy professionals play a critical part in responding to emergency events such as a natural disaster or infectious disease outbreak. You may sign up as a volunteer on the Kentucky Pharmacists Association (KPhA) website, *www.kphanet.org,* or by simply sending an email directly to Leah Tolliver at ltolliver@kphanet.org.

Please join the emergency preparedness program and help to recruit other volunteers!

Unit-Dose Packaging Precautions

Submitted by Virginia Whitt, PharmD Candidate, Sullivan University College of Pharmacy

The Board has recently received many questions regarding the expiration date of unit-dose packaging, as well as packaging requirements for light-sensitive medications. Per United States Pharmacopeia (USP) Chapter <1146> Packaging Practice—Repackaging a Single Solid Oral Drug Product Into a Unit-Dose Container, "In the absence of stability data for the drug product in the repackaged container, the beyond-use dating [BUD] period is one year or the time remaining of the expiration date, whichever is shorter. If current stability data are available for the drug product in the repackaged container, the length of time established by the stability study may be used to establish the [BUD] but must not exceed the manufacturer's expiration date." If containers have undergone performance testing, manufacturers will rank their products as Class A-D per USP standards. The expiration date of these products is dependent upon the performance class. Please consult with your providers to best

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FOUNDATION

National Pharmacy

The applicability of articles in the *National Pharmacy Compliance*
by examining the law of

National Vaccine Safety Surveillance Program Available for Reporting Adverse Events

The Vaccine Adverse Event Reporting System (VAERS) eSubmitter program, a national vaccine safety surveillance program cosponsored by the Centers for Disease Control and Prevention (CDC) and Food and Drug Administration (FDA), is available for the reporting of any clinically significant adverse event that occurs after the administration of any vaccine licensed in the United States. VAERS information is analyzed by CDC and FDA to identify new safety concerns. VAERS reports can be filed by anyone, including health care providers, manufacturers, state immunization programs, and vaccine recipients. Vaccine recipients are encouraged to seek help from their health care provider when filling out the VAERS form. Health care providers can find information about submitting a report on the VAERS website at *https://vaers.hhs.gov/professionals/index*.

Improper and Unsafe Vaccine Storage

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.*

Few issues are more important than proper storage and handling of vaccines, because their ability to prevent disease is dependent on these factors. To maintain stability, most vaccines must be stored in a refrigerator or freezer, and many also require protection from light. Excessive heat or cold – even a single exposure in some instances – can reduce vaccine potency. These temperature excursions are often due to improper refrigeration or freezer units, inadequate thermostat controls, and refrigeration/freezer units with inadequate space to allow good air circulation and even temperatures.

Improper and unsafe storage can also result in serious errors caused by selecting the wrong vaccines, diluents, and other medications with look-alike names and/or labeling and packaging. Storing vaccines close to each other has led to dispensing and administering the wrong vaccine or wrong form of vaccine (eg, adult versus pediatric). Storing vaccines too close to non-biologic medications in a refrigerator or freezer has also led to serious adverse outcomes, particularly when the mix-up involved a vaccine and a high-alert medication. For example, vials of insulin have frequently been mistaken as influenza vaccine, and various neuromuscular blocking agents have been used to reconstitute vaccines or were mistaken as influenza or hepatitis B vaccines.

Store vaccines in their own dedicated refrigeration and freezer units. Regular temperature monitoring is necessary, and technology is available to assist with alarmed, continuous monitoring devices that can alert staff via email and pager if a unit is out of specified range. Separate vaccine vials and syringes into bins or other containers according to vaccine type and formulation, keeping diluents with the appropriate vaccines. Never store different vaccines in the same containers. Do not store vaccines with similar labels, names, abbreviations, or overlapping components immediately next to each other or on the same shelf. Separate the storage areas of pediatric and adult formulations of vaccines. Label the specific locations where vaccines are stored to facilitate correct age-specific selection and to remind staff to combine the contents of vials. ISMP's March 26, 2015 newsletter[1] contains additional strategies, as does a Vaccine Storage & Handling Toolkit available from CDC.[2]

References

1. ISMP. Recommendations for practitioners to prevent vaccine errors. Part 2: analysis of ISMP vaccine errors reporting program (VERP). *ISMP Medication Safety Alert!* 2015;20(6):1-6.
2. CDC. Vaccine storage & handling toolkit. www.cdc.gov/vaccines/hcp/admin/storage/toolkit/storage-handling-toolkit.pdf. June 2016.

