Kansas Board of Pharmacy

NEWSLETTER

Compliance | Licensing & Registration | K-TRACS

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What's Inside:

KBOP Regulation Changes

The following is a brief synopsis of recent Board Regulation changes that went into effect on June 2, 2023:

PIC Designation and Responsibilities (KAR 68-1-2a, 68-1-9)

- When a PIC resigns, facilities have 30 days to designate a new PIC with the Board using the BA-50. If the facility is unable to designate a PIC within 30 days, the owner can request a 30-day extension from the Board. Responsibility rests with the facility owner.
- PIC requirements apply to all facilities that require PICs, not just pharmacies.
- PIC is responsible for all operations and compliance in the pharmacy, including:
  - Available as necessary
  - Personnel records, including job duties, training, and education
  - Policies and procedures (minimum requirements listed in regulation)
  - Direct supervision of all pharmacy personnel, security, and drugs
  - Drug recall procedure
  - Records of drug distribution, packaging, repackaging, and compounding
  - Review and posting of each Board Newsletter
- An outgoing PIC must resign in writing to the Board within 5 days. Use the BA-50 or resign through the elicense portal. Do not wait until the new PIC is selected.
- An outgoing PIC must inventory all controlled substances and drugs of concern no more than two days prior to ceasing to serve as PIC. In limited circumstances, the facility owner can contact their inspector by email to request another pharmacist complete the outgoing inventory.
- An incoming PIC must inventory all controlled substances and drugs of concern within two days of beginning to serve as PIC.
- An incoming and outgoing PIC can do a simultaneous inventory on the outgoing PIC's last day if both are physically present, actively participate, and sign the joint inventory.
- An incoming PIC must sign a statement to the Board acknowledging acceptance of the responsibilities of PIC.

UPCOMING MEETINGS

July 14: K-TRACS Advisory Committee
July 26-27: Board of Pharmacy
Sept. 28: Board of Pharmacy

Pharmacist CE (KAR 68-1-1b)

- Beginning July 1, 2023, pharmacists renewing their license are required to complete a one-hour CE course provided by the Board.
- The Board will create a new course every 18-24 months.
- Counts toward 30-hour renewal requirement and is approved for ACPE credit.
- The 2023/2024 course will be available online, on-demand, at no cost.
- Applies to all pharmacists licensed in Kansas (not just residing/practicing in Kansas).
- See more information about the course on page 10.

Prescription "Scan and Shred" (KAR 68-7-8)

- Allow pharmacies the option to scan and digitize prescription records and then shred paper copies (except controlled substances per DEA). It's the responsibility of each pharmacist, intern, and technician to ensure that the scan is complete and accurate.
- Pharmacy software must capture and store exact, color, legible image of front and back of original prescription. Electronic backup of prescription files must occur at least every 7 days.
- Inspectors must have access to the image and electronic annotations during inspections and upon request. The pharmacy does not have to maintain a color printer if a color PDF can be sent (emailed) to the Board.
- Electronic prescriptions do not have to be printed if regulation requirements are met.
- Paper originals must be securely destroyed.
- Pharmacy must have policies and procedures for "scan and shred," including annual review.
- Check with insurance or other contractors!

Pharmacists Filling Prescriptions (KAR 68-2-20)

- The following duties cannot be delegated by a pharmacist:
    - Final verification
    - Documentation of final verification
    - Direct supervision of an intern or technician
- Pharmacists may delegate any nonjudgmental function to an intern or technician but must conduct in-process and final checks for medication preparation (except under KAR 68-7-11).
- Counseling may be provided by the pharmacist using any communication method if the patient does not present at the pharmacy.

Medical Care Facilities (KAR 68-7-11)

- Duties previously limited to nurses, now expanded to include Physician Assistants (PAs):
    - May obtain drugs for inpatient administration based on a medication order and with approval of the PIC.
    - May enter the pharmacy and remove a single dose of medication from stock for immediate administration to the patient.
    - May be permitted in the pharmacy without pharmacist on premises.
- Medication orders must be reviewed by a pharmacist within 3 days of the date written (previously 7 days).

