September 2014

Kentucky Board of Pharmacy News

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Drug Manufacturer, Home Medical Equipment Provider, and Wholesale Distributor Renewal Deadline September 30, 2014

Drug manufacturer, home medical equipment provider, and wholesale distributor permits/licenses expire on September 30, 2014. 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's 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 a United States Post Office Box address only will **not** be accepted and will be returned. All incomplete applications will be returned. Remember, the deadline is September 30, 2014.

Board Meeting and Retreat 2014

The Hilton Lexington Downtown in Lexington, KY, will be the site of the 2014 Board meeting/retreat. The Board meeting will begin at 9 AM on Friday, November 7, 2014, and at the end of the Board meeting agenda, the retreat will begin that day if time permits. The retreat will continue or begin the next morning, Saturday, November 8, 2014, at 9 AM.

The Board would request any individual or organization to submit topics to be discussed at the Board retreat. Please submit any suggestion(s) to the Board office either by mail, fax, or e-mail. The Board will set the agenda at the September 10, 2014 meeting. If you have any questions, please contact the Board office.

Compliance Corner

Submitted by Steve Hart, RPh, Pharmacy Inspections and Investigations Coordinator

201 Kentucky Administrative Regulation (KAR) 2:015 states:

Section 5. (1) A pharmacist shall:

(a) Complete a minimum of one and five-tenths (1.5) CEU (fifteen (15) contact hours) annually between January 1 and December 31; and

(b) Not transfer or apply excess hours or units for future years.

Were you audited for continuing education (CE) this year? Many of you were, and many of you were in violation of 201 KAR 2:015 Section 5(a). In November 2010, the Board clarified CE requirements for all pharmacists licensed in Kentucky. The following is taken from the minutes of that meeting.

Continuing Education for Pharmacists. KRS 315.065 states that an HIV/AIDS continuing education (CE) program must be done "at least one (1) time every ten (10) years." The statute went into effect in 2002. The Board determined that if a pharmacist has done at least one hour of approved HIV/AIDS CE in the ten year time period of 2002 through 2012, and the CE certificate can be produced, the pharmacist shall be compliant. The pharmacist must complete at least one hour of HIV/AIDS CE in every 10 year time frame. For example, if the HIV/AIDS CE was obtained in 2005, the pharmacist must obtain at least one hour no later than 2015.

After discussion the Board determined that pharmacists that have a Kentucky pharmacist's license but do not practice in Kentucky must meet Kentucky continuing education requirements including obtaining at least one hour of approved HIV/AIDS CE in the ten year time frame of 2002 through 2012. Mr. Burleson was directed to send a letter to all Kentucky licensed pharmacists and all out of state permit holders explaining the Board's decision regarding HIV/AIDS CE and CE requirements for Kentucky licensed pharmacists not practicing in Kentucky.

A CE violation results in a $500 fine and double the amount of CE short of the 15-hour requirement because the pharmacist has submitted a falsified renewal application. This violation is considered minor and can be expunged after three years.

Why was I audited? The Board has access to a new service, CPE Monitor®. If the pharmacist profile was complete and accurate, Accreditation Council for Pharmacy Education-accredited providers could report your hours to CPE Monitor for the Board to verify. Several pharmacists have CPE Monitor accounts that are not complete. During the audit, it was identified that pharmacists licensed in multiple jurisdictions did not have all their licenses listed in their profile. If your Kentucky license is not listed in your profile, the Board cannot access your results. The second issue identified during the audit was that the CE program providers lacked an accurate CPE Monitor account number for the participant in the program.

