December 2019

# Kentucky Board of Pharmacy News

*Published to promote compliance of pharmacy and drug law*

State Office Building Annex, Suite 300 • 125 Holmes Street • Frankfort, KY 40601

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

## 2020 Pharmacist License Renewals

Pharmacist licenses expire on February 28, 2020. The Board will send out a **postcard** the first week of January 2020 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 Kentucky Administrative Regulations 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.

## 2020 Pharmacy Technician Registration Renewals

Pharmacy technician registrations expire on March 31, 2020. The Board will send out a **postcard** the first week of February 2020 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*.**

## Mandatory KASPER-KOG Account Compliance

Kentucky Revised Statute 218A.202(2) requires that any pharmacist authorized to dispense controlled substances must register and maintain a Kentucky All Schedule Prescription Electronic Reporting (KASPER) account. KASPER is administered by the Cabinet for Health and Family Services (CHFS), Office of Inspector General, Drug Enforcement and Professional Practices branch. CHFS has recently implemented a new secure login system to access KASPER called Kentucky Online Gateway (KOG). A pharmacist without a KASPER account must create a KOG account. A pharmacist with an existing KASPER account must transition the existing account to a new KOG account. Failure to create a KOG account results in the pharmacist no longer having direct access to obtain KASPER reports.

The only exemption for not obtaining a KASPER account is if the place of employment does not have a Drug Enforcement Administration (DEA) registration. Examples include if the pharmacy is a non-dispensing pharmacy, the pharmacist is a consultant pharmacist, or the pharmacist is not currently practicing pharmacy. A Kentucky-licensed pharmacist employed by an out-of-state pharmacy with a DEA registration must have an active KASPER and KOG account. A Kentucky-licensed pharmacist who accesses KASPER through an integrated system must have an active KASPER and KOG account.

Kentucky pharmacy law does not require mandatory use of KASPER by a pharmacist. However, use of the system is beneficial in determining the legitimacy of a prescription and fulfilling corresponding responsibility.

During pharmacist renewal, all Kentucky-licensed pharmacists are required to verify that they have a KASPER account or meet the exclusion of not working at a DEA-registered pharmacy. Please take a moment to review the status of your KASPER account to avoid

*continued on page 4*

# National Pharmacy Compliance News

**December 2019**

NABPF
National Association of Boards of Pharmacy Foundation

The applicability of articles in the *National Pharmacy Compliance News* to a particular state or jurisdiction can only be ascertained by examining the law of such state or jurisdiction.


## USP Postpones Official Dates of USP General Chapters Revisions and Additions

United States Pharmacopeial Convention (USP) has announced that the effective date of the following changes to USP general chapters will be postponed:

- General Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations
- General Chapter <797> Pharmaceutical Compounding – Sterile Preparations
- General Chapter <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging

The delay is in accordance with USP's Bylaws, which require the official date of the standard to be postponed while an appeal is pending. In the meantime, conformance with the official versions of Chapters <795> and <797>, including the section "Radiopharmaceuticals as CSPs," will remain official, according to a notice posted to the USP website.

Revisions to USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings are not subject to pending appeals, and will become official on December 1, 2019. During this interim period, Chapter <800> is "informational and not compendially applicable," according to the USP notice. However, the organization encourages utilization of the chapter in the interest of advancing public health. USP also notes that it plays no role in enforcement and that regulators continue to have the authority to make their own determinations regarding enforceability of Chapter <800>.

## FDA Issues Statement on Compounded Bulk Drug Substances Ruling

A US district court judge in Washington, DC, recently upheld Food and Drug Administration's (FDA's) interpretation of clinical need regarding bulk substances that may be used by outsourcing facilities in drug compounding. In response to the ruling, FDA has released a statement commending the decision as a "victory for public health in the first such case since the Drug Quality and Security Act (DQSA) was enacted."

In March 2019, FDA announced that vasopressin would not be included as an approved bulk drug substance because there is already an approved product on the market to meet the same medical needs. The ruling was in response to a challenge of that interpretation. In their statement, the agency states that they will continue to evaluate bulk drug substances nominated for use in compounding by outsourcing facilities using the same interpretation of clinical need.

"Our compounding work remains a top priority at the agency. We've long recognized that compounded drugs can serve an important role for patients whose medical needs cannot be met by an FDA-approved drug product," the agency states. "But compounded drugs are not approved by the FDA and, therefore, have not been evaluated for safety, efficacy or quality. We've seen first-hand the harm they can cause patients when they're not appropriately compounded."