Packaging and Labeling in Advance of Immediate Need (KAR 68-7-15, 68-7-16)

- Adds devices to all requirements.
- The pharmacist must verify and document verification of packaged drugs/devices prior to release from, or use by, the facility.
- The beyond-use date (BUD) shall be the manufacturer's expiration date, the maximum allowed BUD for the packaging, or not more than 12 months from the date of packaging, whichever is earlier.
- Each label shall contain:
    - Generic drug name and manufacturer. If brand name drug is used, brand name may be substituted for generic.
    - Strength and quantity
    - Lot number, date of packaging, name of personnel responsible for packaging
    - BUD
    - Any necessary auxiliary labels
- If the pharmacy record includes the manufacturer name, lot number, date of packaging, and name of personnel responsible for packaging, this may be removed from the label.

Prescription Refill Transfers (KAR 68-7-19)

- Transfers may only be initiated by authorization from a patient or caregiver.
- Transferring pharmacy shall cancel ("void") the prescription and document:
    - Receiving pharmacy name, address, phone number
    - Receiving pharmacy DEA number for C-III, IV, and V prescriptions
    - Date of request
    - Date of transfer
    - Name of person transferring and name of supervising pharmacist
    - Name of person receiving and name of supervising pharmacist
- Receiving pharmacy must add to current documentation:
    - Name of person transferring and name of supervising pharmacist
    - Name of person receiving and name of supervising pharmacist
- If the pharmacy uses electronic recordkeeping, that system may be used to document in lieu of manual documentation on paper prescription.
- Transferring and receiving pharmacies using a common recordkeeping system permitting electronic transfer of prescriptions shall ensure there are policies and procedures to accommodate the regulation requirements in the shared system.
- Pharmacists and interns under direct supervision of a pharmacist may transfer/receive refillable prescriptions by direct verbal communication, fax, or automated computer software.
- Technicians under direct supervision of a pharmacist may transfer/receive refillable prescriptions for non-controlled substances by fax or automated computer software, if the technician has passed a certification exam approved by the Board.
- A pharmacist or intern may forward an original, unfilled prescription. A technician cannot.

Controlled Substance Act

- Updates to definitions (KAR 68-20-1)
- Inventories (KAR 68-20-16)

  - Required to be kept as outlined in federal regulations and must include drugs of concern.
  - Controlled substance inventories are required to be kept in hard-copy form at the facility for five years and must include:
    - Date of inventory
    - Name, license, registration number, signature of each person participating
    - Documentation of whether taken before open or after close; 24-hour facilities document exact time of inventory
  - After the initial inventory, subsequent inventory is required at least annually but no more than 375 days after the previous inventory
  - Inventory for all substances must be completed on the same day
    - CII: exact count
    - CIII-V: Exact count except for bulk oral liquid dosage forms
- Prescriptions (KAR 68-20-18)
  - A pharmacist shall not fill a prescription for a controlled substance or drug of concern for office use. A pharmacist may invoice a registrant for distribution of a controlled substance or drug of concern.
  - No pre-printed or rubber-stamped prescriptions
  - Electronic prescriptions must meet federal requirements
  - C III-V prescriptions may be issued as paper or electronic prescriptions or transmitted by the prescriber or the prescriber's agent to the pharmacy orally or by fax. Except as authorized by KAR 68-2-22, each non-paper prescription order shall be reduced to hard copy as soon as it is reviewed by the pharmacist. The hard copy must include everything normally required except the signature of the prescriber in the case of oral transmission and must include the name of the person transmitting the prescription. *Note:* Per K.S.A. 65-16,128, every prescription order issued for a controlled substance that contains an opiate shall be transmitted electronically.
  - If multiple C-II prescriptions are legitimate, meet the requirements, and do not cause harm or risk to the patient, the pharmacist can fill multiple prescriptions in accordance with the dates indicated by the prescriber for a patient to receive up to a 90-day supply of medication.
- Recordkeeping and Pharmacy Prescription Application (KAR 68-20-18a)
  - Controlled substances must be dispensed pursuant to KAR 68-20-18.
  - Controlled substances shall be supplied for immediate administration pursuant to a medication order.
  - Each dispense, partial fill, or refill of a prescription for a controlled substance shall be entered on the back of the prescription with the date, quantity, and name or initials of the pharmacist providing the final verification, or a pharmacy prescription application may be used for the storage and retrieval of this information if the following conditions are met:
    - Each computerized system shall provide online retrieval, by computer monitor display or hard-copy printout, of original prescription order, refill, and partial fill information for prescription orders. Each display or printout shall include:
      - The original prescription number;
      - the date of issuance of the original prescription order by the prescriber;
      - the dates of dispensing or partial filling;
      - the full name and address of the patient;
      - the name, address, and DEA registration number of the prescriber;

- the name, strength, dosage form, quantity of the controlled substance prescribed, and the quantity dispensed, if different from the quantity prescribed;
- the identification code, or name or initials of the dispensing pharmacist;
- the total number of refills authorized by the prescriber, if applicable and allowable; and
- the total number of doses dispensed to date for that prescription order.

