December 2020

Kansas State Board of Pharmacy News

Published to promote compliance of pharmacy and drug law

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Announcements

- Regular updates regarding Kansas State Board of Pharmacy guidance and information on coronavirus disease 2019 (COVID-19) can be found on the Board website. This includes information about operations, waivers, renewals, exams, fingerprinting, inspections, pharmacy frequently asked questions, and more. The Board has extended remote work options through February 2021.
- Welcome Janay Davis! Ms Davis is the Board's new administrative assistant. She is originally from Oklahoma City, OK, and just recently moved to Kansas. Ms Davis has two brothers and a nephew, enjoys traveling, bowling, watching funny movies, and dancing. She comes to the Board from the Oklahoma Department of Human Services, where she served for seven years as an administrative assistant for the Temporary Assistance for Needy Families program. Ms Davis is excited about her new role and enjoying the awesome team she is working alongside at the Board. If you call the Board office, you will most likely get to speak with her, so please extend a welcome.
- **New:** Follow the new Kansas Prescription Drug Monitoring Program (K-TRACS) Facebook page at *https://www.facebook.com/ktracs.*
- Follow the Board on Twitter @KSBOP or on Facebook (*www.facebook.com/KansasStateBoardOfPharmacy)* for news, updates, and more!

Immunization Authority Under the Federal PREP Act

The United States Department of Health and Human Services (HHS) expanded the Public Readiness and Emergency Preparedness Act (PREP Act) to include authority for pharmacists to order and administer immunizations to children ages three to 18 years of age, and order and administer COVID-19 immunizations (once approved by Food and Drug Administration). In addition, HHS has granted authority for interns and technicians to administer these immunizations under the direct supervision of the pharmacist who has ordered the immunization. Qualified pharmacists, interns, and technicians must have completed an Accreditation Council for Pharmacy Education (ACPE)-accredited continuing pharmacy education (CPE) immunization certification course, and pharmacists must have completed a two-hour, ACPE-accredited CPE course in immunizations within the current state licensure period. Additional requirements are listed in the PREP Act amendments. All pharmacy personnel are required to be properly licensed/registered in Kansas to perform these functions.

The federal guidance does **not** require a physician protocol and independently authorizes pharmacists to order immunizations. Pharmacists may continue using a physician protocol but cannot update the protocol to cover any immunization not authorized by Kansas Statutes Annotated (K.S.A.) 65-1635a.

Please continue to review the Board's guidance on COVID-19 for updated information.

What Does Compliance Look Like?

Pursuant to Kansas Administrative Regulations (K.A.R.) 68-20-15b, either the pharmacist-in-charge (PIC) or the pharmacy owner shall notify the Board in writing within one day of any suspected diversion, theft, or loss of any controlled substance (CS) and, upon completion, shall provide the Board with a copy of the completed Drug Enforcement Administration (DEA) Form 106 issued by the US Department of Justice.

This regulation became effective on January 4, 2019. The regulation specifies **any** suspected diversion, theft, or loss must be reported. Notification should be given within the first 24 hours. Once the pharmacy has conducted the audit and determines the quantity of CS diverted, stolen, or lost, DEA Form 106 should be completed and filed with the Board and DEA, and a copy should be retained for the pharmacy records.

Each PIC and pharmacy owner shall provide effective controls and procedures to guard against theft and diversion of CS (K.A.R. 68-20-15a(a)). Effective controls will vary across pharmacies, and each PIC should conduct a risk assessment and implement safeguards necessary to prevent any loss of CS.

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National Pharmacy Compliance News

December 2020

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 Recommends Health Care Providers Discuss Naloxone With Patients Receiving Opioids, OUD Treatment

Recognizing the importance of discussing naloxone with patients receiving opioids or medications to treat opioid use disorder (OUD), Food and Drug Administration (FDA) recommends that health care providers include such discussions as a routine part of prescribing these medications. Further, the agency is requiring label changes to these medications to include this recommendation. The revised labels will encourage health care providers to discuss the availability of naloxone with patients and caregivers, both when beginning and renewing treatment. The labeling changes also suggest that providers prescribe naloxone to patients being prescribed opioids who are at increased risk of opioid overdose.

"Even during this global pandemic, we have continued to prioritize addressing the opioid crisis," said FDA Commissioner Stephen M. Hahn, MD, in a press release. "Today's action can help further raise awareness about this potentially life-saving treatment for individuals that may be at greater risk of an overdose and those in the community most likely to observe an overdose. We will use all available tools to address this crisis, and we know efforts to increase access to naloxone have the potential to put an important medicine for combatting opioid overdose and death in the hands of those who need it most – those at increased risk of opioid overdose and their friends and family."

