June 2015

Kentucky Board of Pharmacy News

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Pharmacy Renewal Deadline June 30, 2015

Pharmacy permits expire June 30, 2015. A pharmacy permit can be renewed online. A postcard explaining the renewal process was mailed to each pharmacy around May 1, 2015. If you want to send in a paper renewal, this 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. Please be reminded that if your resident pharmacy has an address change, relocates within the current premises of the existing permit, or has a change of ownership, you must complete a new pharmacy application. A pharmacy application with a United States Post Office Box address only will **not** be accepted and will be returned. All incomplete applications will be returned. All paper renewal applications must be in the Board office by the close of the day June 30, 2015.

Steve Hart

The Board, at its April 15, 2015 meeting, named Steve Hart, RPh, as the executive director to replace Michael A. Burleson, RPh, who had previously announced his retirement effective August 1, 2015. Steve currently serves as the pharmacy inspections and investigations coordinator for the Board. He will be working with Mike over the next few months to transition into the position.

Statutes/Regulations 2015

HIV/AIDS: House Bill (HB) 248 passed and was signed by Governor Steve Beshear during the 2015 Kentucky Legislative Session. This bill repeals the pharmacist requirement that one hour of HIV/AIDS continuing education must be obtained at least every 10 years. This will become law June 24, 2015.

Medication Synchronization: Senate Bill (SB) 44 passed and was signed by Governor Beshear during the 2015 Legislative Session. This bill takes effect **January 1, 2016.** Any individual or group health benefit plan that provides benefits for prescription drugs shall provide a program for synchronization of medications when it is agreed among the insured, a provider, and a pharmacist that synchronization of multiple prescriptions for the treatment of a chronic illness is in the best interest of the patient for management or treatment of a chronic illness, provided that the medications:

- Are covered by the individual or group health benefit plan;
- Are used for treatment and management of chronic conditions that are subject to refills;
- Are not Schedule II or III controlled substances containing hydrocodone;
- Meet all prior authorization criteria to the medications at the time of the synchronization request;
- Are of a formulation that can be effectively split over required short fill periods to achieve synchronization; and
- Do not have quantity limits or dose optimization criteria or requirements that would be violated in fulfilling synchronization.

This bill also includes language requiring the Kentucky Department for Medicaid Services or a managed care organization to provide a program for synchronization for patients covered under these plans.

Collaborative Care Agreement: HB 377 was passed and signed by Governor Beshear during the 2015 Legislative Session. This bill will become law on June 24, 2015. This bill creates a new definition of "collaborative care agreement."

Collaborative care agreement means a written agreement between a pharmacist or pharmacists and a practitioner or practitioners that outlines a plan of cooperative management of patients' drug-related health care needs where:

1. Patients' drug-related health care needs fall within the practitioner's or practitioners' statutory scope of practice
2. Patients are referred by the practitioner or practitioners to the pharmacist or pharmacists
3. The agreement:
   - Identifies the practitioner or practitioners and the pharmacist or pharmacists who are parties to the agreement;
   - Specifies the drug-related regimen to be provided, and how drug therapy is to be monitored; and
   - Stipulates the conditions for initiating, continuing, and discontinuing drug therapy and conditions that warrant modifications to dose, dose regimen, dosage form, or route of administration.

The Board is currently drafting an amendment for 201 KAR 2:220 that will align with HB 377.

Heroin: SB 192 passed and was signed into law by Governor Beshear during the 2015 Legislative Session. This bill was signed into law as an emergency bill; therefore, this became law on March 25, 2015.

This bill allows a pharmacist to dispense naloxone pursuant to a physician-approved protocol. The Board, in consultation with the Kentucky Board of Medical Licensure, shall promulgate administrative regulations to establish certification, educational, operational, and protocol requirements.

Continued on page 4

FDA's New Database Simplifies Searching for Guidance Documents

Food and Drug Administration (FDA) has released a new database that houses most FDA guidance documents for regulatory professionals. The guidance documents for nearly all FDA-regulated professions and industries are available in a searchable database that allows users to enter keywords that update automatically as they are typed. Search results may also be narrowed by product, date, document type, and other terms. The database also indicates whether there is an open comment period and the deadline for submitting comments.

