December 2018

Kansas State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Announcements

- In August 2018, the Kansas Hospital Association released a simplified risk management reporting form for use in reporting standard of care III and IV events to the various state regulatory agencies licensing individuals and facilities. The Kansas State Board of Pharmacy will accept this form, either electronically or hard copy, in lieu of the Board's C-100 complaint form or as formal notice to the Board. The form can be found at *www.kha-net.org/advocacy/regulatory/default.aspx* or on the Board website at *https://pharmacy.ks.gov/resources-consumer-info-2/complaint-process.*
- On behalf of the Board and other government agencies, **thank you** Kansas pharmacists! Recent legal cases have been successful in ensuring the protection of the public due in large part to the Kansas pharmacy community's integrity, vigilance, and dedication to doing what is right for patients.
- Follow us on Twitter (@KSBOP) or on Facebook *(www.facebook.com/kansasstateboardofpharmacy)* for news, updates, and more!

K-TRACS: Do Not Forget Drugs of Concern

Kansas Statutes Annotated (K.S.A.) 65-1682 defines a drug of concern as "any drug that demonstrates a potential for abuse and is designated as a drug of concern in rules and regulations promulgated by the board." Here are two key reminders regarding **prescriptions** designated as drugs of concern by the Board, which are required to be submitted to the Kansas Prescription Drug Monitoring Program (K-TRACS) clearinghouse:

1. Effective July 2018, gabapentin was added to the list and must be reported to K-TRACS.
2. Any product containing ephedrine or pseudoephedrine (PSE) that is dispensed to a patient **by prescription** must be reported to K-TRACS.

Failure to comply with K.S.A. 65-1682 and Kansas Administrative Regulations (K.A.R.) 68-21-7 may result in disciplinary action against a pharmacy registration and/or pharmacist-in-charge (PIC) license.

Pharmacy Technician Certification Examination

Before the October 2019 renewal period for pharmacy technicians, each pharmacy technician initially registered **on or after July 1, 2017,** whose registration expires on October 31, 2019, will be required to pass a national pharmacy technician certification examination (K.A.R. 68-5-17).

The Board has approved the Pharmacy Technician Certification Board and the National Healthcareer Association's Examination for the Certification of Pharmacy Technicians, also known as ExCPT. Please contact either organization for more information regarding its pharmacy technician certification examination.

If a pharmacy technician has already passed an approved exam, please email pharmacy@ks.gov, fax, or mail a copy of the certificate to the Board office along with the pharmacy technician's name and Kansas registration number.

Any technician who is unable to take or pass an approved exam may request a six-month extension at least 30 days before the pharmacy technician's registration expiration date. The reason for the request should be limited to the following: previous exam failures, a delay in training, a natural event/disaster, a change in employment, or medical necessity.

2019 Retail Dealer Renewals

The Board's retail dealer permits expire February 28, 2019. Permits may be renewed either online or by mail from mid-January 2019 through February 28, 2019. For renewal instructions, visit *www.pharmacy.ks.gov.*

- **Online:** Use the Board's secure online payment portal to renew each permit. If you do not have a username and password or have forgotten them, click

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National Pharmacy Compliance News

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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.

SAMHSA Publishes Guidance for Treating OUD

To help broaden health care professionals' understanding of medications that can be used to treat Americans with opioid use disorder (OUD), the Substance Abuse and Mental Health Services Administration (SAMHSA) offers guidance on clinical best practices in the February 2018 publication titled *Treatment Improvement Protocol 63, Medications for Opioid Use Disorder.* The publication reviews the use of the three Food and Drug Administration (FDA)-approved medications used to treat OUD – methadone, naltrexone, and buprenorphine – and other strategies and services needed to support recovery for people with OUD.

Additionally, in February 2018, SAMHSA released the publication *Clinical Guidance for Treating Pregnant and Parenting Women with Opioid Use Disorder and Their Infants,* which offers standard approaches for health care professionals. This publication provides evidence-based treatment options, including pharmacotherapy with methadone, buprenorphine, and buprenorphine/naloxone, for pregnant women with OUD. The clinical guidance also helps health care professionals and patients determine the most clinically appropriate action for a particular situation and informs individualized treatment decisions. Both publications can be found in the Publications section of SAMHSA's website at *www.samhsa.gov*.

