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Testimony concerning HB 2253
House Social Services Budget Committee
Presented by Alexandra Blasi, Executive Secretary
On behalf of
The Kansas State Board of Pharmacy

Chairman Carpenter and Members of the Committee:

The Kansas State Board of Pharmacy respectfully submits this testimony in support of HB 2253 and appreciates the Committee's consideration of the bill. House bill 2253 (and its correlate, SB 168) provides necessary updates to the Kansas Prescription Monitoring Program Act, otherwise known as the K-TRACS program. While the Board is responsible for operation of the K-TRACS program, it is also subject to oversight of the K-TRACS Advisory Committee, which is composed of prescribers, pharmacists, and a member of law enforcement. The Board and Advisory Committee have worked hard over the 12-year life of the program to provide essential functionality and services, while aiming to help healthcare providers prioritize patient safety; promote community health; prevent the misuse, abuse, and diversion of controlled substances and drugs of concern; and preserve legitimate access to controlled substances. Information on the program's success and status can be found in the enclosed 2022 K-TRACS Legislative Report.

Program History

In 2008, the legislature created the Prescription Monitoring Program Act to establish and maintain a prescription drug monitoring program for Schedule II through IV controlled substances and other drugs of concern. Law enforcement and health agencies recognized the abuse and diversion of controlled substances as an increasing threat. As a result, K-TRACS is a potent tool in aiding in the identification of patients with drug-seeking behaviors, providing treatment, and educating the public. Each pharmacy is required to electronically submit information to K-TRACS for each controlled substance prescription or drug of concern dispensed in an outpatient setting to a Kansas patient. If a prescriber or a pharmacist has a concern about a patient, they can look up the patient's prescription history in K-TRACS. Because K-TRACS is a real-time, web-based system, patient information can be obtained instantly from any location at any time with the proper login credentials. Prescribers and pharmacists must register for K-TRACS through the Board prior to utilizing the system. Each dispensing pharmacy is required to post a notice to patients about the availability and reporting of this information. Law enforcement and other state agencies have limited access to the program, but may request records with proper legal authority. In 2012, medical examiners were permitted access to K-TRACS so they could investigate and determine cause of death. In addition, de-identified or aggregate data may be provided to requestors for educational or research purposes.

In 2012, the Advisory Committee was authorized to review and analyze data for purposes of identifying patterns and activity of concern, notify prescribers and pharmacies who prescribed or dispensed the prescriptions, notify law enforcement or appropriate regulatory boards for additional investigation, and create guidance for review and potential referral of individual cases. The Advisory Committee meets bimonthly and has adopted guidance to flag concerning patterns of prescribing, dispensing, or purchasing for further evaluation based on K-TRACS data and publicly available information.

Purpose of HB 2253

Over the past several years, the Board and K-TRACS Advisory Committee have identified several necessary updates to the Prescription Monitoring Program Act. The bulk of current law remains unchanged from the

implementing legislation in 2008, and the most recent additions occurred in 2012. Technology has evolved substantially since that time, as well as the landscape of prescription monitoring. The amendments in HB 2253 reflect the Board's and Advisory Committee's recommendations, which have also been discussed with relevant stakeholder organizations. The Board believes there is consensus support for such changes and worked with legislators to introduce the bill last session.

The amendments align with the K-TRACS mission and goals, and aim to do the following:

- Increase K-TRACS utilization and ease of use;
- Protect patient information and data security;
- Provide more accurate and timely patient information to K-TRACS users; and
- Enhance opportunities for clinical intervention.

Recommendations in HB 2253

The Board recommends the following amendments which are not related to funding and are anticipated to have minimal financial impact:

