June 2021

Kansas State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Announcements

- Regular updates regarding Kansas State Board of Pharmacy guidance and information on the coronavirus disease 2019 (COVID-19) can be found on the Board website. This includes information about operations, waivers, renewals, exams, fingerprinting, inspections, pharmacy frequently asked questions, and more. The Board has extended remote work options through December 2021.
- Kansas Tobacco Cessation Help is a free, newly revised tobacco cessation online training. It is a self-paced course that guides you through seven modules, each ranging from 15-30 minutes. The modules cover enhanced Quitline services, Kansas Medicaid cessation benefits, vaping, teen tobacco use, behavioral health, and Quitline counseling call samples. To review a summary of each module or register for the training, please visit *https://quitlogixeducation.org/kansas.*
- Welcome new Senior Administrative Assistant Jeanine Brizendine! Having spent most of her life in Kansas, Jeanine and her husband, Jerry, recently returned to the area from a six-year adventure in Florida. Jeanine has been a pharmacist in many practice settings, including retail, hospital, home care, and long-term care. Most recently, Jeanine served as pharmacy manager at a new hospital near Tampa, FL. She has one sister and one nephew, both of whom live in Kansas City, KS. Jeanine and Jerry enjoy international travel. Jeanine's other interests include sewing, yoga, and long walks outside. Jeanine is excited to join the Board and looks forward to once again serving the profession of pharmacy in the state of Kansas.
- The Kansas Prescription Drug Monitoring Program (K-TRACS) has developed best practices to assist pharmacists in retail settings with implementing K-TRACS use effectively in their pharmacies. The best practices address how pharmacists can access K-TRACS, when they should consult patient prescription histories, and how to use the data they find. Learn more about best practices by visiting *http://ktracs.ks.gov/pharmacists/best-practices.*
- At the April 1, 2021 meeting, the Board adopted new guidance concerning mobile disaster response units for pharmacies: Reports & Guidance Documents.

Technician Registration

Certification Extension Waivers Expire June 30, 2021

In September and October 2020, some pharmacy technicians were approved for the technician certification extension (Form LA-75). These technicians were granted an extension to provide proof of completion of a national certification exam until June 30, 2021. Registrations issued after July 1, 2017, require proof of completion of the national certification examination to the Board office. For those technicians granted a waiver, failure to provide proof by June 30 will result in the technician's registration being canceled. Please email pharmacy@ks.gov or fax 785/296-8420 a copy of the Pharmacy Technician Certification Board's Pharmacy Technician Certification Exam (PTCE) or the Exam for the Certification of Pharmacy Technicians (ExCPT) certificate. Individuals with expired certifications will not be able to reapply for registration as a pharmacy technician in Kansas until they have passed the certification exam.

The Board has approved the PTCE and the National Healthcareer Association's ExCPT.

Registrations Expiring October 31, 2021

Any pharmacy technician who is unable to take or pass the PTCE or ExCPT by October 31, 2021, may request a six-month extension at least 30 days before the technician's registration expiration date by completing a Technician Certification Extension Request Form LA-75.

Employment or Contact Information Update for Technicians, Interns, and Pharmacists

Within 30 days of obtaining new employment or ceasing employment, every registered pharmacy technician, intern, and pharmacist shall notify the Board office by completing Form LA-50 or by logging in to the eLicense portal.

1. Create a username and password in the eLicense portal by clicking Sign-Up.
2. Sign in to eLicense under the User Logon section.

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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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3. Click Update Account/Employer Information.
4. Click Add in the employer section to add the pharmacy information.
5. Click Save.

Every pharmacy technician, intern, and pharmacist who changes their residential address, email address, or legal name shall, within 30 days thereof, notify the Board office by completing Form LA-40 or by logging in to the eLicense portal.

1. Create a username and password in the eLicense portal by clicking Sign-Up.
2. Sign in to eLicense under the User Logon section.
3. Click Update Account/Employer Information.
4. Click Edit Info to update your address, email, or phone number.
5. Click Save.

Licensees who want to change their name must complete Form LA-40. This must be accompanied by a copy of the legal document authorizing or granting the change.

2021 Pharmacist Renewal

Pharmacist licenses expiring June 30, 2021, are now eligible for renewal. To renew, visit the eLicense portal on the Board website to log in with your username and password, review and update contact information and other required items, answer the disciplinary history questions, and complete the renewal certification. Use the secure payment processing portal to submit your payment by credit card, debit card, or electronic check. Online renewals must be dated and time stamped on or before 11:59 PM CDT on June 30, 2021. All other renewals will be considered late and require payment of the late fee. Pharmacists are not authorized to practice until the renewal and the late fee are submitted to the Board office.

Pharmacists are required to have completed 30 hours of continuing pharmacy education (CPE) between July 1, 2019, and the date of their renewal (no later than June 30, 2021). There is no grace period for completion of CPE. For ways to reduce your continuing education audit risk, see the Board's June 2018 *Newsletter.*

New This Year! If you renewed online and answered "No" to all disciplinary questions, you can immediately print your 2021 pharmacist license renewal certificate and pocket card. The Board will not print/mail these items. If additional copies are needed, log back in and print/download a copy. If you answered "Yes" to a disciplinary question, you can verify that your renewal has been received by visiting the License Verification page and checking for the updated expiration date. You should also receive a confirmation email when renewing online.

