September 16, 2024

Mr. Adam Proffitt, Director Division of the Budget Landon State Office Building 900 SW Jackson, Ste. 504-N Topeka, Kansas 66612

Dear Mr. Proffitt:

As Executive Secretary of the Kansas State Board of Pharmacy, I hereby submit for your consideration the Fiscal Year 2025, 2026 and 2027 budget document for the agency. It has been prepared in accordance with the budget instructions. To the best of my knowledge and belief, the information and explanation included in this budget request are correct and complete.

Please let me know if I can provide any additional information which you or your budget analyst may require.

Sincerely,

Alexandra Blasi, JD, MBA Executive Secretary Kansas State Board of Pharmacy

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#### AGENCY MISSION, PHILOSOPHY, GOALS AND STRUCTURE:

The mission of the Kansas State Board of Pharmacy is to ensure that all persons and entities conducting business relating to the practice of pharmacy in this state are properly licensed and registered. This will protect the public's health, safety and welfare as well as promote the education and understanding of pharmacy related practices.

It is the agency's philosophy that the Board will act in accordance with the highest standards of ethics, accountability, efficiency, and openness. The Board subscribes to the ideal that pharmacy practice is a public trust. The Board approaches its activities with a deep sense of purpose and responsibility. The public and regulated community alike can be assured of a balanced and sensible approach to regulation. In carrying out its mission, the Board strives to be courteous, professional, flexible, honest, and helpful in all dealings with the public and the regulated community. It strives to provide the public with clear, easy-to-understand, and accurate information about services. It strives to actively listen so as to better anticipate the needs of the public and regulated community and be fully responsive to concerns regarding Board services.

Protection is afforded through oversight, enforcement, and inspection activities carried out by the Board. The Board consists of seven members appointed by the Governor. Six members are licensed pharmacists with a minimum of five years of experience and the seventh is a member of the general public. The current Board members are: Terica Gatewood, PharmD, Topeka, President; Erick Axcell, PharmD, Lawrence, Vice President; Jonathan Brunswig, PharmD, Scott City; Tiffany Strohmeyer, PharmD, Topeka; Andrew Truong, PharmD, Wichita; William Walden, RPh, Iola; and Lucinda Noches Talbert, Public Member, Kansas City. The Board Members discuss and formulate public policy with regard to the practice of pharmacy during quarterly Board meetings, in accordance with the Kansas Open Meetings Act. The rules and regulations are upheld in accordance with the procedures set forth in the Kansas Administrative Procedure Act. The Board ensures that members of the public have input into the rulemaking process via task forces, public hearings, public forums, newsletters, requests for public comment, web meetings, and electronic media or other forms of communication. The Board, through its licensing services, ensures that applicants related to the manufacture, distribution, compounding, dispensing, and sale of prescription and non-prescription drugs and devices, including controlled substances, have met standards established by the Kansas Legislature and the Board.

The Board operates two programs and undertook a new strategic plan for FY 2021 – FY 2025. The **Regulatory Program** enables the Board to carry out its licensing and compliance activities, and has the following goals:

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- · Protection Ensure that the practice of pharmacy protects the health, safety, and welfare of Kansas citizens and provide transparency to members of the public.
- · Compliance Facilitate compliance with, foster respect and appreciation for, and educate on Kansas statutes, rules, and regulations regarding the practice of pharmacy and proper manufacturing, distribution, and dispensing/sale of prescription and non-prescription drugs and devices for businesses and individuals doing business in or with the state of Kansas.
- · Regulatory Footprint Review and align statutes and regulations to be consistent with current pharmacy practice standards.
- · Collaboration Collaborate with stakeholders and regulatory healthcare partners to establish consistent standards of pharmacy practice across professions and occupations.

The **Drug Monitoring Program** authorizes the Board to protect Kansas citizens with the goal of overseeing, tracking, and monitoring the dispensing/sale of controlled substances, drugs of concern, and over-the-counter methamphetamine precursors, as well as administering the Kansas Medication Disposal Program and Utilization of Unused Medication Donation Program.

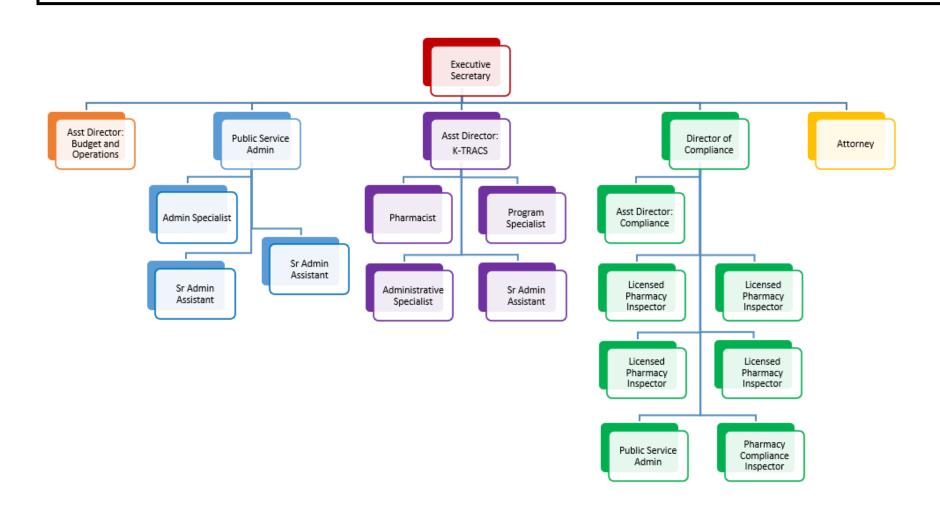
The Board has addressed societal and industry trends that pose risks to the safety net established to protect Kansans. Recent initiatives have included steps to address standards for facilities compounding bulk medications, appropriately register and outline requirements for facilities operating in the pharmaceutical supply chain, expand training for pharmacy technicians, increase access to and enhance Board resources, ensure continuity of patient care, enhance public awareness of and access to the prescription drug monitoring program, and avert diversion, counterfeiting and illegal prescription drug sales. The Board has also adopted necessary regulations and protocols to support availability of emergency opioid antagonists such as naloxone and expand immunization authority. The Board provides annual reports to the legislature concerning its programs.

