Kansas Board of Pharmacy

NEWSLETTER

Compliance | Licensing & Registration | K-TRACS

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What's Inside:

New Regulation: Pharmacy Owner Responsibilities

The Board adopted K.A.R. 68-2-24 concerning pharmacy owner responsibilities, which became effective on October 27, 2023. The new regulation indicates:

- The pharmacy owner is responsible for ensuring the pharmacy is operated in compliance with state and federal laws and regulations and all policies and procedures are consistent with state and federal laws and regulations. This includes K-TRACS compliance.
- The pharmacy owner shall not prohibit or prevent pharmacy personnel from complying with state and federal laws and regulations, and shall not penalize, prohibit, or prevent a pharmacist from conducting an in-person inspection of a prescription, drug or device, or product verification.
- A person that has had any license or registration denied, revoked, or suspended by the Board is not permitted in a pharmacy. This includes working as a clerk. (Note: A person may be permitted if the licensee or registrant has subsequently been issued an active license or registration by the Board.)

e-Prescriber Waiver Guidance Document

At their September 2023 meeting, the Board adopted a new Guidance Document regarding when a prescriber must request a waiver before non-electronically prescribing a controlled substance in schedule II-V that contains an opiate. While the Board's guidance is primarily aimed at prescribers, pharmacists should be aware of their responsibilities when they receive a non-electronic prescription for a controlled substance in schedule II-V that contains an opiate.

If the pharmacist receives a non-electronic prescription as described above, the pharmacist should be aware that the prescription **may** include the additional words "waiver" or "exempt." Regardless, the pharmacist **shall not** be required to verify the validity of the waiver or exemption, either with the prescriber or the Board, regardless of whether the prescription includes or does not include any additional words.

While neither the letter of the law nor the Board's interpretation requires a pharmacist to verify, the Board has reinforced their previous guidance on dispensing: each pharmacist must use their professional judgment in dispensing valid prescriptions.

Complaint Process

The Board strongly encourages consumers and licensees to file a complaint anytime they have a concern related to the appropriate or lawful practice of pharmacy in Kansas by a licensee or registrant.

Upon receipt of a Complaint Form, the following takes place:

- Board staff notify the complainant that their complaint has been received and provide a reference number.
- The Executive Secretary reviews the complaint, and the Director of Compliance assigns an appropriate investigator.
- A Board Investigator conducts an investigation to compile a report that is presented to the Board.
- The Investigative Member of the Board reviews the Investigative Report to determine if any possible violations of Kansas Law have occurred.
- The Board determines if disciplinary action or a hearing is warranted and notifies the appropriate parties.

If necessary, a hearing with the licensee is arranged according to the Kansas Administrative Procedure Act. The hearing is to give the licensee an opportunity to present his/her case. There is a possibility that the complainant and appropriate other parties will need to appear at the hearing, but this is not always the case. The complainant will be given ample advance notice should we request their presence.

The Board accepts anonymous complaints and keeps certain information confidential during the course of the investigation. However, sometimes an investigation may reveal a "likely" individual that may have made the complaint to the Board.

Pursuant to 65-1627k, certain complaint and investigation records of the Board are considered confidential.

(a) Any complaint, investigation, report, record or other information relating to a complaint or investigation that is received, obtained or maintained by the Board shall be confidential and shall not be disclosed by the Board or its employees in a manner that identifies or enables identification of the person who is the subject or source of the information, except the information may be disclosed:
    1. In any proceeding conducted by the Board under the law or in an appeal of an order of the Board entered in a proceeding, or to any party to a proceeding or appeal or the party's attorney;
    2. to the person who is the subject of the information or to any person or entity when requested by the person who is the subject of the information, but the Board may require disclosure in such a manner that will prevent identification of any other person who is the subject or source of the information; or
    3. to a state or federal licensing, regulatory or enforcement agency with jurisdiction over the subject of the information or to an agency with jurisdiction over acts or conduct similar to acts or conduct that would constitute grounds for action under this act. Any confidential complaint or report, record or other information disclosed by the board as authorized by this section shall not be disclosed by the receiving agency except as otherwise authorized by law.

(b) Except as provided in subsection (a), no applicant, registrant or individual shall have access to any complaint, investigation, report, record or information concerning a complaint or investigation in progress until the investigation and any enforcement action is completed.

Sample Immunization Protocol

Just a reminder! Pharmacists may enter into an immunization protocol with a Kansas-licensed physician to administer vaccines or authorize pharmacist interns to administer vaccines. The 2021 updates to the Kansas Pharmacy Practice Act require any immunization protocol be signed by the authorizing physician and the administering pharmacist. Copies of the signed protocol should be retained for five years at the location(s) where immunizations are provided, but do not need to be sent to the Board office.