Coalition Reports Impact of Educational Efforts on Safe Acetaminophen Use

The Acetaminophen Awareness Coalition reports that progress has been made to increase consumer awareness about the safe use of acetaminophen. The coalition also notes a decline in unintentional overdoses. The National Poison Data System's 2015 report indicates unintentional acetaminophen exposures, including dosing errors and accidental misuse, have decreased through 2013 after a peak in 2009. In addition, a nationwide survey indicates the number of consumers who understand that exceeding the recommended daily dose of acetaminophen may lead to liver damage has increased to 87% in 2013 from 78% in 2010. The survey also reports the number of consumers who think it is important to check the medicine label for the maximum daily dose increased to 98% in 2013 from 93% in 2010.

Developed in 2011, the Know Your Dose campaign encourages pharmacists and other health care providers to talk to their patients about medicine safety and acetaminophen use. The Know Your Dose campaign offers a list of helpful health tips to share with patients, including the following:

(1) Read and follow the label.
(2) Know which medicines contain acetaminophen.
(3) Take only one medicine at a time that contains acetaminophen.

(4) Ask a health care provider or pharmacist about dosing instructions or medicines that contain acetaminophen.

Pharmacists may download or order free educational materials, including posters, flyers, and talking points, to give their patients on the Know Your Dose website, *www.knowyourdose.org*.

FDA Offers Webinars on Online Drug Information Resources for Students and Clinicians

FDA's Division of Drug Information in the Center for Drug Evaluation and Research presents a series of CE webinars targeted toward students and health care providers who wish to learn more about FDA and drug regulation. The webinars are presented by FDA staff and allow participants to interact with staff. Previous webinar topics have included an overview of FDA's expanded access program and the pregnancy and lactation labeling rule. The webinars and presentation slides can be accessed on FDA's website at *www.fda.gov/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/ucm228391.htm*.

Fresenius Kabi Recalls Sensorcaine-MPF (Bupivacaine HCl) Injection, USP

In April 2016, Fresenius Kabi USA recalled a single lot of Sensorcaine®-MPF (bupivacaine HCl) injection, USP, 0.75%, 7.5 mg/mL, 30 mL fill in a 30 mL vial, because of visible particulate matter characterized as glass observed by the company during inspection of reserve samples. The recalled product was shipped in the US to wholesaler and distributor outlets between March 4, 2016, and March 21, 2016, and has an expiration date of September 2019. The recall affects lot number 6111504, product code 470237, and National Drug Code number 63323-472-37. The product is supplied as 0.75% strength in a 30 mL single-dose flint molded vial and is packaged in units of 25. To date, Fresenius Kabi has not received any reports of adverse events regarding this recall, indicates the press release posted to the FDA website.

Health care facilities that have the affected lot are instructed to immediately discontinue distributing, dispensing, or using the lot and return all units to Fresenius Kabi. Distributors are instructed to immediately notify their customers who have been shipped or may have been shipped the recalled product. Adverse reactions or quality problems may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting program at *www.fda.gov/MedWatch*. Additional details are available on FDA's website at *www.fda.gov/Safety/Recalls/ucm497812.htm*.

Oral Liquid Docusate Sodium by PharmaTech Recalled Due to Contamination

In July 2016, FDA alerted health care providers that PharmaTech, LLC, of Davie, FL, voluntarily recalled all non-expired lots of Diocto Liquid, a docusate sodium solution distributed by Rugby Laboratories of Livonia, MI. The affected product was distributed nationwide in one-pint (473 mL) bottles with a Rugby label. FDA confirmed the product has been contaminated with *Burkholderia cepacia,* a bacteria linked to an outbreak in five states. The safety alert indicates FDA has received several adverse event reports of *B. cepacia* infections in patients, and some of these reports identify liquid docusate sodium products manufactured by companies other than PharmaTech. FDA and CDC continue to investigate the extent of this issue in order to identify other potentially contaminated liquid docusate sodium products. FDA joins CDC in recommending that clinicians not use any liquid docusate sodium product as a stool softener or for any other medical purpose. Adverse events or side effects may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch*. More information may be found in the safety alert on FDA's website at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm511528.htm*.

