



Kansas State Board of Pharmacy

Published to promote compliance of pharmacy and drug law

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Announcements

- ◆ Facility permits are eligible for renewal through June 30, 2018. Use the [eLicense portal](#) to renew each permit through an automated process, pay using the secure portal, and **immediately print the 2018 permit**. If additional copies are needed, log back in and print/download a copy. For nonresident pharmacy permits, see the next article.
- ◆ A reminder that Kansas pharmacy technicians with registrations expiring October 31, 2018, must have completed **20 hours of approved continuing education (CE)**. This CE will need to have been earned between September 1, 2016, and the date of renewal. Information about approved CE may be found on the Kansas State Board of Pharmacy website at <http://pharmacy.ks.gov/licensing-registration/ce>.
- ◆ The Board recently adopted new regulations concerning sterile and nonsterile compounding consistent with United States Pharmacopeia Chapters <795> and <797>. Copies of the approved regulations and new regulations anticipated to go out for public comment are available on the Board's website at <http://pharmacy.ks.gov/statutes-regs/proposed-changes>.
- ◆ Governor Jeff Colyer, MD, launched [Kansas Public Square](#), the state's new website for posting meetings and minutes, adding a new layer of transparency in state government. The Board will post all meetings to Public Square in addition to the Board's website.
- ◆ Update your bookmarks: Board disciplinary orders have been reorganized by individual last name (pharmacists, interns, and technicians) at <http://pharmacy.ks.gov/statutes-regs/individual-disciplinary-actions>, and by facility name at <http://pharmacy.ks.gov/statutes-regs/facility-disciplinary-actions>.
- ◆ CE providers: After submission of a course to the Board for approval, the course may be advertised as "Pending Approval by the Board" **only!**

Nonresident Pharmacy Renewal Requirements

Nonresident pharmacy permits are eligible for renewal through June 30, 2018. Use the [eLicense portal](#) to renew each permit individually and pay using the secure portal.

Pursuant to Kansas Administrative Regulation (K.A.R.) 68-7-12a, Kansas now requires each registered nonresident pharmacy to provide the Board with proof of a satisfactory inspection of the pharmacy conducted within the previous 18-month period and to designate a Kansas-licensed pharmacist-in-charge (PIC). To remain registered in Kansas, each nonresident pharmacy will be required to do the following in conjunction with the online renewal:

1. Provide an inspection report conducted at the current physical location of the pharmacy after January 1, 2017.
 - a. The inspection can be completed by the resident state board of pharmacy or the National Association of Boards of Pharmacy® (NABP®) through its Verified Pharmacy Program® (VPP®). Self-inspection reports will not be accepted. Proof of completion of the VPP application may be provided if the site visit has not yet occurred.
 - b. This will be a continuing requirement for all future renewals.
2. Designate a Kansas-licensed pharmacist as the PIC.
 - a. The pharmacy can provide the Kansas license number for the current PIC or designate a new PIC licensed in Kansas by uploading the BA-50 PIC change form, which may be found on the renewal portal. If this process is followed correctly, the pharmacy will avoid paying an additional PIC change fee.
 - b. The BA-50 form should include the signatures of the outgoing and incoming PICs and be submitted with the 2018 renewal.
 - c. Non-Kansas-licensed pharmacists should contact NABP to begin the Electronic Licensure Transfer Program® process. They will be required to take and pass the Kansas-specific Multistate Pharmacy Jurisprudence Examination®.

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National Pharmacy Compliance News

June 2018



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 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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- d. If the new PIC was previously licensed in Kansas, but has let the license lapse, he or she will need to complete the reinstatement process through the Board using the LA-60 form available on the Board's website.
- e. If the new PIC is currently licensed in Kansas and has been licensed for more than two years, but has never served as a PIC at a facility located in Kansas, he or she will need to take and pass the Board's PIC exam. The new PIC may request the exam by emailing pharmacy@ks.gov. Please provide the facility number and the PIC's name and Kansas license number.

After July 1, 2018, an outgoing PIC must submit the signed Part A of the BA-50 form to the Board within five days of leaving the position. The pharmacy will have 30 days from the outgoing PIC's last day to designate a new Kansas-licensed PIC and submit Part B of the BA-50 form to the Board with proper payment. If the pharmacy is unable to secure a Kansas-licensed PIC within 30 days, a waiver can be requested by following the instructions on Part C of the BA-50 form. Waivers will not be granted for the initial PIC change completed in conjunction with the 2018 renewal.

Pharmacist Renewals

Pharmacist licenses expiring June 30, 2018, are now eligible for renewal. To renew, visit the [eLicense portal](#) on the Board's website to log in using 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 date/time-stamped on or before 11:59 PM CDT on June 30, 2018. All other renewals will be considered late and will require payment of the late fee, and pharmacists are not authorized to practice until the renewal (and late fee) are submitted to the Board office.

Pharmacists are required to have completed 30 hours of continuing pharmacy education (CPE) between July 1, 2016, and the date of their renewal (no later than June 30, 2018). There is no grace period for completion of CPE.

To verify your renewal has been received, visit the [License Verification](#) page and check for the updated expiration date. You should also receive a confirmation email when renewing online.

If you have any questions regarding the renewal process, visit the Board's website and review the renewal instructions for your license/registration type and the Board's [frequently asked questions](#). If after reviewing this information, you are still unable to resolve your issue, please email the Board at pharmacy@ks.gov and a staff member will respond as soon as possible.

Ways to Reduce CE Audit Risk

As part of the renewal, pharmacists and technicians must attest to completion of all CE hours required by law to renew their license or registration.