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#### **FINANCING:**

Expenses of the Board are met through the fees assessed for new applications, biennial renewals, annual registration of pharmacy-related businesses, late fees, open record fees, administrative fines, probation fees, grants, and gifts. The agency retains 90% of all revenues received through licensure and registration and the remaining 10% is paid to the State General Fund (SGF) up to \$100,000 per year. One hundred percent of grant monies are retained by the agency. The Board's estimated spending authority from fee funds for FY2025 is \$2,726,649. The Board's requested, estimated spending authority from fee funds for FY2026 is \$2,947,109. The Board's requested, estimated spending authority from fee funds for FY2027 is \$3,607,526.

In addition to the Board's normal operating budget, the agency has received grants and gifts that have been applied toward special programs operated by the Board. The Board received several federal grants from 2009 to 2014 (totaling over one million dollars) to fund the Prescription Drug Monitoring Program (PDMP), known as K-TRACS. The Board does not currently generate any revenue from the PDMP. The Board has partnered with the Kansas Department of Health and Environment (KDHE) for enhancement of the PDMP as well as other educational and research projects since 2017. The CDC awarded new funds to KDHE for the period September 2023 – August 2028, under which the Board is a sub-recipient entering Year 2 of the program (September 1, 2024 – August 31, 2025). The Board is the recipient of a 2020 Harold Rogers grant, which will be winding up March 31, 2025, after two no-cost extensions. Last year, the Board was also awarded a 2023 Harold Rogers grant to ensure ongoing PDMP work through September 2026, and was recently informed of our automatic eligibility for a non-competitive supplement and extension through March 2027. While this has not been awarded yet, the Board has a high degree of confidence in receipt of supplement funds and has included them in this submission. The Board is also engaged as a project partner by the Kansas Department on Aging and Disability Services for a grant awarded by the U.S. Department of Health and Human Services Substance Abuse and Mental Health Services Administration (SAMHSA) through 2026.

As a temporary solution for FY2018 and FY2019, K-TRACS costs were covered by surplus fee fund dollars from the agencies regulating prescribers and dispensers in Kansas, including the Board of Pharmacy, Board of Healing Arts, Dental Board, Board of Nursing, and Board of Optometry. The Board engaged stakeholders and researched permanent funding options for this statutorily-mandated and vital program, and determined that a permanent funding solution is necessary for ongoing maintenance and support of the PDMP. In 2021, the legislature authorized \$200,000 annually from the new Opioid Settlement Litigation Fund under the authority of the Kansas Attorney General to be transferred each July

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1<sup>st</sup> for the operation and maintenance of the K-TRACS program.

The Board's cash flow fluctuates throughout the year based on the irregular receipt of applications and renewals. Currently the retail dealers renew in February, pharmacists and businesses renew in May-June, and pharmacy technicians renew in September-October. The pharmacists and pharmacy technicians have biennial renewals, which are divided evenly into two groups.

#### **STATUTORY HISTORY:**

Congress has the authority to regulate drugs pursuant to its powers under the "commerce clause" (Article 1, Section 8) of the United States Constitution, which grants Congress authority to regulate commerce among the states. This type of commerce is known as interstate commerce. States derive their authority to regulate intrastate commerce and, more particularly, drug distribution, from the Tenth Amendment to the U.S. Constitution. The powers granted to or reserved for the states are those that are not assigned specifically to the federal government or prohibited specifically from the states. The federal government has left the issue of prescribing and dispensing to the states under their authority to protect the public's health, safety, and welfare. Regulation of the manufacture, sale, and distribution of drugs and poisons began in Kansas with the passage of enabling legislation in 1885.

In the 1930s, sensational drug abuse cases contributed to the enactment of the Federal Food, Drug and Cosmetic Act by Congress. The dispensing of certain drugs was restricted by the Act to the pharmacist and only pursuant to a prescription. The Durham-Humphrey Amendment to the Act was enacted in 1951 distinguishing, at the federal level, those drugs requiring a prescription from nonprescription drugs or over-the-counter drugs. In addition to requiring a prescription for specific drugs, the Durham-Humphrey Amendment also provided provisions for the receipt of oral prescriptions as well as for the refilling of prescriptions.

Until the middle of the twentieth century, pharmacists in small, independently-owned, retail outlets dispensed most drugs. The post-World War II hospital construction boom, however, increased the number and capability of hospitals, leading to increased drug dispensing from hospital pharmacies.

By 1970, several other major developments precipitated a half-century of change in the profession. These included the growth of corporately

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owned "chain" stores; the sudden growth of long-term care facilities; the development of new drugs; and, in 1970, the passage of the Controlled Substance Act. The Controlled Substance Act is the principal federal law regulating the manufacture, distribution, dispensing and delivery of drugs or substances which are subject to, or known to have the potential for, abuse or physical or psychological dependence. Pharmacists are subject to federal drug control laws as well as drug control laws of the state in which they are licensed and practicing – unless such practice is exclusively in a federal facility such as the Veteran's Administration Hospital. Most states have enacted their own version of the controlled substance act based on the federal provisions. These developments required many changes in the law and increases in the number of regulations.

By 1970, the Kansas Pharmacy Practice Act had been amended several times to reflect changes occurring in the industry. As the roles of pharmacists and other health care professionals expanded and the market has become increasing global, laws and regulations have adapted and changed in coordination with other regulatory bodies. The FDA's recent approval of drugs like Shingrix, a vaccine to prevent shingles, and Epidiolex, the first FDA-approved medication with cannabidiol as the active ingredient, as well as new devices like the Proteus ingestible event sensor have required adjustments to state regulatory frameworks and controlled substance acts. In addition, the global economy of pharmaceuticals has necessitated the Federal Drug Supply Chain Security Act, which created a 10-year roll-out of national track and trace laws for the manufacture, distribution, and sale of all drugs and devices, with final requirements going into effect in November 2024. Emerging topics include increased consumer access to pharmacy services in the form of telepharmacy or secure vending machines, increase in the prevalence and oversight of sterile and nonsterile compounding, specialty pharmacy white-bagging, shifting the role of boards of pharmacy to a standard of care instead of a prescriptive model, and increased scope of practice for pharmacists as a result of increased needs and access to care.

