June 2021

Kentucky Board of Pharmacy News

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2020 Continuing Education Requirements Deferred

At the March 30, 2021 Kentucky Board of Pharmacy meeting, the Board voted unanimously to defer the 2020 continuing education (CE) requirements until December 31, 2021, due to the coronavirus disease 2019 (COVID-19) pandemic. Kentucky requires 1.5 CE units (or 15 CE hours) per calendar year. Because of the COVID-19 pandemic, Kentucky-licensed pharmacists who did not obtain 1.5 CE units (15 CE hours) by December 31, 2020, will be given until December 31, 2021, to obtain 3 CE units (30 CE hours) anytime between January 1, 2020, and December 31, 2021. For pharmacists who self-reported CE violations on the 2021 pharmacist's renewal, disciplinary actions will not be taken as long as 3 CE units (30 CE hours) are obtained between January 1, 2020, and December 31, 2021.

2021 Legislative Highlight – HB 219

All bills, other than those with specific provisions regarding an effective date, passed during the 2021 legislative session and signed by Governor Andy Beshear or vetoed by Governor Beshear and overridden by the legislature, will go into effect on June 29, 2021, including House Bill (HB) 219.

HB 219, sponsored by Representatives Danny Bentley, Steve Sheldon, and 10 others, updates Kentucky Revised Statute (KRS) 217.177: Sale and disposal of hypodermic syringes or needles.

Beginning June 29, 2021, pharmacists will no longer be required to obtain the identification of a person who wants to purchase hypodermic syringes and needles or maintain a logbook recording the name and address of the purchaser, the quantity purchased, the date of the purchase, and the intended medical use. Pharmacists will be able to offer hypodermic syringes and needles for sale to any person who wants to purchase them if the following are made available:

1. written or electronic educational materials on safe and proper disposal of hypodermic syringes and needles;
2. written or electronic educational or referral information for syringe exchange service programs and substance use disorder treatment; and
3. a verbal, physical, or electronic offer to provide a naloxone prescription for opioid overdose.

These three requirements do not apply if the hypodermic syringes and/or needles are dispensed pursuant to a prescription or in conjunction with a prescription medication that requires reconstitution or administration by a syringe.

KRS 218A.510 was also updated so that hypodermic syringes and needles being sold by a pharmacist without a prescription and without recording information in a logbook are not considered drug paraphernalia.

Kentucky Board of Pharmacy Committee Reports

The Advisory Council consists of Matt Martin, chair; Chris Clifton; Jason Poe; Tyler Bright; Anthony Tagavi; Wesley Rowe; Cindy Cummings; Laurel Smith; and Donna Drury, consumer member. They are presently working on a review of current regulations to clarify record keeping/remote order entry due to the passage of HB 219; emergency preparedness; and an evaluation of the National Association of Boards of Pharmacy® Emergency Passport Program.

The Diversity and Inclusion Task Force consists of Shannon Borden, co-chair; Crystal Isaacs, co-chair; April Cox; Brett Vickey; Brittany McIntyre; Brittany Smith; Candace Olusola; David Bennington; Elsayed Hassan; Hayden Pehl; Heejoo Kim Wilson; Jacqueline Clark; James Mitchell; Katie Blain; KD Hereford; Kripa Patel; Molly Murtaugh; Sondra Tapper; Thomas A. Miller III; Tiffany Self Vicars; DeAundre Bumpass, University of Kentucky College of Pharmacy student representative; and Davida Braxton, Sullivan University College of Pharmacy student representative. The Board charged this task force with the following:

- gather/evaluate/collect data to determine the need for a strategic plan to address diversity and inclusion in the Kentucky pharmacy community;
- develop a clear cultural competency plan that addresses diversity and inclusion in the Kentucky pharmacy community;
- implement ways to spearhead access to pharmacy services to reach those in underrepresented/underserved demographics by evaluating the disparity among rural and urban populations;

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National Pharmacy Compliance News

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NABPF
National Association of Boards of Pharmacy Foundation

Guidelines, Materials Available to Health Care Providers for Safely Administering COVID-19 Vaccines

Guidelines and materials are available to support health care providers with safely administering the coronavirus disease 2019 (COVID-19) vaccine, including safe practice recommendations from the Institute for Safe Medication Practices (ISMP) and a United States Pharmacopeia (USP) toolkit.

