September 15, 2023

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 2024 and 2025 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

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:

- 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.

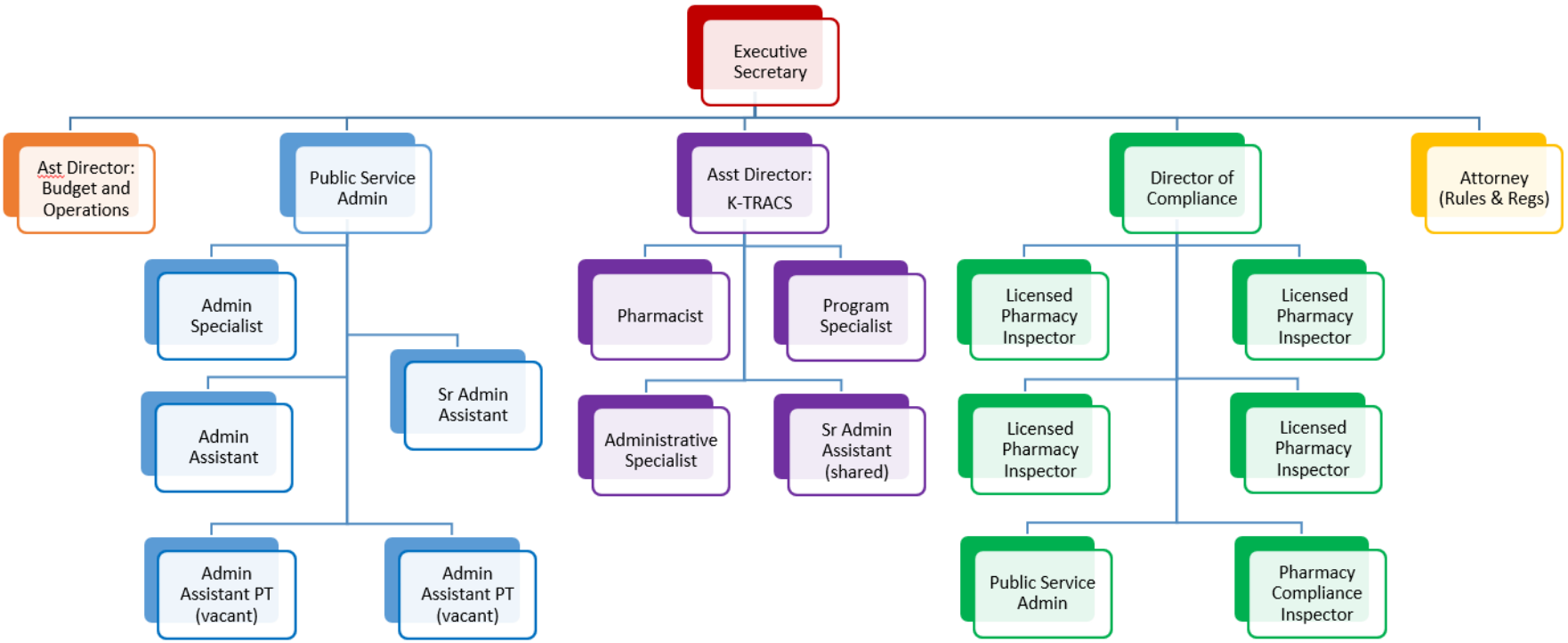
Narrative Information—DA 400

Division of the Budget

State of Kansas

Agency Board of Pharmacy

Program Agency Operations



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, 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 FY2024 is $3,378,262. The Board's requested, estimated spending authority from fee funds for FY2025 is $3,692,553.

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. A sub-recipient contract is currently underway but has not yet been finalized between the Board and KDHE for Year 1 (September 1, 2023 – August 31, 2024). The Board is the recipient of a 2020 Harold Rogers grant through September 30, 2024, and has applied for the 2023 Harold Rogers grant for another two-year extension of PDMP work. 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 2019, the legislature authorized a continuation of the fee fund transfers and supplemental funding from the State Drug Manufacturer's Rebate Fund for FY2020 and FY2021 to cover K-TRACS costs. 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 1st for the operation and maintenance of the K-TRACS program. While this funding has enabled the Board to cease collections from other fee-funded agencies, it falls short of the approximately $250,000 needed to operate the program

annually. The Board would greatly appreciate consideration of an additional $50,000 of support from the Opioid Settlement Litigation Fund in future years.