More recently, the Board has worked with drug manufacturers to ensure access to pharmaceuticals and the integrity of the prescription drug supply chain. Unprecedented demand for medications in the GLP-1 category despite manufacturer shortages have necessitated direct engagement from the Board and other healthcare regulatory partners.

The Board recently has adopted regulations concerning incident reports and continuous quality improvement in pharmacies, minimum requirements for non-controlled prescriptions, and K-TRACS. The Board will continue its efforts to achieve its mission to protect Kansas consumers and promote quality health care in the field of pharmacy using the least restrictive means available.

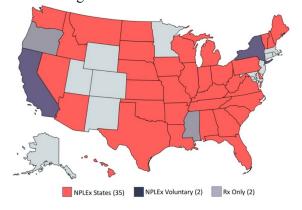
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### PHARMACY LEGISLATION IN THE PAST DECADE:

### **Methamphetamine Abuse**

The Sheriff Matt Samuels bill, adopted in 2007, made all forms of over-the-counter ephedrine and pseudoephedrine (PSE) a Schedule V controlled substance in Kansas following the growth of methamphetamine use and manufacturing in Kansas. Subsequently, the 2009 legislature authorized creation of a statewide electronic logging system for the sale of methamphetamine precursors in pharmacies. Kansas pharmacies now participate in the National Precursor Log Exchange (NPLEx) which is a collaboration led by the National Association of Drug Diversion Investigators, as well as law enforcement, health care professionals, state regulatory agencies, and pharmaceutical manufacturers. NPLEx is funded by manufacturers of cold medications that are meth precursors and the system is free of charge to any state. This includes access to the database; IT assistance to pharmacies and law enforcement; and training and media. The system operates as a state-wide, real-time, stop sale, electronic tracking system for all PSE products sold. The stop sale functionality has an override feature to allow completion of the sale if the pharmacy thinks that denying the request would create a threat to the safety of the pharmacist or their staff. That data is subject to annual FBI audits and is under tight security policies including independent security testing, HIPAA compliance, and disaster recovery. The system has been aggregated with data from other states to provide multi-state stop sale functionality. There are currently 35 states requiring NPLEx and two states participating voluntarily. The following map shows the states currently reporting to and tracking sales in NPLEx.



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There are approximately 558 pharmacies that are actively using NPLEx in Kansas. Those pharmacies that do not sell PSE items over the counter are exempt from reporting. The Board entered into a Memorandum of Understanding with the KBI in June of 2011. The Memorandum defines the roles of the Board and the KBI with respect to the utilization of, and the security of, information in the system. The KBI is the liaison between all state and subdivision law enforcement for training and access to data needed from the system and the Board provides the training and access to the pharmacies. The Board promulgated rules and regulations for the statewide, real-time, stop sale, electronic tracking for all PSE products sold in Kansas. The Board staff has monthly contact with NPLEx and with the KBI unless there are problems within the system. The Board is tracking data on the total number of boxes sold, the total grams sold, and the total transactions that have been blocked. In addition, K-TRACS requires any prescription product containing pseudoephedrine be reported to the program as a drug of concern. This change was recommended in order to capture the sale of prescription PSE items, which are exempt from reporting to NPLEx and previously went unchecked.

## **Prescription Drug Monitoring Program**

In 2008, the legislature created the Prescription Drug Monitoring Act to establish and maintain a PDMP 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. The PDMP is a potent tool in aiding in the identification of patients with drug-seeking behaviors, providing treatment, and educating the public. Each dispenser (pharmacy) is required to electronically submit information to the Board's central data collection system, known as K-TRACS, for each controlled substance prescription or drug of concern dispensed in an outpatient setting. 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, webbased 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 using 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 the PDMP 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. The Board has expanded its web presence by creating and updating <a href="https://www.ktracs.ks.gov/">https://www.ktracs.ks.gov/</a>. The website includes guidelines, best practices, prescribing and dispensing trends, and the Board's annual <a href="https://www.ktracs.ks.gov/">K-TRACS Legislative Report</a>.

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The authorizing legislation for K-TRACS also created two notable prohibitions. 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. Additionally, K.S.A. 65-1688 provides that no prescriber or dispenser shall have a duty or mandatory requirement to use K-TRACS.

In addition to controlled substances, K-TRACS tracks other drugs of concern in Kansas, identified by the Board in K.A.R. 68-21-7. The Board amended K.A.R. 68-21-7 in 2018, adding the drug "gabapentin" to the list. This change correlated with similar scheduling in other states and significant evidence of abuse and misuse by patients in recent years, often resulting in death when consumed in conjunction with other controlled substances.

The Act also created a PDMP Advisory Committee, subject to the oversight of the Board, composed of prescribers and dispensers from various healthcare disciplines. In 2012, the Committee was authorized to review and analyze data for purposes of identifying patterns and activity of concern, notifying prescribers and dispensers who prescribed or dispensed the prescriptions, notifying law enforcement or appropriate regulatory boards for additional investigation, and creating guidance for review and potential referral of individual cases. The 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. Such guidance is meant to direct staff in regularly evaluating the large volume of K-TRACS data to identify suspicious cases for the Committee to review.

Since its inception, the Board has primarily operated the program on federal grant funds. These funds have been used to enhance the program to meet the needs of K-TRACS users. The Board offers electronic health record system integration for prescribers and pharmacists in Kansas to access K-TRACS in a way that streamlines clinical workflows. This project delivers a more efficient and patient-oriented program, saves time, and increases utilization of K-TRACS. The project was initially funded by a grant from the Centers for Disease Control awarded to KDHE. The Board hopes that federal grant funds will continue to support connection costs for Kansas electronic health records and pharmacy management systems approved for integration, which will further the K-TRACS mission.

During the 2022 legislative session, the Board introduced legislation to update the PDMP Act, which resulted in passage of Senate Bill 200. The updates included additional pharmacy data reporting requirements, expanded access to select healthcare individuals and groups, allowances for the Committee to incorporate information and make referrals and additional measures to secure confidential K-TRACS information.