After numerous reports of errors or hazards associated with the administration of COVID-19 vaccines, ISMP is sharing safe practice recommendations.

A new USP toolkit is also available to facilitate operational efficiencies that can help accelerate delivery and support safe handling of COVID-19 vaccines while maintaining quality and ultimately the public's trust. Download the USP toolkit.

FDA Issues Guidance to Protect Consumers From Methanol Poisoning

Food and Drug Administration (FDA) has issued guidance for industry, *Policy for Testing of Alcohol (Ethanol) and Isopropyl Alcohol for Methanol, Including During the Public Health Emergency (COVID-19).* The guidance is intended to help pharmaceutical manufacturers and pharmacists who engage in drug compounding to avoid using pharmaceutical alcohol contaminated with or substituted with methanol in drug products. FDA noted that methanol is not an acceptable ingredient for any drug product and should not be used. The guidance is available on the FDA website.

Standardize Concentrations for Oral Liquid Preparations

ISMP Institute for Safe Medication Practices An ECRI Affiliate

This column was prepared by ISMP, an ECRI affiliate. Have you experienced a medication error or close call? Report such incidents in confidence to ISMP's National Medication Errors Reporting Program online at www.ismp.org *or by email to ismpinfo@ismp.org to activate an alert system that reaches manufacturers, the medical community, and FDA. To read more about the risk reduction strategies that you can put into practice today, subscribe to the ISMP Medication Safety Alert! newsletters at* www.ismp.org.

Few would disagree that standardizing the concentrations of drugs has enormous potential for increasing safety, especially in pediatric care. Standardization limits the risk of variation, especially when patients are transitioned from hospital to home or have prescriptions filled at different pharmacies. However, ISMP has learned of multiple instances in which unrecognized differences or changes in drug concentrations led to confusion and dosing errors.

In one example, a patient was prescribed hydroxyurea, an antineoplastic agent. The community pharmacy compounded a 50 mg/mL suspension for the patient with instructions to take 13 mL (650 mg) for each dose. When the patient was later admitted to the hospital, the inpatient pharmacy prepared their standard concentration of 100 mg/mL, but the same dose volume of 13 mL was ordered. As a result, the patient received doses of 1,300 mg for several days before the error was recognized. It is unclear why the community pharmacy prepared a 50 mg/mL concentration. Perhaps the prescriber ordered that concentration or that was the concentration with which the pharmacist was most familiar.

Similar concentration mix-ups have been reported in literature. In one case, the oral class 1c antiarrhythmic medication flecainide was involved. The parents of a nine-month-old infant were told to increase the child's dose volume of flecainide to 4 mL, assuming the concentration was 5 mg/mL as in the original prescription.[1] However, the parents refilled the prescription at a different pharmacy and received the drug in a 20 mg/mL concentration. The patient received 80 mg/4 mL, a fourfold overdose, resulting in wide complex tachycardia and QRS prolongation.

There have been efforts, including those by a collaborative led by the University of Michigan[2]and the American Society of Health-System Pharmacists (ASHP)[3], to publish lists of consensuses and literature-based standard concentrations. In fact, for the medications involved in the cases above, both the University of Michigan and ASHP standard recommendations are in alignment – hydroxyurea 100 mg/mL and flecainide 20 mg/mL. However, the outreach and communication of these standardization efforts do not appear to be reaching prescribers and pharmacists. Both inpatient and outpatient practitioners need to get on the same set of standard concentrations for compounded oral liquids. It is imperative that both medical and pharmacy professional organizations develop and implement effective strategies to reach and influence practitioners to use the published standard concentrations. ISMP urges prescribers and pharmacists to review the University of Michigan and

ASHP lists and consider adopting the proposed standard concentrations. Your efforts can help reduce the risk of medication errors.

