March 2018

Kansas State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

800 SW Jackson St, Ste 1414 • Topeka, KS 66612 • *https://pharmacy.ks.gov*

Announcements

- Welcome! Megan Alford joined the Kansas State Board of Pharmacy in January as a full-time senior administrative assistant in the Licensing Division. Her main duties include business and facility registration. Megan graduated from the University of Kansas with a bachelor of arts degree in American studies and history. She is originally from Shawnee, KS, and moved to Topeka, KS, in 2016. Megan is excited to be a part of the staff and has learned so much about the Board.
- The Board is still accepting requests for integration of K-TRACS, the Kansas prescription drug monitoring program, into pharmacy management systems. Integration increases the availability, ease of access, and use of a patient's controlled substance (CS) prescription history for making critical and informed dispensing decisions in your clinical workflow, saving approximately 4.22 minutes per patient on average. For more information, visit *http://pharmacy.ks.gov/k-tracs-responsive/k-tracs-statewide-integration.*
- The following regulations are out for public comment: Kansas Administrative Regulations (K.A.R.) 68-13-2, 68-13-3, 68-13-4, 68-21-7, and 68-5-17. The Board will hold a public hearing at 1 PM on March 8, 2018, at 800 SW Jackson, Lower Level, Topeka. For more information, visit *http://pharmacy.ks.gov/statutes-regs/proposed-changes.*

New Nonresident Pharmacy Requirements

Pursuant to 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). While these changes are already in effect, the Board has granted a waiver through June 30, 2018, to afford currently registered nonresident pharmacies sufficient time to comply and minimize any economic impact to the pharmacy.

During the 2018 renewal period (May 15-June 30, 2018), in addition to completing the renewal application, each nonresident pharmacy will be required to do the following to remain registered in Kansas:

1. Provide an inspection report conducted at the current physical location of the pharmacy no more than 18 months prior to the date of renewal; and
2. Designate a Kansas-licensed pharmacist as the PIC.

In January, information was mailed to each nonresident pharmacy registered with the Board with detailed instructions related to these changes. A copy of the letter may be found at *http://pharmacy.ks.gov/licensing-registration/business-facility* along with several frequently asked questions. Please review this information and be prepared!

Emergency Preparedness for Pharmacies

Having a plan in place in case of emergency is a great idea for any pharmacy, but especially in Kansas, which gets its fair share of natural disasters. Having a plan **before** disaster strikes helps to ensure that the pharmacy and its staff can survive the event. While the following list contains many ideas and suggestions, it is not all-inclusive, and plans should be developed specific to the pharmacy and its needs.

Before an Emergency

1. Retain an easily accessible list of all employees and their contact information, including cell phone number, home phone number, email addresses, and emergency contact person.
2. Make a list of phone and fax numbers for local doctors' offices, hospitals, nursing homes, and other pharmacies in the event that they need to be contacted due to closure of the pharmacy.
3. Make a list of contact information for gas, electric, and water utilities, as well as the phone company, internet provider, and alarm company. Preplan potential alternatives with these service providers.
4. Keep the phone number and the account number for your drug wholesaler readily available.
5. Anticipate power outages. In some situations, a portable generator may be necessary. Coolers and ice or ice packs should be available to store refrigerated products.
6. Develop professional relationships with one or more contractors in the event that their services are needed to secure the pharmacy after a disaster.

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National Pharmacy Compliance News

March 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 Draft Guidance Addresses Delayed Enforcement of DSCSA Requirements for Product Identifiers

Food and Drug Administration (FDA) issued a draft guidance for industry that informs manufacturers and other supply chain stakeholders that although manufacturers are to begin including a product identifier on prescription drug packages and cases on November 27, 2017, FDA is delaying enforcement of those requirements until November 2018 to provide manufacturers additional time and avoid supply disruptions. The compliance policy outlined in the June 2017 draft guidance, *Product Identifier Requirements Under the Drug Supply Chain Security Act – Compliance Policy,* applies solely to products without a product identifier that are introduced into commerce by a manufacturer between November 27, 2017, and November 26, 2018. While manufacturers work to meet product identifier requirements, they must comply with other Drug Supply Chain Security Act (DSCSA) requirements. The draft guidance can be accessed from FDA's website at *www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/ucm565358.htm.*

Amount of Prescribed Opioids Remains High, Reports CDC

The amount of opioids prescribed remains approximately three times as high as in 1999, despite reductions in each year after 2010 through 2015. Centers for Disease Control and Prevention (CDC) researchers analyzed retail prescription data to assess opioid prescribing in the United States from 2006 to 2015 and county-level prescribing patterns in 2010 and 2015. According to a CDC report, results of the study showed higher amounts of opioids were prescribed in counties that had a greater percentage of non-Hispanic white residents, a higher prevalence of diabetes and arthritis, micropolitan status (ie, town/city; nonmetro), and higher unemployment and Medicaid enrollment rates. The researchers conclude that health care providers should carefully weigh the benefits and risks when prescribing opioids outside of end-of-life care, follow evidence-based guidelines (eg, CDC's *Guideline for Prescribing Opioids for Chronic Pain*), and consider non-opioid therapy for chronic pain treatment.