The complete list of changes is available through an July 2020 Drug Safety Communication.

Proposed Rule to Require Electronic Submission of DEA Form 106

A proposed rule requiring accurate electronic submission of DEA Form 106 was published by Drug Enforcement Administration (DEA) in the *Federal Register* on July 29, 2020. The form, used by DEA registrants to report thefts or significant losses of controlled substances (CS), would also need to be submitted within a 15-day time period under the proposed rule. DEA registrants who experience theft or loss of CS would still be required to notify the DEA Field Division Office in their area, in writing, within one business day of discovery. According to the announcement published in the *Federal Register,* this requirement will impact the remaining 0.5% of DEA Form 106 responses that are reported by paper.

Inappropriate FentaNYL Patch Prescriptions at Discharge for Opioid-Naïve, Elderly Patients

This column was prepared by the Institute for Safe Medication Practices (ISMP), an ECRI affiliate. Have you experienced a medication error or close call? Report such incidents in confidence to ISMP's National Medication Errors Reporting Program online at www.ismp.org *or by email to ismpinfo@ismp.org to activate an alert system that reaches manufacturers, the medical community, and FDA. To read more about the risk-reduction strategies that you can put into practice today, subscribe to the ISMP Medication Safety Alert!® newsletters at* www.ismp.org.

ISMP recently heard from a long-term care (LTC) pharmacy about an increase in the prescribing of transdermal fenta**NYL** patches for elderly patients. In most cases, the pharmacists reviewing the patients' orders determined that the fenta**NYL** patches had been inappropriately prescribed for opioid-naïve patients, sometimes to treat acute pain rather than chronic pain. One of the more common underlying causes appears to be a knowledge deficit about the dangers of prescribing this opioid analgesic to opioid-naïve patients. Several of the events began in a hospital, with opioid-naïve patients receiving prescriptions for fenta**NYL** patches after treatment in an emergency department (ED) or upon discharge and transfer to a LTC facility. Prescribing a fenta**NYL** patch to elderly, opioid-naïve patients can result in fatal or life-threatening respiratory depression and overdose.

In one event, an 88-year-old resident from a LTC facility fell and was taken to a local hospital ED, where multiple rib fractures were diagnosed. Upon discharge

from the ED, the resident was prescribed a fenta**NYL** patch, 25 mcg/hour, every 72 hours. At the LTC facility, a consultant pharmacist reviewed the medication orders and the resident's medication history. The pharmacist determined that the resident had not received a prescription for opioids in the past year, revealing he was opioid-naïve. The consultant pharmacist contacted the prescribing ED physician to discuss the order for the fenta**NYL** patch. The ED physician reported that the resident had received "three small IV push doses" of fenta**NYL** in the ED, mistakenly believing this meant the resident was opioid-tolerant.

Additionally, the ED physician had prescribed the fenta**NYL** patch because the resident had a documented allergy to codeine. The ED physician mistakenly believed the fenta**NYL** patch was the only viable option. The consultant pharmacist clarified that the LTC records indicated that the resident had experienced mild nausea and an upset stomach while taking **HYDRO**codone and acetaminophen when he was younger, which is not an allergy but rather a mild intolerance. The ED physician changed the resident's analgesic to oral oxy**CODONE** 5 mg as needed every four to six hours.

Reliance on product labeling and practitioner education alone will not prevent life-threatening errors with fenta**NYL** patches. Yes, health care practitioners should be educated about safe prescribing, and their competency should be verified as a prerequisite to prescribing. But there will always be those who are unaware of the risks they take prescribing fenta**NYL** patches to opioid-naïve patients to treat acute pain. Thus, system safeguards must be established to avoid the risk of harm.

Fenta**NYL** patches should only be prescribed for patients who are opioid-tolerant with persistent, moderate-to-severe chronic pain that requires around-the-clock, long-term opioid administration. In 2018, ISMP called for the elimination of prescribing fenta**NYL** patches for opioid-naïve patients and/or patients with acute pain in our *Targeted Medication Safety Best Practices for Hospitals*. In 2020, this best practice was incorporated into a new best practice (No.15) to verify and document the patient's opioid status and type of pain before prescribing and dispensing extended-release opioids.