FDA Issues Final Guidance Policy on Outsourcing Facilities

In May 2018, FDA issued a new policy designed to address any ambiguity around how to define the physical features and operations of outsourcing facilities. According to FDA Commissioner Scott Gottlieb, MD, the policy in the final guidance, *Facility Definition Under Section 503B of the Federal Food, Drug, and Cosmetic Act,* will help to:

- ensure that compounded drugs are made under appropriate quality standards;
- provide transparency to patients and health care providers about the standards under which the compounded drugs that they purchase are made; and
- respond to stakeholder feedback requesting guidance on the meaning of "facility" under section 503B.

In the guidance, FDA explains that a section 503A establishment compounding drugs pursuant to patient-specific prescriptions may be located near or in the same building as the outsourcing facility provided that they are completely separate. As explained in the guidance, the boundaries between the section 503A establishment and outsourcing facility should be clear and may include permanent physical barriers, such as walls or locked doors, and the two operations should not share rooms, equipment, supplies, or pass-through openings (eg, they may not subdivide a room with temporary barriers such as curtains). The guidance further explains that the labeling should clearly identify the compounder who produced the drug. Lastly, the guidance reminds industry and stakeholders that all drug products compounded in an outsourcing facility are regulated under section 503B and are subject to current good manufacturing practice requirements, even if those drug products are compounded pursuant to patient-specific prescriptions. Additional information can be located at *www.fda.gov/newsevents/newsroom/fdainbrief/ucm607339.htm.*

EU-US Mutual Recognition Agreement Now Operational Between FDA and 12 Member States

In January 2018, FDA confirmed the capability of four more European Union (EU) member states – Czech Republic, Greece, Hungary, and Romania – to carry out good manufacturing practice inspections at a level equivalent to the United States. With the addition of the four EU member states, FDA can now rely on inspection results from 12 EU member states. The mutual recognition agreement between the EU and US to recognize inspections of manufacturing sites for human medicines conducted in their respective territories is progressing as planned, with plans for the agreement to be operational in all EU member states by July 15, 2019, indicates a European Medicines Agency (EMA) press release. In 2017, FDA determined the agency will recognize eight European drug regulatory authorities in Austria, Croatia, France, Italy, Malta, Spain, Sweden, and the United Kingdom as capable of conducting

inspections of manufacturing facilities that meet FDA requirements. The EMA news release, "Four more EU Member States benefit from EU-US mutual recognition agreement for inspections," can be found in the News and Events section at *www.ema.europa.eu.*

US Surgeon General Advisory Urges More Individuals to Carry Naloxone

In an April 2018 advisory, US Surgeon General Jerome M. Adams, MD, MPH, emphasizes the importance of more individuals knowing how to use naloxone and keeping it within reach. Surgeon General Adams recommends that family, friends, and those who are personally at risk for an opioid overdose keep the drug on hand. As stated in the advisory, expanding the awareness and availability of naloxone is a key part of the public health response to the opioid epidemic. The Surgeon General advisory on naloxone is part of the Trump Administration's ongoing effort to respond to the sharp increase among drug overdose deaths, notes a US Department of Health and Human Services (HHS) news release. HHS also has a website, *www.hhs.gov/opioids,* with resources and information for individuals who want to fight the opioid crisis in their communities or find help for someone in need. The advisory and news release can be found at *www.surgeongeneral.gov*.