Emergency Response CE

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

The Kentucky Pharmacists Association (KPhA), in partnership with the Kentucky Department for Public Health, is developing a

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National Pharmacy

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

New Educational Video for Pharmacists Addresses Prescription Drug Abuse

The National Association of Boards of Pharmacy® (NABP®) and the Anti-Diversion Industry Working Group (ADIWG), a consortium of pharmaceutical manufacturers and distributors of controlled substances (CS), have released an educational video for pharmacists to help them identify the warning signs of prescription drug abuse and diversion when dispensing CS prescriptions. The video, entitled "Red Flags," encourages pharmacists to help combat this national problem by exercising their professional judgment to ensure that the prescriptions they dispense were written for a legitimate medical purpose, and to act upon any unusual behavior they observe.

Drug Enforcement Administration and various state pharmacy boards have described "red flags" as circumstances surrounding the presentation of a CS prescription that should raise reasonable suspicion about the validity of that prescription. The video highlights a number of these potential warning signs, some of which are not easy to spot, by weaving personal narratives with interactions between pharmacists and customers.

The video is available in the Pharmacists section of the AWAR$_X$E® Prescription Drug Safety website at *www.AWARERX.ORG/pharmacists*.

Root Causes: A Roadmap to Action

This column was prepared by the Institute for Safe Medication Practices (ISMP). ISMP is an independent nonprofit agency and federally certified patient safety organization that analyzes medication errors, near misses, and potentially hazardous conditions as reported by pharmacists and other practitioners. ISMP then makes appropriate contacts with companies and regulators, gathers expert opinion about prevention measures, and publishes its recommendations. To read about the risk reduction strategies that you can put into practice today, subscribe to ISMP Medication Safety Alert!® Community/Ambulatory Care Edition by visiting www.ismp.org. *ISMP provides legal protection and confidentiality for submitted patient safety data and error reports. Help others by reporting actual and potential medication errors to the ISMP National Medication Error Reporting Program Report online at* www.ismp.org. *E-mail: ismpinfo@ismp.org.*

Errors are almost never caused by the failure of a **single** element in the system. More often, there are **multiple** underlying system failures that lead to an error, many of which can be identified when the involved health care providers take the time to uncover them.

Consider the following error: A doctor sent a hand-written order for car**bam**azepine 400 mg twice daily for an adult patient with a history of seizures.

The pharmacist entered the medication into the profile of a four-year-old child with the same last name as the adult patient for whom the medication had been prescribed.

The pharmacist failed to notice that the patient was a child, as age was not in a prominent location on the order entry screen. The nurse failed to recognize that the dose was too high and administered 400 mg of car**bam**azepine to the child. She also never thought to question why the pharmacy would send oral tablets for a four-year-old child, considering that the drug is available in chewable tablets and as a liquid suspension.

The nurse **assumed** that the child was receiving the medication because he had a history of seizures. However, the nurse did not check the patient's medical record. In fact, the child did **not** have a history of seizures.

The parents had a very limited understanding of English, so they were unable to intervene to correct the erroneous seizure history.

The error was finally detected after the child became lethargic and developed nausea and vomiting. At the time of discovery, the child's car**bam**azepine level was 18 mcg/mL; levels greater than 12 in pediatric patients are supratherapeutic.[i]

It may be discouraging to see how many things go wrong when a medication error reaches a patient. However, a thorough root cause analysis (RCA) can uncover the latent failures and produce an action plan to avoid future errors.

ISMP, through a generous grant from the National Association of Boards of Pharmacy Foundation™, has developed the *Root Cause Analysis Workbook for Community/Ambulatory Pharmacy.* The workbook is designed to assist community pharmacy personnel in completing RCA for a sentinel event that may have occurred in their pharmacy. The RCA workbook uses a specific set of steps and associated tools to identify the primary causes of the **sentinel event.**

The goal of the RCA is to create an action plan framework, including risk-reduction strategies, communication and implementation strategies, and measurement of effectiveness.

RCA for **sentinel events** is required in the Center for Pharmacy Practice Accreditation's standards developed by NABP, American Pharmacists Association, and American Society of Health-System Pharmacists Association, as well as by several boards of pharmacy in conjunction with their continuous quality improvement regulations.