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# **Applicant Backgrounds**

In 2009, the legislature authorized the Board to fingerprint and conduct a criminal background check on any applicant or licensee to further safeguard the public. The Board requires fingerprints of pharmacy technician applicants, pharmacy intern applicants, and pharmacist applicants. The Board does not generate revenue from any fingerprinting but collects a fee that is passed directly to the KBI (100%). The KBI submits an invoice to the Board monthly and the Board pays the money out of the fee fund. The Board also contracts with the KBI to enroll all fingerprinted applicants and licensees in the RapBack Program, which provides updated criminal history reports on any new offense events for each enrolled individual. KBI charges an annual \$3.00 fee for each enrolled individual, but this fee is incorporated into the license or registration renewal fee. The Board updated its Fingerprint and Criminal History Record Check Reports Policy in 2021 to ensure compliance with state and federal requirements, as well as the new KCHAT electronic background report system established by the KBI. The Board updated application forms and instructions to comply with 2022 House Bill 2495 which requires the Board disclose and explain to applicants that fingerprints will be retained by the KBI and FBI for enrollment in the Rap Back program, and that the Board notify the KBI when fingerprints are to be removed due to denial, revocation, or expiration of a license or registration. The Board also supported KBI's introduction of 2024 SB 491, which was passed during the 2024 legislative session and updates Kansas background check requirements. Recently, the Board has worked with KBI to implement background check fee waivers to comply with 2024 HB 2745, discussed in more detail below.

# **Electronic Prescribing**

Electronic prescribing has increased substantially since the DEA first published a rule on it in 2010. Since then, the Board has implemented statutory and regulatory changes to allow for electronic prescribing practices. House Bill 2119 became effective on July 1, 2019, and mandated electronic prescribing of controlled substance opioids beginning July 1, 2021. The Board is responsible for issuing waivers to prescribers unable to comply with the mandate or qualifying for waiver under certain exemptions. This requirement is consistent with federal rules that require electronic prescribing of all controlled substances for Medicare patients, enforceable in 2024. The Board established and implemented a prescriber waiver process in January 2021 and updated processes earlier this year. Waivers expire each June 30 and December 31 and require the prescriber to request and justify renewal of the waiver from the Board.

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#### **DSCSA**

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. The DSCSA is designed to track prescription drugs distributed in the U.S. from the manufacturer all the way to the point of dispensing to the patient. Through the DSCSA, potentially dangerous or hazardous drugs will be eliminated from the drug supply chain and consumers will be better protected from possible counterfeit, stolen, contaminated, or harmful prescription drugs. Although implementation was scheduled over a 10-year period, guidance documents and rules are gradually being made available to states regarding product identification, tracing, verification, detection and response, notification, and licensing/registration. In order to comply with initial phases of the DSCSA, Kansas was required to update statutes and regulations to properly register and regulate wholesale distributors, manufacturers, outsourcing facilities, third-party logistics providers, reverse distributors, repackagers, and other involved entities. Senate Substitute for House Bill 2055 included the bulk of these statutory changes, and became effective in April 2017. In January 2020, the Board adopted new and amended regulations for each facility type and provided six months for facilities to come into compliance with new standards. The Board successfully completed migration of each facility registrant into the appropriate new registration categories in July 2020. As a follow-up to this initiative, Substitute for Senate Bill 238 became effective May 2021 and clarified requirements for manufacturers, including non-resident and virtual facilities.

The FDA released proposed rules in February 2022 creating new "ceiling" restrictions for states which, if enacted, would mandate substantial additional updates to Kansas laws regulating these entities. The Board submitted official comments to the FDA expressing concerns and requesting clarification of the proposed rules in the following categories: federal preemption, public safety, administrative procedures, consideration of applicant history and criminal record checks, renewals, discipline, unlawful operations, inspection allowances and requirements, time to effect change, and the financial and resource burden to the Board.

Last year, the <u>FDA announced</u> a one-year delay (to November 2024) of enforcement of the serialization and electronic trace interoperability requirements for trading partners and states. The FDA has also now provided details concerning exemptions for small dispensers, and methods for facilities to request federal waivers. The Board is drafting regulations for final implementation, anticipated to be considered for adoption in 2025. The Board was also engaged as a pilot project state and continues as a regulatory partner with the National Association of Boards of Pharmacy on a project called "<u>Pulse</u>," a platform for state regulators and trading partners to easily and electronically meet federal requirements. All platform elements required by the Board are provided free of charge.

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# **Kansas Controlled Substance Act and Emergency Scheduling Authority**

Under K.S.A. 65-4102, the Board must annually submit to the legislature a report on substances proposed by the Board for scheduling, rescheduling, or deletion by the Legislature with respect to any one of the schedules listed in the Kansas Controlled Substance Act. The Board works with the KBI, law enforcement, and other stakeholders to make such recommendations each year.

The Board also has emergency scheduling authority for controlled substances. Upon notice or its own motion, the Board can schedule, on an emergency basis, any substance which is an analog of a currently-scheduled controlled substance, or any new drug which is found to pose an imminent hazard to public safety. Such scheduling lasts until July 1 of the following calendar year, giving the legislature sufficient time to consider and effect permanent scheduling of the drug. Last year, the Board utilized its emergency scheduling authority twice and introduced a bill to the Legislature to codify those and other scheduling changes in January. The substance of this bill was adopted in 2024 HB 2547 and became effective July 1, 2024. The Board also supported a friendly amendment adding tianeptine ("gas station heroin") to Schedule I.

# Occupational Regulation, Temporary Emergency Licenses, and Electronic Credentials

Effective July 1, 2021, the Kansas legislature adopted Substitute for House Bill 2066 which shortened the period of time in which regulatory bodies are required to issue occupational credentials to military servicemembers or military spouses seeking to establish residency in Kansas and provide for expedited credentialing of non-military prospective residents. The law expands and clarifies conditions on expedited occupational credentialing and permits temporary credentialing during states of emergency and the use of electronic credentials. The Board is now required to issue licenses and registrations to a military servicemember or spouse within 15 days from the date of the submission of a "complete application," as defined by the bill, or within 45 days for all other applicants. The Board must also expedite out-of-state credentials for a six-month probationary period for military servicemembers and military spouses who do not qualify for reciprocity but meet certain other requirements, and the law authorizes the Board to grant credentials to applicants who meet certain experiential or non-resident qualifications or temporary permits provided that doing so would not jeopardize the public health and safety.