2021 Pharmacy and Facility Renewal

Pharmacy and other facility permits are eligible for renewal through June 30, 2021. Use the eLicense portal to renew each permit through an automated process and pay using the secure portal.

- Wholesale distributors (5-), nonresident pharmacies (22-), and outsourcing facilities (20-) should allow 10 business days for Board review and approval. Once approved, the facility can log back in and print/download a copy of the renewed permit.
- All other facilities may **immediately** print the 2021-2022 renewal permit. If additional copies are needed, the facility can log back in and print/download a copy of the renewed permit.

Nonresident pharmacies and facilities: If you have not received an in-person or virtual inspection from your home state or the National Association of Boards of Pharmacy® (NABP®) in the time frame required for Kansas renewal (18 months for pharmacies, 36 months for all other facilities) due to the COVID-19 pandemic, the following should be submitted with your renewal:

- Completed Self-Inspection Attestation Form (N-300)
- Completed self-inspection using the appropriate form found at the bottom of the Businesses & Facilities page on the Board's website:
  - nonresident pharmacy – NRI-22
  - wholesale distributor – I-05
  - nonresident nonprescription drug distributor – NRI-06

Virtual Distributors and Manufacturers

Kansas recently passed legislation allowing the Board to recategorize virtual distributors and virtual manufacturers as well as nonresident manufacturers in Kansas. This should alleviate several new requirements imposed on wholesale distributors in 2020, which are not applicable to virtual or manufacturing facilities. During the 2021 renewal period (May 17 – June 30, 2021), virtual distributors, virtual manufacturers, and nonresident manufacturers will be required to do the following to remain registered in Kansas:

- Complete and submit a BR-04 manufacturer renewal application from the Board's website along with the renewal fee. Submissions must be received or postmarked no later than June 30, 2021.
- Nonresident facilities must attach a copy of the most recent inspection report conducted at the current physical location within the past three years by the state of residence, NABP, or Food and Drug Administration (FDA).
- Virtual facilities must attach a list of all products manufactured – as well as the name, address, and phone number of all FDA-registered contract manufacturers – and attach the most recent report of an FDA inspection of manufacturing activities for each manufacturer contracted with the virtual facility to provide any product that is shipped into Kansas.

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Failure to submit a completed BR-04 and payment by June 30, 2021, will result in expiration of the registration. Expired registrations are not authorized to do business in Kansas.

What Does Compliance Look Like?

Beyond-use dates (BUDs) or expiration dates are required on all prescription labels, per Kansas Administrative Regulation 68-7-14(a)(7).

Once a product is removed from the manufacturer's bottle, the drug is assigned a BUD. The BUD is typically a year from the date dispensed. However, there are many instances where the date should be shorter than a year:

- the manufacturer's expiration date printed on the stock bottle is shorter than the year;
- the manufacturer requires a shorter date upon dispensing;
- the drug is from a prescription returned to stock; or
- the drug is a compound.

In these instances, the pharmacist must change the BUD on the label or train the technicians to make the change during the labeling process. Failure to do so would lead to a drug that has been mislabeled and the patient using the drug past the original BUD. Once past the original BUD, the product would be considered adulterated.

Where Does Your Pharmacy Buy Its Drugs?

Please review and verify that the companies your pharmacy purchases drug products from are registered with the Board. It is illegal for any company to ship drugs or prescription devices into the state of Kansas without being registered with the Board. Buying from unregistered companies could compromise patients and lead to violations of the federal Drug Quality and Security Act.

Inspections! Are You Ready?

To ensure that you are prepared, please have the following items **readily retrievable:**

- Drug Enforcement Administration (DEA) registration
- annual inventory of controlled substances (CS) and any pharmacist-in-charge (PIC) change inventories for the last year
- Combat Methamphetamine Epidemic Act self-certification
- posted licenses and registrations – personal addresses may be covered
- policies and procedures
- technician list
- technician training documentation
- prescription files – be prepared to assist in review of electronic prescriptions
- logbook or daily printouts
- vaccination protocol, administration records, and CPR cards
- incident reports – these are required to be printed and signed by each person involved
- continuous quality improvement (CQI) documentation for meeting and actions
- drug invoices from wholesale distributors, manufacturers, and other pharmacies
- completed copies of DEA Forms 222 and/or completed electronic Controlled Substance Ordering System orders
- loss and theft reports (DEA-106)
- compounding records, if compounding is performed (certificates of analysis; certifications; formulation, compounding, and batch records; and training records for all personnel involved in compounding)

Questions? Call the inspector or make a list for when the inspector visits.

What does readily retrievable mean?

- Can all relevant documents be located within a few minutes of request by an inspector?
- Does staff know where these documents are located?
- Can staff locate the documents when the PIC is not present?