Additionally, the researchers conclude that state and local jurisdictions can use these findings along with prescription drug monitoring program (PDMP) data to identify prescribing patterns that place patients at risk for opioid use disorder and overdose and to target interventions with prescribers based on opioid prescribing guidelines. The July 7, 2017 *Morbidity and Mortality Weekly Report,* "Vital Signs: Changes in Opioid Prescribing in the United States, 2006–2015," can be accessed on the CDC website at *www.cdc.gov/mmwr/index.html* in the Weekly Report section.

AMA Opioid Task Force Encourages Co-Prescribing Naloxone to At-Risk Patients

The American Medical Association (AMA) Opioid Task Force encourages physicians to consider co-prescribing naloxone when it is clinically appropriate to do so. The AMA Opioid Task Force offers several questions for determining whether to co-prescribe naloxone to a patient or a patient's family member or close friend, which may be found in the August 2017 document, "AMA Opioid Task Force naloxone recommendations," available on the AMA opioid microsite at *https://www.end-opioid-epidemic.org.*

The Naloxone section of the AMA opioid microsite also offers physicians multiple resources on co-prescribing naloxone in their practice and community. To help end the opioid epidemic, the AMA Opioid Task Force made several recommendations for physicians, including registering and using state PDMPs, training and education on evidence-based treatment, and promoting safe storage and disposal of opioids and medications.

Opioid Addiction Medications Should Not Be Withheld From Patients Taking Benzodiazepines or CNS Depressants

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 in an FDA Drug Safety Communication announcement at *www.fda.gov/Drugs/DrugSafety/ucm575307.htm.*

New Study Shows Substantial Variation in the Availability of Pharmacies Across the Country

Despite the rising number of US pharmacies from 2007 to 2015, the availability of pharmacies varied significantly across local areas, indicates a new study. The study, *The availability of pharmacies in the United States: 2007–2015,* found that the number of community pharmacies increased 6.3% from 63,752 to 67,753 between 2007 and 2015. Although the number of pharmacies per capita remained at 2.11 per 10,000 individuals between 2007 and 2015, the researchers found substantial variation across counties. "Some counties have 13 pharmacies per capita, while others have none," said Dima Qato, lead study author and assistant professor of pharmacy systems, outcomes and policy, in a University of Illinois at Chicago (UIC) news release.

In 2015, counties in the highest quintile had nearly three-fold more pharmacies than those in the lowest quintile. Counties in the lowest quintile are located in the Pacific West, Southwest, and Great Lakes regions, while counties with the highest tend to be located in the Northeast, Southeast, Northern Appalachia, and Plains states. The researchers conclude that future programs and policies should address the availability of pharmacies and ensure that pharmacy characteristics, including accommodations such as multilingual staffing and home delivery, align with local population needs.

To view the study, visit *https://doi.org/10.1371/journal.pone.0183172.* The UIC news release is available at *https://today.uic.edu/access-to-pharmacies-limited-to-some-patients.*

Consent Decree Entered Against Outsourcing Facility Isomeric Pharmacy Solutions

Under a consent decree of permanent injunction entered in August 2017, Isomeric Pharmacy Solutions of Salt Lake City, UT, its owners, and chief operating officer are prohibited from manufacturing, processing, packing, holding, or distributing drugs until they comply with the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its regulations, in addition to other requirements. Isomeric manufactured and distributed purportedly sterile drug products, including injectable and ophthalmic drugs, that were adulterated because the drugs were made under insanitary conditions and in violation of current good manufacturing practice requirements under the FD&C Act, according to the complaint for permanent injunction. The complaint also alleges that Isomeric manufactured and distributed unapproved drugs and drugs that were misbranded because their labeling did not bear adequate directions for use. Isomeric initially registered as an outsourcing facility in July 2015 and reregistered in December 2015 and January 2017. Additional information is available in an FDA news release at *www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm570130.htm.*

FDA Issues Warning on Alcohol Pads or Benzalkonium Chloride Antiseptic Towelettes Made by Foshan

In September 2017, FDA alerted health care providers and patients to not use alcohol pads or benzalkonium chloride antiseptic towelettes made by Foshan Flying Medical Products Co, Ltd, located in China, due to lack of sterility assurance and other quality issues. These products are distributed by Total Resources International, of Walnut, CA, and Simple Diagnostics, Inc, of Williston Park, NY. The use of these alcohol pads and antiseptic towelettes could cause infections.

