



# Kansas State Board of Pharmacy

*Published to promote compliance of pharmacy and drug law*

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## Announcements

- ◆ Looking for an inspection report? Emails from the Kansas State Board of Pharmacy containing a completed facility inspection report will be sent from [elicense@netpointhosting.com](mailto:elicense@netpointhosting.com). Make sure to set your spam or junk mail settings to allow emails from this address. The email subject line will be “Kansas Board of Pharmacy Inspection Report,” and it will be sent to the pharmacy email with the personal email address of the pharmacist-in-charge (PIC) copied.
- ◆ For updates on formal guidance documents adopted by the Board, visit the Board website at <https://pharmacy.ks.gov/statutes-regs/reports-guidance-docs>.
- ◆ Follow the Board on Twitter (@KSBOP) or on Facebook ([www.facebook.com/kansasstateboardofpharmacy](http://www.facebook.com/kansasstateboardofpharmacy)) for news, updates, and more!

## New Board Regulations and Guidance

On November 27, 2018, the Board adopted several new and amended regulations, which became effective on January 4, 2019. Changes to Kansas Administrative Regulations (K.A.R.) 68-7-10, 68-9-2, and 68-9-3 align definitions with statutory changes and allow nurses and other healing arts professionals to access automated drug delivery systems in long-term care facilities, pharmacies, and other facilities to administer medications to patients consistent with their respective practice acts. This should eliminate the perceived need for nurses to also be registered as pharmacy technicians.

The Board also adopted new regulations, effective January 4, 2019, that establish additional licensee and registrant notification requirements. K.A.R. 68-2-23 requires each owner of a Kansas-registered pharmacy to notify the Board within 30 days of any denial, limitation, suspension, revocation, voluntary surrender, or other disciplinary action taken by the state of Kansas or another jurisdiction against the pharmacy, the pharmacy owner, or any application,

license, registration, or permit held by the pharmacy owner. K.A.R. 68-20-15b requires either the PIC or the pharmacy owner to notify the Board in writing within one day of any suspected diversion, theft, or loss of any controlled substance (CS) and provide a copy of Drug Enforcement Administration (DEA) Form 106 upon completion. K.A.R. 68-7-25 requires each pharmacist, pharmacy technician, and pharmacy student to notify the Board within 30 days of any criminal arrest, charge, or conviction rationally related to drugs or the practice of pharmacy, or any denial, limitation, suspension, revocation, voluntary surrender, or other disciplinary action taken by the state of Kansas or another jurisdiction against any professional or occupational application, license, registration, or permit held by the individual.

For updates regarding proposed Board regulations, please visit <https://pharmacy.ks.gov/statutes-regs/proposed-changes>.

## Intern Immunization Authority

The Board recently adopted guidance to provide clarification regarding whether pharmacy students or interns who administer vaccines are required to have a signed vaccination protocol with licensed physicians. Interns are authorized to administer vaccines under Kansas Statutes Annotated 65-1635a only under the direct supervision and control of a pharmacist. Each intern is required to complete a CPR course and an immunization training course approved by Accreditation Council for Pharmacy Education (ACPE) or the Board and have a current CPR certificate. The supervising pharmacist is also required to complete a CPR course and an immunization training course approved by ACPE or the Board and have a current CPR certificate. The supervising pharmacist is responsible for ensuring that he or she has a current, signed protocol with a licensed physician to administer vaccinations and that all requirements are met for administering, recording, and reporting all vaccinations administered by the intern

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# National Pharmacy Compliance News

March 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.

## **Final Guidance Documents Address FDA Policies Related to DSCSA**

To help ensure that prescription drug products are identified and traced properly as they move through the supply chain in compliance with federal law, Food and Drug Administration (FDA) issued two final guidance documents related to the Drug Supply Chain Security Act (DSCSA). Released on September 19, 2018, the following final guidance documents will help ensure there are no disruptions in the supply chain as manufacturers and repackagers include a product identifier on the package or case.

- ◆ *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy* addresses industry-wide readiness for implementation of the new requirements aimed at enhancing the security of the drug supply chain. As the agency continues to work with stakeholders to ensure proper implementation of the law, this guidance document specifies FDA's one-year delay in enforcing the manufacturers' requirement to include a product identifier on the package or case of products to November 27, 2018.
- ◆ *Grandfathering Policy for Packages and Homogenous Cases of Product Without a Product Identifier* outlines the circumstances in which packages and cases of product that were in the supply chain before the November 2018 product identifier requirement are considered grandfathered. The grandfathering policy describes the circumstances under which products already in the supply chain can remain in distribution without being relabeled with a product identifier.

The final guidance documents can be found at [www.fda.gov/newsevents/newsroom/fdainbrief/ucm621095.htm](http://www.fda.gov/newsevents/newsroom/fdainbrief/ucm621095.htm).