It is also important for pharmacists to provide patients or caregivers with appropriately sized metric-only dosing devices (eg, oral syringes) to measure and administer doses. Label directions for patients and caregivers should include the dose in terms of mL (not teaspoonfuls), matching the dosing device. The community pharmacy label should also include the concentration next to the drug name. To be sure patients or caregivers are able to use the dosing device and measure the proper dose, use the teach-back method to demonstrate how to measure and administer prescribed amounts. This also gives pharmacists, patients, and caregivers an opportunity to catch an error.

References

1. Wang GS, Tham E, Maes J, et al. Flecainide toxicity in a pediatric patient due to differences in pharmacy compounding. Int J Cardiol. 2012;161(3):178-9.
2. *www.mipedscompounds.org/*
3. *www.ashp.org/-/media/assets/pharmacy-practice/s4s/docs/Compound-Oral-Liquid.ashx*

Opioid Use Disorder Educational Programs, Resources Available for Pharmacists

Through its Opioid Use Disorder (OUD) Education Program, the College of Psychiatric and Neurologic Pharmacists (CPNP) provides educational programs and resources that can help pharmacists during the ongoing opioid epidemic. These educational opportunities include Accreditation Council for Pharmacy Education-approved, on-demand programs covering subjects such as pharmacotherapy for OUD, comorbid disorders, and chronic pain and OUD. Toolkits and guides are available to assist pharmacists in the areas of intervention, medication management, and naloxone access.

These educational materials and resources can be accessed through the CPNP website.

National Diabetes Prevention Program – How Pharmacists Can Get Involved

Pharmacists can play a key role in preventing type 2 diabetes by helping to expand the reach of the National Diabetes Prevention Program (National DPP) – a program led by the Centers for Disease Control and Prevention (CDC) that makes it easier for patients with prediabetes or who are at risk for type 2 diabetes to participate in evidence-based lifestyle changing programs to reduce their risk and improve overall health. CDC offers an action guide for community pharmacists that outlines ways pharmacies can raise awareness of prediabetes. The National DPP is a partnership among private and public organizations to screen and test for prediabetes and refer people with prediabetes to a CDC-recognized lifestyle change program participating in the National DPP, and deliver the National DPP lifestyle change program. More information about how pharmacists can participate is available on the CDC website.

Surgery Patients Receive More Opioids in the US Than in Other Countries

Patients in the US are prescribed a disproportionally higher number of opioids after surgeries compared to surgery patients in other countries, according to a new study. The study, published in the *Journal of the American College of Surgeons,* reviewed data from 2,024 surgery patients and found that 83% of US patients without pain were prescribed opioids, compared with 8.7% of non-US patients without pain. The authors concluded that US patients are prescribed more amounts of opioids at higher rates regardless of the severeness of their post-surgical pain. The authors recommend that more efforts are made toward ensuring that opioid prescriptions are tailored to patients' needs.

The full text of the study can be accessed by visting *www.journalacs.org/article/S1072-7515(20)32336-X/fulltext.*

Study Finds 94% Drop in Symptomatic COVID-19 Cases With Pfizer's Vaccine

A study by Israel's largest health care provider, health maintenance organization Clalit, reported that there is a 94% drop in symptomatic COVID-19 cases with the Pfizer vaccine. The study represents 600,000 people who received two doses of the Pfizer COVID-19 vaccine in Israel. Clalit, which covers more than half of all Israelis, noted the same group who received the COVID-19 vaccine doses was also 92% less likely to develop serious illness from the virus. The study compared the vaccine recipient group to another group of the same size and medical history who had not received the vaccines. Read the full study here.