Consider:

- ◊ Developing a documents list with location identified
- ◊ Keeping the documents (inventory, incident reports, CQI, technician training, policy/procedures) in one location like a file box or cabinet

K-TRACS to Begin Pharmacist Peer-to-Peer Outreach

K-TRACS will launch a new program later this year focused on peer-to-peer clinical outreach education with Kansas pharmacists. This outreach program – also known as academic detailing – will include one-on-one, customized training that presents the latest evidence-based research on a variety of dispensing topics.

The goal of each session will be to help pharmacists make changes to improve patient outcomes and promote patient safety when dispensing CS. Each session will be tailored to the needs of the pharmacist and pharmacy.

Clinical outreach education is less about lectures, presentations, and one-sided conversations, and more about understanding the needs of the pharmacist, pharmacy, and community. It is about working toward solutions that incorporate the best practices and evidence available for the industry.

Many state health departments and large health systems across the country, including the Department of Veterans Affairs, have implemented these types of academic detailing programs on a variety of topics – from antibiotic stewardship and opioid safety to HIV prevention and cancer screenings.

Over the next few months, you will hear more about the K-TRACS academic detailing program for Kansas pharmacies. Stay tuned.

Pharmacists Continue to Sign on to Statewide Naloxone Protocol

Opioid-involved overdose deaths continue to increase in Kansas, highlighting the importance of the availability of naloxone for consumers.

More than 200 pharmacies in Kansas have at least one staff pharmacist who can dispense naloxone according to the statewide protocol; however, many counties still do not have this avenue for getting naloxone into the hands of patients.

Data from emergency medical services, emergency departments, and death certificates show increases in opioid overdoses in the latest data available.

How can you help?

- View the Board's infographic to understand the need for expanded access to naloxone
- Sign the statewide naloxone protocol
- Learn about resources for patients who cannot afford naloxone

Warning – Misrepresentation and Failure to Disclose

Over the past several months, the Board has noted a disturbing trend in the number of applications from pharmacists, interns, and technicians who fail to accurately report criminal offenses and/or disciplinary history. According to Kansas Statutes Annotated 65-1627, the Board may deny an application, limit/suspend/revoke a license or registration, or levy a fine against anyone who has obtained, renewed, or reinstated, or **attempted** to obtain, renew, or reinstate, a license or registration by false or fraudulent means, including misrepresentation. The law does not require that this misrepresentation be made intentionally for the Board to take action. Furthermore, applicants are required to certify on each original or renewal application that "the information provided is true, correct, and complete to the best of their knowledge."

Personal history and disciplinary questions **must** be answered honestly on all applications to avoid negative consequences. Required disclosures include **all** arrests and/or charges, even if a charge was never filed, the charge was dismissed, there was no conviction, a court date has not been scheduled, or the applicant completed a diversion program, or suspended imposition of sentence. Applicants often provide excuses to the Board based on alleged misinformation about "clean" records from courts or attorneys, or certain offenses not showing up on previous employment background checks. The Board's background check is completed by the Kansas Bureau of Investigation. It shows **everything.** When in doubt, disclose the offense! The Board does not consider anything outside its jurisdiction. To assist individuals in understanding application questions and what must be disclosed or reported, the Board has published the following web page: Personal History Reporting Resources.

The Board also works with NABP and the National Practitioner Data Bank to receive information about any professional or occupational license, permit, or registration held by the applicant. Any discipline, reprimand, or other action against one of these licenses, registrations, or permits should also be disclosed to the Board on the application.

It is imperative that original and renewal applicants fully and accurately report criminal offense and disciplinary history information to the Board. The Board takes this matter very seriously and, as a result, has directed staff to scrutinize these applications more closely as of June 1, 2021, and refer them for possible disciplinary action, which may include denial or revocation. When assisting applicants with paperwork, supervisors and PICs **should not** make assumptions about criminal history or disciplinary information and **should** make every effort to emphasize the importance of responding honestly to questions and providing the requested Form S-150 and supplemental information to the Board where appropriate.

As an additional reminder, Kansas pharmacists, interns, and technicians are required to report any new criminal offense or discipline to the Board within 30 days.

Revoked Licenses and Registrations

In an effort to provide greater transparency to pharmacists, the Board will publish a list of revocations against Kansas pharmacists, interns, and technicians in its quarterly *Newsletter.* The Board encourages the PIC to verify the registration status of all employed technicians at least twice a year (June and November are recommended). The Board's license verification website is a secure and primary source of credential verification information, and is as authentic as a direct inquiry to the Board: *https://ksbop.elicensesoftware.com/portal.aspx.*

Please take notice of the Board's revocation action taken on these licenses, permits, and registrations:

- Brooks, Diera 24-111343, Case 21-038
- Hernandez, Nadia 24-110312, Case 21-025
- Ledesma, Carolyn 24-108136, Case 21-030 (suspended)
- Stone, Chelsea 14-05470, Case 21-031

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Alexandra Blasi, MBA, JD - State News Editor
Lemrey "Al" Carter, PharmD, MS, RPh - National News Editor & Executive Editor
Amy Sanchez - Publications and Editorial Manager