▪ Each pharmacist who uses a pharmacy prescription application shall document that the information in the pharmacy prescription application is correct each time the pharmacist fills, refills, or partially fills any controlled substance.

- If the pharmacy prescription application produces a hard-copy printout of each day's prescription order data, the printout shall be:
  - verified, dated, and signed by the pharmacist who filled or partially filled the prescription order.
  - provided to each pharmacy using the computerized system within 72 hours of the date on which the controlled substance was dispensed.
  - verified and signed by each pharmacist involved in dispensing.
- In lieu of signing a hard-copy printout of each day's controlled substance prescription order data, the pharmacy owner shall maintain a bound logbook or separate file in which each pharmacist involved in the dispensing shall sign a statement each day, attesting to the fact that the information entered into the pharmacy prescription application that day has been reviewed by the pharmacist and is correct as shown.

▪ Each pharmacy prescription application shall have the capability of producing a printout of any fill data that the facility is responsible for maintaining. Each printout shall include an audit trail for any specified strength and dosage form of any controlled substance, by brand, generic name, or both, in addition to:

- The name of the prescriber;
- the name and address of the patient;
- the quantity dispensed on each fill;
- the date of dispensing of each fill;
- the name or identification code of the dispensing pharmacist; and
- the number of the original prescription order.

▪ If a pharmacy experiences an outage of the pharmacy prescription application, the pharmacy shall have an auxiliary procedure that will be used for documentation of partial fills and refills.

- C-IIs (KAR 68-20-19)
  - A prescription may not be dispensed:
    - more than 90 days after the date of issue;
    - before any date indicated on the prescription by the prescriber that it may not be filled before that date; or
    - after any date indicated on the prescription by the prescriber that it may not be filled after that date.
  - Regulations are updated to include requirements for electronic C-II prescriptions.

    - Any prescription for a C-II may be partially filled at the request of the patient or the prescriber. The pharmacist shall not fill or partially fill any remaining portions of the prescription more than 30 days after the date written. Total quantity dispensed shall not exceed the total prescribed. Exception for the 60-day partial fill allowance in long-term care facilities or hospice.
    - Updating labeling requirements to match state (KAR 68-7-14) and federal (21 CFR 290.5)
- Adding C-V prescriptions to the regulation governing C-III and IV prescriptions (KAR 68-20-20)
- Any controlled substance (II-V) that is not prescription-only may be sold by a pharmacist to a consumer without a prescription if: (KAR 68-20-22)
    - Methamphetamine precursors are sold in compliance with federal regulations
    - Other substances are:
        - Sold only by a pharmacist
        - Max quantity sold within 48 hours to same consumer
            - No more than 240 cc (8oz) or 48 dosage units of any substance containing opium
            - No more than 120 cc (4oz) or 24 dosage units of any other substance
        - Consumer is at least 18 years old and provides valid ID
        - Maintain bound record book (must be paper)

Prescription Monitoring Program Act

- Updates to definitions (KAR 68-21-1)
- Dispensations must be submitted by the end of the next business day from the day when they were sold.
    - Based on updates to K.S.A. 65-1683 last year, the sold date is also required to be reported.
- Zero reports are required by the end of the next business day following a day when no controlled substances or drugs of concern were dispensed.
- Criteria for receiving an exemption from reporting requirements has changed, and exemptions must be renewed annually. More information: Reporting to K-TRACS (ks.gov)
- Reporting format updated to ASAP 4.2B
- Pharmacies must correct reporting errors within 7 days of discovering the error or being notified of the error by the Board or the Board's designee, which includes the K-TRACS vendor, Bamboo Health.
- Waivers allowing for submission of paper reports no longer allowed.
- Updates to program information access restrictions (KAR 68-21-5)
- See more information on updates to K-TRACS Reporting Requirements on page 9.