When entering discharge and transfer orders, interactive alerts requiring confirmation that the patient is opioid-tolerant and experiencing chronic pain might help prevent inappropriate prescribing, as might hard stops if patients do not meet prescribing criteria. Consider creating a daily list of discharge prescriptions and transfer orders for fenta**NYL** patches generated from the order entry system, and requiring a hospital pharmacist to review them to verify that the patient is opioid-tolerant and has chronic pain.

Engage patients. Educate all patients prescribed a fenta**NYL** patch and their caregivers about how to use the patch safely.

SAMHSA Health Privacy Rule Revised to Better Integrate, Coordinate Care for Patients With SUD

A revised Substance Abuse and Mental Health Services Administration (SAMHSA) rule will make it easier for people diagnosed with substance use disorders (SUDs) to receive integrated and coordinated care. The revisions to the agency's Confidentiality of Substance Use Disorder Patient Records regulation, 42 CFR Part 2, advances the integration of health care for individuals with SUDs while maintaining critical privacy and confidentiality protections.

According to a US Department of Health and Human Services (HHS) press release, under Part 2, a federally assisted SUD program may only disclose patient identifying information with the individual's written consent, as part of a court order, or under a few limited exceptions. In addition, health care providers, with patients' consent, will be able to more easily conduct quality improvement, claims management, patient safety, training, and program integrity efforts.

The revised rule modifies several major sections of Part 2, including provisions related to records, consent requirements, and research, among others. For a list of changes in the final rule, visit the HHS Fact Sheet.

HHS Assistant Secretary for Mental Health and Substance Use Elinore F. McCance-Katz, MD, PhD, the head of SAMHSA, further stated, "Modernizing 42 CFR Part 2 will strengthen the nation's efforts to reduce opioid misuse and abuse and to support patients and their families confronting substance use disorders. The rule will make it easier for primary care clinicians to treat individuals with substance use disorders."

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Employees also have a responsibility to report drug diversion. Title 21 Code of Federal Regulations 1301.91 states that "a failure to report information of drug diversion will be considered in determining the feasibility of continuing to allow an employee to work in a drug security area," such as a pharmacy with CS.

K-TRACS Survey Shows Program's Impact, Areas for Improvement

According to survey results, 97% of K-TRACS users believe K-TRACS has a positive impact on preventing prescription drug misuse, abuse, and diversion in the state of Kansas.

K-TRACS disseminated a survey over the summer to gauge user perceptions and identify areas for improvement. Approximately 11% of pharmacists registered to use K-TRACS responded to the survey, with 330 responses recorded from active user pharmacists.

One of the most significant survey results was the importance of K-TRACS integration with pharmacy management systems in pharmacists' frequency of use and perceived barriers to use. Of pharmacists using an integrated system, 73% report using the system daily compared to just 32% of non-integrated pharmacists.

Additionally, integrated pharmacists and prescribers both reported higher levels of "no barriers" to K-TRACS usage (38%) compared to non-integrated users (27%). Among non-integrated users, workflow interruptions and frequent password changes were the highest-rated barriers.

To address concerns about the frequency of password changes, K-TRACS has changed its requirements. **Users are now only required to change their passwords every six months.** Security requirements such as type of characters and length of password required remain the same.

Other significant survey findings include:

- 97% of pharmacists believe the prescription drug data they report to K-TRACS is accurate and complete, and overall, 95% of users believe K-TRACS data is accurate.
- Pharmacists reported that their communication has increased and/or improved the most (77%) with prescribers as a result of using K-TRACS, followed by other pharmacists (67%), internal pharmacy staff (62%), and patients (60%). Only 6% of pharmacists reported no change in communication levels as a result of using K-TRACS.
- The most common scenarios in which both pharmacists and prescribers use K-TRACS are when they suspect misuse or "doctor/pharmacy shopping" behavior among patients, when patients request early refills, and before prescribing or dispensing for new patients.

You can read the full survey report on the K-TRACS website at *http://bit.ly/ktracs-report.*

K-TRACS Updates

Data Validation Review

K-TRACS began a data validation project earlier this year to review the accuracy of prescriptions reported to K-TRACS by Kansas pharmacies. Through October 2020, K-TRACS has contacted 80 pharmacies and reviewed 461 prescriptions. Prescription errors occur when information on the original prescription as required by the Pharmacy Practice Act does not match what was submitted to K-TRACS. To date, the project has a 0.2% prescription error rate.