A sample immunization protocol is provided on the Board website at https://pharmacy.ks.gov/resources-consumer-info-2/collaborative-practice. This is **only an example** and is not intended to be a required template. Each physician and pharmacist should form their own agreement for a written protocol that complies with Kansas law.

The Board has also updated its Guidance on Vaccination Administration Authority for pharmacy interns and pharmacy technicians. Pharmacy technicians were authorized to administer immunizations in Kansas beginning July 1, 2023.

Nonresident Facilities – Address Change Applications

Nonresident facility address change applications must include a satisfactory inspection at the new address, as well as a home state permit at the new address (if applicable). Applications that are missing these required elements will be denied; the registrant's permit at the previous address will also be cancelled. If the facility is relocating and it will take more than 30 days to receive an inspection at the new address, the facility may need to close/cancel their existing Kansas registration and apply for a new registration at the new location after an inspection is completed. All business must cease during the period the facility is not registered. See K.S.A. 65-1643, 65-1643d, 65-1645, 65-1655, 65-1655a, and 65-1655b.

ANNOUNCEMENTS

- The Board recommends you verify the registration status of each pharmacy technician in your pharmacy at least twice a year in November (after the technician registration expiration date) and May (after the CE audit and tech exam waivers). Check using the eLicense Portal .

- 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 name and Kansas registration number.

Board Inspector Retires After 35 Years of State Service

Jim Kinderknecht, RPh, retired from the Board on September 29. Kinderknecht has been a Kansas pharmacist for 63 years and spent 38 years spanning two stints with the Board as an inspector. He received the designation "Inspector Emeritus" from the Board and was honored during a retirement ceremony. The Board appreciates Kinderknecht's dedication to the profession of pharmacy, public health, and the safety of the citizens of the State of Kansas. Kinderknecht has been an inspector during the appointment of more than 30 different Board members, and the Board believes he has the lengthiest state pharmacy service record of any employee in the Kansas Board of Pharmacy's history.

Kinderknecht made investigating consumer complaints and drug diversion cases a top priority as an inspector. He also commonly educated pharmacists about appropriate patient counseling during inspections. During brief periods, Kinderknecht served as the only Board inspector and drove across the entire state to conduct inspections and investigations. The Board estimates he has traveled an average of 10,200 miles per year in his role at the Board, for a total of more than 357,000 miles! He also served as Interim Executive Director on occasions the position was vacant and provided training and education to new directors.

Prior to joining the Board, Kinderknecht owned St. Marys Pharmacy for 21 years and worked in hospitals, retail pharmacies and long term care consulting. He is looking forward to spending his retirement with his family.

K-TRACS Honors Longtime Committee Members

The Board expresses its sincere gratitude to longtime K-TRACS Advisory Committee members Max Heidrick, RPh, and Van Coble, RPh. Heidrick served on the committee since its inception in 2008 and was a Board member prior to his committee appointment. Coble served on the committee for a decade. Both represented the Kansas Pharmacists Association and brought experience from their independent retail pharmacy careers that proved valuable in helping guide the direction of the K-TRACS program and in evaluating patterns and activity of concern among the patient and healthcare provider populations.

COMPLIANCE CORNER

Immunizing Without a Protocol

During the COVID-19 public health emergency, many pharmacists began immunizing in accordance with the federal PREP act instead of pursuant to the previous method of entering a protocol with a physician as allowed by Kansas statute. Now that the allowances under the PREP Act have changed, have you updated your practice? The Eleventh Amendment to the PREP Act has extended pharmacist, pharmacist intern, and pharmacy technician allowances until December 31, 2024, but only for federal covered countermeasures of COVID-19

vaccines, seasonal influenza vaccines, and COVID-19 tests. Board inspectors are finding instances of immunizations being administered without a protocol that are outside the scope of the PREP Act allowances. If you are choosing to immunize without a physician protocol, please make sure you are up to date with what the PREP Act does, and does not, allow you to do. More information: Federal Register Notice of the Eleventh Amendment to the PREP Act.

DEA Extends Telemedicine Flexibilities

On October 10, 2023, the DEA issued a second temporary extension to the prescribing of controlled substances through telemedicine visits. This new extension changes the original extension to authorize DEA-registered practitioners to prescribe controlled substances via COVID-19 telemedicine flexibilities through December 31, 2024, and removes the requirement that the patient-practitioner telemedicine relationship be established before November 11, 2023. More information about the extension: Federal Register Notice of the Second Temporary Extension of COVID-19 Telemedicine Flexibilities for Prescription of Controlled Substances.