## HHS, FDA Publish New Action Plan for Importation of Certain Prescription Drugs

The US Department of Health and Human Services (HHS) and FDA have published a Safe Importation Action Plan to allow for the safe importation of certain drugs originally intended for foreign markets. The action plan outlines two possible pathways:

- **Pathway 1** would rely on the authority in the Federal Food, Drug, and Cosmetic Act Section 804 to authorize demonstration projects to allow importation of drugs from Canada. The proposed rules would include conditions to ensure the importation poses no additional risk to consumers and must result in a significant cost reduction.
- **Pathway 2** would allow manufacturers to import versions of FDA-approved drug products that they sell in foreign countries that are the same as the US versions. Manufacturers would use a new National Drug Code for those products, potentially allowing them to offer a lower price than what their current distribution contracts require.

The action plan states that the final proposal for these rules may differ from the descriptions "to reflect further consideration of the relevant issues."

"Today's proposal is the result of the hard work by the dedicated staff of the FDA, in close collaboration with HHS and the White House, to identify potential pathways we can pursue to support the safe importation of certain prescription drugs," said Acting FDA Commissioner Ned Sharpless, MD in a press release. "We've been keenly focused on ensuring the importation approaches we've outlined pose no additional risk to the public's health and safety. We know there are many operational challenges to address through each of these pathways, and are actively working through them as we look to formally announce these policies, with opportunity for public comment, in the coming months."

The full action plan can be accessed via the HHS website at *https://www.hhs.gov/sites/default/files/safe-importation-action-plan.pdf.*

## Pain Reliever Misuse Decreased by 11% in 2018, NSDUH Survey Indicates

Prescription drug misuse, including abuse of stimulants and pain relievers, decreased in 2018, according to the recently released 2018 National Survey on Drug Use and

Health (NSDUH). The annual survey, conducted by the Substance Abuse and Mental Health Services Administration (SAMHSA), a division of HHS, is a primary resource for data on mental health and substance use, including abuse of prescription drugs, among Americans.

Key findings of the 2018 NSDUH include:

- Past-year abuse of psycotherapeutics decreased from 6.6 from 6.2%.
- Past-year abuse of pain relievers decreased from 4.1% to 3.6%.
- Past-year abuse of stimulants decreased from 2.1% to 1.9%.
- Past-year abuse of opioids decreased from 4.2% to 3.7%.

"This year's National Survey on Drug Use and Health contains very encouraging news: The number of Americans misusing pain relievers dropped substantially, and fewer young adults are abusing heroin and other substances," said HHS Secretary Alex Azar. "At the same time, many challenges remain, with millions of Americans not receiving treatment they need for substance abuse and mental illness. Connecting Americans to evidence-based treatment, grounded in the best science we have, is and will remain a priority for President Donald Trump, for HHS, and for SAMHSA under Assistant Secretary Elinore McCance-Katz."

A recorded presentation of the data, along with a written summary and the full report are available on the SAMHSA website at *https://www.samhsa.gov/data/nsduh/reports-detailed-tables-2018-NSDUH.*

## Additional Efforts Needed to Improve Naloxone Access, CDC Says

A new Vital Signs report published by the Centers for Disease Control and Prevention (CDC) states that naloxone dispensing has grown dramatically since 2012, with rates of naloxone prescriptions dispensed more than doubling from 2017 to 2018 alone. However, the rate of naloxone dispensed per high-dose opioid dispensed remains low, with just one naloxone prescription dispensed for every 69 high-dose opioid prescriptions.

The researchers for the report examined dispensing data from IQVIA, a health care, data science, and technology company that maintains information on prescriptions from 50,400 retail pharmacies, representing 92% of all prescriptions in the US. According to their analysis, dispensing rates were higher for female recipients than for male recipients, and higher for persons aged 60-64 years than for any other age group. The researchers also found that the rate of naloxone prescriptions dispensed varied substantially across US counties, with rural and micropolitan counties more likely to have a low-dispensing rate.

"Comprehensively addressing the opioid overdose epidemic will require efforts to improve naloxone access and distribution in tandem with efforts to prevent initiation of opioid misuse, improve opioid prescribing, implement harm reduction strategies, promote linkage to medications for opioid use disorder treatment, and enhance public health and public safety partnerships," the report states in its conclusion. "Distribution of naloxone is a critical component of the public health response to the opioid overdose epidemic."