Pharmacist Statewide Protocol

The Collaborative Drug Therapy Management Advisory Committee has adopted the following Protocol for Suspected Acute Uncomplicated Lower Urinary Tract Infection in Women, which is now available on the Board website for review and participation: https://pharmacy.ks.gov/resources-consumer-info-2/collaborative-practice.

To participate, pharmacists must complete the following:

1. Complete the training and obtain necessary credentials
2. Review and Sign the Protocol

    Acute Uncomplicated UTI - Women 18-64

3. Maintain a copy of the Protocol for 10 years at each location where it is used by the pharmacist. (Copies do not need to be sent to the Board office.)

The Board has also published answers to frequently asked questions and will update that document with additional information as necessary. Participating pharmacists are required to exercise standard of care in addition to following the protocol in providing services.

Pharmacy Technician Updates

Technician Immunizations

During the 2023 session, the Kansas Legislature passed SB 131, which became effective July 1, 2023. The law updates K.S.A. 65-65-1635a to allow pharmacy technicians to administer immunizations under the direct supervision of a pharmacist. Previous authority was limited to that under the Federal PREP Act. Participating technicians must be over 18 years of age, complete the ACPE training course, and have a current CPR certificate.

The Board will review updates at its meeting on July 27, 2023, to expand its Guidance Document for Intern Vaccination Administration Authority to include pharmacy technicians. If approved, the guidance will include: "Technicians are not required to have a signed protocol or be party to a protocol between their supervising pharmacist and a licensed physician."

Pharmacy Technician Certification Examination

All pharmacy technicians registered on or after July 1, 2017, will be required to pass a national pharmacy technician certification examination (KAR 68-5-17).

The Board has approved the Pharmacy Technician Certification Board (PTCB) and the National Health Career Association Examination for the Certification of Pharmacy Technicians (ExCPT). Please contact either organization for more information regarding the 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 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 technician's registration expiration date by completing an LA-75 Technician Certification Extension Request (Form LA-75).

Technicians are required to complete 20 hours of ACPE continuing education for each biennial renewal period. The hours must be complete within the registration period, i.e., November 1, 2021-October 31, 2023 (for licenses expiring October 31, 2023.

ANNOUNCEMENTS

- The Board will only accept current versions of Board of Pharmacy forms. Old forms will be returned (with payment) directly to the sender without processing. Current forms are available on the website: Board of Pharmacy Forms (ks.gov)
- The National Association of Boards of Pharmacy has compiled resources to help you prepare for DSCSA changes going into effect in November 2023. Familiarize yourself with the changes.

GET TO KNOW A BOARD MEMBER — Andy Truong, PharmD

Andy Truong, PharmD, is the pharmacy manager of a local specialty pharmacy in Wichita. He has been a member of the Board since 2020 and currently serves as the alternate investigative member. He also recently attended the National Association of Boards of Pharmacy (NABP) conference, serving as the voting delegate for Kansas.

Board member Andy Truong with Bart and Willie

At each NABP annual meeting, each board's delegate has the opportunity to vote on open officer and member positions of the executive committee, as well as voting upon proposed resolutions and amendments to the NABP constitution.

"It was a privilege and honor to be able to serve as our board's delegate, where I was able to cast votes that aligned with the best interests of my fellow board members and the agency," Truong said.

The results of the elections and proposed resolutions will ultimately set the direction of NABP over the next year to help the Kansas board address important issues in pharmacy practice and regulations.

"The networking opportunities found at the national and district meetings are invaluable to me as a board member. Over the three days, I was able to engage with dozens of other board members, where we exchanged ideas and experiences on how we were handling varying issues in pharmacy practice. I was particularly

enlightened by learning about how other boards were managing topics such as telepharmacy, technician scope, and point-of-care testing and treatment," Truong said.

The theme of this year's meeting was "Framing a New Practice Mindset." The pharmacy profession will always be subject to rapid changes in response to the frequent demands of the healthcare landscape, whether or not we are ready to make these changes.

"It is imperative that boards of pharmacy can collaborate to continue keeping patient safety at the highest regard, yet also have a renewed mindset where we are eliminating barriers that are restricting pharmacists and technicians from practicing at the top of their licenses. I was energized by the content shared about the work completed by various NABP task forces over the past year with recommendations to advance the pharmacy technician role and embrace technological innovations in pharmacy practice," Truong said.