NABP Executive Director/Secretary Addresses Pharmacists' Involvement in COVID-19 Vaccination During FIP Webinar

NABP Executive Director/Secretary Lemrey "Al" Carter, PharmD, MS, RPh, presented during the International Pharmaceutical Federation's (FIP's) Regulators' Forum on pharmacists' involvement with COVID-19 vaccination on February 4, 2021. The webinar addressed a new regulatory vaccination preparedness self-assessment tool and risk assessment, the expanded roles for pharmacists, and data FIP has collected on vaccinations by pharmacists. View the webinar here.

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- provide diversity and cultural competency CE training for pharmacists/technicians and encourage various pharmacy organizations to provide the same courses to members;
- work with colleges of pharmacy to continue to recruit and retain a more diverse student body and pool of pharmacists serving as preceptors; and
- determine methods to engage women and minorities in leadership and professional advocacy activities.

The Medication Safety Committee consists of Donna Drury, consumer member; Elizabeth Hess; Melissa Robertson; Theresa Porter; Jessica Schmurr; Amanda Thompson; Amy Billimoria; Katie Johnson; and Dreama Johnson, pharmacy technician representative. The Board charged the committee to advise the Board on medication error matters. The committee's first task will be the consideration of the Institute for Safe Medication Practices (ISMP) "Medication Safety Self Assessment" for resolution in medication error disciplinary cases.

The Pharmacy Technician Committee consists of Sarah Lawrence, chair; Sarah Lisenby; Hope Maniyar; Martika Martin; John Long; David Figg; Jill Rhodes; Peter Cohron; and Melissa Burgess. The Board charged the committee to explore whether Kentucky would like to consider specific pharmacy technician categories. If so, determine the following: the job description; the duties that may be performed; and any education requirements for each category.

The Regulation Committee consists of Ralph Bouvette, chair; Catherine Hanna; Chris Palutis; Elisha Bischoff; Jennifer Grove; Joel Thornbury; Michael Burleson; Kimberly Croley; and Chris Killmeier. The committee is currently working on a new regulation addressing nonresident pharmacy permits; amending 201 Kentucky Administrative Regulation 2:074 regarding decentralized pharmacies; amending regulations to modernize language to keep pace with advances in technology; and drafting a repository regulation.

Medication Safety Resources

Each year the Board receives about 25 to 30 medication error complaints from consumers. These complaints include receiving the incorrect quantity, the incorrect strength, not performing an appropriate drug utilization review, and receiving another patient's medication. In an effort to better address the medication safety concerns of the public, the Board inspection staff recently participated in the ISMP Medication Safety Intensive workshop.

If you find yourself involved in a medication error, a near miss, or want to evaluate your practice setting for medication safety, ISMP has resources and tools to evaluate the situation and determine a course of action, and to help make changes to prevent future errors. They have free self-assessments available for different practice settings including community, long-term care, and hospital pharmacies. The self-assessments are complex, incorporate all pharmacy staff, and can take weeks to complete, but they do provide a foundation for evaluating your practice setting. The self-assessments are focused on the pharmacy as a system and not the pharmacists and technicians.

The Agency for Healthcare Research and Quality (AHRQ) has free surveys on Patient Safety Culture that can be used in many health care settings including community, long-term care, and hospital pharmacy settings. These are surveys taken by the pharmacy staff, which help assess the safety culture of the organization. The surveys help to evaluate conditions that could possibly contribute to medication errors and lead to changes to prevent these errors in the future.

When a medication error or near miss occurs, it is beneficial to involve the entire pharmacy team to gain input on how to make meaningful changes. Educating the pharmacy staff alone does not fix errors. There must be a more holistic approach to the problem. ISMP and AHRQ provide some resources to help develop and maintain a pharmacy practice setting where medication errors are less likely to happen.

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.

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