



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, 2019. Use the [eLicense portal](#) to renew each permit through an automated process, pay using the secure portal, and **immediately print the 2019 permit**. If additional copies are needed, log back in and print or download a copy. Nonresident pharmacies are required to submit an inspection report for the current physical location of the pharmacy conducted after January 1, 2018, by the resident state's board of pharmacy or by the National Association of Boards of Pharmacy® through its Verified Pharmacy Program®.
- ◆ A new [eLicense](#) feature allows pharmacists to use the eLicense portal to provide the Kansas State Board of Pharmacy with notification of a pharmacist's resignation as the pharmacist-in-charge (PIC) at a pharmacy.
- ◆ **Reminder:** It is each licensee's responsibility to personally notify the Board via mail, fax, or email of a change in address or employment. Failure to do so may result in disciplinary action and will result in missed correspondence from the Board.
- ◆ The Board recently adopted fee increases for pharmacist and facility applications and renewals. Copies of newly adopted regulations and draft regulations for public comment are available on the Board website at <http://pharmacy.ks.gov/statutes-regs/proposed-changes>.
- ◆ House Bill 2119 will become effective on July 1, 2019. The new law authorizes pharmacists to administer injectable medications pursuant to a prescription order, unless the prescription includes the wording, "not to be administered by a pharmacist." The law also mandates (with exceptions) electronic prescribing of controlled substances (CS) that contain an opiate, beginning on July 1, 2021.
- ◆ Follow the Board on Twitter (@KSBOP) or on Facebook (www.facebook.com/KansasStateBoardOfPharmacy) for news, updates, and more!

Pharmacist Renewals

Pharmacist licenses that expire on June 30, 2019, are now eligible for renewal. To renew, go to the [eLicense portal](#) on the Board website, log in using your username and password, review and update your 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 and time stamped on or before 11:59 PM CDT on June 30, 2019. All other renewals will be considered late and will require payment of the late fee. Pharmacists renewing late 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 education (CE) between July 1, 2017, and the date of renewal (no later than June 30, 2019). There is no grace period for completing CE. For ways to reduce your CE audit risk, see the Board's [June 2018 Newsletter](#).

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

Changes for Pharmacy Technician Registrations

The Board now requires all technicians registered after July 1, 2017, to pass a national certification examination before the first renewal. To differentiate technicians who need to pass the examination from those who do not, new pharmacy technician registrations will now have a prefix of 24 until the technician provides proof of passing a national certification examination. This change began with technician registrations issued on or after January 1, 2019. Once technicians have passed either the Pharmacy Technician Certification Board examination or the Exam for the Certification of Pharmacy Technicians, they should submit proof to the Board within 30 days or before the first renewal, whichever

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National Pharmacy Compliance News

June 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 Launches Pilot Program to Improve Security of Drug Supply Chain With an Innovative Approach

Food and Drug Administration (FDA) has launched a pilot program allowing participants representing the various parts of the drug supply chain to pilot innovative and emerging approaches for enhanced tracing and verification of prescription drugs in the United States' supply chain. The program is in line with FDA's ongoing efforts to prevent suspect and illegitimate products from entering the supply chain, according to an [FDA press release](#). Eligible manufacturers, repackagers, and other stakeholders can apply to participate in the program, which will inform the development of the enhanced electronic, interoperable track-and-trace system for industry set to go into effect in 2023 in accordance with the Drug Supply Chain Security Act (DSCSA), enacted by Congress on November 27, 2013.

The pilot technologies of this program may become part of FDA's enhanced expectations for reliable track-and-trace systems, which will be designed to reduce diversion of drugs distributed domestically and to keep counterfeit drugs from entering the supply chain. The DSCSA pilot project program is intended to help identify and evaluate the most efficient processes to comply with and apply drug supply chain security requirements and will aid in identifying attributes the system will need for enhanced product tracing and verification, as well as electronic means to share the information. FDA recently issued draft guidance on the use of product identifiers with a unique serial number to improve verification down to the package level. FDA has also provided draft guidance for verification systems to quarantine and investigate suspect and illegitimate drugs.

Additional information on the FDA pilot program is available in a February 8, 2019 announcement in the [Federal Register](#).

FDA Announces New Efforts to Increase Oversight and Strengthen Regulation of Dietary Supplements

Noting that three in four Americans now take at least one dietary supplement on a regular basis, and that the dietary supplement industry has expanded to include as many as 80,000 different products for consumers, FDA Commissioner Scott Gottlieb, MD, has announced new plans to increase the agency's oversight of dietary supplements.