This ISMP RCA workbook is suitable for use in community pharmacy, mail-order pharmacy, or other ambulatory pharmacy practice settings that need to investigate a **sentinel event.** For more information and to access the **free** workbook, visit *www.ismp.org/tools/rca/.*

[i] *http://pediatrics.aappublications.org/content/113/2/406.abstract*

FDA Withdraws Approval of Some High Dose Acetaminophen Products

Food and Drug Administration (FDA) is withdrawing approval of 108 abbreviated new drug applications (ANDAs) for prescription combination drug products containing more than 325 mg of acetaminophen per dosage unit. For the 108 ANDAs, the manufacturers asked to withdraw their applications, as announced in the March 27, 2014 *Federal Register* notice. A second *Federal Register* notice addresses the applications of six manufacturers who have discontinued marketing their products, but who have not withdrawn their applications. The notice also announces FDA's intention to begin the process of withdrawing approval of those applications.

In light of these announcements, and to protect patients from inadvertent acetaminophen overdose, NABP advises that pharmacies no longer dispense combination drugs containing more than 325 mg of acetaminophen per dosage unit. NABP also advises that pharmacists consult with prescribers to discuss alternative products with lower acetaminophen doses.

FDA asked manufacturers to voluntarily withdraw these products from the market to reduce the risk of severe liver injury from inadvertent acetaminophen overdose. In January 2014, FDA recommended that providers consider prescribing acetaminophen products containing 325 mg or less per dose. The original announcement may be found in the Drug Safety and Availability section of FDA's website at *www.fda.gov/Drugs/DrugSafety*.

NCPDP Recommends Standardized Metric Measurements on Oral Liquid Medication Labels

The National Council for Prescription Drug Programs (NCPDP) has issued new recommendations and guidance for standardizing the dosing designation used on prescription container labels of oral liquid medications dispensed by community pharmacies in order to reduce dosing errors. NCPDP notes that such errors have been "a source of concern for many years," and that dosing errors involving young children are of particular concern because they may be more susceptible to harm from measurement errors and overdoses. The paper outlines the following recommendations for the dosing designation on prescription container labels for oral liquid medications:

- The millimeter (mL) should be used as a standard unit of measurement.
- Dose amounts should always use leading zeros before decimal points for amounts less than one and should not use trailing zeros after a decimal point.
- Dosing devices with numeric graduations and units corresponding to the container label should be made easily and universally available. For example, a device should be included with each dispensed medication.

The white paper was developed following a meeting with stakeholders representing 27 participants, including NABP. In addition to its general recommendations, the white paper also issued calls to action for relevant stakeholders, including government agencies, standards organizations, pharmacists and pharmacy technicians, pharmacy leadership, and health care associations. The white paper, *NCPDP Recommendations and Guidance for Standardizing the Dosing Designations on Prescription Container Labels of Oral Liquid Medications,* is available for download from the NCPDP website at *http://ncpdp.org/Education/Whitepaper*.

USP Proposes New General Chapter Addressing Compounding of Hazardous Drugs

In an effort to protect health care providers and personnel who handle hazardous drugs, United States Pharmacopeial Convention (USP) has proposed new General Chapter <800> Hazardous Drugs–Handling in Healthcare Settings. The new proposed chapter addresses standards that apply to all personnel who compound hazardous drug preparations and all places where hazardous drugs are prepared, stored, transported, and administered. The new chapter also covers standards for receiving, storing, compounding, dispensing, administering, and disposing of nonsterile and sterile products and preparations. The proposed chapter applies to all personnel who are involved in handling hazardous drugs, including health care providers and staff, occupational health and safety specialists, and human resources. General Chapter <800> was published in the May/June issue of *Pharmacopeial Forum,* and may currently be viewed on the USP website at *www.usp.org/usp-nf*. Comments were accepted until July 31, 2014.