NABP Seeks Pharmacists From Districts 1, 5, and 7 to Serve as Volunteer Item Writers

The National Association of Boards of Pharmacy® (NABP®) is seeking pharmacists who reside in states in the following districts to serve as volunteer item writers:

- **District 1:** Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Vermont.
- **District 5:** Iowa, Minnesota, Nebraska, North Dakota, and South Dakota.
- **District 7:** Alaska, Idaho, Montana, Oregon, Washington, and Wyoming.

In an effort to secure more individuals representative of these areas of the country, NABP encourages pharmacists in all areas of practice as well as school and college of pharmacy faculty who reside in these states to apply.

NABP uses volunteer item writers to develop questions for the following examination programs: North American Pharmacist Licensure Examination® (NAPLEX®), Multistate Pharmacy Jurisprudence Examination® (MPJE®), Foreign Pharmacy Graduate Equivalency Examination® (FPGEE®), Pharmacy Curriculum Outcomes Assessment® (PCOA®), and Pharmacist Assessment for Remediation Evaluation® (PARE®).

Interested individuals should complete the online Item Writer Volunteer Interest Form available at in the Meetings section of the NABP website. Individuals who are selected will receive further information on opportunities to attend and participate in NABP-hosted workshops.

For more information about NABP item writing, visit the Meetings section of the NABP website at www.nabp.pharmacy, or contact CompAssess@nabp.pharmacy.

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understand expiration dating on the repackaging of pharmaceuticals. Class A products are given a year or the expiration date, whichever is shorter. Class B products, however, are given six months or the expiration date, whichever is shorter. Further information can be researched on expiration dating via USP Chapter <671> Containers—Performance Testing.

Another important consideration when repackaging into unit-dose containers are those medications that require light-sensitive packaging. An all-inclusive list is unavailable, but please remember to be cautious and look for packaging considerations before ordering unit-dose blister packs and bingo cards for your facilities.

Risk, Recognition, Resolution: Addiction and Health Care Professionals

Submitted by Brian Fingerson, RPh, Pharmacist Recovery Network

Risk

There are risk factors in the development of the disease of addiction for persons in the fields of health care. They can include:

- Genetics: If a person or persons in your family tree had or has an addiction, you are at a much greater risk of developing the disease of addiction than someone who does not.
- Stress: I have not met anyone yet, either in his or her professional schooling or his or her professional life, who is stress-free. Stress increases one's chances for developing addiction.
- Knowledge: There is sometimes a feeling that knowing about medications and physiology provides protection – it does not.
- Access: People in the health care professions often have easier access to drugs of abuse than those who are not.
- Abuse, neglect, or other traumatic experiences in childhood.
- Mental disorders such as depression and anxiety.
- Early use of drugs.

Recognition

There are signs and symptoms that are recognizable in our colleagues, ourselves, and our patients that can be indicators of a potential problem that needs to be addressed.

These can include, but are not limited to:

- Bloodshot eyes, pupils larger or smaller than usual.
- Changes in appetite or sleep patterns. Sudden weight loss or weight gain.
- Deterioration of physical appearance or personal grooming habits.
- Unusual smells on breath, body, or clothing.
- Tremors, slurred speech, or impaired coordination.
- Drop in attendance and performance at work or school.
- Unexplained need for money or financial problems. May borrow or steal to get it.
- Engaging in secretive or suspicious behaviors.
- Sudden change in friends, favorite hangouts, and hobbies.
- Frequently getting into trouble (eg, fights, accidents, illegal activities).
- Unexplained change in personality or attitude.
- Sudden mood swings, irritability, or angry outbursts.
- Periods of unusual hyperactivity, agitation, or giddiness.
- Lack of motivation; appears lethargic or "spaced out."
- Appears fearful, anxious, or paranoid with no reason.

Resolution

So, what do you do about it? Can you call your licensing board? Do you notify someone in student affairs? If you are fortunate enough to live in a state that has a professional program, either freestanding or through the licensing board or board of registry, call them. You may be able to receive help without this becoming a matter of public record. If in doubt, you may contact me for referral at **Brian Fingerson, RPh, Kentucky Professionals Recovery Network, 202 Bellemeade Rd, Louisville, KY 40222, 502/749-8385, kyprn@att.net, *www.kyprn.com.***

Official Method of Notification

The *Kentucky Board of Pharmacy Newsletter* is considered an 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.** Please read them carefully. The Board encourages you to store them electronically in a folder or keep them in the back of the *Kentucky Pharmacy Law Book* for future reference.

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.

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