New Integration Options

Integrated K-TRACS users now have the option to include prescription drug data from Colorado, Missouri, and Oklahoma in their patient searches within integrated pharmacy systems. Integrated pharmacies must make a request with the K-TRACS software vendor, Appriss Health, to connect to any or all of the states, and the states must approve the connection. Requests may be made by visiting *https://share.hsforms.com/1Yj3xpv8ESluUicIgdc5Baw1pr00.* For more information about available connections, please visit *http://ktracs.ks.gov/using-k-tracs/state-to-state-integration.*

Reporting Veterinarian Prescriptions

Pharmacies are required to report to K-TRACS all CS and drugs of concern, including gabapentin, dispensed to non-human patients in the same manner as those for human patients. For veterinarians and other prescribers without a DEA number, dispensations can be submitted to K-TRACS with a valid National Provider Identifier (NPI) number only. For dispensations without an associated DEA or NPI, such as for prescriptions issued by some veterinarians, please contact K-TRACS at pmpadmin@ks.gov or 785/296-6547 for submission instructions specific to your pharmacy and/or the prescriber.

Kansas Electronic Prescribing Requirements

Effective July 1, 2021, every prescription order issued for a CS in Schedules II-V that contains an opiate shall be transmitted electronically (See K.S.A. 65-16,128). The Board was tasked with issuing waivers to prescribers who qualify for one or more of the exceptions outlined in the statute. A prescriber may request a waiver from the Board through December 31, 2021. If a waiver is granted, the prescriber may request that such waiver be renewed through June 30, 2022. The Board will publish guidance on the waiver request process in mid-January 2021 on the Board website.

If a prescriber prescribes a CS by non-electronic prescription, the prescriber must indicate the prescription is made pursuant to a Board waiver. **The pharmacist/pharmacy is not required to verify the validity of any**

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waiver, either with the prescriber or the Board, but may do so in accordance with K.S.A. 65-1637. The Board will publish additional information on how pharmacists/pharmacies may verify an approved prescriber waiver.

2021 Retail Dealer Renewals

The Board retail dealer permits expire **February 28, 2021.** Permits may be renewed either online or by mail from mid-January through February 28, 2021. For renewal instructions, visit *www.pharmacy.ks.gov.*

Use the Board's secure online payment portal via the eLicensing quick link to renew each permit. If you do not have a username and password or have forgotten, under Existing Licensee Registration, click "Sign-Up" 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 by credit/debit card or electronic check, and **immediately print the 2021 permit(s).**

Upcoming Events

December 4, 2020, 9 AM, WebEx

K-TRACS Advisory Committee Meeting – *https://intercall.webex.com/intercall/j.php?MTID=mbf5a04737b66a7678a9d4082d77eba85*

December 10, 2020, 8:30 AM, WebEx

Board of Pharmacy Quarterly Meeting – *https://intercall.webex.com/intercall/j.php?MTID=mbc35e1b4d0ab81cd18cd1e4a1bbd83a5*

2021 Board of Pharmacy Meeting Dates

- February 19, 2021
- April 1, 2021
- June 3, 2021
- August 19, 2021
- September 30, 2021
- December 2, 2021

2021 K-TRACS Advisory Committee Meeting Dates

- January 22, 2021, 11:30 AM
- February 12, 2021, 11:30 AM
- March 19, 2021, 9 AM
- April 16, 2021, 11:30 AM
- May 21, 2021, 11:30 AM
- June 18, 2021, 9 AM
- July 16, 2021, 11:30 AM
- August 13, 2021, 11:30 AM
- October 22, 2021, 9 AM
- December 10, 2021, 11:30 AM

Revoked Licenses and Registrations

In an effort to provide greater transparency to pharmacists, the Board will publish a list of revocations against Kansas pharmacists, interns, and technicians in its quarterly *Newsletter.* The Board encourages the PIC to verify the registration status of all employed technicians at least twice a year (June and November are recommended). The Board's license verification website is a secure and primary source of credential verification information, and is as authentic as a direct inquiry to the Board: *https://ksbop.elicensesoftware.com/portal.aspx.*

Please take notice of the Board's revocation action taken on these licenses, permits, and registrations:

- Boren, John 14-06604, Case 19-603
- Bryant, Lavonte 14-107989, Case 20-263
- Pitts, Jami 1-111332, Case 20-262
- Skeels, Zachary 24-109890, Case 20-269
- Ward, Marisa 24-109956, Case 20-270
- Williams, Lensie 24-109757, Case 19-459

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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