ANNOUNCEMENTS

Reminder: Advance Practice Registered Nurses no longer require a responsible physician to practice in Kansas. Therefore, no supervising physician is required on a prescription issued by a Kansas-licensed APRN.

Update: An updated copy of the Board Rules and Regulations manual is available on the Board website.

K-TRACS UPDATE

K-TRACS Reporting Changes

The deadline for pharmacies to comply with implementation of new K-TRACS reporting requirements is November 1, 2023. K-TRACS has published a guidance document and updated its data submitter guide to assist pharmacies and their vendors with navigating these changes.

These changes are the result of updates to K.S.A. 65-1683 in 2022 and the Board's adoption of revisions to K.A.R. 68-21-1 through 68-21-5, which became effective June 2, 2023 (see page 6 for more information).

The guidance document is available on the K-TRACS website and has been disseminated to all major software vendors and all Kansas pharmacists-in-charge. Questions should be directed to pmpadmin@ks.gov.

Animal Prescriptions

Please note that clarifications regarding animal prescriptions are included in the guidance document. Pharmacies should not change how animal prescriptions are entered into pharmacy management systems, but vendors will need to alter how the prescriptions are reported from the pharmacy to K-TRACS.

How to Improve Reporting of Patient Names & Addresses

In any given month, K-TRACS receives thousands of prescription records containing PO boxes for patient addresses. K.S.A. 65-1626 (a) defines address, in relation to a prescription, as "the physical address where a

patient resides, including street address, city and state." Patient records in pharmacy dispensing systems should be updated to reflect the patient's physical address to ensure that address is transmitted to K-TRACS correctly.

K-TRACS also receives prescriptions with "unknown" and "need info" addresses. While placeholders may be needed while the pharmacy is confirming the information, the address must be updated to reflect the patient's physical address. If the patient is homeless, pharmacies can use the patient's nearest intersection or the term "homeless" as the street address instead of "unknown."

Patient names should be verified against the prescription, and pharmacies should double-check the spelling of patient names to ensure accuracy. Correct patient names are critical to K-TRACS users' ability to search for and successfully locate patient records in the K-TRACS database. Examples of incorrect names include:

- Including instructions or locations about the patient in the name, i.e., John Smith Always Mail, Jane Jones LTC, etc.
- Reversing the patient's first and last names, i.e., Smith John, Jones Jane, etc.
- Spelling names like they sound via phoned-in prescription instead of verifying spelling, i.e., Jane Jones instead of Jayne Jones or John Smith instead of Jon Smith
- Using abbreviations like Rev., Fr., Sr., Dr. as the patient's first name

Pharmacies may be contacted to correct patient names and addresses when these issues are discovered by K-TRACS staff.

Continuing Education

To comply with KAR 68-1-1b, all pharmacists renewing their license after July 1, 2023, will be required to complete 1 hour of continuing education designated by the Board as part of their 30-hour requirement for renewal. The course currently designated by the Board is titled "K-TRACS for Pharmacies: Good Data In, Good Data Out." It is self-paced, available online and focuses on K-TRACS reporting requirements and use of patient prescription history in clinical decision-making.

The course is available for 1 hour of ACPE credit for both pharmacists and technicians. *Note: There is no Kansas regulatory requirement for technicians to complete the course.* Enroll in the course after July 17th: https://pharmacy.ks.gov/k-tracs/pharmacists/continuing-education

The Kansas State Board of Pharmacy has collaborated with the Accreditation Council for Pharmacy Education to award continuing pharmacy education credit for this activity: UAN KS7002-0000-23-001-H03-P and UAN KS7002-0000-23-001-H03-T (1.0 contact hours, knowledge-based activity).

REVOKED LICENSES & 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 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:

- Anderegg, Maxwell, 1-106515 Case 22-302
- Fursman, Carly, 24-117159 Case 23-255
- Jones, Bre'anna, 24-116283 Case 23-270
- Money, Bryce, 24-114457 Case 23-230
- Nichols, Sheryl, 14-17507 Case 23-227
- Tang, Heather, 24-116750 Case 23-244
- Thomas, Victoria, 24-117039 Case 23-269
- Vaughan, Rivfka, 14-13314 Case 23-272
- Williams, Dajiah, 24-114022 Case 23-276

National News

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