AUGUST 24, 2025

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ACPE UAN 0143-9999-25-078-L03-P/T

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DISCLOSURES

- Alexandra Blasi, faculty for this CE activity, has no relevant financial relationship(s) with ineligible companies to disclose.
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LEARNING OBJECTIVES

- Identify recent changes to Board statutes and regulations
- Explain new guidance from the Board
- Provide opportunities for licensee engagement and participation
- Review new Board members
- Discuss the K-TRACS program and best practices

PRE-TEST QUESTIONS

1. Who are the new Kansas Board of Pharmacy Members?
2. Where can I find draft regulations being considered for promulgation by the Board?
3. How often should the PIC have quarterly CQI meetings with staff?
4. What law governs the compounding of GLP-1 and similar medications?
5. How many FTEs can a pharmacy have and still be considered a small dispenser under DSCSA?

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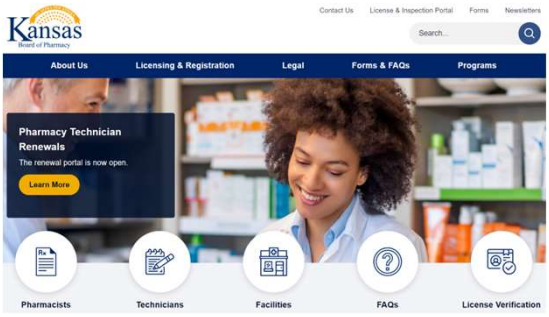
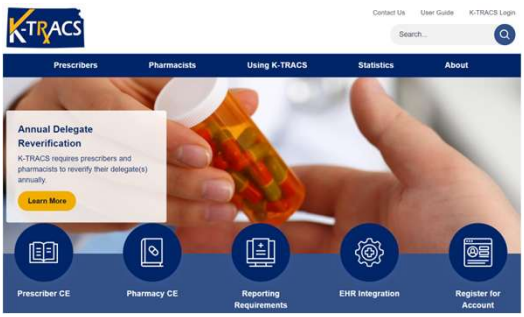
BOARD AND K-TRACS WEBSITE

www.pharmacy.ks.gov



www.ktracs.ks.gov



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NEWSLETTERS AND CE

- PIC must review and post Board Newsletter in pharmacy
  - Released by Board in odd months (Jan, Mar, May, Jul, Sept, Nov)
  - Emailed and posted to Board website
  - https://www.pharmacy.ks.gov/about-us/newsletters
- Pharmacist Renewals – 30 hrs CE
  - New required Board CE Course (1-hr), KAR 68-1-1b
    - ACPE-approved
    - Free, online, on-demand
  - 2025 Renewal: K-TRACS online course
  - 2026-2027 Renewals – Newsletter Articles
  - https://pharmacy.ks.gov/k-tracs/pharmacists/continuing-education

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2025 WELLBEING FIRST CHAMPION!

- This annual distinction means that our pharmacist, pharmacist intern, and technician applications and renewals are free from intrusive and stigmatizing language around mental health care and treatment. We have taken steps to ensure that our workforce can seek needed care without fear of losing their license
- ALL IN: Wellbeing First for Healthcare, a national coalition of leading healthcare organizations that work to remove barriers for health workers to access mental health care.
- https://drlornabreen.org/

2025 LEGISLATION

- SB 63 – related to gender-affirming pediatric healthcare
- SB 67 – Nurse Anesthetists
- HB 2134 – Updates to Kansas Open Records Act
- SB 77 - Requiring state agencies to provide notice of revocation of regulations to the public
- SB 193 – Additional allowances for law enforcement providing emergency opioid antagonists
- SB 250 – "Right to Try"
- HB 2291 – Regulatory Sandbox

2024 REGULATION CHANGES

- Delivery of prescriptions dispensed to an alternate site for administration, KAR 68-7-20a
  - Regulates "white bagging"
  - Requires "originating pharmacies" to maintain policies and procedures for record-keeping, tracking, confidentiality, and ensuring the drug reaches the administering facility in good condition.
  - Requires "originating pharmacies" to ship drugs properly, notify the administering facility of expected shipment, and process of returning unopened prescription medication.
  - Details the process for returning unadulterated prescriptions to stock.
- Pharmacy Owners Responsibilities, KAR 68-2-24
  - Each pharmacy owner shall not prohibit or prevent their pharmacy employee from complying with pharmacy law.
  - Each pharmacy owner shall not punish or prevent a pharmacist from conducting an in-person inspection of a drug/device.
  - Each pharmacy owner will not allow an individual who has had their pharmacy license or registration denied/revoked/suspended into the pharmacy unless it was re-instated.