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Pharmacists & Technicians:
Don't Miss Out on Valuable CPE Credit.
Set Up Your NABP e-Profile and Register for CPE Monitor Today!

Continuing pharmacy education (CPE) providers who are accredited by the Accreditation Council for Pharmacy Education (ACPE) have integrated CPE Monitor® into their systems and are requiring pharmacists and pharmacy technicians to provide an NABP e-Profile ID number and date of birth (MMDD) in order to process ACPE-accredited CPE credit.

Visit ***www.MyCPEmonitor.net*** to set up your NABP e-Profile and register for CPE Monitor and avoid possible delays in your CPE reporting.

CPE Monitor is a national collaborative service from NABP, ACPE, and ACPE providers that will allow licensees to track their completed CPE credit electronically.

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statewide plan for pharmacy emergency preparedness. It includes serving as the operational lead for a mobile pharmacy unit. A one-hour CE program on emergency response for pharmacists is available. The program is provided at pharmacy district meetings and the KPhA annual and mid-year conferences. The next meeting at which the program will be provided, along with a tour of the mobile pharmacy, is the Bluegrass Pharmacists Association Meeting, which will be held on Tuesday, September 23, 2014, at 6 PM at the Hilton Lexington Suites in Lexington.

Please contact Leah Tolliver for further information. Her contact information is ltolliver@kphanet.org and 502/227-2303.

Addiction

Submitted by Brian Fingerson, RPh, Kentucky Professionals Recovery Network

Addiction is a disease of the brain and its chemistry. Those of us with a scientific background may wonder how something like a 12-step program (Alcoholics Anonymous, Narcotics Anonymous, or one of the many others out there) may work in a changing a person, especially one in the thralls of addictive disease. Maybe, just maybe, you can believe it works if you see it work. An actual demonstration may be what convinces you. What you may read in books and what you may hear people say may not be enough to convince you. But when you see a real, honest-to-goodness change take place in a person, a change from a drunkard or addict to a sober, useful citizen, that is something you can believe because it can be seen. We have seen this with our own eyes through the Pharmacist Recovery Program.

Please know that there is help available for you or a colleague should you find yourself in a situation that seems hopeless as a result of a substance or behavior. Help is as close as a call to Brian Fingerson at 502/749-8385. The Kentucky Professionals Recovery Network e-mail is kyprn@att.net, and its website is *www.kyprn.com.*

Frequently Asked Question

Question: Can a resident at a hospital prescribe a controlled substance utilizing the hospital's Drug Enforcement Administration (DEA) registration, as long as the resident is prescribing from the hospital?

Answer: Yes. Following is the Code of Federal Regulations (Title 21 CFR Section 1301.22).

(c) An individual practitioner who is an agent or employee of a hospital or other institution may, when acting in the normal course of business or employment, administer, dispense, or prescribe controlled substances under the registration of the hospital or other institution which is registered in lieu of being registered him/herself, provided that:

(1) Such dispensing, administering or prescribing is done in the usual course of his/her professional practice;

(2) Such individual practitioner is authorized or permitted to do so by the jurisdiction in which he/she is practicing;

(3) The hospital or other institution by whom he/she is employed has verified that the individual practitioner is so permitted to dispense, administer, or prescribe drugs within the jurisdiction;

(4) Such individual practitioner is acting only within the scope of his/her employment in the hospital or institution;

(5) The hospital or other institution authorizes the individual practitioner to administer, dispense or prescribe under the hospital registration and designates a specific internal code number for each individual practitioner so authorized. The code number shall consist of numbers, letters, or a combination thereof and shall be a suffix to the institution's DEA registration number, preceded by a hyphen (e.g., APO123456-10 or APO123456-A12); and

(6) A current list of internal codes and the corresponding individual practitioners is kept by the hospital or other institution and is made available at all times to other registrants and law enforcement agencies upon request for the purpose of verifying the authority of the prescribing individual practitioner.

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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