FDA placed all drug products made by Foshan on import alert on May 23, 2017, to stop these products from entering the US. However, FDA is concerned these products might still be in distribution in the US. FDA also sent Foshan a warning letter on August 1, 2017, for violations of current good manufacturing practice regulations. FDA initially contacted Foshan regarding a recall on May 25, 2017, and had several follow-up meetings with the company. Foshan has not taken action to remove its alcohol pads or antiseptic towelettes from the market. The safety alert posted to FDA's website may be found at *www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm574576.htm.*

Pharmacies and health care facilities that have alcohol pads and antiseptic towelettes labeled by Total Resources or Simple Diagnostics should immediately stop using them and discard the products. Adverse events or side effects related to the use of these products may be reported to FDA's MedWatch Safety Information and Adverse Event Reporting Program at *www.fda.gov/MedWatch/report.*

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7. Identify employees who are trained in basic first aid and CPR.
8. Keep an emergency kit with the following items:
   a. Battery-powered radio and National Oceanic and Atmospheric Administration weather radio with alert function
   b. Extra batteries
   c. Flashlight
   d. Nonperishable food
   e. First aid kit
   f. Whistle to signal for help
   g. Dust or filter masks
   h. Moist towelettes for sanitation
   i. Wrench or pliers to turn off utilities
   j. Garbage bags with plastic ties

During an Emergency

Tornado: Determine ahead of time a place to take shelter. Storm shelters and basements provide the best protection. If an underground shelter is not available, go to an interior room or closet on the lowest floor possible. Avoid windows, doors, and outside walls. Stay in the shelter until the danger has passed. If time allows, secure CS and other drugs.

Fire: Develop an escape plan and make sure all employees know the location of fire extinguishers before a fire emergency. Install smoke detectors and regularly test their operability. If a fire occurs, evacuate the pharmacy following the plan and work to help any customers who may be in the pharmacy.

After an Emergency

1. Make sure all employees and customers are accounted for. Administer first aid if necessary and call 911 for more severe injuries.
2. Determine if the pharmacy/building is safe to be in. Evacuate if it is not safe.
3. Notify the Board inspector as soon as practicable if the pharmacy has received significant damage or if there is drug loss.
4. Complete a CS inventory. If CS are lost in a disaster, a Drug Enforcement Administration Form 106 should be completed.
5. The National Council for Prescription Drug Programs has resources for pharmacies in declared emergencies. Visit the following website for more information: *https://www.ncpdp.org/NCPDP/media/pdf/NCPDPEmergencyPreparednessInformation_v1_4.pdf.*

The Board is dedicated to helping pharmacies through the process of a disaster.

Can a Pharmacist Administer Shingrix?

With the Food and Drug Administration's approval and the subsequent launch of Shingrix®, pharmacists have been asking if Kansas law allows pharmacists to administer this vaccine. The state vaccination protocol statutes do not delineate which vaccinations pharmacists are allowed to give. The answer to this question is going to be found in the vaccination protocol for each pharmacist.

Look closely at the protocol and see if the allowed vaccination descriptions contain any wording that would exclude Shingrix. For example, does the protocol specify Zostavax® instead of the zoster vaccine, or does it state subcutaneous zoster vaccine? If the wording would exclude Shingrix, then the vaccination protocol must be updated before administration. However, if the vaccination protocol simply identifies "zoster vaccine" or "shingles vaccine," then that includes Shingrix.

As always, any vaccine can only be administered based on a valid vaccination protocol. A prescription only allows a vaccine to be dispensed, not administered. And, if needed, do not forget to have the vaccination protocol updated to administer vaccines, other than influenza, to persons aged 12 and older per the changes made to Kansas Statutes Annotated 65-1635a(a) by the Kansas Legislature in 2017.

Upcoming Events

March 8, 2018, 8:30 AM
Board of Pharmacy Quarterly Meeting
800 SW Jackson, Lower Level, Topeka

April 27, 2018, 9 AM
Prescription Monitoring Program Advisory Committee Meeting
800 SW Jackson, Lower Level, Topeka

June 14, 2018, 8:30 AM
Board of Pharmacy Quarterly Meeting
800 SW Jackson, Lower Level, Topeka

The *Kansas State Board of Pharmacy News* is published by the Kansas State Board of Pharmacy and the National Association of Boards of Pharmacy Foundation® (NABPF®) to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of NABPF or the Board unless expressly so stated.

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