June 2018

Kentucky Board of Pharmacy News

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Renewal Deadline June 30, 2018

Pharmacy permits, third-party logistics provider licenses, and outsourcer facility licenses expire on June 30, 2018. Online renewal became available beginning May 1, 2018. A postcard explaining the renewal process was mailed to each facility around May 1, 2018. 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.* Contact the Board office if you have questions concerning the renewal process. A new facility application must be completed if the resident facility has an address change, a relocation within the current premises of the existing permit, or a change of ownership. A facility application with only a United States Post Office Box address 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 on Friday, June 29, 2018.

Legislative Highlights 2018

Pilot Project for Pharmacist-Led Medication-Assisted Treatment Therapy: House Bill (HB) 246 was sponsored by Representative Danny Bentley (R-Russell, KY), one of two pharmacists in the General Assembly, and signed by Governor Matt Bevin. This legislation will allow pharmacies to participate in a pilot project for pharmacist-led medication-assisted treatment for opioid use disorder. This bill builds on the Board-authorized protocol regulation approved by the Board.

Safe Medication Disposal: Senate Bill (SB) 6, sponsored by Senator Alice Forgy Kerr (R-Lexington, KY), would have required a pharmacist to offer to sell a safe disposal mechanism that sequesters or deactivates the active ingredients in prescription drugs. The House amended the legislation to allow a pharmacist to make safe disposal mechanisms available and to require pharmacists to inform patients about safe disposal of medications. The legislation also allows information to be provided to patients in writing, verbally, or by posting a sign. SB 6 became law without the governor's signature.

Anti-Gag Order Legislation: HB 463, sponsored by Representative Michael Meredith (R-Oakland, KY), will ensure that patients are not paying too much for prescriptions. The bill will prohibit insurance companies or pharmacy benefit managers from prohibiting pharmacists from telling patients that they can get a prescription cheaper than their copay if they pay cash.

Compounding Inspections

As of January 1, 2018, 201 Kentucky Administrative Regulation (KAR) 2:076 requires pharmacies engaging in nonsterile compounding to comply with the January 1, 2014 version of United States Pharmacopeia (USP) Chapter <795> and pharmacies engaging in sterile compounding to comply with the June 1, 2008 version of USP Chapter <797>. The pharmacy and drug inspectors are inspecting to these standards. There are three separate inspection forms used: one for general pharmacy, one for nonsterile compounding, and one for sterile compounding. The number of inspection forms completed will depend on the type of pharmacy practice. Along with the compounding inspection forms, the pharmacy and drug inspectors will be issuing a letter to the pharmacist-in-charge requesting that a corrective action plan be submitted to the inspector within seven days addressing any noncompliance issues. If there are substantial noncompliance issues, the pharmacy may be reinspected for compliance.

Pharmacies that are compounding with hazardous drugs are required to follow the hazardous drug compounding sections of USP Chapters <795> and <797>.

A pharmacist may submit a waiver request to the Board requesting that specific portions of USP Chapters <795> and/or <797> be waived. The waiver will be considered at the next regularly scheduled Board meeting. In considering the waiver request, the Board will take into account a show of good cause balanced with the best interest of the public health, safety, and welfare.

The Board's inspection staff have agreed to participate in the National Association of Boards of Pharmacy® (NABP®) Multistate Pharmacy Inspection Blueprint Program. NABP is attempting to standardize an inspection process for pharmacies that dispense compounded preparations across state

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National Pharmacy Compliance News

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NABPF
National Association of Boards of Pharmacy Foundation

FDA Requires Labeling Update on Opioid-Containing Cough and Cold Medicines

In January 2018, Food and Drug Administration (FDA) announced that the agency is requiring safety labeling changes to limit the use of prescription opioid cough and cold medicines containing codeine or hydrocodone in children younger than 18 years old because the serious risks of these medicines outweigh their potential benefits in this population. After safety labeling changes are made, these products will no longer be indicated for use to treat cough in any pediatric population and will be labeled for use only in adults aged 18 years and older. In addition, labeling for the medications will be updated with additional safety information for adult use. This update will include an expanded Boxed Warning notifying consumers about the risks of misuse, abuse, addiction, overdose and death, and slowed or difficult breathing that can result from exposure to codeine or hydrocodone. Additional information is available in FDA's news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm592109.htm.*

Latest NDTA Shows Opioids Pose Significant Impact to Public Health

Drug Enforcement Administration (DEA) indicates a significant shift in the overall drug threat reported by law enforcement over the last 10 years with opioids (including controlled prescription drugs, fentanyl and other synthetic opioids, and heroin) reaching epidemic levels and impacting significant portions of the United States. According to the *2017 National Drug Threat Assessment (NDTA)* report, every year since 2001, controlled prescription drugs, specifically opioid analgesics, have been linked to the largest number of overdose deaths of any illicit drug class, outpacing those for cocaine and heroin combined.