These initiatives include communicating to the public as soon as possible when there is a concern about a dietary supplement on the market, ensuring that the regulatory framework is flexible enough to adequately evaluate product safety, and continuing to work closely with industry partners. FDA is also developing new enforcement strategies to respond to entities that violate standards established under the Dietary Supplement Health and Education Act of 1994.

On February 11, 2019, FDA sent 12 warning letters and five online advisory letters to foreign and domestic companies that are illegally selling more than 58 products. The products are illegally marketed as unapproved new drugs that make unproven claims about preventing, treating, or curing Alzheimer's disease, as well as a number of other serious diseases and health conditions, such as diabetes and cancer. In his statement, Gottlieb noted that most stakeholders in the industry act responsibly, but he expressed concern over the ability of bad actors to exploit the system by providing potentially dangerous products and making unproven or misleading claims about the health benefits supplements may offer.

FDA is planning a public meeting on this topic during the second quarter of 2019. For more information, view the FDA statement at <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm631065.htm>.

Trump Administration Releases National Drug Control Strategy to Reduce Drug Trafficking and Abuse

As the opioid crisis continues to claim the lives of tens of thousands of Americans each year, the Office of National Drug Control Policy has released its *National Drug Control Strategy*. The *Strategy* breaks down the administration's priorities in addressing the crisis, with an emphasis on three areas: prevention, treatment and recovery, and reducing availability.

- ◆ **Prevention** efforts are focused on educating both consumers and caregivers about the dangers of opioid misuse and include a new national media campaign, continued efforts to expand prescription monitoring programs (PMPs), and improving the ability of state, local, and tribal communities to identify and prevent substance abuse.
- ◆ **Treatment and recovery recommendations** in the *Strategy* include improving access to naloxone, improving evidence-based addiction treatment, and eliminating barriers for accessing treatment.

- ◆ **Reducing availability** strategies are focused on disrupting illegal supply chains, defeating drug traffickers, increased cooperation with international partners, and combating illegal internet drug sales.

The document notes that the “most important criterion of success” is saving lives and calls for the federal government to work closely with state and local governments, as well as other stakeholders. Additional information, including the full strategy document, is available on the White House website at <https://www.whitehouse.gov/opioids>.

National Association of Boards of Pharmacy® (NABP®) and its member boards of pharmacy remain committed to advancing best practices for PMPs in the interest of public health. NABP’s PMP data sharing system, NABP PMP InterConnect®, facilitates the secure transfer of PMP data across state lines and provides an effective means of combating drug diversion and drug abuse nationwide. In addition, NABP and its member boards continue efforts to educate consumers about prescription drug safety. The NABP AWARD® Prescription Drug Safety Program’s Drug Disposal Locator Tool has more than 6,000 disposal locations and continues to add new locations to provide consumers with a safe way to dispose of medication and help prevent misuse and abuse of prescription medications. For more information about PMP InterConnect and the AWARD program, visit the Initiatives section of the NABP website at www.nabp.pharmacy.

New Study Predicts Opioid Epidemic Will Worsen Over the Next Decade

More than 700,000 people will die from opioid overdoses between 2016 and 2025, and annual overdose deaths will reach nearly 82,000 by 2025, estimates a new study published to *JAMA Network Open*. The estimate is based on an analysis of data from the National Survey on Drug Use and Health and the Centers for Disease Control and Prevention from 2002 to 2015.

Researchers also projected that intervention efforts focused on lowering the incidence of prescription opioid misuse would help to reduce the number of deaths 3.8% to 5.3%, a figure the researchers described as “modest,” due to the changing nature of the opioid crisis. The study notes that more people are directly initiating opioid use with illicit opioids rather than prescription drugs, and illicit opioids have become more lethal with the availability of illegally manufactured fentanyl.

The researchers encourage policymakers to take “a stronger and multipronged approach” to reduce the impact of the ongoing opioid overdose epidemic. The full article is available at <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2723405>.

FDA Warns of Potential Blood Pressure Medication Shortages Due to Recalls

FDA is warning health care providers and consumers of a shortage of angiotensin II receptor blockers, commonly used to treat high blood pressure. A growing list of medications containing valsartan, losartan, and irbesartan have been recalled from the market for containing an impurity that may present a cancer risk to patients. The issue was first detected in the summer of 2018, according to a statement posted to the FDA website. Since then, FDA has placed a Chinese manufacturer of the active ingredient on import alert to stop their imports, and FDA is working with other manufacturers to recall affected medications.