Expanding Pharmacists' Scope of Practice Linked to Improved Cardiovascular Outcomes

Elevating pharmacy involvement in patient care and using a team-based care model are among the effective strategies for preventing cardiovascular disease that were identified in a new guide developed by the Centers for Disease Control and Prevention's (CDC's) Division for Heart Disease and Stroke Prevention (DHDSP). The guide, *Best Practices for Cardiovascular Disease Prevention Programs: A Guide to Effective Health Care System Interventions and Community Programs Linked to Clinical Services,* describes the scientific evidence behind each strategy, including collaborative drug therapy management, enabled by a collaborative practice agreement, and medication therapy management. To be included in the guide, strategies had to be supported by multiple high-quality research studies that demonstrated evidence of effectiveness in controlling blood pressure or cholesterol levels. More details about the best practice strategies along with resources and tools for implementing the strategies identified by CDC's DHDSP can be found at *www.cdc.gov/dhdsp/pubs/guides/best-practices/index.htm.*

Pharmacists Are Critical to Drug Supply Chain Integrity, States FIP

Medicines are specialized commodities and, if they are not managed rationally or appropriately, they are equivalent to a dangerous substance, indicates the International Pharmaceutical Federation (FIP). In a May 2018 report, *Pharmacists in the supply chain: The role of the medicines expert in ensuring quality and availability,* FIP provides a global picture of the role of pharmacists in supply chains, the tasks currently undertaken by pharmacists in different countries, and pharmacists' unique competencies. Based on reviews of literature, survey data, and case studies from nine countries, pharmacists were identified as having expertise that is critical to supply chain integrity. According to FIP, pharmacists and those who are involved in the planning, procurement, manufacture, storage, and distribution of medicines must:

- ♦ consider how to most effectively use the skills of the staff and personnel available;
- ♦ provide and seek training where needed; and
- ♦ keep their systems and role descriptions under review in order to adapt to changing circumstances.

FIP's report and news release can be located at *www.fip.org/news_publications.*

Emergency Department Visits for Opioid Overdoses Rose 30%

From July 2016 through September 2017, reports of emergency department (ED) visits for opioid overdoses – including prescription pain medications, heroin, and illicitly manufactured fentanyl – rose 30% in all parts of the US, according to a CDC report. The Midwest saw opioid overdoses increase 70% during this time period. According to the March 9, 2018 *Morbidity and Mortality Weekly Report*, coordinated action between EDs, health departments, mental health and treatment providers, community-based organizations, and law enforcement can prevent opioid overdose and death. People who have had an overdose are more likely to have another; thus, being seen in the ED is an opportunity for action. EDs can provide naloxone, link patients to treatment and referral services, and provide health departments with critical data on overdoses. The CDC report, "Vital Signs: Trends in Emergency Department Visits for Suspected Opioid Overdoses — United States, July 2016–September 2017," can be accessed at *http://dx.doi.org/10.15585/mmwr.mm6709e1.*

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"Sign-Up" under Existing Licensee Registration, and create a username and password. Large corporate entities can batch-renew all relevant permits at the same time. Log in to the account and select "Renew License," where you can complete your renewal, pay the renewal fee using a credit/debit card or electronic check, and **immediately print the 2019 permit(s).** Electronic renewals must be date/time-stamped on or before 11:59 PM CST on February 28, 2019.

- **Mail:** Paper forms can be found on the Board's website and can be filled out electronically for individual or multiple permits. The forms must be postmarked or hand-delivered no later than February 28, 2019, to the Board office along with a check or money order made payable to the **Kansas State Board of Pharmacy.** Please allow 10 business days for the Board to process your renewal. To verify that your renewal has been processed, visit the License Verification page on the Board website and check for the updated expiration date.

Failing to renew on or before 11:59 PM CST February 28, 2019, will result in your permit being canceled. You will then be required to complete a new application. A facility with a canceled permit cannot sell non-prescription medications until the new application is submitted and approved by the Board.

Emergency Outpatient Supply in the Hospital Setting

When a patient visits an emergency room in a medical care facility, there is sometimes a need to provide the patient with a limited interim supply of medication(s) until a retail pharmacy is open to fill a prescription. In these instances, the following applies:

- The drugs must be prepackaged (prepack) by a pharmacist and include the drug name and strength, quantity, manufacturer, lot number, and beyond use date. An approved nurse may prepare the prepack in the pharmacy for the pharmacist to check, but the pharmacist must perform the final verification before the medications can be supplied.
- Prior to supplying the patient with the prepack, the nurse must finish labeling the prepack with the patient's and prescriber's name, adequate directions for use, date of supply, and identification number for the supply.
- The nurse must adequately record the distribution of the interim supply in accordance with K.A.R. 68-7-11(d)(2)(B).

