September 2019

Kansas State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Announcements

- Looking for fall reading material or good professional development? The Kansas State Board of Pharmacy suggests the following texts.
  - ◊ *Communication Skills in Pharmacy Practice: A Practical Guide for Students and Practitioners* by Robert S. Beardsley, Carole L. Kimberlin, and William N. Tindall
  - ◊ *Communication Skills for Pharmacists: Building Relationships, Improving Patient Care* by Bruce A. Berger
- The Board is pleased to announce that Jennifer Donnelly, MPH, has been selected to fill the position of assistant director of the Kansas Prescription Drug Monitoring Program (K-TRACS). The Board hopes to fill her current epidemiologist position later this fall.
- The Board recently released several new and amended regulations for public comment. Visit *http://pharmacy.ks.gov/statutes-regs/proposed-changes* for more information.
- Follow the Board on Twitter @KSBOP or on Facebook *(www.facebook.com/KansasStateBoardOfPharmacy)* for news, updates, and more!

New Board Members Appointed

The Board is pleased to announce Governor Laura Kelly's recent appointment of Terica Gatewood, PharmD, RPh, and Tiffany Strohmeyer, PharmD, RPh, to the Board. They will each serve a four-year term, ending in 2023.

Dr Gatewood has been employed with Genoa Healthcare since 2014. She currently serves as the associate director of talent acquisition and is responsible for university relations and sourcing of leadership candidates throughout the organization. Her past experience with Genoa also includes serving as the pharmacy site manager within Valeo Behavioral Health Center in Topeka, KS. Dr Gatewood received her doctor of pharmacy degree from the University of Kansas School of Pharmacy in 2007. She has been a pharmacy preceptor for the university since 2014, receiving the Preceptor of the Year Award in 2016-2017 for instruction and leadership. She attends yearly student events at the university to lecture on pharmacy practice, legislative issues, and the pharmacist's role in community mental health centers. Dr Gatewood served as a board member for the Kansas Pharmacists Association as the district 2 director for two years. She is the current chairperson of the Government Affairs Committee for the organization, where she helps organize legislative events, conducts committee calls, and oversees grassroots and member initiatives. Furthermore, she has advocated on pharmacy and mental health issues before legislative committees in both the Kansas House and Senate. Dr Gatewood is involved in several community organizations, including the National Alliance on Mental Illness (NAMI) of Kansas and the Kansas Mental Health Coalition. She helps organize Genoa pharmacy teams to raise funds to support mental health during the annual NAMIWalks Kansas. She is also involved in supporting Valeo Behavioral Health and its mission to help individuals and their families in the Topeka community.

Dr Strohmeyer is a pharmacist and co-owner of Barry's Drug Center and Dunne's Pharmacy, two independent retail pharmacies located in Manhattan, KS. In addition to her retail pharmacy experience, Dr Strohmeyer is the pharmacist-in-charge of an ambulatory surgery center and performs long-term care consultations in the Manhattan area. A proud alumna of the University of Kansas, Dr Strohmeyer obtained her doctor of pharmacy degree with distinction in 2000. A two-time kidney transplant recipient, Dr Strohmeyer makes Topeka her home, where she is active in the Junior League of Topeka and a past Topeka Top 20 Under 40 honoree.

The Board also wishes to thank Robert Haneke, PharmD, RPh, and Chad Ullom, RPh, for their eight years of service to the Board.

National Pharmacy Compliance News

September 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.

FDA Changes Opioid Labeling to Give Providers Better Information on Tapering

Noting that the agency remains focused on striking the right balance between policies that reduce the rates of opioid addiction while still allowing patients and health care providers access to appropriate pain treatments, Food and Drug Administration (FDA) has announced required changes to the prescribing information for all opioid analgesic medications used in the outpatient setting. The changes, announced in a Drug Safety Communication, provide expanded information to health care providers on how to safely decrease the dose in patients who are physically dependent on opioids. FDA intends for this information to be used when health care providers and patients have decided together that a decrease in dose or discontinuation of opioids is appropriate.

"Rapid discontinuation can result in uncontrolled pain or withdrawal symptoms. In turn, these symptoms can lead patients to seek other sources of opioid pain medicines, which may be confused with drug-seeking for abuse," the agency said in the communication. "Patients may attempt to treat their pain or withdrawal symptoms with illicit opioids, such as heroin, and other substances."

In addition to these changes, an FDA press release also announced that additional policies related to the opioid crisis are forthcoming. These include a requirement for immediate-release formulations of opioids to be made available in fixed-quantity packaging that contain doses more typical of what patients may need for common acute pain conditions and procedures. The full press release is available in the News and Events section of the FDA website.

DEA Warns of Scam Calls Targeting Pharmacists and Other DEA-Registered Providers

Health care providers and other members of the public have reported receiving phone calls from people claiming to represent Drug Enforcement Administration (DEA), and threatening legal action against them if a large fine is not paid immediately over the phone. According to a DEA press release, this scam used fake names and badge numbers, or the names of well-known senior officials with DEA, and threatened victims with arrest, prosecution, imprisonment, and revocation of their DEA numbers. The agency emphasizes that DEA will never contact practitioners by phone to demand money or any form of payment. DEA will not request any personal or sensitive information by phone, and notification of legitimate investigation or legal action is made via official letter or in person.

