Kansas Board of Pharmacy

NEWSLETTER

Compliance | Licensing & Registration | K-TRACS

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What's Inside:

DSCSA: How to Prepare

In November 2013, the Drug Supply Chain Security Act (DSCSA) was signed into law as Title II of the Federal Drug Quality and Security Act. Over a 10-year period ending in November 2023, the DSCSA was designed to track and trace prescription drugs distributed in the U.S. from the manufacturer all the way to the point of dispensing to the patient. Kansas law also requires that pharmacies, distributors, 3PLs, and manufacturers comply with all federal DSCSA requirements.

On August 25, the FDA announced a one-year "stabilization period" for DSCSA requirements that go into effect on November 27, 2023. In essence, the FDA is providing a delay of enforcement until November 2024. "FDA believes the compliance policies … will help supply chain stakeholders, particularly trading partners, by accommodating the additional time that may be needed to continue to develop and refine appropriate systems and processes to conduct interoperable, electronic tracing at the package level, to achieve robust supply chain security under the [DSCSA] while helping ensure continued patient access to prescription drugs."

While this will give everyone more time to obtain compliance, there is still a lot of work to be done in a short period of time and **this should not be used as an excuse to rescind contracts, slow progress toward compliance, or delay implementation until November 2024.**

In fact, there are many current DSCSA requirements with which Kansas facilities may not be in compliance.

- Does your facility conduct verifications for all upstream and downstream trading partners to ensure they are "authorized trading partners?" An authorized trading partner must have a registration in their state of residence and in Kansas (if non-resident).
- Do you have policies and procedures for ensuring authorized trading partners and verification?
- Do you verify that your distributor is an authorized distributor for the drug manufacturer (check manufacturer website)?

Effective November 27, 2023, DSCSA requires manufacturers, distributors, and dispensers to provide and receive transaction information (TI), including product identifier, and transaction statements in a secure, electronic, and interoperable manner. Paper transaction histories will no longer be provided. In addition, pharmacies are required to have policies and procedures for identifying, quarantining, and tracing suspect or illegitimate products (as defined by DSCSA). The Board will also have a role in this process, and **the initiation of a trace request by the Board must be responded to by a dispenser or trading partner within two days.**

A number of resources are available to assist dispensers with understanding current and future requirements under the DSCSA:

- ASHP Outline of Requirements
- NABP Free Home Study Videos and Upcoming Roundtables
- DSCSA Readiness Assistance — this site was developed collaboratively among supply chain trading partners to house educational information dispensers may find useful to assist in DSCSA implementation.

The Board has been engaged in a pilot project with the National Association of Boards of Pharmacy (NABP) for operation and implementation of their new platform, which will enable states to quickly and easily meet DSCSA requirements. Pulse by NABP™ is an inclusive, accessible, and secure digital platform that simplifies the process of achieving DSCSA compliance. Pulse provides access to user-friendly tools and a comprehensive network of verified relationships, enabling consistent communication with trusted partners across the supply chain. The Board hopes to use Pulse to contact trading partners and, potentially, to generate trace requests on suspect or illegitimate products.

Pharmacy Technician Examination, CE, and Renewal

Technician Registrations

Any pharmacy technician who is unable to take or pass the PTCB or ExCPT certification exam by **October 31, 2023**, may request a six-month extension at least 30 days before the technician's registration expiration date by completing a Technician Certification Extension Request Form (LA-75).

Continuing Education

All Kansas pharmacy technician registrations expiring October 31, 2023 must complete 20 hours of ACPE/Board approved Continuing Education before their renewal. The 20 hours must be earned between November 1, 2021 - October 31, 2023.

Renewal

Pharmacy Technicians expiring October 31, 2023, can renew online beginning in mid-September. Renewal instructions are available at https://pharmacy.ks.gov/licensing-registration/pharmacy-technicians. To renew, go to ksbop.elicensesoftware.com/portal_logon.aspx.

Failing to renew on or before 11:59pm CST October 31, 2023, will result in the registration being cancelled.

COMPLIANCE CORNER

Pre-Opening Inspections

The Kansas Board of Pharmacy inspectors will inspect a facility BEFORE a registration is issued. The inspection will be conducted during normal business hours and requires the presence of the pharmacist-in-charge if the facility type requires a pharmacist-in-charge. Other facilities must have the designated responsible person or owner present for the preopening inspection.

You can see an inspection form used by the inspectors as a general guide to what will be observed. Not all items on the list are required for every business. Inspectors will survey for the specific requirements for each business type. Please review the statutes and regulations available on the board website for our requirements specific to your business type.

During the inspection, ALL portions of the building must be available to be inspected. Locked doors must be able to be opened for the inspection. If there is a basement or upstairs as part of the building, those areas must be available as well. Any portion of the building where access is denied to the inspector shall cause the preopening inspection to be noncompliant and no registration issued.

Prescription Forgery

BEWARE! Prescription forgery is on the rise. Fake prescriptions are being phoned, faxed, and electronically sent in Kansas. Over the past couple of years countless reports have been received by the Board from pharmacists receiving fake prescriptions for large quantities of promethazine with codeine syrup, usually accompanied by a prescription for an antibiotic, a steroid, or an inhaler to make it seem more legitimate. Most recently in the Wichita area there have been reports of forged prescriptions for promethazine (plain) syrup in large quantities paired with a prescription for benzonatate.