The database can be accessed at *www.fda.gov/RegulatoryInformation/Guidances/default.htm*.

2014-2015 Targeted Medication Safety Best Practices for Hospitals

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.*

The purpose of the Targeted Medication Safety Best Practices (TMSBP) for Hospitals is to identify, inspire, and mobilize widespread, national adoption of consensus-based best practices on specific medication safety issues that continue to cause fatal and harmful errors in patients despite repeated warnings in ISMP publications. These best practices are realistic practices, already adopted by many organizations, upon which hospitals can focus their medication safety efforts. The best practices are applicable to all types of hospitals including, but not limited to, critical access hospitals, cancer hospitals, and children's hospitals. They may also be applicable to other health care settings, as well as non-inpatient areas of hospitals and hospital systems. These best practices have been reviewed by an external expert advisory panel and approved by the ISMP Board of Trustees. Related issues of the *ISMP Medication Safety Alert!* are referenced after each best practice.

Recurrent Issue of Serious Harm

Oral methotrexate for non-oncological indications administered daily instead of weekly or twice weekly is a recurrent issue and one of the six TMSBPs.

ISMP has published this error in seven *ISMP Medication Safety Alert!* issues from 1996 to 2013. Although dosed daily for oncology purposes, it is used weekly or twice weekly to treat a variety of autoimmune diseases (eg, psoriasis, severe rheumatoid arthritis). Error reports point to inadvertent ordering and/or entering as daily instead of weekly or twice weekly, and lack of patient education/understanding of medication dosing schedule. To minimize the risk of error, **Best Practice 2** calls for hospitals to:

a) Use a weekly dosage regimen default for oral methotrexate. If overridden to daily, require a hard stop verification of an appropriate oncologic indication.
b) Provide patient education by a pharmacist for all weekly oral methotrexate discharge orders.

Question: Does the best practice of a weekly frequency default for oral methotrexate apply to a specialty cancer hospital?

Answer: The intent of this best practice is to reduce errors when methotrexate is prescribed as a weekly regimen for non-oncologic or oncologic indications. Even when used for oncologic purposes, oral methotrexate is sometimes prescribed as a weekly regimen, not daily. Thus, this best practice applies to all patient care settings, including specialty cancer hospitals.

Teaching Points (Both Verbal and Written)

- Explain the weekly dosing schedule.
- Explain that taking extra doses is dangerous.
- Have the patient repeat back the instructions.
- Provide the patient with the free ISMP high-alert medication consumer leaflet on methotrexate (found at *www.ismp.org/AHRQ/default.asp)*.

To read all of the best practices, visit *www.ismp.org/Tools/BestPractices/default.asp.*

ACPE Releases Updated Definition of CPE and Guidance on CPD

The Accreditation Council for Pharmacy Education (ACPE) has released two documents that provide guidance and support for continuing pharmacy education (CPE) and continuing professional development (CPD). The two documents, approved by the ACPE board of directors, are described below.

- The revised *Definition of Continuing Education for the Profession of Pharmacy* defines the quality of CPE required by ACPE and the competencies required for CPE activity content. The *Definition* document will assist providers of CPE in planning activities that will be applicable to the professional development of pharmacists and certified pharmacy technicians.
- The *Guidance on Continuing Professional Development (CPD) for the Profession of Pharmacy* incorporates feedback from a broad survey of the pharmacy profession that was conducted in July 2014. The *Guidance* document provides details on the learning activities that may contribute to the professional development of both pharmacists and pharmacy technicians beyond CPE, and also "provides a process for pharmacists and pharmacy technicians to meet and maintain defined competencies in areas relevant to their respective professional responsibilities."

Additional information, including links to the documents, is available in a press release on the ACPE website at *www.acpe-accredit.org/pdf/ACPEAdvancesCPE-CPDforPharmacists.pdf*.