Like all state boards of pharmacy in the United States, the Kansas Board requires all pharmacists and technicians to participate in CE activities as a prerequisite for active license renewal. An important tool available for tracking CE is CPE Monitor[®], a national collaborative service from NABP, the Accreditation Council for Pharmacy Education (ACPE), and ACPE-accredited providers. This integration creates a single repository system for storing ACPE-accredited CE. Through NABP e-Profile Connect, CPE Monitor can be used by pharmacists to track credits and by state boards to audit licensees for CE compliance.

Kansas has been using CPE Monitor for auditing purposes for several years. In Kansas, if the Board can authenticate that all required CE units have been completed by the licensee or registrant electronically through CPE Monitor, no CE audit letter is mailed to that individual. All other licensees and registrants are mailed a hard copy audit letter typically two to four months following the renewal. Those licensees and registrants must provide the Board with proof of CE following the stringent requirements of K.A.R. 68-1-1b (pharmacists) or K.A.R. 68-5-18, which can be found on the Board's website at <http://pharmacy.ks.gov/licensing-registration/ce>.

Even though audit risk may be lowered by using CPE Monitor, pharmacists and technicians are still accountable to ensure CE credit is reported accurately. Pharmacists and technicians should be aware of the following when using CPE Monitor:

- ◆ For non-Kansas residents, it is important to select Kansas as a state of licensure/registration when setting up or editing their NABP e-Profile and CPE Monitor. Otherwise, the Kansas Board will not be able to access their record.
- ◆ Make sure CE has been completed in the correct time frame. For the upcoming Kansas pharmacist renewal, CE will need to have an activity date between July 1, 2016, and June 30, 2018. Pharmacists licensed in multiple states will likely have different time periods and varied CE requirements for each state.
- ◆ Many providers require completion of an evaluation or survey within a certain number of days of the CE activity in order to receive credit. If the evaluation is not completed within the renewal time frame, the activity will not show up in CPE Monitor.
- ◆ Providers have a maximum of 60 days after their CE activity to process and upload participant credit into CPE Monitor. That means CE completed in June may not be reported until August.

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- ◆ After completion, ensure that completed CE activity displays in the e-Profile properly. Common mistakes made when registering for a CE activity that can cause it to not transfer properly are an incorrect name, date of birth, or NABP e-Profile ID number.
- ◆ The Board currently has no requirement that pharmacists and technicians use CPE Monitor. However, if an individual wants ACPE-accredited providers to automatically submit CE credit to NABP, he or she must register for CPE Monitor.

Pharmacists who have not completed required CE hours by June 30 may renew on inactive status until the CE is completed. However, a pharmacist cannot engage in the practice of pharmacy while in inactive status. Once the CE is completed, the pharmacist may then provide proof to the Board and request active status. This option is **not** available for technicians.

K-TRACS News

Please visit <http://ktracs.ks.gov>, the new online home of K-TRACS, the Kansas prescription drug monitoring program. Staff has also created a new [K-TRACS poster](#) that can be downloaded and used in the pharmacy for customer notification or other promotional material.

The Board is still accepting requests for [INTEGRx8](#), the statewide integration of K-TRACS data into pharmacy management systems. Integration increases the availability, ease of access, and use of a patient's controlled substance prescription history for making critical and informed dispensing decisions in your clinical workflow, saving approximately 4.22 minutes per patient on average.

The Board recently [amended K.A.R. 68-21-7](#) to include any product, compound, mixture, or preparation containing gabapentin as a drug of concern in Kansas. This regulation will take effect and require reporting to K-TRACS on July 25, 2018.

In conjunction with the Kansas Department of Health and Environment and the Centers for Disease Control and Prevention Data-Driven Prevention Initiative, a new public dashboard was created using K-TRACS and other data to shine a light on prescription opioids and other epidemiological data in Kansas. Visit www.preventoverdoseks.com for more information.

What Does Compliance Look Like: Training of Technicians

The PIC is required to ensure the pharmacy has a current technician training course designed around how the pharmacy functions. In Kansas, there are seven minimum training requirements that must be met:

1. Knowledge and understanding of the different pharmacy practice settings;
2. Knowledge and understanding of the duties and responsibilities of a pharmacy technician in relationship to

other pharmacy personnel and knowledge of standards, ethics, laws, and regulations governing the practice of pharmacy;

3. Knowledge of and the ability to identify and employ pharmaceutical and medical terms, abbreviations, and symbols commonly used in prescribing and dispensing drugs and in record keeping;
4. Knowledge of and the ability to carry out calculations required for common dosage determinations;
5. Knowledge and understanding of the identification of drugs, drug dosages, routes of administration, dosage forms, storage requirements, and manufacturer recalls;
6. Knowledge of and the ability to perform the manipulative and record-keeping functions involved in and related to dispensing prescriptions or other drug distribution systems; and
7. Knowledge of and the ability to perform procedures and techniques, including aseptic techniques, related to the compounding, packaging, and labeling of drugs.

The PIC shall permit a pharmacy technician to continue to perform technician functions if he or she has successfully completed the training course within 180 days after hire. The training documentation for the technician shall reflect competency in the seven training requirements and the date of completion. The PIC shall conduct an annual review of the pharmacy technician training course with documentation of when the review is complete.

For compliance with K.A.R. 68-5-15, documentation records shall be maintained at the pharmacy in a manner available for inspection by a Board inspector.

Upcoming Events

June 13-14, 2018, 8:30 AM

Board of Pharmacy Quarterly Meeting
University of Kansas Hospital, Heart Center, Room 6802
4000 Cambridge St, Kansas City, KS

July 27, 2018, 9 AM

Prescription Monitoring Program Advisory Committee Meeting
800 SW Jackson, Lower Level, Topeka, KS

September 13, 2018, 8:30 AM

Board of Pharmacy Quarterly Meeting
800 SW Jackson, Lower Level, Topeka

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