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During the 2024 legislative session, this law was expanded to waive all application and renewal fees for military spouses who are assigned to a Kansas military station. This includes waiver of the KBI criminal background check fee. Though the law did not become effective until July 1, 2024, the Board worked swiftly to implement this waiver beginning in May 2024, and made the policy decision to permanently expand waivers of application and renewal fees to include active-duty military service members assigned to a Kansas military station.

### **Pharmacist Standards and Scope of Practice**

The Board has implemented statutory and regulatory changes to support how standards of pharmacy practice have changed:

- Words like "refill" were changed to "continuation of therapy that contains no changes," and authorizes pharmacists to use their professional judgment to exercise prescription adaptation for non-controlled medications.
- Updates also clarified the process for transferring unfilled patient prescriptions, a topic which has caused patients and pharmacies significant difficulty in recent years due to the opioid epidemic and new DEA rules. New language allows a pharmacy to forward (not transfer) an original, unfilled prescription to another pharmacy at the request of the patient. Certain federal requirements exist for this process and prescriptions for controlled substances are required to be forwarded electronically.
- The Board established a maximum limit of five attempts for the national pharmacy practice exam and state pharmacy law exam.
- Pharmacist scope of practice was expanded to including initiation of therapy within the framework of a statewide protocol for the following health conditions: influenza, streptococcal pharyngitis, and urinary tract infection. These protocols were developed and adopted by the Collaborative Drug Therapy Management Committee in 2023.

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### **PERFORMANCE MEASURES:**

# **Regulatory Program**

The Kansas State Board of Pharmacy Regulatory Program goals include:

1. Licensing – Ensure that the practice of pharmacy protects the health, safety, and welfare of Kansas citizens and provide transparency to members of the public.

Key Performance Measures include:

- percentage of initial applications processed within 30 days of completion during the previous fiscal year; and
- percentage of initial applications for military service members or spouses processed within 15 days of completion during the previous fiscal year.
- 2. Compliance Facilitate compliance with, foster respect and appreciation for, and educate on Kansas statutes, rules, and regulations regarding the practice of pharmacy and proper manufacturing, distribution, and dispensing/sale of prescription and non-prescription drugs and devices for businesses and individuals doing business in the state of Kansas.

Key Performance Measures include:

- percentage of resident pharmacy inspections conducted within the past 24 months; and
- percentage of investigations completed within nine months during the previous calendar year.

# <u>Licensing Objectives – Licensure, Registration, and Education</u>

1. Require those applying for pharmacist licensure by examination to pass a national uniform qualifying examination, a state specific law examination, and successfully complete 1,500 clock hours of qualifying pharmaceutical experience.

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- 2. Require those applying for pharmacist licensure by reciprocity to provide proof satisfactory to the Board of having the education and training required of applicants for licensure by examination and to pass a state specific law examination.
- 3. Require newly-registered pharmacy technicians to complete an on-the-job training program and successfully pass a practice-based certification exam prior to their first biennial renewal.
- 4. Require those businesses applying for registration to provide adequate information regarding ownership and compliance with Board standards.
- 5. Require licensed pharmacists and registered technicians to complete continuing pharmacy education to renew.

# Performance Measure Indicators for Regulatory Program: Licensing

Performance Measure	FY2020	FY2021	FY2022	FY2023	FY2024	FY2025 Est	FY2026 Est
Percentage of initial applications processed within 30 days of receipt during previous fiscal year	79.96%	64.21%	75.98%	78.06%	78.69%	75%	75%
Percentage of initial applications processed within 30 days of completion during previous fiscal year	95.37%	74.21%	97.20%	97.68%	98.04%	97%	97%

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Percentage of initial applications for military service members or spouses processed within 15 days of completion during the previous fiscal year			100%	94.74%	97.14%	90%	90%
Percentage of online renewals for previous fiscal year*	98.40%	98.80%	99.20%	99.52%	99.31%	99.00%	99.00%
Number of CE courses approved for previous fiscal year	60	54	62	73	42	50	50

Initial Applications: The Board licensing staff processes applications in the order received. Applicants with incomplete forms are contacted by email to provide missing information/documentation and given a timeline for follow-up. Once complete, applications are typically processed within one to two business days. Completed facility applications requiring a pre-opening inspection are forwarded to the appropriate inspector within a few business days and all inspections are conducted within 90 days. Applications that indicate an ownership issue, disciplinary history, or criminal offense history are forwarded to the compliance division for investigation and review, which can take up to six months depending on the responsiveness of the applicant. Once an investigation is complete, the Board's investigative member makes a determination.

Number of CE Courses Approved: The Board appoints a Continuing Education Review Committee, including one Board member and several pharmacy educators, to review and approve continuing education courses on behalf of the Board. Pharmacists are required to complete 30 hours of approved CE during each biennial renewal period, and pharmacy technicians are required to complete 20 hours of approved CE during each biennial renewal period. The Board accepts CE approved by the Accreditation Council for Pharmacy Education, Pharmacy Technician Certification Board, National Healthcare Association, or other state boards of pharmacy. In addition, CE providers and licensees may submit other CE courses to the Board for review and approval. There is no fee for this application or review and the Board has made efforts in recent years to increase awareness of this option to apply for credit as few as 10 days prior to a course.

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# **Statistics for Licensing and Registration**

		FY15	FY16	FY17	FY18	FY19	FY20	FY21	FY22	FY23	FY24
Individuals											
	Intern/Student	1,165	1,158	1,134	1,086	1,000	1,049	1,006	947	892	830
	Pharmacists	5,197	5,364	5,705	6,783	6,500	7,632	7,694	7,967	8,244	8,399
	Technicians	7,377	7,600	8,049	8,000	8,050	7,566	7,570	7,726	7,858	7,522
Facilities											
	Ambulance	161	173	180	183	175	182	190	196	196	191
	Analytical Lab	26	29	32	32	29	34	33	35	36	35
	County Health, Family Planning	103	105	103	103	98	105	114	117	117	120
	Distributor	1,043	1,100	1,171	1,197	1,125	1,138	960	969	971	951
	Distributor (non-prescription)	107	110	102	108	97	76	80	90	74	81
	Durable Medical Equipment	421	438	457	422	427	431	441	445	452	452
	Institutional Drug Room	55	56	56	49	52	72	74	74	79	81
	Manufacturer	13	15	16	15	16	17	459	572	620	641
	Outsourcing Facility						26	34	38	40	35
	Pharmacy (Resident)	901	924	922	935	921	918	905	913	911	908
	Pharmacy (Non-Resident)	839	960	992	982	616	667	716	771	785	830
	Research & Teaching	90	99	127	119	100	126	108	104	101	98
	Retail Dealer	1,528	1,515	1,541	1,616	1,600	1,625	1,664	1,716	1,739	1,720
	Sample Distributor	44	41	42	31	31	21	23	32	34	40
	Third-Party Logistics Provider						105	155	197	228	269
	Third-Party Logistics Provider (non-prescription)						25	37	42	46	49
Total		19,070	19,687	20,629	21,661	20,837	21,815	22,263	22,951	23,423	23,252