In the statement, FDA notes that the risk to individual patients remains very small, but that there is still reason to be concerned about the potential health risks. Medications with these impurities are believed to have been in the market for about four years.

“Now that these risks are identified, we’re applying what we’ve learned to the evaluation of similar manufacturing processes where we now know these risks could arise,” the statement notes. The FDA press release is available at <https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm629796.htm>.

FDA Releases Two Draft Guidances Related to REMS Programs

FDA has released two new draft guidances to ensure risk mitigation programs put in place for certain drugs and biologics, as required for approval, are working. The agency’s primary risk management tool is FDA-approved product labeling. However, in limited cases, FDA may require a Risk Evaluation and Mitigation Strategy (REMS) to help ensure a drug’s benefits outweigh its risks.

The following guidances relate to the assessment of REMS programs:

- ◆ **REMS Assessment: Planning and Reporting Guidance for Industry** describes how to develop a REMS Assessment Plan.
- ◆ **Survey Methodologies to Assess REMS Goals That Relate to Knowledge Guidance for Industry** provides recommendations on conducting REMS assessment surveys to evaluate patient or health care provider knowledge of REMS-related information.

FDA states that the goal in providing this guidance for REMS is to ensure constant improvement of their safety programs and establish the most efficient and effective programs moving forward, to optimize patient care and keep consumers safe and healthy. More information on REMS is available on the FDA website at <https://www.fda.gov/drugs/drugsafety/remis>.

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is earlier. The registration number will then change to a prefix of 14 with the same digits following it.

The first batch of technicians with the new certification examination requirement will renew their licenses this fall. Kansas Administrative Regulations (K.A.R.) 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 [Form LA-75: Technician Certification Extension Request](#), which should be used to make such a request. The technician will need to provide an approved reason for the request. The options include a previous examination failure, a late or delayed start to training or preparation, a change in employment, a major medical event, or a natural disaster. It is the technician's responsibility to present documentation that proves the extension should be granted. 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 the Board approves the request for an extension, the technician will still need to renew his or her registration before the expiration date. The technician's registration status will be "Active-Pending Renewal," and the expiration date will be updated to April 30, 2020. The technician will receive an updated pocket card with the new expiration date and a stamp that indicates the technician is on a waiver. Once the technician passes a national certification examination and provides proof to the Board, staff will approve the renewal and issue a registration with an expiration date of October 31, 2021. If the technician does not pass the national certification examination by April 30, 2020, the renewal will be denied.

If the Board denies the request for an extension, the technician will need to pass a national certification exam before renewing the registration. 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.

What Does Compliance Look Like?

- ◆ **Technician List:** Every pharmacy must maintain a list of currently employed pharmacy technicians per Kansas Statutes Annotated (K.S.A.) 65-1663(i). While on duty, each technician must wear a name badge identifying him or her as a technician.
- ◆ **Sterile and Nonsterile Compounded Products:** Please be aware of the documentation required when compounding. Please refer to K.A.R. 68-13-2 through K.A.R. 68-13-4.
- ◆ **Inspector Access to Required Records:** K.S.A. 65-1629, 65-1642, 65-1643, 65-1655, 65-1695, and 65-4131, and K.A.R. 68-5-15 and 68-7-20 are just a few of the

statutes and regulations that allow Board inspectors to access and collect records as needed for inspections and investigations. In some instances, when records must be printed, the inspectors will give time to produce the records based on the type of record. The time ranges from 48 hours for records maintained at a central record location to 72 hours for information maintained in an automated system. Please work with the inspectors to make sure the pharmacy can provide the requested documents. An inability to provide the records could result in disciplinary action for the pharmacy and/or PIC.

- ◆ **Documentation:** If a statute or regulation requires documentation, please document. As the old saying goes, "If it's **not** documented, it's **not** done."
- ◆ **Five Years:** This is the length of time required for a pharmacy to maintain all records. If you keep any records electronically, be sure you can access them for up to the full five years. In the past, a pharmacy thought the wholesaler kept the Controlled Substance Ordering System records, only to find out that the wholesaler just kept the previous two years. Another pharmacy changed wholesalers and lost all past records. Whether the records are invoices, patient profiles, or prescriptions, be sure your pharmacy can access all required records for the full five-year record retention period. Plus, some insurances and Medicare/Medicaid may require a longer retention period.
- ◆ **Expediting the Inspection of Your Pharmacy/Facility:** Each PIC should view the sample inspection form online and make sure that at least these items are easily located when the inspector arrives. Examples include the annual CS inventory, incident reports, continuous quality improvement documentation, the technician list, and CPR cards for immunizers posted at a level that is easily viewed. View the inspection report sample at <https://pharmacy.ks.gov/licensing-registration/business-facility>.