2024 REGULATION CHANGES

- Continuous Quality Improvement (CQI), KAR 68-19-1
- What are the big changes to the process?
  - Communicate with each employee involved in the incident.
  - Complete a root cause analysis.
  - Create a corrective action plan.
  - Create a summary and communicate its contents with staff by the 15th of each even month.
  - The ability to actively participate in a PSO (Patient Safety Organization) to fulfill some of the CQI requirements.
  - Review of an incident begins within seven days of becoming aware of the incident.
  - Review of the incident must be completed within 30 days of the incident report's creation.
- Who is responsible?
  - The pharmacist-in-charge (PIC) has the ultimate responsibility to make sure the program is established and maintained.
  - A pharmacist that becomes aware of an incident shall report the incident to the PIC and shall prepare an incident report per K.A.R. 68-7-12b.
  - Ultimately, everyone is responsible to work to decrease the errors in the pharmacy.

2025 REGULATION CHANGES

- K.A.R. 68-7-10. Emergency medication kits in long-term care facilities.
  - eKits
- K.A.R. 68-7-10a. Pharmacy based drug dispensing systems in a facility.
  - Automation
- K.A.R. 68-21-2. K-TRACS electronic reports.
  - Adding a reporting exemption for 24-hour supplies to inmates at a correctional institutions.

KANSAS RULEMAKING PROCESS

- To promulgate a regulation, the Kansas Board must follow the rulemaking procedures specified in the Administrative Procedure Act. The general process* is summarized below (note: the Board may stop pursuing a regulation at any point in the process):
  1. The Board becomes aware of changes necessary to their regulations.
  2. The Board approves the proposed draft regulation.
  3. Stakeholders have the opportunity to review the draft regulation.
  4. The Board submits the draft regulation to:
     - The Department of Administration,
     - The Attorney General, and
     - The Division of the Budget.
  5. The Board hears public comments on the proposed draft regulation.
  6. The Board votes to either adopt, reject, or table the regulation.
  7. If the Board votes to adopt, the regulation becomes effective 15 days after publication in the Kansas Register.

See K.S.A. 77-420

REGULATIONS IN DRAFT

- https://www.pharmacy.ks.gov/legal/proposed-state-reg-changes
- KAR 68-1-1a – Application for registrations or permits; withdrawal of application
- KAR 68-5-17 – Pharmacy technicians; certification examination; request for extension
- KAR 68-7-14 – Prescription labels
- KAR 68-7-21 – Institutional drug rooms
- KAR 68-7-26 – Application for licenses, registrations, or permits; withdrawal of application
- KAR 68-14-9 – DSCSA Notification and Compliance
- KAR 68-20-15b – Notification to board; suspected diversion, theft, or loss of controlled substances

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DRAFT COMPOUNDING REGULATION CHANGES

- 68-7-24 – Compounding: Hazardous Drugs
- 68-10-1 – Compounding: Radiopharmaceuticals
- 68-13-2 - Compounding: Definitions
- 68-13-3 – Compounding: Nonsterile preparations
- 68-13-4 – Compounding: Sterile preparations

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EXAMINATION OF EXPIRED PHARMACY TECHNICIANS

- Board Guidance updated May 22, 2024
- LA-75 requests for additional time now accepted until October 31
- All registered or expired technicians now have the option of a 6-month extension to pass the exam
  - Provides guidance for pharmacy technicians who originally registered after July 1, 2017, and needs more time to pass the PTCB or ExCPT certification examination.
  - Provides guidance for pharmacy technicians who originally registered before July 1, 2017, have since let their registration expire due to not renewing, and are seeking to reapply.
- Regulation change pending (KAR 68-5-17)