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# **Compliance Objectives**

- 1. Promptly review and investigate all complaints and referrals filed with the Board.
- 2. Conduct routine inspections of all registered pharmacies, institutional drug rooms, DME providers, manufacturers, distributors, non-prescription distributors, and county health/family planning facilities located in Kansas.
- 3. Audit pharmacist licensees for compliance with biennial continuing education requirements.
- 4. Require licensees serving as pharmacist-in-charge (PIC) of a pharmacy to accept responsibility for the pharmacy, conduct controlled substance inventories, notify the Board of certain incidents or actions, and comply with all federal and state statutes and regulations pertaining to the operation and management of the pharmacy.
- 5. Initiate disciplinary action against or enter into voluntary consent agreements with all licensees and registrants based on violations of the Kansas Pharmacy Practice Act and related regulations, in accordance with the Kansas Administrative Procedures Act.
- 6. Issue "cease and desist" orders and/or seek injunctions to stop unlicensed or unregistered persons or entities providing services in Kansas which may be misleading or dangerous to the public.

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#### Performance Measures for Regulatory Program: Compliance

Compliance Performance Measures	2019	2020	2021	2022	2023	2024ytd	2025est	2026est
Number of complaints received during calendar year	41	109	165	115	153	115	125	125
Number of compliance investigations conducted during calendar year	581	532	541	599	791	474	500	500
Number of applications or renewals referred to compliance division during calendar y	278	236	318	477	487	209	250	250
Number of denied applications during calendar year	86	40	110	72	66	40	60	60
Number of revoked licensees/registrants during calendar year	106	54	38	22	81	45	60	60
Number of other disciplinary actions during calendar year	248	215	118	181	439	206	300	300
Pecentage of resident pharmacy inspections conducted within past 24 months	98.1%	92.8%	80.5%	93.4%	95.1%	97.7%	90.0%	90.0%
Percentage of other facility resident inspections conducted within past 36 months	78.7%	73.3%	82.5%	94.8%	94.7%	82.9%	85.0%	85.0%
Percentage of investigations completed within nine months during calendar year	97.2%	98.5%	97.8%	95.3%	99.1%	99.8%	95.0%	95.0%

Complaints and Investigations: Complaints are received from the public as well as referrals and notifications from Kansas state and local government offices, other states, federal agencies, and the national practitioner databank. The Board has improved messaging to consumers to increase awareness about the type of matters and potential resolution available under the Board's authority, resulting in a decrease in allegations over which the Board has no jurisdiction (i.e. cost of prescription medications, prescribing, insurance, etc.). The Board assigns complaints to one of eight investigators for additional review. Investigation information includes data for <u>all</u> compliance investigations conducted by the agency, including those related to inspections, complaints, applications, renewals, criminal history reports, and information provided by licensees and registrants. This allows the Board to more accurately track employee workload and agency resources associated with all compliance-related matters.

Discipline and Revocations: Due to special state allowances during the public health emergency, no CE audit was conducted in FY2021 or FY2022. Increased disciplinary numbers are likely the result of a return to the audit in FY2023. The Board utilizes warning letters to express concerns to licensees and registrants about compliance issues that might be deterred and noted without the issuance of formal discipline. The majority of revocations are related to licensee and registrant failure to respond to the Board, diversion or theft of drugs, or significant criminal offenses that have or could endanger the public in the pharmacy setting. The Board reports all disciplinary orders to the National Association of Boards of Pharmacy and National Practitioner Databank, in addition to posting them on the Board website for public access and transparency.

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Consent Agreements are utilized wherever possible to decrease litigation costs or potential controversy in issuing discipline. Therefore, hearings are often legally complex, lengthy, and involve significant expense for the Board.

Inspections: The Board employs one pharmacy technician and six licensed pharmacists to operate as inspectors and conduct unannounced, routine inspections of all resident pharmacies and other registered facilities. Inspectors focus on education and compliance prior to recommending discipline to the Board. An influx of emergency or high-priority complaints and investigations often causes routine inspections to decrease in priority. As a result, the Board has moved from a three-tiered system (yes, no, not applicable) for inspection reports to a five-tiered system (compliant, needs improvement, not compliant, unassessed, and not applicable) to more accurately reflect the items assessed during inspections and more practically track the need for more/less frequent inspections.

Compounding: Despite agency efforts to manage inspector workload, there have been several areas of substantial impact to the volume of work assigned to the Compliance team over the past few years. Many pharmacists are practicing sterile and nonsterile compounding within the pharmacy setting, which requires a more lengthy and robust inspection consistent with the best practices outlined by the U.S. Pharmacopeia and adopted by the Board by regulation in 2019 (K.A.R. 68-13-2, *et seq.*). Compounding inspections may take 0.5-4 days depending on the magnitude of the pharmacy's operation. The Board has worked to ensure that all inspectors are adequately trained and certified to conduct these inspections, but the time commitment is much more substantial than previous years. This is in addition to the increased workload due to complaints, investigations, impaired practitioners, and other inspector responsibilities.

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# **Drug Monitoring Program**

The Kansas State Board of Pharmacy Drug Monitoring Program tracks prescriber, dispenser and patient information for all scheduled substances and drugs of concern dispensed in Kansas or to an address in Kansas. Goals include:

- 1. Protect patient safety.
- 2. Promote community health.
- 3. Prevent abuse, misuse, and diversion of scheduled substances and drugs of concern.
- 4. Preserve patient access to scheduled substances and drugs of concern for legitimate medical use.