## **First FDA-Approved Drug Containing Extract From Cannabis Plant to Be Placed in Schedule V**

On September 27, 2018, the United States Department of Justice and Drug Enforcement Administration (DEA) announced that Epidiolex® – which contains cannabidiol, a chemical constituent of the cannabis plant, and is the first FDA-approved drug to contain a purified extract from the plant – is being placed in Schedule V of the Con-

trolled Substances Act. FDA approved Epidiolex for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older on June 25, 2018. Additional information is available in the announcement at [www.dea.gov/press-releases/2018/09/27/fda-approved-drug-epidiolex-placed-schedule-v-controlled-substance-act](http://www.dea.gov/press-releases/2018/09/27/fda-approved-drug-epidiolex-placed-schedule-v-controlled-substance-act).

## **ASHP Guidelines Provide Recommendations for Preventing Patient Harm From Medication Errors**

New guidelines from the American Society of Health-System Pharmacists (ASHP) describe opportunities for pharmacists on interprofessional teams to prevent errors across the continuum of care in hospitals and health systems. The “ASHP Guidelines on Preventing Medication Errors in Hospitals” are intended to apply to the acute care setting because of the special collaborative processes established in this setting. However, these guidelines may be applicable to practice settings outside of the acute care setting, especially in health systems.

Further, the ASHP press release notes that the guidelines address numerous areas in the medication-use process where errors may occur, including: patient admission; selection and procurement; storage; ordering, transcribing, and reviewing; preparation; dispensing; administration; monitoring; evaluation; and patient discharge. Published in the October 1, 2018 issue of the *American Journal of Health-System Pharmacy*, the guidelines are available at [www.ajhp.org/content/75/19/1493](http://www.ajhp.org/content/75/19/1493). ASHP's October 2, 2018 press release can be found in the News section at [www.ashp.org](http://www.ashp.org).

## **FDA's Final Guidance Documents Address Compounding and Repackaging of Radiopharmaceuticals**

On September 26, 2018, FDA published the final guidance titled *Compounding and Repackaging of Radiopharmaceuticals by Outsourcing Facilities*. In this final guidance for industry, FDA sets forth its policy regarding compounding and repackaging of radiopharmaceuticals for human use by entities that are registered with FDA as outsourcing facilities. This guidance describes how FDA generally intends to apply section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to radiopharmaceuticals compounded by outsourcing facilities.

In addition, this guidance describes the conditions under which FDA generally does not intend to take action for violations of certain provisions of the FD&C Act when an outsourcing facility repackages radiopharmaceuticals, according to the *Federal Register* notice at [www.gpo.gov/fdsys/pkg/FR-2018-09-26/pdf/2018-20901.pdf](http://www.gpo.gov/fdsys/pkg/FR-2018-09-26/pdf/2018-20901.pdf).

At the same time, FDA published the final guidance titled *Compounding and Repackaging of Radiopharmaceuticals by State-Licensed Nuclear Pharmacies, Federal Facilities, and Certain Other Entities*. This guidance sets forth FDA's policy regarding compounding and repackaging of radiopharmaceuticals for human use by state-licensed nuclear pharmacies, federal facilities, and other entities that hold a radioactive materials license for medical use issued by the Nuclear Regulatory Commission or by an Agreement State. Because such radiopharmaceuticals are not eligible for exemptions from provisions of the FD&C Act related to the production of drugs, FDA is issuing this guidance to describe the conditions under which it generally does not intend to take action for violations of certain provisions of the FD&C Act when these entities compound or repackaging radiopharmaceuticals. More details are available in the *Federal Register* notice at [www.gpo.gov/fdsys/pkg/FR-2018-09-26/pdf/2018-20902.pdf](http://www.gpo.gov/fdsys/pkg/FR-2018-09-26/pdf/2018-20902.pdf).

### **Pharmacy Toolkit Encourages Conversations With Patients About Prescription Opioids**

In collaboration with its pharmacy partners and several state pharmacy associations, Allied Against Opioid Abuse (AAOA) developed a Pharmacy Toolkit to help pharmacists engage and educate patients about the safe use, storage, and disposal of pain medicines. The AAOA Pharmacy Toolkit includes resources to help pharmacists raise awareness among patients about their rights, risks, and responsibilities associated with prescription opioids. These resources include: a pharmacy display, patient handout, patient engagement guide, tips for talking with patients and caregivers, prescriber engagement guide, safe storage and disposal training, and social graphics. To learn more about the Pharmacy Toolkit and to obtain these resources, visit AAOA's website at <https://againstopioidabuse.org>.

### **Biosimilars Added to FIP's Policy on Pharmacists' Right to Substitute a Medication**

To account for the emergence of biological medicines and their biosimilars onto the medical landscape, the International Pharmaceutical Federation (FIP) has added

biosimilars to its policy on pharmacists' right to substitute one medicine for another. The revised Statement of Policy titled "Pharmacist's authority in pharmaceutical product selection: therapeutic interchange and substitution" includes the core principles of the original statement and the following:

- ◆ generic substitution is recommended as part of the pharmacist's dispensing role;
- ◆ pharmacists should be provided with bioavailability data by regulatory authorities and manufacturers; and
- ◆ a medicine should only be substituted with a product containing a different active ingredient in agreement with the prescriber.