DEA asks anyone who receives a call from a person purporting to be a DEA special agent or other law enforcement official asking for money to refuse the demand and report the threat using the online form or by calling 877/792-2873. Reporting these calls will assist DEA in investigating and stopping this activity.

FDA Officials Outline 2019 Efforts to Improve Quality of Compounded Drugs

Recognizing the important roles compounded drugs can play in patient care, FDA plans to continue its efforts to improve the quality of compounded drugs. According to a statement posted to the FDA website, these priorities include:

- maintaining quality manufacturing compliance,
- strengthening and refining regulations on compounding from bulk drug substances,
- finalizing the agency's memorandum of understanding with the states, and
- issuing revised draft guidance for compounding by hospital and health systems.

"We've worked to refine our existing practices, shape new policies and increase the frequency of our communications with industry, Congress, states and patients concerning our programs," then-Commissioner Scott Gottlieb, MD, and Deputy Commissioner Anna Abram said in a statement published on the FDA website. "We anticipate that 2019 will be an equally productive year for the FDA's compounding program, with better quality continuing to be our top priority as part of our ongoing effort . . . to improve the quality of compounded products for consumers . . ."

In addition, Gottlieb and Abram's statement notes that the agency will continue to work closely with stakeholders on these steps and any other compounding-related measures not outlined in the statement.

China Agrees to Stricter Fentanyl Production Laws Following Pressure From US Lawmakers

China has announced that all variations of the powerful opioid product, fentanyl, will be treated as controlled substances (CS). According to a press release from Senator Tom Cotton, the announcement came after a bipartisan group of United States lawmakers, including Cotton, introduced Senate Bill 1044, a bill designed to apply pressure to the Chinese government to make all forms of synthetic opioids illegal and to provide US law enforcement with more tools and resources to go after illicit traffickers in China, Mexico, and other countries.

"Combating the flow of illicit fentanyl into our country is imperative in the fight to save American lives from the opioid crisis," Senate Minority Leader Chuck Schumer said in the press release. "We must hold China accountable for their role in the fentanyl trade. China's new regulation to make all fentanyl categories illegal is an important step and the administration deserves praise for their efforts to secure this change. However, we have to demonstrate that we will demand China enforce these laws and take strong action against opioid traffickers."

In a December meeting with President Donald Trump, China's President Xi Jinping promised to classify fentanyl as a CS following a 2018 report by the US-China Economic and Security Review Commission that found China to be "the largest source of illicit fentanyl and fentanyl-like substances" in the US, according to a report from NPR. The latest increase in opioid-related overdose deaths has been largely attributed to the availability of illegally manufactured fentanyl.

Two Lots of Transdermal Fentanyl Patches Recalled Due to Product Mislabeling

Alvogen, Inc, of Pine Brook, NJ, is recalling two lots of Fentanyl Transdermal System 12 mcg/h transdermal patches to the consumer level after a small number of cartons were found to contain 50 mcg/h patches. Though the 50 mcg/h patches are individually labeled correctly, accidental application of the higher dosage patch instead of the prescribed 12 mcg/h patch could result in serious, life-threatening, or fatal respiratory depression. The company has not received any reports of adverse events related to this issue.

The company is notifying its distributors and direct customers by certified letter and is arranging for the return and replacement of all recalled products. Pharmacies are asked to stop dispensing any product subject to the recall. Consumers that have affected products should immediately remove any patch currently in use and contact their health care provider. Patients with unused product should return it to the point of purchase for replacement.

Additional information on the recall, including the affected lot numbers and customer service contact information, is available in a press release posted to the FDA website. Adverse reactions and quality problems can be reported to the FDA MedWatch Safety Information and Adverse Event Reporting Program.

FDA Releases Toolkit to Help Promote Safe Opioid Disposal

FDA has made a new resource available for consumers and health care providers to help promote and educate individuals about how to safely dispose of unused opioids. The free Safe Opioid Disposal – Remove the Risk Outreach Toolkit includes video, radio, and print public service announcements, social media graphics and posts, fact sheets, drop-in content, and website badges that health care providers and other interested individuals and organizations can use to promote the message of opioid safety. The toolkit and its resources can be accessed on the Ensuring Safe Use of Medicine section of the FDA website.

An additional resource available to help consumers find disposal kiosks available year round is the National Association of Boards of Pharmacy® (NABP®) Drug Disposal Locator Tool, available in the AWAR$_X$E® Prescription Drug Safety section of the NABP website, *www.nabp.pharmacy/initiatives/AWARxE.* With more than 6,500 disposal sites in the continually updated database, consumers can enter location information to find the nearest disposal sites to them using a map.