- Defining and including the term "Audit Trail Information" to ensure sufficient protection of K-TRACS user data by identifying it as confidential and preventing public disclosure. Sec. 1 (a) and Sec. 4 (a).
- Defining the term "delegates" and allowing prescribers and pharmacists to designate delegates that could access and query the K-TRACS system on their behalf. Delegates would be limited to specific healthcare support staff, including nurses, EMTs, and pharmacy technicians. This access is allowed in all state programs and the K-TRACS vendor provides adequate security controls for such user accounts. Sec. 1 (c) and Sec. 4. (c)(12).
- Eliminating the waiver for pharmacies to submit paper records to the K-TRACS program, which reduces security risks and improves efficiency. No paper reports have been received by the Board in more than five years so no impact to pharmacies is anticipated. Sec. 2 (d).
- Permitting the Advisory Committee to enable new features in K-TRACS which may provide additional information related to the patient's controlled substance prescriptions and history.
    - Collect the diagnosis code for prescription information to K-TRACS if/when this information may become available in the future. Transmitting diagnosis code with electronic prescriptions is increasing in frequency in other states, including Ohio, and the Board would like to prepare for this possibility. Sec. 2 (b) (15).
    - Collect or incorporate information related to the dispensation or administration of naloxone, an opioid antagonist that reverses the effects of an opioid overdose event. Sec. 2 (d).
    - Incorporate the date and/or fact of death for a patient from the Kansas Office of Vital Statistics, which would clearly identify a patient as deceased and stop any prescriptions from being written or dispensed post-mortem. Sec. 2 (d).
- Expanding limited access to K-TRACS data for the following individuals or organizations, which were specifically requested by these groups and supported by the Advisory Committee.
    - Kansas impaired provider programs monitoring substance abuse recovery for prescribers and pharmacists. Sec. 4 (c)(11).
    - Practitioners and pharmacists conducting research approved by an institutional review board and who have obtained patient consent for the disclosure of their K-TRACS record. Sec. 4 (c)(14).
    - An overdose fatality review board established by the State of Kansas. Sec. 4 (c)(15).
    - A medical care facility's aggregate, deidentified K-TRACS data for research purposes. Sec. 4 (f).
- Adding appropriate notification requirements for K-TRACS users and regulatory agencies concerning continued access to K-TRACS.
    - Any K-TRACS user that no longer qualifies by law for access to K-TRACS must notify the Board within 30 days. Sec. 4 (d).
    - Prescriber regulatory boards must notify the Board within 30 days of any disciplinary action that would necessitate terminating or suspending that prescriber's access to K-TRACS. Sec. 4 (e).

    - Any prescriber or pharmacist must notify the Board within 30 days of any action that would disqualify one of their delegates from continued access to K-TRACS (i.e., termination of employment, disciplinary action, etc.). Sec. 4 (f).
- Authorizing the Advisory Committee to make confidential patient referrals to the Kansas Department on Aging and Disability Services (KDADS) only when the Advisory Committee believes the patient may need clinical intervention but they cannot identify a recent prescriber for intervention. KDADS would be prohibited from further disclosure if patient contact cannot be made. Sec. 4 (g)(1).
- Authorizing the Board to terminate or suspend K-TRACS access and make a referral to the user's regulatory board upon an indication of unlawful system access or use. Sec. 4 (g)(3).
- Updating record retention and storage requirements for K-TRACS data to ensure compliance with current technology standards and allow for sufficient research and analysis. Sec. 5 (b).
- Adding a mid-level prescriber to the membership of the Advisory Committee. The Act did not contemplate PA or APRN prescribing, which has evolved since the implementing legislation. In its discretion, the Board has appointed an APRN to the Advisory Committee for the past three years and it has been a beneficial addition. Some stakeholders do not support the shared membership (PA or APRN) and believe two separate members should be added (PA and APRN). Sec. 6 (a)(8).

New Recommendations

In the past year since introduction of HB 2253, the Board and Advisory Committee identified two data collection fields that are needed to ensure accurate prescription information is transmitted to K-TRACS and available to prescribers and pharmacists. The Board has already been working with the Revisor's Office to bring these edits in amendment form.

First, there is increasing confusion about the "date the prescription was filled" versus the "date the prescription was sold." Currently, K-TRACS only collects the first data point. However, the fill date in a pharmacy is often different from the date the prescription is actually sold and dispensed to the patient which could be many days later. Making both dates available would eliminate confusion and ensure more accurate and complete patient information. This is especially important if a patient never picks up the prescription, causing the pharmacy to report the prescription to K-TRACS on the date filled even though the patient may never retrieve it and, therefore, the prescription should not have been reported to K-TRACS.

Second, changes in veterinary prescribing have shifted the location where some animal owners receive prescriptions for their animals. While veterinary prescribing and dispensing is exempt from K-TRACS, veterinary prescriptions dispensed in Kansas pharmacies are reported to K-TRACS under the human owner's name. To distinguish the human owner's personal patient prescriptions from their animal's prescriptions, adding a species code to the required submission information is imperative. Most systems already have this functionality and could easily report the data point to K-TRACS.