From 2007 to 2010, responses to the National Drug Threat Survey indicate cocaine was the greatest national drug threat, followed by a significant decline as the heroin threat increased between 2010 and 2016, eventually becoming the greatest national drug threat in 2015.

Illicit fentanyl and other synthetic opioids, primarily sourced from China and Mexico and shipped directly to the US or trafficked overland via Mexico and Canada, are contributing factors in the current synthetic opioid overdose epidemic. Traffickers in the US usually mix fentanyl into heroin products and sometimes other illicit drugs or press it into counterfeit prescription pills, often without users' awareness, which leads to overdose incidents, notes the *2017 NDTA.* To access the *2017 NDTA,* visit *www.dea.gov/divisions/hq/2017/hq102317.shtml.*

FDA Recognizes Eight European Drug Regulatory Authorities Capable of Conducting Inspections

FDA has determined it will recognize eight European drug regulatory authorities as capable of conducting inspections of manufacturing facilities that meet FDA requirements. The eight regulatory authorities found to be capable are those located in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom. This achievement marks an important milestone to successful implementation and operationalization of the amended Pharmaceutical Annex to the 1998 US-European Union (EU) Mutual Recognition Agreement, which enables US and EU regulators to utilize each other's good manufacturing practice inspections of pharmaceutical manufacturing facilities. "By partnering with these countries, we can create greater efficiencies and better fulfill our public health goals, relying on the expertise of our colleagues and refocusing our resources on inspections in higher risk countries," said FDA Commissioner Scott Gottlieb, MD, in a news release located at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm583057.htm.*

Incorrect Use of Insulin Pens at Home Can Cause Severe Hyperglycemia

The National Coordinating Council for Medication Error Reporting and Prevention has issued an alert on the incorrect use of insulin pens at home causing severe hyperglycemia in patients, including one reported fatality. The Institute for Safe Medication Practices National Medication Errors Reporting Program has received several reports of patients who failed to remove the inner cover of standard insulin pen needles prior to administering insulin. In the latest such event, a patient with type 1 diabetes did not know to remove the standard needle cover and was unaware she was using the pen incorrectly and had not been receiving any of the insulin doses; the patient developed diabetic ketoacidosis as a result and died.

Since insulin pens may differ between pens with automatic needle retraction devices and those with standard needle covers that require manual removal before administering insulin, it is imperative that removal of

needle covers be explained to patients who are issued standard insulin pens during their diabetes education. Pharmacists should verify that a patient understands the appropriate administration technique whenever pens and insulin needles are dispensed, notes the alert, which can be viewed at *www.nccmerp.org/sites/default/files/nan-20171012.pdf.*

FDA Advises on Opioid Addiction Medications and Benzodiazepines

Opioid addiction medications – buprenorphine and methadone – should not be withheld from patients taking benzodiazepines or other drugs that depress the central nervous system (CNS), advises FDA. The combined use of these drugs increases the risk of serious side effects; however, the harm caused by untreated opioid addiction usually outweighs these risks. Careful medication management by health care providers can reduce these risks, notes a safety alert. FDA is requiring this information to be added to the buprenorphine and methadone drug labels along with detailed recommendations for minimizing the use of medication-assisted treatment drugs and benzodiazepines together.

Health care providers should take several actions and precautions and should develop a treatment plan when buprenorphine or methadone is used in combination with benzodiazepines or other CNS depressants. Additional information may be found at *www.fda.gov/Drugs/DrugSafety/ucm575307.htm.*

Only About 3% of Pharmacies and Other Entities Voluntarily Maintain a Prescription Drug Disposal Bin, GAO Reports

In response to the US Senate Judiciary Committee's request to review DEA's requirements for authorized collectors of prescription drugs and participation rates, the US Government Accountability Office (GAO) found that only about 3% of pharmacies and other entities eligible to collect unused prescription drugs for disposal have volunteered to do so. As of April 2017, 2,233 of the 89,550 eligible entities had registered with DEA to use disposal bins to collect unused prescription drugs. The majority of the authorized collectors were pharmacies, followed by hospitals or clinics. Factors that affected voluntary participation in maintaining disposal bins for the public included cost, uncertainty of proper implementation, and participation in other drug disposal efforts.