Hospira Issues Recall for Multiple Lots of Ketorolac Tromethamine Injection Due to Potential Contamination

Hospira, Inc, of Lake Forest, IL, has issued a voluntary recall of ketorolac tromethamine injection, USP in the United States and Singapore due to potential particulate matter. The presence of particulate was confirmed through a customer report of visible floating particulate that was identified as calcium-ketorolac crystals. If in-

jected, medications contaminated with particulate matter may cause localized inflammation, allergic reaction, granuloma formation, or microembolic effects. Multiple lots are impacted by this recall and are listed in a press release posted to the FDA website at *www.fda.gov/Safety/Recalls/ucm433857.htm*. The lots were distributed from February 2013 to December 2014 in the US. To date, there have been no cases of adverse events associated with this medication. Adverse reactions may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program.

FDA Warns of Counterfeit Cialis Tablets Entering the US

Potentially dangerous, counterfeit versions of Cialis® 20 mg tablets were intercepted in the mail before reaching a US consumer, warns FDA. Laboratory analysis of the counterfeit product showed that it contained multiple active ingredients that could lead to adverse effects or harm if used, indicates an FDA Drug Safety Announcement. The agency reminds US consumers to only buy prescription medications from state-licensed pharmacies located in the US. FDA notes that it cannot confirm that the manufacturing, quality, storage, and handling of products ordered from unlicensed websites follow US standards because the products are from an unknown source.

To help consumers identify these counterfeit medications, FDA provides guidelines in the safety announcement. For example, these counterfeits list "AUSTR81137" on the front of the bottle and lack a National Drug Code number. Other possible identifiers include misspellings and unusual colors on the label, and a manufacturer listed as "112 Wharf Road, WEST RYDE, NSW 2114" on the side of the bottle.

To date, FDA is not aware of any adverse events associated with these counterfeit medications; however, consumers are encouraged to talk to a health care provider about their condition and options for treatment if a counterfeit product was received.

The National Association of Boards of Pharmacy® (NABP®) has reviewed more than 10,900 websites selling prescription drugs to patients in the US and found that nearly 97% are operating out of compliance with pharmacy laws and practice standards established to protect the public health. To help consumers in the US find the safest sources for purchasing medications online, NABP developed the Verified Internet Pharmacy Practice Sites® (VIPPS®) program. NABP encourages consumers to look for the VIPPS Seal and to check NABP's list of accredited sites on the AWAR$_X$E® Prescription Drug Safety Program website. In addition, consumers may soon watch for pharmacy sites using the newly launched .pharmacy Top-Level Domain; sites in the domain (with a website address ending in .pharmacy) will be reviewed by NABP and approved only if they are legitimate online pharmacies or pharmacy resources adhering to applicable pharmacy laws and best practices.

Additional details on the counterfeit Cialis are available in a Drug Safety Announcement posted to the FDA website at *www.fda.gov/Drugs/DrugSafety/ucm431071.htm*. More information on VIPPS and other NABP programs is available in the Programs section of the NABP website, *www.nabp.net*.

New FDA Drug Info Rounds Training Videos Review Drug Disposal and REMS

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 "Disposal of Unused Medicines," pharmacists discuss how consumers can safely dispose of expired or unused medications to prevent abuse or misuse and accidental poisoning.
- In "REMS," pharmacists discuss the many components of Risk Evaluation and Mitigation Strategies (REMS) and how they can help manage a drug product with known or potential serious risks.

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*.

FDA Issues New Drug Labeling Rules to Benefit Pregnant, Breastfeeding Women

FDA announced new prescription drug labeling requirements that will clarify how medications might affect women who are pregnant or breastfeeding and men and women of reproductive potential. The final "Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling Rule" removes the previously used pregnancy letter categories – A, B, C, D, and X – and places information into three main categories:

- **Pregnancy:** Labor and delivery guidelines now fall under this category, which also now includes information for pregnancy exposure registries. Such registries track data on the effects of certain approved medications on pregnant and breastfeeding women.
- **Lactation:** Previously labeled "Nursing Mothers," this category provides information such as how much drug is secreted through breast milk and the potential effects on a breastfed infant.
- **Females and Males of Reproductive Potential:** This is a new category that includes information on how a certain medication might affect pregnancy testing, contraception, and infertility.