Kansas Medicaid

The Board has been in active discussions with the Kansas Medicaid program and understands an amendment to the bill is needed to address new requirements for Medicaid providers under the federal SUPPORT Act. The Board supports the friendly amendment to HB 2253 and will continue to work with Kansas Medicaid on this matter.

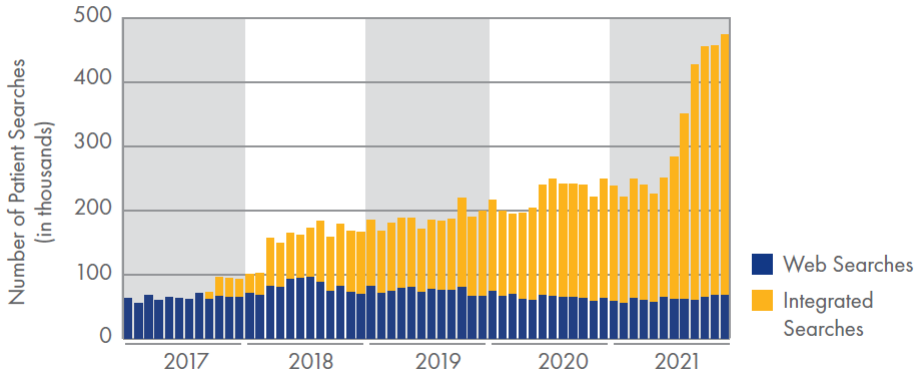
Funding

The Board does not generate any revenue from K-TRACS. Instead, the agency applied for and received several federal grants from 2009-2014 to fund K-TRACS outright. Unfortunately, grant funds are now only available for program enhancements and short-term projects. Regular program maintenance costs for staff, software, and supplies must be funded at the state level. Additionally, pursuant to K.S.A. 65-1684, the Board shall not impose any charge for the establishment or maintenance of K-TRACS on a registered wholesale distributor, pharmacist,

pharmacy, or prescriber. Though the Board has established a long-term funding plan for the bulk of the K-TRACS expenses, there is one remaining expense that is not yet funded: integration of K-TRACS data into electronic health records systems and pharmacy management systems.

During FY2017, grant funds were awarded to the Kansas Department of Health and Environment (KDHE) for enhancement of K-TRACS, and the Board was engaged as a sub-recipient project partner through August 2019. The CDC awarded new funds to KDHE for the period September 2019 – August 2022, again including the Board as a sub-recipient under the grant. No sub-recipient contract has yet been finalized or presented for Year 4 (September 1, 2022 – August 31, 2023) of the grant, but one is anticipated. Funds from this grant award primarily cover the cost of integrating K-TRACS information directly into the electronic health records of prescribers and the pharmacy management systems of pharmacists to provide easier access to K-TRACS information. As seen in the graph below, this functionality has increased K-TRACS utilization exponentially (yellow bars).

FIGURE 2. Number of Searches by Month and Type



Unfortunately, the Board will not be able to cover the costs if/when grant funds are no longer available. Costs for integration for FY 2022 are $814,113, which represents 43% of the total K-TRACS budget. The Board will continue to pursue all federal grant opportunities. To ensure adequate planning for continuation of integration services in the event grant funds are exhausted, the Board recommends creating a fee-based structure for participants in the integration program, which would only be activated if grant funding opportunities cease. 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 at the facility. This approach ensures costs would be manageable for all facilities and not act as a deterrent for use of this K-TRACS feature. Additionally, the traditional K-TRACS software would remain available to prescribers and pharmacists **free of charge**. The facility cost may range from $500 to $5,000 per year. The Board would provide the exact costs through administrative regulations in consultation with stakeholders and the Advisory Committee.

The Board is sensitive to the financial impact this may have on K-TRACS users but believes the value of the integration program outweighs the costs for integrated facilities. If the legislature disagrees and grant funding ends, K-TRACS will continue to operate without integration and still provide patient information to prescribers and pharmacists using the base level K-TRACS platform. The Board would hope that any financial concerns could be discussed and addressed without impacting other necessary updates to the Act.

Senate Committee Hearing and Passage

The Board had the privilege of presenting these changes to the Kansas Prescription Monitoring Program Act (SB 168) to the Senate Committee on Public Health and Welfare earlier during the 2022 legislative session. There was no opposition during the bill hearing. The Senate Committee supported the Board's efforts and voted to recommend the bill favorably for passage, as amended. The final bill form included the amendments outlined above. In addition, the Senate Committee amended the bill to specify that the above funding mechanism would

only be utilized by the Board after grant funds had been fully exhausted. The Board supported this amendment. While the full Senate has not yet heard SB 168, the Board is hopeful that both SB 168 and HB 2253 could come out of the respective legislative chambers in identical form and be adopted into law later this year.