Additional information about the FDA campaign can be found at *https://www.fda.gov/drugs/buying-using-medicine-safely/ensuring-safe-use-medicine.*

Pharmacy Technician Examination, CE, and Renewal Updates

Examination

The Board now requires all technicians registered after July 1, 2017, to pass a national certification examination before their first renewal. The first batch of technicians with the new certification exam requirement is renewing in September-October 2019 and must pass either the Pharmacy Technician Certification Board examination or the Exam for the Certification of Pharmacy Technicians before renewing their registration.

Kansas Administrative Regulations 68-5-17 allows for a technician to request a six-month extension if he or she is unable to take or pass the examination. The Board has created the LA-75 Technician Certification Extension Request Form, which should be used to make such a request. Additional information can be found in the Board's June 2019 *Newsletter.* Requests must be submitted to the Board before the technician renews and no later than October 1, 2019. Requests received after this date will be denied.

If a technician has not been granted a waiver and has not successfully passed a national certification exam prior to October 31, 2019, the technician should **not** renew and should stop working as a technician after the registration expires. Renewing without proof of passing an exam will result in denial. Any technician whose renewal is denied or expires will need to pass a national certification examination before filing a new technician registration application.

Continuing Education

All Kansas pharmacy technician registrations expiring on October 31, 2019, must have completed 20 hours of continuing education (CE) – or the prorated amount of CE based on the issue date and the expiration date of the technician registration – before renewal. Those 20 hours must have been earned between September 1, 2017, and the day of renewal in 2019.

CE may be approved for pharmacists or pharmacy technicians, or may be earned for national certification. However, all CE must be approved by one of the following:

1. **Accreditation Council for Pharmacy Education:** To receive credit, register for CPE Monitor®.
2. **Another state board of pharmacy:** To receive credit, submit a copy of the certificate of completion to the Kansas Board within 30 days of course completion.
3. **The Kansas State Board of Pharmacy:** To receive CE approval from the Board, submit a request for approval to the Board at least 10 days prior to the course using the E-200 Request Form. A list of pre-approved Kansas CE courses is also available on the Board website. To receive credit, submit a copy of your certificate of completion to the Board within 30 days of course completion.

Renewal

Pharmacy technicians with licenses expiring on October 31, 2019, can renew online beginning in early September. Renewal instructions:

- Visit *http://ksbop.elicensesoftware.com/portal_logon.aspx.*
  - ◊ New users: click "Sign-Up" and create a username and password.
- Log in and select "Renew License."
- Review and update information, certify completion of the required CE hours, answer disciplinary questions, and submit the renewal.
- Use the secure online payment portal to pay $20 plus a small transaction fee by credit/debit card or electronic check, **or** follow the instructions to print and mail a $20 check or money order to the Board.
- Allow 10 business days for the Board to process your renewal.
- Visit the License Verification page to check for an updated expiration date.

Failing to renew on or before 11:59 PM CDT on October 31, 2019, will result in the registration being canceled. Technicians with canceled registrations cannot work and will be required to complete a new application and fingerprint card to continue working ($67 cost).

Pharmacies utilizing/employing technicians with canceled registrations will be in violation of the Kansas Pharmacy Practice Act and may be disciplined by the Board.

EPA Ban on Sewering Hazardous Waste Pharmaceuticals

A message from the Kansas Department of Health and Environment

Effective August 21, 2019, health care facilities, including pharmacies, may no longer dispose of pharmaceuticals that are hazardous waste by flushing them or putting them down the drain. This requirement (40 Code of Federal Regulations 266.505) is part of the United States Environmental Protection Agency's (EPA's) final rule for the management of hazardous waste pharmaceuticals. The other provisions of the rule do not take effect in Kansas until they are adopted by the state.

EPA plans to have information about the prohibition of sewering hazardous waste pharmaceuticals available on its website soon. For additional information about the

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management of hazardous waste, you may visit the Kansas Department of Health and Environment Bureau of Waste Management website at *www.kdheks.gov/waste* or call Brian Burbeck at 785/296-1613.

What Does Compliance Look Like?

A Reminder on Prescriptions for Vaccines

A prescription for a vaccine only authorizes the pharmacist to dispense the vaccine, not administer it. This fact is not changed by recent legislation. The passage of 2019 House Bill 2119 allows for the pharmacist to administer a drug by injection that can be safely self-administered by a patient. However, a vaccine is not considered to be a drug for self-administration.

A pharmacist may dispense a vaccine that is not on his or her immunization protocol based on a prescription received from a prescriber.

A vaccination protocol is not required to dispense a vaccine prescription received from a prescriber.

If a patient presents with a prescription for a vaccine with the intent of the pharmacist administering it, the immunizing pharmacist should follow his or her vaccination protocol procedures.

In accordance with the appropriate authority, pharmacists administering any vaccine or prescription are still required to have the requisite training and education necessary to safely administer the medication to a patient.

Upcoming Events

September 11, 2019, 8:30 AM – Business Meeting

September 12, 2019, 8:30 AM – Administrative Hearings

Board of Pharmacy Quarterly Meeting
714 SW Jackson, Suite 100, Topeka

November 22, 2019, 9 AM

PMP Advisory Committee Meeting (in person)
800 SW Jackson, Lower Level, Topeka

The *Kansas State Board of Pharmacy News* is published by the Kansas State 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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