

Point-of-Care Testing; K-TRACS Amendments; SB 200

SB 200 amends the Pharmacy Act of the State of Kansas (Pharmacy Act) to include point-of-care testing for and treatment of certain health conditions (therapy).

The bill also amends provisions of the Prescription Monitoring Program Act (Program Act) to add to the list of information a dispenser may submit to the Prescription Monitoring Program (K-TRACS), amends the list of individuals who may request and receive data from K-TRACS, amends how data are stored outside of K-TRACS, and adds one member to the K-TRACS Advisory Committee for a total of ten members.

The provisions of the bill relating to K-TRACS will take effect upon publication in the *Kansas Register*.

Therapies Covered

The bill authorizes a pharmacist to initiate therapy within the framework of new statewide protocols for the following health conditions:

- Influenza;
- Streptococcal pharyngitis; or
- Urinary tract infection.

Statewide Protocols

The bill authorizes the state Collaborative Drug Therapy Management Advisory Committee (Collaborative Committee) to adopt a statewide protocol for each of the conditions listed above. In establishing such statewide protocols, the Collaborative Committee is required to specify:

- The medications or categories of medications included in the protocol for each health condition;
- The training and qualifications required for pharmacists to implement the protocols;
- Requirements for documentation and maintenance of records, including:
 - Patient inclusion and exclusion criteria;
 - Medical referral criteria;
 - Patient assessment tools based on current clinical guidelines;
 - Follow-up monitoring or care plans; and

- The pharmacist's adherence to the applicable protocols; and
- Communication requirements, including, but not limited to, notification of the patient's personal or primary care provider.

Disciplinary Action

The bill authorizes the State Board of Pharmacy (Board) to deny a license application or renewal or to revoke or suspend the license of a pharmacist if the Board finds the pharmacist has violated the provisions relating to the initiation of therapy or failed to practice within the framework of the protocols established by the Collaborative Committee.

Pharmacy Act Definition

The bill amends the definition of "practice of pharmacy" in the Pharmacy Act to include the initiation of therapy for the conditions listed above.

Program Act Definitions

The bill adds definitions to the Program Act and amends others, as follows:

- Adds "audit trail information" to mean information produced regarding requests for K-TRACS data that the Board and the K-TRACS Advisory Committee use to monitor compliance with the Program Act;
- Adds "delegate" to mean:
 - A registered nurse, licensed practical nurse, respiratory therapist, emergency medical responder, paramedic, dental hygienist, pharmacy technician, or pharmacy intern who has registered for access to the K-TRACS database as an agent of a practitioner or pharmacist;
 - A death investigator who has registered for limited access to K-TRACS as an agent of a medical examiner, coroner, or another person authorized under law to investigate or determine causes of death; or
 - An individual authorized to access the database by the Board in rules and regulations;
- Amends "dispenser" to include a pharmacy as an entity that delivers a scheduled substance or drug of concern to an ultimate user;
- Adds "pharmacy" to mean a premises, laboratory, area, or other place currently registered with the Board where scheduled substances or drugs of concern are offered for sale or dispensed in the state; and
- Adds "program" to mean the prescription monitoring program (K-TRACS).

K-TRACS Information

The bill amends a provision in the Program Act requiring a dispenser to submit to the Board by electronic means information required by the Board regarding each prescription dispensed for scheduled substances and drugs of concern. The bill adds to the list of information a dispenser may submit, as required by the Board:

- The diagnosis code;
- The patient's species code; and
- The date the prescription was sold.

The bill also removes the Board's authority to issue a waiver to a dispenser to allow submission of data by paper or other non-electronic means.

The bill authorizes the Board to enable features and include additional information in the database, including:

- The date or fact of death;
- The dispensation or administration of emergency opioid antagonists, as defined in statute; and
- The data related to an overdose event.

K-TRACS Data

The bill amends the Program Act to include audit trail information as privileged and confidential information not subject to subpoena or discovery in civil proceedings.