# **K-TRACS**

In FY2024, K-TRACS continued work to support its strategic plan to ensure the highest quality of data in K-TRACS; support initiatives to increase K-TRACS utilization across the state of Kansas; and support positive patient outcomes by investigating and identifying instances of misuse and/or diversion of controlled substances in Kansas.

Key Performance Measures for the K-TRACS program include:

- the number of registered users;
- the number of patient queries; and
- the rate per quarter of multiple provider episodes among patients receiving prescription opioids.

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#### **Performance Measures for K-TRACS**

# Number of Registered K-TRACS Users (Prescribers and Dispensers as of June 30 of each year)

K-TRACS began evaluating its user data in 2021 to ensure appropriate access to confidential patient information, which resulted in a reduction of user accounts due to non-use and expired authority to practice in Kansas.

	2019	2020	2021	2022	2023	2024	2025est	2026est
Registered Prescribers	10481	10829	9438	10572	10548	10916	11250	11500
Registered Dispensers	4367	3395	3809	3629	3782	4076	4100	4125
Total	14848	14224	13247	14201	14330	14992	15350	15625

# Number of K-TRACS Patient Queries (as of June 30 each year)

K-TRACS averages approximately 387,000 patient queries per month. The increase in patient queries can be attributed in large part to the uptake of electronic health record and pharmacy system integrations with K-TRACS, which delivers patient information to healthcare providers more quickly and can be streamlined into a clinical workflow. Over 80% of patient searches are routinely conducted through integrated systems. K-TRACS anticipated a slight decline in patient searches in FY24 due to improvements in quality in how searches are recorded in the system.

	2019	2020	2021	2022	2023	2024	2025est	2026est
<b>Total Queries</b>	2,105,100	2,407,981	2,855,531	5,295,053	5,957,162	4,648,928	4,500,000	4,200,000

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# **Number of Healthcare Facilities Integrated with K-TRACS**

Healthcare organizations can request integration with their electronic health records or pharmacy dispensing system to deliver quick access to K-TRACS patient reports for their providers.

	2019	2020	2021	2022	2023	2024	2025est	2026est
Number of Active Integrations	144	179	179	282	331	398	425	450

# Percentage of Registered Users Conducting Patient Searches on K-TRACS (as of June 30 each year)

	2019	2020	2021	2022	2023	2024	2025est	2026est
Percent of Registered Prescribers Conducting Patient Searches	50%	50%	52%	55%	59%	52%	53%	54%
Percent of Registered Dispensers Conducting Patient Searches	61%	53%	48%	46%	49%	49%	50%	51%

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# **Number of Connected States and Organizations**

K.A.R. 68-21-6 allows K-TRACS to share data with other prescription drug monitoring programs through a data sharing hub. States with similar laws and permissions for PDMP users enter into a memorandum of understanding to enable prescribers and dispensers to query patient data in multiple states. Kansas is currently connected to 38 states, districts and territories, including most Midwest states and the Military Health System.

Year	2019	2020	2021	2022	2023	2024	2025est	2026est
Interstate Connections	32	37	37	37	37	38	38	38

# Number of Threshold Patients (as of June 30 of each year)

Threshold patients are those individuals who meet the criteria for multiple provider episodes, also known as "doctor shopping" behavior. Threshold patients are defined as those receiving controlled substance prescriptions from at least five prescribers and five pharmacies within a 90-day period. K-TRACS displays unsolicited reports to prescribers and pharmacists when an individual meets this threshold.

	2019	2020	2021	2022	2023	2024	2025est	2026est
Number of Threshold Patients	85	38	34	30	44	24	22	20
Rate of multiple provider episodes for prescription opioids per 100,000 Kansas residents	6	3.5	2.9	1.5	1.7	1.4	1.4	1.4

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# **Discussion on Historical Expenditures and Ending Cash Balance:**

In the past, the K-TRACS program has been largely supported with federal grants and special revenue fund dollars, including opioid settlement funds. The Board will continue to apply for grants and collaborate with project partners as a grant subrecipient to ensure sufficient K-TRACS support. However, opportunities for such applications beyond current awards will likely not be available until Spring 2026 or later. The Board has a long record of successful federal grant awards. Therefore, adjustments to decrease the request for expenditure authority from the Pharmacy Fee Fund are likely in future years. This will positively impact the Board's projected ending cash balance for FY2027.

The Board has consistently demonstrated its commitment to good stewardship of state and federal dollars, routinely and voluntarily reducing its request for expenditure authority upon reaching the current fiscal year. Additionally, the Board has not exceeded its expenditure authority in at least the last decade, and always ends the fiscal year under budget.

The Board last increased fees in May 2019 and does not anticipate the need for additional increases.

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#### **Overview of Agency Budget at Each Request Level – FY2025:**

The proposed budget for Fiscal Year 2025 will allow the agency to continue to grow and develop major initiatives, including:

- Maintaining strong agency programs, services, and resources;
- Providing sufficient and permanent funding for staff and resources for the K-TRACS program;
- Updating statutes and regulations consistent with current pharmacy practice standards;
- Increasing ease of access for individual and facility applicants; and
- Increasing real-time agency communications and services for applicants and licensees/registrants, as well as information for consumers.

The Board's total adjusted budget request for FY2025 is \$3,907,711 with \$2,726,649 funded from the fee fund, \$80,307 from the K-TRACS fund, \$214,460 from the 2020 Harold Rogers grant, \$325,280 from the 2023 Harold Rogers grant, \$164,424 from the SAMHSA grant, and \$396,591 from the KDHE grant.

<u>Salaries and Wages FY2025</u>. In FY2025, the Board requests to fund 20 full-time staff persons. Two of the 20 full-time staff are temporary, grant funded positions. Salaries for these temporary positions will be covered by the 2020 and 2023 Harold Rogers grants and the SAMHSA grant. The Board's total FY2025 adjusted budget request for salaries is \$2,086,716 with \$1,706,514 funded from the fee fund, \$75,307 from the K-TRACS fund, \$24,710 from the 2020 Harold Rogers grant, \$195,993 from the 2023 Harold Rogers grant, \$72,416 from the SAMHSA grant, and \$11,776 from the KDHE grant.

