

**CONFERENCE COMMITTEE REPORT BRIEF
SENATE BILL NO. 200**

As Agreed to March 28, 2022

Brief*

SB 200 would amend 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 would amend 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), amend the list of individuals who may request and receive data from K-TRACS, amend how data is stored outside of K-TRACS, and add one member to the K-TRACS Advisory Committee for a total of ten members. The provisions of the bill relating to K-TRACS will be in effect upon publication in the *Kansas Register*. The bill would also make technical amendments.

Therapies Covered

The bill would authorize 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 would authorize 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 would be 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:

*Conference committee report briefs are prepared by the Legislative Research Department and do not express legislative intent. No summary is prepared when the report is an agreement to disagree. Conference committee report briefs may be accessed on the Internet at <http://www.kslegislature.org/kldr>

- 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 would authorize the State Board of Pharmacy (Board) to deny a license application or renewal or 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 new statewide protocols established by the Collaborative Committee.

Pharmacy Act Definition

The bill would also amend 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 would add definitions to the Program Act and amend others, as follows:

- Add "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;
- Add "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;
- Amend "dispenser" to include a pharmacy as an entity that delivers a scheduled substance or drug of concern to an ultimate user;
- Add "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

- Add “program” to mean the prescription monitoring program (K-TRACS).

K-TRACS Information

The bill would amend 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 would add 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 would remove 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 would authorize 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 would amend the Program Act to include audit trail information as privileged and confidential information not subject to subpoena or discovery in civil proceedings.

The bill would amend 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 would expand 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 (KDHE) 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 would require an individual registered for access to the K-TRACS database to notify the Board in writing within 30 calendar days of any action that would disqualify the individual from being authorized to receive K-TRACS data.

The bill would require 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 would disqualify a practitioner from being authorized to receive K-TRACS data.

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

Data Reviews

The bill would authorize the Committee to notify the Disability and Behavioral Health Services Section of the Kansas Department for Aging and Disability Services (KDADS) 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 would replace 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 would require 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 would authorize the K-TRACS Advisory Committee to make such report.

Data Authorizations

The bill would authorize 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 would authorize 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 would prohibit 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 would amend 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 would expand 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.

Conference Committee Action

The Conference Committee agreed to the provisions of SB 200, as amended by the House Committee on Health and Human Services, regarding point-of-care testing. The Conference Committee also agreed to add the contents of HB 2253, as amended by the House Committee on Social Services Budget, regarding amendments to the Prescription Monitoring Program Act.

Background

SB 200 (Point-of-care Testing)

The bill was introduced by the Senate Committee on Public Health and Welfare at the request of Senator Erickson.

Senate Committee on Public Health and Welfare

At the Senate Committee hearing on February 25, 2021, representatives of Balls Food Stores, Kansas Association of Chain Drug Stores, and Walmart provided **proponent** testimony. Proponents stated the bill would expand health care access for individuals without easy access to urgent care providers.

Written-only proponent testimony was provided by Americans for Prosperity, Currus Independent Pharmacies of Kansas, Kansas State Board of Pharmacy, and Kansas Pharmacists Association.

Representatives of the Kansas Academy of Family Physicians, Kansas Chapter of the American Academy of Pediatrics, and Kansas Medical Society (KMS) provided **opponent** testimony. The opponents stated the bill, as introduced, grants unnecessarily broad authority to pharmacists.

Written-only opponent testimony was provided by the Kansas Association of Osteopathic Medicine and Kansas Chiropractic Association.

No neutral testimony was provided.

The Senate Committee amended the bill to:

- Allow a pharmacist to initiate therapy within the framework of a statewide protocol for influenza, streptococcal pharyngitis, or urinary tract infection [Note: The amendment was retained by the Conference Committee.];
- Allow the Collaborative Committee to adopt a statewide protocol for each condition listed above [Note: The amendment was retained by the Conference Committee.];
- Require the Collaborative Committee to consider appropriateness of therapy based upon the factors above [Note: The amendment was not retained by the Conference Committee.]; and
- Amend the definition of “practice of pharmacy” in the Pharmacy Act to include the initiation of therapy for the health conditions specific above [Note: The amendment was retained by the Conference Committee.].

House Committee on Health and Human Services

At the House Committee hearing on March 14, 2022, representatives of Americans for Prosperity, Balls Food Stores, and Kansas Association of Chain Drug Stores provided **proponent** testimony. Proponents stated the bill would expand health care access for individuals without easy access to urgent care providers.

Written-only proponent testimony was provided by representatives of Currus Independent Pharmacies of Kansas, The Kansas Chamber, Kansas State Board of Pharmacy, Kansas Pharmacists Association, Richey's Drug Store, Inc., and Walmart.

Written-only opponent testimony was provided by representatives of the Kansas Academy of Family Physicians and the Kansas Chapter of the American Academy of Pediatrics.

Neutral testimony was provided by a representative of KMS, who provided background on the collaboration among the parties to arrive at a base compromise prior to the Senate Committee hearing during the 2021 Legislative Session. The representative noted the continued work to fine-tune the language of the compromise following the 2021 Session to address KMS concerns regarding the need to further refine the criteria the Collaborative Committee would consider in determining the appropriateness of the therapy. The representative stated the language of the further refined compromise is included in the KMS testimony as a proposed amendment.