GAO found that participation rates varied by state. Connecticut, Missouri, and Maine had the lowest participation rates as of April 2017. North Dakota had the highest participation rate, followed by Alaska. The report, *Preventing Drug Abuse: Low Participation by Pharmacies and Other Entities as Voluntary Collectors of Unused Prescription Drugs,* is located on the GAO website at *www.gao.gov/products/GAO-18-25.*

One in Five Drivers Uses a Prescription Drug That Can Impair Driving Despite Receiving Warnings

A new study that analyzes data from the National Roadside Survey of Alcohol and Drug Use, 2013-2014, found that one in five drivers has taken prescription drugs that could impair driving despite having been warned about the risks. The authors of the study, "Receipt of Warnings Regarding Potentially Impairing Prescription Medications and Associated Risk Perceptions in a National Sample of U.S. Drivers," indicate that of the 7,405 random drivers who completed the prescription drug portion of the survey, almost 20% reported recent use (within the past two days) of a potentially impairing prescription drug.

Compared to people who were prescribed antidepressants (62.6%) and stimulants (57.7%), those who were prescribed sedatives (85.8%) and narcotics (85.1%) were most likely to report receiving warnings about the potential of these drugs to affect driving from their health care provider, pharmacy staff, or medication label.

Several European countries have introduced color-coded categories (ie, no, minor, moderate, and major influence on driving) to drug labeling to increase patient safety. Beyond labeling, the authors of the study note it is important that health care providers consistently communicate with patients about their medications' driving-related risks. The study was published online in the *Journal of Studies on Alcohol and Drugs* on October 31, 2017, and can be found at *https://doi.org/10.15288/jsad.2017.78.805.*

PTCB CPhT Program Earns Accreditation From the American National Standards Institute

The Pharmacy Technician Certification Board's (PTCB's) Certified Pharmacy Technician (CPhT) Program has earned accreditation from the American National Standards Institute (ANSI) Personnel Certification Accreditation Program through December 2022. ANSI is the first personnel certification accreditation body in the US to meet internationally accepted practices for accreditation. "We were the first pharmacy technician certification program to receive accreditation by the National Commission for Certifying Agencies (NCCA) in 2006, and now we are the first and only program to achieve ANSI accreditation," said PTCB Executive Director and Chief Executive Officer William Schimmel in a news release. More details are available in PTCB's December 18, 2017 news release, which can be found in the News Room section of *www.ptcb.org.*

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lines. This allows participating states to eliminate the need to perform their own inspections of out-of-state pharmacies. Both the Blueprint Program and Kentucky inspections are performed to the standards of USP Chapters <795> and <797>. If you would like a Blueprint Program inspection, please let the inspector know.

USP Chapters <795> and <797> Revision

USP has released the timelines for the revisions of USP Chapters <795> and <797>.

USP Chapter <795> dates:

- March 30, 2018 – Proposed revision available on *www.usp.org*
- July 31, 2018 – Comment period ends
- June 1, 2019 – Intended publication date of final version
- December 1, 2019 – Anticipated official date of final version

USP Chapter <797> dates:

- July 27, 2018 – Proposed revision available on *www.usp.org*
- September 5, 2018 – Open microphone session with USP
- November 30, 2018 – Comment period ends
- June 1, 2019 – Intended publication date of final version
- December 1, 2019 – Anticipated official date of final version

USP Chapter <800>: According to USP, Chapter <800> Hazardous Drugs—Handling in Healthcare Settings is not under review for revision.

The anticipated date of all three chapters to become official is December 1, 2019. The Board encourages pharmacists and staff to read the proposed revisions and submit comments. The USP Expert Committees read and consider every comment.

Pharmacy Sanitation

By Amanda Harding, Pharmacy and Drug Inspector

Kentucky has a regulation, 201 KAR 2:180, that addresses pharmacy sanitation. This regulation requires that designated pharmacy area(s) be maintained in a clean and sanitary condition, adequately lighted and ventilated, and have proper temperature control. All equipment used in the storage, compounding, and dispensing of drugs or medicines must also be kept in a clean and sanitary manner.

Pharmacy staff must maintain clean and sanitary conditions when performing dispensing functions. The staff in most pharmacies are exposed to a variety of germs and dirt from interactions with sick patients and handling cash. The proper use of equipment and hand hygiene when handling medications can prevent the transfer of these germs to patients.

Some poor techniques the Board inspectors have observed include pharmacy technicians pouring medication into a bare hand before running the medication through a counting machine; pharmacists pouring medication into a bare hand to visually verify a prescription; and filling blister packs, bubble packs, or medication planners with bare hands. All of these tasks can be accomplished using equipment, including personnel protective equipment (ie, gloves), that would allow staff to avoid touching medication.

Not maintaining clean and sanitary conditions could constitute unethical or unprofessional conduct.

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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