Contractual Services FY2025. The agency's major expenditures in this category are for rent; licensing software; K-TRACS AWARxE<sup>TM</sup> base software; K-TRACS INTEGRx8 system software that integrates K-TRACS data into electronic health record systems for prescribers and pharmacists in Kansas; communication expenses; in-state and out-of-state travel for inspectors, board members, and office staff; and professional service fees such as attorney fees, OITS fees, and KsPRN fees. The Board's total FY2025 adjusted budget request for contractual services is \$1,742,695 with \$943,534 from fee funds, \$5,000 from the K-TRACS fund, \$189,751 from the 2020 Harold Rogers grant, \$128,087 from the 2023 Harold Rogers grant, \$91,508 from the SAMHSA grant, and \$384,815 from the KDHE grant.

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<u>Commodities FY2025.</u> The agency's major expenditures in this category include office supplies and equipment, computer systems, gasoline, and parts and supplies for the Board's nine vehicles. The Board's total FY2025 adjusted budget request for commodities is \$46,200 with \$44,500 funded from fee fund, \$1,200 from the 2023 Harold Rogers grant, and \$500 from the SAMHSA grant.

<u>Capital Outlay FY2025.</u> Expenditures in this category include office equipment, furniture, and vehicles. The Board's total FY2025 adjusted budget request for capital outlay is \$30,100 all from fee funds.

**Hospitality FY2025.** The Board's base budget request for hospitality for FY2025 is \$2,500.

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# Overview of Agency Budget at Each Request Level – FY2026:

The proposed budget for Fiscal Year 2026 will allow the agency to continue to grow and develop initiatives outlined in this narrative.

The Board's total adjusted budget request for FY2026 is \$4,026,809 with \$2,947,109 funded from the fee fund, \$326,060 from the K-TRACS fund, \$633,271 from the 2023 Harold Rogers grant, \$117,995 from the SAMHSA grant, and \$2,374 from the KDHE grant.

<u>Salaries and Wages FY2026</u>. In FY2026, the Board requests to fund 20 full-time staff persons. Two of the 20 are full-time staff are temporary, grant funded positions. Salaries for these temporary positions will be covered by the 2023 Harold Rogers grant and the SAMHSA grant. The Board's total FY2026 adjusted budget request for salaries is \$2,178,067 with \$1,896,933 funded from the fee fund, \$22,298 from the K-TRACS fund, \$183,283 from the 2023 Harold Rogers grant, \$73,179 from the SAMHSA grant, and \$2,374 from the KDHE grant.

<u>Contractual Services FY2026</u>. The agency's major expenditures in this category are for rent; licensing software; K-TRACS AWARxE™ base software; K-TRACS INTEGRx8 system software; communication expenses; in-state and out-of-state travel for inspectors, board members, office staff; and professional service fees such as attorney fees, OITS fees, and KsPRN fees. The Board's total FY2026 adjusted budget request for contractual services is \$1,767,237 with \$970,371 from fee funds, \$303,762 from the K-TRACS fund, \$448,788 from the 2023 Harold Rogers grant, and \$44,315 from the SAMHSA grant.

<u>Commodities FY2026.</u> The agency's major expenditures in this category include office supplies and equipment, computer systems, gasoline, and parts and supplies for the Board's nine vehicles. The Board's total FY2026 adjusted budget request for commodities is \$48,505 with \$46,805 funded from fee fund, \$1,200 from the 2023 Harold Rogers grant, and \$500 from the SAMHSA grant.

<u>Capital Outlay FY2026.</u> Expenditures in this category include office equipment, furniture, and vehicles. The Board's total FY2026 adjusted budget request for capital outlay is \$31,000 all from fee funds.

**Hospitality FY2026.** The Board's base budget request for hospitality for FY2026 is \$2,500.

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# Overview of Agency Budget at Each Request Level – FY2027:

The proposed budget for Fiscal Year 2027 will allow the agency to continue to grow and develop initiatives outlined in this narrative.

The Board's total adjusted budget request for FY2027 is \$4,079,065 with \$3,607,526 funded from the fee fund, \$199,254 from the K-TRACS fund, \$213,857 from the 2023 Harold Rogers grant, and \$58,428 from the SAMHSA grant.

Salaries and Wages FY2027. In FY2027, the Board requests to fund 20 full-time staff persons. Two of the 20 full-time staff are temporary, grant funded positions. The SAMHSA grant expires September 30, 2026, and the 2023 Harold Rogers grant award expires March 31, 2027. Therefore, these grants will only cover applicable positions for part of the fiscal year. Salaries for these positions for the remaining months will be covered by the K-TRACS fund. The Board's total FY2027 adjusted budget request for salaries is \$2,188,870 with \$1,906,271 funded from the fee fund, \$142,519 from the K-TRACS fund, \$121,652 from the 2023 Harold Rogers grant, and \$18,428 from the SAMHSA grant.

Contractual Services FY2027. The agency's major expenditures in this category are for rent; licensing software; K-TRACS AWARxE<sup>TM</sup> base software; K-TRACS INTEGRx8 system software; communication expenses; in-state and out-of-state travel for inspectors, board members, and office staff; and professional service fees such as attorney fees, OITS fees, and KsPRN fees. The Board's total FY2027 adjusted budget request for contractual services is \$1,774,640 with \$1,585,700 from fee funds, \$56,735 from the K-TRACS fund, \$92,205 from the 2023 Harold Rogers grant, and \$40,000 from the SAMHSA grant. Because all known federal grant funds for contractual services will have been expended early in FY2027, the Board's contractual service request for FY2027 from the fee fund includes \$593,920 to continue the K-TRACS INTEGRx8 software program.

<u>Commodities FY2027.</u> The agency's major expenditures in this category include office supplies and equipment, computer systems, gasoline, and parts and supplies for the Board's nine vehicles. The Board's total FY2027 adjusted budget request for commodities is \$48,635 all from fee funds.

<u>Capital Outlay FY2027.</u> Expenditures in this category include office equipment, furniture, and vehicles. The Board's total FY2027 adjusted budget request for capital outlay is \$64,920 all from fee funds.

**Hospitality FY2027.** The Board's base budget request for hospitality for FY2027 is \$2,500.