The Vital Signs report can be accessed at *www.cdc.gov/mmwr/volumes/68/wr/mm6831e1.htm.*

## Altaire Pharmaceuticals Recalls Multiple OTC Ophthalmic Products

Due to a lack of sterility assurance, Altaire Pharmaceuticals, Inc, is voluntarily recalling over-the-counter (OTC) drug products and lots sold as generic ophthalmic medications at Walgreens, Walmart, CVS, and other retail pharmacies. To date, there have been no reports of adverse events related to the recalled products.

A full list of the affected products and lot numbers, as well as instructions on how to return the product, are available through the following press releases:

- Altaire Pharmaceuticals, Inc. Issues Voluntary Recall Of Multiple Ophthalmic Products Sold At CVS
- Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products Sold at Wal Mart
- Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products Sold at Walgreens
- Altaire Pharmaceuticals, Inc. Issues Voluntary Recall of Multiple Ophthalmic Products

Adverse reactions or quality problems experienced with the use of this product may be reported to FDA's MedWatch Adverse Event Reporting program.

## Pharmacists Invited to Participate in NAPLEX Pharmacy Practice Survey

The National Association of Boards of Pharmacy® (NABP®) sent email invitations to randomly-selected pharmacists in all areas of practice encouraging them to participate in the NAPLEX Pharmacy Practice Analysis Survey. Analysis of the survey results is used to evaluate the North American Pharmacist Licensure Examination® (NAPLEX®) competency statements.

The analysis of practice supports the relevance of the NAPLEX competency statements, which define the content for the examination. This analysis helps ensure that competency statements, otherwise known as the examination "blueprint," are in line with pharmacy practice standards and measure the knowledge, skills, and abilities of entry-level pharmacists. In addition, the review supports the NABP mission to protect the public health by providing the state boards of pharmacy with a reliable means of assessing competency that assists them with licensure decisions to support safe and effective practice.

*continued from page 1*

any delays in renewing your license. For instructions on how to access KASPER through CHFS's new secure portal, review the following instruction document, which is also available on the Board's Frequently Asked Questions web page under Pharmacist FAQs at *https://chfs.ky.gov/agencies/os/oig/dai/deppb/Documents/MandatoryKASPERKOGAccountInstructions.pdf.*

## 2020 CAPTASA Conference

The 2020 Clinical Applications of the Principles in Treatment of Addictions and Substance Abuse (CAPTASA) Conference will be held Friday and Saturday, January 24-25, 2020, at the Embassy Suites Hotel in Lexington, KY. Information on the conference, hotel, and registration can be found at *www.CAPTASA.org*.

## Recognitions

The Board would like to recognize the following individuals for their service and dedication to the Board.

- Sarah Lawrence has served a three-year term on the Advisory Council. Her term expires December 31, 2019.
- Sandra Anderson has served a seven-year term on the Pharmacy Recovery Network Committee. Her term expires December 31, 2019.
- Julie Owen has served a seven-year term on the Pharmacy Recovery Network Committee. Her term expires December 31, 2019.
- Mandy Jones has served a seven-year term on the Pharmacy Recovery Network Committee. Her term expires December 31, 2019.
- Craig Martin has served as president of the Board for 2019.

## Kevin's Law

Advocacy for emergency access laws gained momentum following the death of 36-year-old Ohio resident Kevin Houdeshell in January 2014, who died awaiting a new refill for his insulin during the holiday season while his doctor was away.

Most state laws only allow for emergency prescription refills of up to 72 hours but many life-sustaining medications, such as insulin, cannot be dispensed in 72-hour quantities.

Following his passing, Kevin's family has advocated for emergency prescription refill legislation across the United States to ensure that patients always have access to the medication they need to survive, even if their prescription has expired.

Emergency refills are instrumental in a variety of situations:

- Delays in refill requests between physician and pharmacy
- Travel delays
- Shattered or damaged vials or pens
- Natural disasters

In December 2015, Ohio became the first state to pass Kevin's Law, when Governor John Kasich signed House Bill (HB) 188. This law allows pharmacists to dispense up to a 30-day supply of life-sustaining drugs, such as insulin, even if the prescription has expired. Sixteen states have passed Kevin's Law.

**Indiana passed HB 1248 in 2019**

- Includes insulin
- No limits on times you can use the law
- Pharmacists may also prescribe medical devices, including diabetes blood sugar testing supplies, syringes, and pen needles

**Kentucky passed HB 64 in 2019**

- Applies only to insulin and treatments for chronic respiratory illnesses
- No limits on times you can use the law for an emergency refill

## 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.

Larry A. Hadley, RPh - State News Editor

Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor

Amy Sanchez - Communications Manager