The new labeling changes go into effect on June 30, 2015. Over-the-counter medication labels will not be affected. The new rules are available for download through the *Federal Register* at *https://s3.amazonaws.com/public-inspection.federalregister.gov/2014-28241.pdf*.

FDA Approves Zohydro ER With Abuse-Deterrent Properties

In February 2015, FDA approved a new formulation of Zohydro® ER with abuse-deterrent properties. The new formulation uses a technology that allows the drug to maintain its release properties when used as intended, according to a press release from Zogenix. The abuse-deterrent system, known as BeadTek, incorporates "pharmaceutical excipients" that create a viscous gel when the medication is crushed and dissolved in a liquid or solvent, thus making the product more difficult to abuse through methods that involve crushing, breaking, or dissolving the drug. In early 2014, Zohydro ER became the first extended-release, single-ingredient hydrocodone product to receive approval for use in the US. Approval of the drug came under criticism, with some organizations arguing that the potential for addiction, abuse, and misuse could outweigh therapeutic benefits, in part because the drug lacked abuse-deterrent properties. Zogenix indicates that transition to the new abuse-deterrent formulation will take place in second quarter 2015.

Additional information on the new formulation is provided in a press release available on the Zogenix website at *http://ir.zogenix.com/phoenix.zhtml?c=220862&p=irol-newsArticle&cat=news&id=2012326*.

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The administrative regulation shall include:

- Requiring that any dispensing under this law be done only in accordance with a physician-approved protocol, and specifying the minimum required components of any such protocol;
- A required mandatory education requirement as to the mechanism and circumstances for the administration of naloxone for the person to whom the naloxone is dispensed; and
- Requiring that a record of the dispensing be made available to a physician signing the protocol, if desired by the physician.

The administrative regulation may include:

- A supplemental educational or training component for a pharmacist seeking certification and
- A limitation on the forms of naloxone and means of its administration that may be dispensed.

The Board is working on a new regulation required by SB 192, and will notify pharmacists once this becomes law.

SB 192 also allows a local health department to operate a substance abuse treatment outreach program that allows participants to exchange needles and syringes. The local health department must have consent of city or county government. These needles and syringes shall not be considered drug paraphernalia.

Dextromethorphan: HB 24 passed and was signed by Governor Beshear during the 2015 Legislative Session. HB 24 becomes law on June 24, 2015. This bill prohibits the sale of any product containing dextromethorphan to individuals under the age of 18. If seller believes that the prospective buyer is under 18, then the buyer must show a government-issued photo identification card that displays his or her date of birth.

Home Medical Equipment: HB 69 passed and was signed by Governor Beshear during the 2015 Legislative Session. HB 69 becomes law on June 24, 2015. This Bill will only allow the Board to grant a home medical equipment license to a home medical equipment provider that is located in one of Kentucky's seven contiguous states that license home medical equipment providers. The Board may grant a license on the basis of reciprocity to a home medical equipment provider in one of Kentucky's seven contiguous states that does not license home medical equipment providers if the out-of-state provider seeking to operate in Kentucky states by affidavit that he or she has studied, is familiar with, and shall abide by KRS 315.510 to 315.524 and the administrative regulation. Two members of the Board's Advisory Council shall be individual representatives of the home medical equipment provider profession licensed in accordance with KRS 315.518.

TB Reporting: An amended regulation became law on February 26, 2015. This amended regulation requires a pharmacist to give notice if two or more of the drugs listed below are dispensed to be used for initial treatment of active tuberculosis (TB) for an inpatient in a health care facility or to an ambulatory patient in a health facility or a pharmacy:

- Rifampin or rifabutin
- Isoniazid
- Pyrazinamide
- Ethambutol

A report of TB shall be considered priority and shall be reported to the local health department serving the county in which the patient resides; if the local health department cannot be reached, notification shall be given to the Kentucky Department for Public Health. The report shall include information required in Section 4(16) of this administrative regulation and the names of the medications dispensed. The Kentucky Pharmacists Association, Kentucky Department of Public Health, and the Board are developing a form that will assist pharmacists with the requirements of this regulation. To review the entire regulation, visit *www.lrc.ky.gov/kar/902/002/020.htm*.

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 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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