According to FIP's October 2, 2018 press release, the use of generic names is still encouraged, but the revised statement gives focus to the use of international nonproprietary names. The full Statement of Policy and press release are available at [www.fip.org](http://www.fip.org) in their respective sections.

### **FDA Offers CE Course on Reducing Hypoglycemic Events in Patients With Type 2 Diabetes**

FDA is offering a free, one-hour continuing education (CE) course for health care providers (physicians, pharmacists, nurses, and others) about the reduction of hypoglycemic events in patients with Type 2 diabetes. The course, *Leveraging Health Literacy and Patient Preferences to Reduce Hypoglycemic Events in Patients with Type 2 Diabetes*, will describe the prevalence of hypoglycemic events and identify risk factors leading to an event. Available for credit through October 31, 2020, this course will introduce methods of assessing health literacy and numeracy of patients and caregivers; review effective ways to incorporate patient preferences into care plans; and list action steps to reduce the likelihood of a hypoglycemic event for high-risk patients. To participate in this CE course, visit <http://fdapasediabetes.e-paga.com>.

The FDA Center for Drug Evaluation and Research (CDER) is accredited by the Accreditation Council for Pharmacy Education (ACPE) as a provider of continuing pharmacy education (CPE). This program meets the criteria for one contact hour (0.1 CEU) of CPE credit. The ACPE Universal Activity Number for this knowledge-based activity is 0453-9999-17-449-H01-P. Further, FDA's CDERLearn in the CDER offers a variety of learning opportunities, which can be found at [www.fda.gov/Training/ForHealthProfessionals/ucm545645.htm](http://www.fda.gov/Training/ForHealthProfessionals/ucm545645.htm).

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under the pharmacist's supervision in accordance with the Kansas Pharmacy Act. Interns are not required to have a signed protocol or be party to a protocol between their supervising pharmacist and a licensed physician.

### **Welcome New Staff**

**Jennifer Donnelly** is the new Kansas Prescription Drug Monitoring Program (K-TRACS) epidemiologist. Ms Donnelly's primary role will be to analyze the prescription drug data that is collected in K-TRACS to determine the impact of prescription drug misuse in Kansas. She has a master's degree in public health with an emphasis in epidemiology from the Colorado School of Public Health and a bachelor's degree in community health from the University of Northern Colorado. Jennifer is originally from Denver, CO, and has also lived in Baltimore, MD, and Minneapolis, MN. She is happy to be with the Board.

**Lori Haskett** joined the Board as assistant director of licensing and K-TRACS in November 2018. In addition to her licensing supervision responsibilities, Ms Haskett is responsible for oversight and management of the K-TRACS program, which includes applying for new grant opportunities. She maintains and establishes partnerships with other state agencies on existing and future grant opportunities. Ms Haskett previously worked at the Kansas Department of Health and Environment as the director of injury and violence prevention programs for over 16 years. She is currently serving her second term as treasurer for the Safe States Alliance. Ms Haskett also serves as treasurer for the Kansas Public Health Association. Previously, she was on the National Child Passenger Safety Board and volunteered at the local level with United Way and the American Business Women's Association.

### **What Does Compliance Look Like?**

#### **Controlled Substance Inventories**

Kansas statutes and regulations state that each facility that keeps CS is required to perform a complete CS inventory every year and with every incoming and outgoing PIC. There are some common items being overlooked when completing these inventories.

- ◆ All CS (Schedule I through Schedule V) must be inventoried on the same date.
- ◆ All Schedule I drugs must be listed separately from all other controls in the inventory. All Schedule II drugs must be listed separately from all other controls in the inventory.

- ◆ All CS (Schedule I through Schedule V) must be counted. This includes over-the-counter pseudoephedrine and ephedrine products.
- ◆ The inventory needs to include all CS in alternate locations under the control of the pharmacy (intubation boxes, crash carts, surgery suites, ambulances, nursing home e-kits, etc).
- ◆ The inventory must be dated according to the date on which the actual count was taken.
- ◆ The inventory must indicate whether it was completed before opening or after closing for the day.
- ◆ A minimum of eight months and a maximum of 12 months shall have elapsed since the last Kansas annual CS inventory.
- ◆ The outgoing PIC inventory shall be performed by the outgoing PIC before leaving the position but as close as possible to the last day of employment. The incoming PIC inventory shall be performed by the incoming PIC within 72 hours of starting the position. These two inventories may be taken in conjunction as long as both PICs are present, and the date completed meets the requirements for both incoming and outgoing positions. The exceptions for outgoing PICs performing their own inventories are medical emergencies and terminations for causes that involve CS.
- ◆ To document that you are completing the required inventories, the inventory needs to be marked with its purpose: Kansas annual, DEA biennial, outgoing PIC change, incoming PIC change, etc. The inventory may have more than one purpose (eg, Kansas annual and DEA biennial).
- ◆ It is strongly recommended that the name(s) and signature(s) of the person(s) completing and verifying the inventory be included in case questions or problems arise.

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