The House Committee amended the bill to:

- Remove the items the Collaborative Committee would be required to consider in determining the appropriateness of therapy [Note: The amendment was retained by the Conference Committee.];
- Insert items the Collaborative Committee would be required to specify in establishing the statewide protocols [Note: The amendment was retained by the Conference Committee.]; and
- Insert language allowing the Board to take disciplinary action against a pharmacist who violates of the provisions related to the initiation of therapy or fails to practice within the framework of the statewide protocols [Note: The amendment was retained by the Conference Committee.].

The House Committee amendments reflect the compromise language proposed by KMS, with a few technical changes to adhere to Kansas statutory drafting style.

HB 2253 (Amending the Prescription Monitoring Program Act)

The bill was introduced by the House Committee on Social Services Budget at the request of Representative Carpenter.

House Committee on Social Services Budget

In the House Committee hearing on March 9, 2022, **proponent** testimony was provided by representatives of the Board of Pharmacy, Board of Nursing, the Kansas Hospital Association

and KMS. The proponents generally spoke to the updates to K-TRACS, data-sharing guidelines, and funding. According to the representative of the Board, the bill would increase K-TRACS utilization and ease of use, enhance data security, and enable more accurate patient information.

Neutral testimony was provided by representatives of the Kansas Association of Osteopathic Medicine, Kansas Optometric Association, and KDHE.

No opponent testimony was provided.

The House Committee amended the bill to:

- Add or amend definitions for “audit trail information,” “delegate,” “pharmacy,” and “program” in the Program Act [Note: The amendment was retained by the Conference Committee.];
- Expand K-TRACS data requirements to include the diagnostic code, species code, and the date the prescription was sold [Note: The amendment was retained by the Conference Committee.];
- Delete the fees for an initial set up and annual maintenance for the integration of K-TRACS [Note: The amendment was retained by the Conference Committee.];
- Expand the list of persons who may request and receive data from K-TRACS [Note: The amendment was retained by the Conference Committee.];
- Authorize the K-TRACS Advisory Committee to notify KDADS for the purpose of offering confidential treatment services [Note: The amendment was retained by the Conference Committee.]; and
- Expand the membership of the K-TRACS Advisory Committee by one member [Note: The amendment was retained by the Conference Committee.].

Senate Committee on Public Health and Welfare

The Senate Committee did not hold a hearing on the bill but did hold a hearing on the companion bill, SB 168, on February 10, 2022.

On March 23, 2022, the Senate Committee amended the bill to change the effective date from upon publication in the *Kansas Register* to upon publication in the statute book. [Note: The amendment was not retained by the Conference Committee.]

Fiscal Information

SB 200 (Point-of-care Testing)

According to the fiscal note prepared by the Division of the Budget on SB 200 as introduced, the State Board of Pharmacy indicates enactment of the bill would likely increase the necessary staff time to carry out the requirements of the bill; however, those requirements could be completed by current staff and within the State Board of Pharmacy’s current expertise,

due to the prevalence of similar statewide protocols used in other states. Any fiscal effect associated with enactment of the bill is not reflected in *The FY 2023 Governor's Budget Report*.

HB 2253 (Amending the Prescription Monitoring Program Act)

According to the fiscal note prepared by the Division of the Budget on HB 2253 as introduced, the Board indicates enactment of the bill would have no fiscal effect on the Board's expenditures as K-TRACS Advisory Committee members are not paid and meetings are held electronically. The Board states any K-TRACS changes resulting from enactment of the bill would be managed with existing staff, and the bill could create an opportunity for further federal grant funding. The Board states it could implement a fee-for-service integration component if and when federal grant funds are no longer available for the integration program. [Note: The House Committee removed this provision of the bill.] Currently, the integration program is funded by a federal grant from KDHE through August 2022.

The Board recommends creating a fee-based structure for participants in the integration program, which could be activated if grant funding opportunities no longer continue.

The Board proposes structuring these costs in a tiered-system based on the facility type (pharmacy, physician clinic, hospital, or health system) and the number of users or utilization level at the facility. The Board states this approach would ensure that costs would be manageable for all facilities and not act as a deterrent for use of this K-TRACS feature.

Additionally, the Board indicates traditional K-TRACS software would remain available to prescribers and pharmacists free of charge. Based on the current number of facilities voluntarily participating in the INTEGRx8 program, the Board estimates the facility cost would likely range from \$500 to \$3,000 per year. The Board would provide the exact costs through administrative rules and regulations in consultation with stakeholders and the K-TRACS Advisory Committee. Revenue would be deposited into the State Board of Pharmacy Fee Fund, from which expenditures would be made. Integration costs are estimated to be \$814,113 for FY 2022 and \$831,996 for FY 2023.

The Board of Nursing indicates enactment of HB 2283 would have a negligible fiscal effect on expenditures of that agency. The Board of Examiners in Optometry, the State Board of Healing Arts, and the Kansas Dental Board indicate enactment of HB 2283 would have no fiscal effect on the entities.

Any fiscal effect associated with the bill is not reflected in *The FY 2022 Governor's Budget Report*.

Pharmacy Act of the State of Kansas; Collaborative Drug Therapy Management Advisory Committee; health conditions; K-TRACS; Prescription Monitoring Program Act; Prescription Monitoring Program; State Board of Pharmacy; State Board of Pharmacy Fee Fund; pharmacy; prescriptions

ccrb_sb200_01_0000.odt