Compounding With Cannabidiol

This article is reprinted from the International Journal of Pharmaceutical Compounding, Vol. 23 No. 2, with permission from the author, Loyd V. Allen, Jr, PhD, RPh, editor in chief of the International Journal of Pharmaceutical Compounding and Remington: The Science and Practice of Pharmacy, 22nd Edition.

I often receive the question, "Since a CBD [cannabidiol] commercial product has been FDA [U.S. Food and Drug Administration] approved, can I compound with any CBD oil or product?"

At this time, there is only one CBD product that has received FDA approval—Epidiolex—that can be

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used in compounding according to Section 503A of the Federal Food, Drug, and Cosmetic Act (see below).

The FDA has approved a purified form of the drug CBD (Epidiolex). CBD is one of more than 80 active chemicals in marijuana. Epidiolex was approved to treat seizures associated with two rare, severe forms of epilepsy (Lennox-Gastaut syndrome or Dravet syndrome) in patients two years of age and older. Epidiolex (cannabidiol oral solution) contains 100 mg/mL for oral administration.

Cannabidiol is a cannabinoid that naturally occurs in the *Cannabis sativa L.* plant. CBD is a white to pale-yellow crystalline solid that is insoluble in water and is soluble in organic solvents. Epidiolex is a strawberry-flavored clear, colorless to yellow solution supplied in a 105-mL amber glass bottle with a child-resistant closure containing 100 mL of oral solution, each mL containing 100 mg of CBD.

Epidiolex is packaged in a carton with two 5-mL calibrated oral dosing syringes and a bottle adapter. The pharmacy is to provide 1-mL calibrated oral dosing syringes when doses less than 1 mL are required. Epidiolex should be stored in an upright position at controlled room temperature and should not be frozen. It should be used within 12 weeks of first opening the bottle, then any remaining solution should be discarded. Epidiolex contains, in addition to CBD, dehydrated alcohol, sesame seed oil, strawberry flavor, and sucralose.

A summary of Section 503A of the Federal Food, Drug and Cosmetic Act describes compounding as being allowed using drug substances that:

1. comply with standards of an applicable *USP* [*United States Pharmacopeia*] or *NF* [*National Formulary*] monograph, if a monograph exists, and the USP chapter on pharmacy compounding;
2. if such a monograph does not exist, are drug substances that are components of FDA-approved drugs; or
3. appear on a list developed by the FDA that:
 - a. are manufactured by an establishment that is registered and
 - b. are accompanied by valid certificates of analysis for each bulk drug substance and
4. does not appear on a list of drug products that have been withdrawn or removed from the market because such drug or components of such

drug products have been found to be unsafe or not effective, and

5. does not compound regularly or in inordinate amounts any drug products that are essentially copies of a commercially available drug product.

Below are responses to the five requirements listed above.

1. There is no *USP* or *NF* monograph for cannabidiol.
2. Yes, there is an FDA-approved product, Epidiolex.
3. It does not appear on the bulks list.
4. It has not been withdrawn or removed due to safety or efficacy.
5. The Epidiolex product cannot be compounded regularly or in inordinate amounts.

In response to queries of “Why can’t I compound with CBD products sold in the CBD outlets in shopping centers, etc.?” the following is provided. None of these consumer-type products have received FDA approval, and they are not Epidiolex generics. One might consider that they are treated somewhat similarly to dietary supplements with incomplete specifications regarding content, purity, etc., and the lack of enforceable quality control.

The *Warnings and Precautions* section of the official Epidiolex labeling includes hepatocellular injury, somnolence and sedation, suicidal behavior and ideation, hypersensitivity reactions, and withdrawal symptoms. Somnolence occurred in 23% of patients receiving 10 mg/kg/day and 25% of patients receiving 20 mg/kg/day compared with 8% for placebo patients.

In summary, the commercial product Epidiolex is the only source of CBD that can be used in compounding. If used in compounding, one should be completely familiar with the package insert for the Epidiolex product and the patient counseling involved.

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