Respectfully submitted.

Alexandra Blasi, Executive Director
Gayle Donaldson, K-TRACS Assistant Director

Proposed Amendment to SB 168
Senate Committee on Public Health & Welfare
Senator Hilderbrand
February 11, 2022
Prepared by: Jenna Moyer,
Assistant Revisor of Statutes

Session of 2021

SENATE BILL No. 168

By Committee on Ways and Means

2-8

AN ACT concerning health professions and practices; relating to the board of pharmacy; prescription monitoring program act; pertaining to persons permitted to receive program data; data security; user and delegate access; increasing the number of members of the prescription monitoring program advisory committee; providing for initial setup and annual maintenance fees to be charged for program data integration into any other electronic health or pharmacy record system approved by the board; amending K.S.A. 65-1682, 65-1683, 65-1684, 65-1685, 65-1687 and 65-1689 and repealing the existing sections.

Be it enacted by the Legislature of the State of Kansas:

Section 1. K.S.A. 65-1682 is hereby amended to read as follows: 65-1682. As used in this act, unless the context otherwise requires:

(a) *"Audit trail information" means information produced regarding requests for prescription monitoring program data that the board and advisory committee use to monitor compliance with this act.*

(b) "Board" means the state board of pharmacy.

(c) "Delegate" means:

(1) 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 program database as an agent of a practitioner or pharmacist to request program data on behalf of the practitioner or pharmacist;

(2) a death investigator who has registered for limited access to the program database as an agent of a medical examiner, coroner or another person authorized under law to investigate or determine causes of death; or

(3) an individual authorized to access the program database by the board in rules and regulations.

~~(b)~~*(d)* "Dispenser" means a practitioner*, pharmacy* or pharmacist who delivers a scheduled substance or drug of concern to an ultimate user, but does not include:

(1) A licensed hospital pharmacy that distributes such substances for the purpose of inpatient hospital care;

(2) a medical care facility as defined in K.S.A. 65-425, and amendments thereto, practitioner or other authorized person who

administers such a substance;

(3) a registered wholesale distributor of such substances;

(4) a veterinarian licensed by the Kansas board of veterinary examiners who dispenses or prescribes a scheduled substance or drug of concern; or

(5) a practitioner who has been exempted from the reporting requirements of this act in rules and regulations promulgated by the board.

~~(c)~~*(e)* "Drug of concern" means any drug that demonstrates a potential for abuse and is designated as a drug of concern in rules and regulations promulgated by the board.

~~(d)~~*(f)* "Patient" means the~~ person~~ *individual* who is the ultimate user of a drug for whom a prescription is issued or for whom a drug is dispensed~~, or both~~.

~~(e)~~*(g)* "Pharmacist" means an individual currently licensed by the board to practice the profession of pharmacy in this state.

(h) "Pharmacy" means 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 this state.

~~(f)~~*(i)* "Practitioner" means~~ a person~~ *an individual* licensed to practice medicine and surgery, dentist, podiatrist, optometrist or other~~ person~~ *individual* authorized by law to prescribe or dispense scheduled substances and drugs of concern.

~~(g)~~*(j) "Program" means the prescription monitoring program.*

(k) "Scheduled substance" means controlled substances included in schedules II, III or IV of the schedules designated in K.S.A. 65-4107, 65-4109 and 65-4111, and amendments thereto, respectively, or the federal controlled substances act~~(~~,21 U.S.C. § 812~~)~~.

Sec. 2. K.S.A. 65-1683 is hereby amended to read as follows: 65-1683. (a) The board shall establish and maintain a prescription monitoring program for the monitoring of scheduled substances and drugs of concern dispensed in this state or dispensed to an address in this state.

(b) Each dispenser shall submit to the board by electronic means information required by the board regarding each prescription dispensed for a substance included under subsection (a). The board shall promulgate rules and regulations specifying the nationally recognized telecommunications format to be used for submission of information that each dispenser shall submit to the board. Such information may include, but not be limited to:

(1) The dispenser identification number;

(2) the date the prescription is filled;

(3) the prescription number;

(4) whether the prescription is new or is a refill;

(5) the national drug code for the drug dispensed;

(6) the quantity dispensed;
(7) the number of days' supply of the drug;
(8) the patient identification number;
(9) the patient's name;
(10) the patient's address;
(11) the patient's date of birth;
(12) the prescriber identification number;
(13) the date the prescription was issued by the prescriber; ~~and~~
(14) the source of payment for the prescription*; ~~and~~*
(15) the diagnosis code.