The bill amends a provision in the Program Act authorizing the Board to provide data to Board personnel to specify the data provision would be for the purposes of the operation of K-TRACS, in addition to administration and enforcement.

The bill expands the list of individuals who may request and receive data from K-TRACS to include:

- Practitioners, as designated representatives from the Kansas Department of Health and Environment regarding authorized Medicaid program recipients;
- Individuals operating a practitioner or pharmacist impaired-provider program for the purpose of reviewing drugs dispensed to a practitioner or pharmacist enrolled in K-TRACS;
- Delegates of the following individuals currently authorized by the Program Act:

- Individuals authorized to prescribe or dispense scheduled substances and drugs of concern for the purpose of providing medical or pharmaceutical care for their patients and when an individual is obtaining prescriptions in a manner that appears to be misuse, abuse, or diversion of such substances or drugs; and
- Medical examiners, coroners, or other individuals authorized under law to investigate or determine cause of death;
- Individuals or organizations notified by the K-TRACS Advisory Committee;
- Practitioners or pharmacists conducting research approved by an institutional review board with patient consent for the release of program data; and
- An overdose fatality review board established by the State of Kansas.

Database Access Qualifications

The bill requires an individual registered for access to the K-TRACS database to notify the Board in writing within 30 calendar days of any action that disqualifies the individual from being authorized to receive K-TRACS data.

The bill requires the State Board of Healing Arts, Board of Nursing, Kansas Dental Board, and Board of Examiners in Optometry to notify the Board in writing within 30 calendar days of any denial, suspension, revocation, or other administrative limitation of a practitioner's license or registration that disqualifies a practitioner from being authorized to receive K-TRACS data.

The bill requires a practitioner or pharmacist to notify the Board within 30 calendar days of any action that disqualifies a delegate from being authorized to receive program data on behalf of a practitioner or pharmacist.

Data Reviews

The bill authorizes the K-TRACS Advisory Committee to notify the Disability and Behavioral Health Services Section of the Kansas Department for Aging and Disability Services for the purpose of offering confidential treatment services if a K-TRACS Advisory Committee review of K-TRACS data indicates an individual may be obtaining prescriptions in a manner that may represent misuse or abuse of scheduled substances and drugs of concern, and the review does not identify a recent prescriber as a point of contact for potential clinical intervention.

The bill replaces the term "controlled" substances with "scheduled" substances in the provisions of the Program Act relating to the K-TRACS Advisory Committee review of K-TRACS data.

The bill requires the K-TRACS Advisory Committee, if a review of information appears to indicate K-TRACS data has been accessed or used in violation of state or federal law, to

determine whether a report to the board overseeing the license of such individual is warranted and authorizes the K-TRACS Advisory Committee to make such report.

Data Authorizations

The bill authorizes the Board to provide K-TRACS data to medical care facilities for statistical, research, or educational purposes if all identifying information is removed.

The bill authorizes the Board to block any user's access to the K-TRACS database if the Board has reason to believe access to the data is or may be used by such user in violation of state or federal law.

Information Retention and Storage

The bill prohibits K-TRACS data from being stored outside of the database, with the following exceptions:

- Temporary storage necessary to deliver program data to electronic health records or pharmacy management systems approved by the Board;
- Retention of specific information or records related to a criminal or administrative investigation or proceeding;
- Program data provided to public or private entities for statistical, research, or educational purposes after removing information that could be used to identify individual practitioners, dispensers, patients, or persons who received prescriptions from dispensers; or
- Board retention of information for purposes of operation of K-TRACS and administration and enforcement of the Program Act or the Uniform Controlled Substances Act.

The bill amends the Program Act to remove:

- A requirement the information and records be destroyed after five years; and
- An exception to the destruction requirement for records a law enforcement or oversight entity has requested to be retained.

K-TRACS Advisory Committee Membership

The bill expands the membership of the K-TRACS Advisory Committee to a total of ten members by adding one member who is a licensed advanced practice provider nominated by either the Board of Nursing or the State Board of Healing Arts.