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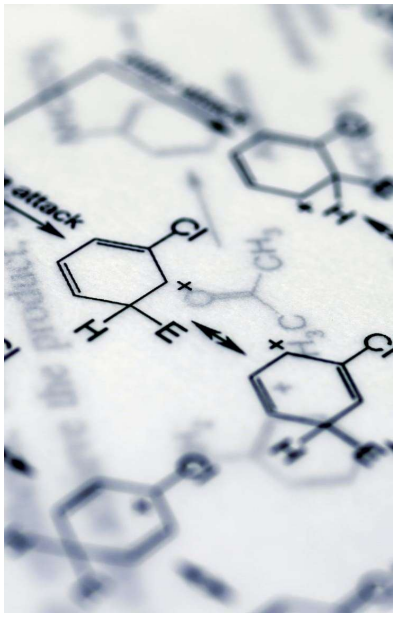
COMPOUNDING AND DISPENSING OF COMPOUNDED GLP-1 AND GIP RECEPTOR AGONISTS

- Board Guidance issued updated guidance April 17, 2025
- Compounding "drug products that are essentially copies of a commercially available drug product" is prohibited unless:
  - The drug is on the FDA drug shortage list, or
  - There is a specific change for an identified patient whose medical needs cannot be met by the commercially available product, e.g. lactose allergy
- Compounders must ensure drug is being compounded with a drug form approved by the FDA, e.g. not a salt form, not for research-only.
- FDA guidance explains what is required for "specific change" for patient
  - Documentation
  - Component parts
- All court-based injunctions and wind-up periods over/denied
- https://www.pharmacy.ks.gov/legal/reports-guidance-docs



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DSCSA READINESS AND ENFORCEMENT

- Trading Partner Exemptions
  - Manufacturers and Repackagers – May 27, 2025
  - Wholesale Distributors – August 27, 2025
  - Dispensers with 26+ FTEs – November 27, 2025
- Waiver, Exception, Exemption (WEE)
- https://www.fda.gov/media/182584/download?attachment
- https://dscsa.pharmacy/
- https://nabp.pharmacy/pulse/

DSCSA BEST PRACTICES (FROM FDA)

- FDA has provided some specific transaction scenarios that could significantly increase the risk of suspect product entering the drug supply chain, and has recommended that trading partners be particularly diligent when engaging in such transactions. Such scenarios include:
  - Purchasing product that is generally in high demand in the U.S. market;
  - Purchasing product that has been or is the subject of a public alert or announcement related to drug quality issued by a trading partner or FDA;
  - Purchasing product that has been or is the subject of an FDA counterfeit alert;
  - Purchasing product from a trading partner that has been involved in business transactions where they sold or delivered illegitimate product; and
  - Purchasing product where the finished dosage form seems questionable (e.g., it has a different shape or color from the FDA-approved product, a different or unusual imprint, an unusual odor, or there are signs of poor quality like chips or cracks in tablet coatings or smeared or unclear ink imprints).
- https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/sterling-distributors-706508-06052025

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POST-TEST QUESTIONS

1. Who are the new Kansas Board of Pharmacy Members?
   a. Bill Walden
   b. Jonathan Brunswig
   c. Janine Ohler
   d. Joanna Robinson
2. Where can I find draft regulations being considered for promulgation by the Board?
   a. Board website at https://www.pharmacy.ks.gov/legal/proposed-state-reg-changes
   b. Join the Mailing List (Bradford.deyoung@ks.gov)
   c. Board Newsletter
   d. All of the above
3. How often should the PIC have quarterly CQI meetings with staff?
   a. Quarterly
   b. Monthly
   c. Bimonthly
   d. Quarterly CQI meetings are no longer required. Bimonthly communication with all pharmacy personnel is required. See KAR 68-19-1.

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POST-TEST QUESTIONS

4. What law governs the compounding of GLP-1 and similar medications?
   a. Federal Law and Guidance
   b. State Law and Guidance
   c. Both a and b
   d. None of the above
5. How many FTEs can a pharmacy have and still be considered a small dispenser under FD&C Act: DSCSA?
   1. 25
   2. 50
   3. 75
   4. 150

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QUESTIONS?

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