;
(16) the patient's species code; and
(17) the date the prescription was sold

(c) The board shall promulgate rules and regulations specifying the transmission methods and frequency of the dispenser submissions required under subsection (b).

(d) ~~The board may issue a waiver to a dispenser that is unable to submit prescription information by electronic means. Such waiver may permit the dispenser to submit prescription information by paper form or other means, provided that all information required by rules and regulations is submitted in this alternative format.~~ *The board may, in consultation with the advisory committee, enable features and include additional information to enhance the program database. Such information may include, but not be limited to:*

(1) The date or fact of death;

(2) the dispensation or administration of emergency opioid antagonists, as defined by K.S.A. 65-16,127, and amendments thereto; and

(3) the data related to an overdose event.

(e) The board is hereby authorized to apply for and to accept grants and may accept any donation, gift or bequest made to the board for furthering any phase of the prescription monitoring program.

(f) The board shall remit all moneys received by it under subsection (e) to the state treasurer in accordance with the provisions of K.S.A. 75-4215, and amendments thereto. Upon receipt of such remittance, the state treasurer shall deposit the entire amount in the state treasury to the credit of the non-federal gifts and grants fund. All expenditures from such fund shall be made in accordance with appropriation acts upon warrants of the director of accounts and reports issued pursuant to vouchers approved by the president of the board or a person designated by the president.

Sec. 3. K.S.A. 65-1684 is hereby amended to read as follows: 65-1684. The board shall not impose any charge for the establishment or maintenance of the prescription monitoring program database on a registered wholesale distributor, pharmacist, dispenser or other person authorized to prescribe or dispense scheduled substances and drugs of concern. The board shall not charge any fees for the transmission of data to the database or for the receipt of information from the database, except

~~that~~ *as provided in this section:*

(a) The board may charge a fee to an individual who requests the individual's own prescription monitoring information in accordance with procedures adopted by the board*; and*

(b)(1) in consultation with the advisory committee, the board may adopt rules and regulations necessary to establish and charge to each integrated entity an initial setup fee and an annual maintenance fee for the integration of program data in any electronic health record or pharmacy management system approved by the board. ~~If the board deems such rules and regulations necessary, such rules and regulations shall be adopted not later than July 1, 2022.~~

(2) All moneys collected under this subsection shall be remitted to the state treasurer in accordance with the provisions of K.S.A. 75-4215, and amendments thereto. Upon receipt of each such remittance, the state treasurer shall deposit the entire amount in the state treasury to the credit of the state board of pharmacy fee fund.

Prior to the establishment or charge of any such fee, the board shall determine that any federal grants that may be expended for integration of program data in electronic health records or pharmacy management systems have been exhausted.

Sec. 4. K.S.A. 65-1685 is hereby amended to read as follows: 65-1685. (a) The ~~prescription monitoring~~ program database, all information contained therein and any records maintained by the board, or by any entity contracting with the board, submitted to, maintained or stored as a part of the database, *including audit trail information,* shall be privileged and confidential, shall not be subject to subpoena or discovery in civil proceedings and may only be used for investigatory or evidentiary purposes related to violations of state or federal law and regulatory activities of entities charged with administrative oversight of those ~~persons~~ *individuals* engaged in the prescribing or dispensing of scheduled substances and drugs of concern, shall not be a public record and shall not be subject to the Kansas open records act, K.S.A. 45-215 et seq., and amendments thereto, except as provided in subsections (c) and (d).

(b) The board shall maintain procedures to ensure that the privacy and confidentiality of patients and patient information collected, recorded, transmitted and maintained is not disclosed to ~~persons~~ *individuals* except as provided in subsections (c) and (d).

(c) The board is hereby authorized to provide data in the ~~prescription monitoring~~ program to the following ~~persons~~ *individuals*:

(1) ~~Persons~~*Individuals* authorized to prescribe or dispense scheduled substances and drugs of concern, for the purpose of providing medical or pharmaceutical care for their patients;

(2) an individual who requests the individual's own prescription monitoring information in accordance with procedures established by the board;

(3) designated representatives from the professional licensing, certification or regulatory agencies charged with administrative oversight