New Version of USP <795> & <797>

The new versions of USP Chapter <795> and <797> went into effect November 1, 2023. What does this mean for facilities in Kansas? The Board is using enforcement discretion to allow a choice.

- If a facility has policies and procedures in place, training completed, and is **ready** for full compliance with the updated versions of the chapters, the facility may follow the new chapters now.
- If a facility is **not ready** for full compliance with the new chapters, they will need to continue compliance with K.A.R. 68-13-2 and K.A.R. 68-13-3 for nonsterile preparations and continue compliance with K.A.R. 68-13-4 for sterile preparations.

The Board will **not** allow a facility to pick and choose parts of the new chapters to follow (such as extended BUDs) while not following others (such as increased frequency of media-fill testing and gloved fingertip sampling). A facility must fully comply with one version or the other.

The Board has begun work on new regulations to adopt USP <795> and <797>. There is no current timeline as to when new regulations may be adopted or implemented in Kansas. However, facilities should be in the process of moving toward full compliance with the new chapters now, as many have a lot of work to do to get there.

FAQ: Partial Fills of CIII-CV

Is it permissible to dispense a C-III, C-IV, or C-V prescription for a quantity less than the face amount prescribed, resulting in a greater number of dispensations than the number of refills indicated on the prescription?

- Yes. Partial filling of a prescription for a controlled substance listed in Schedule III, IV, or V is permissible under federal regulations provided that each partial filling is dispensed and recorded in the same manner as a refilling (i.e., date refilled, amount dispensed, initials of dispensing pharmacist, etc.). The total quantity dispensed in all partial fillings cannot exceed the total quantity prescribed, and no dispensing may occur six (6) months after the date of issue for the prescription.
- See K.A.R. 68-20-20(c) and 21 C.F.R. 1306.23

K-TRACS UPDATE

K-TRACS Implements Reporting Changes on November 1

As of November 1, 2023, the following changes have occurred in K-TRACS that affect how pharmacies report to the program:

- **Sold date** is required to be reported. The sold date should reflect the date the prescription was sold to the patient or patient representative; the date the prescription was mailed or sent out for delivery; and/or the date the prescription was dispensed from a hospital to a patient or patient representative (if applicable). If the sold date is not reported or is a future date, the prescription will result in an error.
- **Species code** is required to be reported. If an animal prescription is reported without a code indicating it is for an animal, the pharmacy will be contacted to correct the issue.
- **Zero reports** are required to be reported by the end of the next business day from when no prescriptions are sold. If a pharmacy does not report on a regular business day or if zero reports are delayed, the pharmacy will be contacted to correct the issue.
- **Prescriber identifiers** must be valid. All DEA numbers and NPI numbers submitted for prescribers must be valid and match the national databases containing this information. Prescriptions for non-controlled gabapentin should contain a valid NPI for human prescriptions or a valid state license number for animal prescriptions. Any invalid identifiers may result in an error.
- **Patient identifiers** must not contain social security numbers. Use a driver's license number or a unique identifier such as first, middle, last initial plus eight-digit date of birth (i.e., ABC01012000).

Reminder: Error correction required within 7 days

If errors occur in the data submitted by the pharmacy, K.A.R. 68-21-2 requires **pharmacies to correct errors within 7 days of notification or discovery**.

Depending on how your pharmacy reports to K-TRACS, your pharmacy may receive daily emails notifying the pharmacy of the file submission status. These emails contain notification of any errors that have occurred. Additionally, all PICs with K-TRACS accounts should be receiving emails when errors occur and emails continue until the errors have been corrected.

K-TRACS staff will also contact pharmacies when errors remain uncorrected. **Pharmacies with uncorrected errors beyond 7 days may be subject to disciplinary action.**

National News

Read the latest news from the National Association of Boards of Pharmacy
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REVOKED LICENSES & REGISTRATIONS

In an effort to provide greater transparency to pharmacists, the Board will publish a list of revocations and suspensions against Kansas pharmacists, interns, and technicians in its quarterly Newsletter. The Board encourages the pharmacist-in-charge 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, as authentic as a direct inquiry to the Board.

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

- Araya, Bereket, 1-16647 Case 23-404
- Cabrera, Fabiola, 24-116548 Case 23-332
- Davis, Brylee, 24-117594 Case 23-335
- Dozier, Kirsten, 24-115441 Case 23-331
- Finney, Sarrina, 24-114045 Case 23-215
- Klein, Jamie, 24-116798 Case 23-310
- Moeder, Dana, 14-18922 Case 23-113
- Padilla, William, 24-113845 Case 23-323
- Sola, Kylie, 14-19284 Case 23-190
- Solano Cano, Mario, 24-113521 Case 23-333
- Young, Seretse, 14-114355 Case 23-320