Questions to consider when presented with a new prescription include whether the drug is known to be abused, whether the pharmacist knows the patient and/or the prescriber, and where the patient lives. If you have questions about any aspect of the prescription order, call the prescriber for clarification at a researched phone number instead of simply relying on the one given on the prescription order.

If you believe that you have received a forged prescription, don't dispense it, and call your local police. Contact other area pharmacies and your Board inspector if you suspect you have discovered a pattern of prescription forgeries. Everyone working together can increase awareness of what to watch for so we can prevent illcit activity.

New Emergency Opioid Antagonist Protocol

The Board has approved a new emergency opioid antagonist (EOA) protocol that adds the recently approved opioid antagonist drug nalmefene in a ready-to-use nasal spray device to the drugs that may be dispensed. The new protocol is available on the Board's website.

The new EOA protocol does not invalidate the previous protocol so there is no requirement to sign and submit a new protocol. A pharmacist may continue to operate under the previous EOA protocol, but they will not be able to dispense nalmefene RTU nasal spray without a prescription if they do not choose to switch to the new one.

Remember:

- Keep copies of all protocols at all pharmacies for 5 years after the protocol was last used at that site.
- A pharmacist only signs one protocol for use at all locations. A separately signed protocol is not required for each practice location. The pharmacist must keep a copy of their protocol at all pharmacy locations where it is utilized.
- Only a copy of the signature page of the protocol, not a copy of the entire document, needs to be sent to the office upon initiation or discontinuation of the EOA protocol. After signing, the protocol can be uploaded to the Board's website, faxed or emailed to the Board office.

Transfer of an Unfilled Controlled Substance Prescription

On July 27, 2023, the DEA issued their final rule "Transfer of Electronic Prescriptions for Schedules II-V Controlled Substances Between Pharmacies for Initial Filling." The Federal Register Notice may be accessed online. Please note that the prescription must be transferred in its electronic form and may not be converted to any other form (ex. paper, facsimile). You will need to verify with your software vendor whether your pharmacy system has electronic forwarding capabilities.

The final rule also says these transfers are only permissible if allowed by state law. Kansas does not have any statutes or regulations that prohibit these transfers if they are done in accordance with all federal rules and regulations.

Picking Up Dispensed Controlled Substance Prescriptions

The Board of Pharmacy does not have any requirements for obtaining or checking ID when a prescription for a controlled substance is being picked up. A pharmacy may choose to establish a store policy requiring ID for picking up controlled substance prescriptions if they wish.

Scan and Shred of Hard Copy Prescriptions

The board has offered guidance in the maintenance of digital copies of noncontrolled substance prescriptions. K.A.R. 68-7-8 requires the digital image to contain the front and back of the prescription. The question has arisen about whether an image of the back of the prescription needs to be scanned and saved if it is blank. The Board stated that an image of the back of the prescription does not need to be created and maintained to be in compliance if the back of the prescription was blank. However, the pharmacy and involved pharmacy staff will be held responsible if there was information on the back and an image was not created and maintained.

Partial Filling of Prescriptions for Schedule II Controlled Substances

The final rule from the DEA regarding partial filling of schedule II prescriptions went into effect August 21, 2023. The final rule includes documentation requirements that pharmacists will want to familiarize themselves with. Please see 21 CFR § 1306.13 for more information.

National News

Read the latest news from the National Association of Boards of Pharmacy
>> Read National News

K-TRACS UPDATE

K-TRACS Reporting Changes Deadline: November 1

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.

The guidance document is available on the K-TRACS website. Pharmacies should notify their software vendors of the required changes. Questions should be directed to pmpadmin@ks.gov.

XDEA Numbers No Longer Valid in K-TRACS Reporting

Starting September 20, prescriptions reported with an "X" DEA number in the Prescriber DEA (PRE02) field will produce an error, requiring record correction to the standard DEA of the issuing prescriber. "X" DEA numbers are no longer recognized as valid by SAMHSA or DEA.

Pharmacies should review their known buprenorphine prescribers and ensure a valid DEA number is associated with the prescriber to prevent errors from occurring when the prescription is reported to K-TRACS.

If an error occurs due to an "X" DEA number reported as the prescriber identifier, pharmacists in charge (PICs) should login to their K-TRACS accounts to correct the error within 7 days of receiving notification (K.A.R. 68-21-2).

For questions, please email pmpadmin@ks.gov or call 785-296-6547.

2023 Kansas Opioid and Stimulant Conference

The Kansas Opioid and Stimulant Conference will be held in Wichita this year at the Hyatt Regency on November 28, 2023, 8am – 5pm. Visit the DCCCA web page to learn more about the agenda and registration. Early bird registration closes October 16.

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:

- Carpenter, Stephanie, 14-18092 Case 23-065
- Christensen, Andrew, 14-107367 Case 23-067
- Farrell, Jennifer, 14-07790 Case 23-081
- Garmany, Breawna, 24-113864 Case 23-302
- Glover Jr., David, 14-112515 Case 23-085
- King, Joy, 14-06144 Case 23-100
- Nuzum, Bailey, 24-117164 Case 23-291
- Palmer, Kylea, 14-108024 Case 23-125
- Smith, Kiana, 14-113187 Case 23-139
- Sosa-Torres, Marisela, 14-111103 Case 23-141
- Turks, Nakeemah, 14-102743 Case 23-151