While this list is a good start, for all requirements please review K.A.R. 68-7-11(d)(2). This regulation and all other pharmacy laws can be found on the Board website at *https://pharmacy.ks.gov/statutes-regs/statutes-regs.*

What Does Compliance Look Like?

1. Post It

a. Technician registrations – K.S.A. 65-1663(j) requires pharmacy technicians to **post** the current registration in the pharmacy where they work. The current registration may have the visible address covered, but the name and expiration date should still be visible.

b. Pharmacist licenses – K.S.A. 65-1641 requires the pharmacist to conspicuously display, **visible to the public,** the pharmacist license where the pharmacist is actively engaged in the profession of pharmacy. The current renewal card should be displayed with the license as it contains the expiration date of the license. If floating or doing relief, the pharmacist's pocket card should be available.

c. Store registration and renewal

d. Drug Enforcement Administration registration (if applicable)

e. PSE certification – This must be renewed annually. The date is found in the upper right corner.

f. Technician ratio – If the pharmacy is utilizing the 3:1 technician to pharmacist ratio, the current national certification of the technicians should be **posted** to document the ability to use the higher ratio.

g. Accredited? Please **post** the accreditation certificate.

h. Name tags – K.A.R. 68-2-15 requires name tags to be **visible** and worn while in the pharmacy. **Post it** on your person.

i. If the pharmacy elects to post it too high on the wall, be prepared to provide a list of all employees to the Board inspector.

2. Continuous Quality Improvement (CQI)

a. Meetings are required to be held quarterly (that is every 90 days).

b. Discuss **all** reportable incidents that occurred and/or were documented during the quarter.

c. **Document** the meeting: include **who** and **when** (the day's date).

d. Incidents may be grouped into reportable incident types and discussed once. Be sure to include all the prescription numbers of that type.

e. **The goal is to reduce errors.**

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f. Make proposed prevention steps progressive. Doing the same thing over and over does not prevent errors from happening. "Slowing down" does not prevent errors.

3. PICs – Did You Know That It Is the PIC's Responsibility To:

a. Ensure the **current** registrations and licenses of all staff are posted.

b. Maintain a list of all technicians employed by the pharmacy.

c. Ensure name tags are worn by all pharmacists, pharmacy interns, and technicians while in the pharmacy.

d. Notify the Board of his or her resignation as a PIC within five days (electronic or paper), regardless of how he or she left the position.

e. Take a **final** inventory upon resigning as PIC.

f. Take a beginning inventory upon becoming PIC (may be done with the outgoing PIC as long as it falls within 72 hours of the change in PIC).

g. Ensure **staff knows** where to find documentation like the controlled substance (CS) inventory, incident reports, CQI, technician training documentation, etc. A sample inspection report may be found on the Board website to make sure the pharmacy has all the required information and documentation.

4. PSE – Report It Somewhere!

a. PSE is Schedule V in Kansas.

b. If PSE is given over-the-counter (OTC), report it to the National Precursor Log Exchange, commonly known as NPLEx.

c. If PSE is dispensed as a prescription, report it to K-TRACS.

d. If OTC PSE is dispensed as a prescription, report it to K-TRACS.

e. If PSE is given as a prescription only, report it to K-TRACS.

f. **Any** amount of PSE in a product makes it scheduled and reportable.

g. **All** the above goes for ephedrine as well.

h. Are PSE and ephedrine, both prescription and OTC, on your annual CS inventory?

5. Compounding

a. The new regulations regarding compounding are K.A.R. 68-13-2, 68-13-3, and 68-13-4.

b. Are you compliant? Be sure to read these regulations, which can be found on the Board website by selecting Statutes & Regs under the Legal drop-down menu, or by visiting *https://pharmacy.ks.gov/statutes-regs/statutes-regs.*

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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