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.

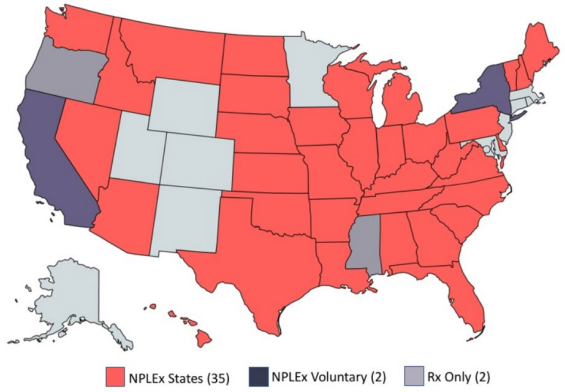
By 1970, several other major developments precipitated a half-century of change in the profession. These included the growth of corporately owned "chain" stores; the sudden growth of long-term care facilities; the development of new drugs; and, in 1970, the passage of the Controlled Substance Act. The 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. All states now allow dispensing of naloxone (emergency opioid antagonist) by pharmacists in accordance with a set protocol. 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 creates a gradual roll-out of national track and trace laws for the manufacture, distribution, and sale of all drugs and devices. 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 during and after the COVID-19 pandemic.

The Board recently has adopted regulations concerning K-TRACS, requirements for pharmacists-in-charge (PIC), pharmacy electronic records retention, drug packaging, labeling, prescription transfers, and controlled substances. 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.

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.



There are approximately 550 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, 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 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 http://ktracs.ks.gov. The website includes guidelines, best practices, prescribing and dispensing trends, and the Board's annual K-TRACS Legislative Report.

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 is the result of similar scheduling in surrounding 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 monthly 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, in conjunction with KDHE, 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 CDC 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.

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 recently 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.

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 is in the process of updating current processes. Waivers expire each June 30 and December 31 and require the prescriber to request renewal of the waiver from the Board.

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 during the COVID-19 pandemic. 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.

The FDA recently announced a one-year delay (to November 2024) of enforcement of the serialization and electronic trace interoperability requirements for trading partners and states. The Board supports the delay based on the need for additional work on interoperability and federal guidance, and is planning to draft regulations in 2024 for regulatory compliance with DSCSA. The Board has been engaged as a pilot project state with the National Association of Boards of Pharmacy on a project called "Pulse" which will enable states and trading partners to quickly and easily meet federal requirements.

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. During 2023, the Board has made such a determination on two occasions upon notification from an Assistant District Attorney for Kansas.

Telepharmacy

In 2018, the Board commenced a pilot project allowing for the operation of a telepharmacy in the state of Kansas. Telepharmacy allows a pharmacist to conduct their review, supervision, verification, and patient counseling responsibilities virtually, while a pharmacy technician staffs the brick-and-mortar pharmacy and conducts the in-person dispensing process. Among other things, the software enables remote prescription verification and live-video counseling with patients including audio and video. The Kansas pilot has been operational for five years, demonstrating success and no increased risk to the public. 2021 Substitute for Senate Bill 238 defines telepharmacy practice and requires the Board to adopt regulations concerning telepharmacy operation by January 1, 2023. Regulations have been drafted and were noticed for public hearing in January 2023. However, upon request by a legislator for additional review of the Board's authority, the Attorney General rescinded his approval pending additional review.

Occupational Regulation, Temporary Emergency Licenses, and Electronic Credentials

Effective July 1, 2021, the Kansas legislature adopted Substitute for House Bill 2066 which amends law to shorten 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.

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.

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.

Licensing Objectives – Licensure, Registration, and Education

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.

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	FY2019	FY2020	FY2021	FY2022	FY2023	FY2024 Est	FY2025 Est
Percentage of initial applications processed within 30 days of receipt during previous fiscal year	78.70%	79.96%	64.21%	75.98%	78.06%	75%	75%
Percentage of initial applications processed within 30 days of completion during previous fiscal year	100%	95.37%	74.21%	97.20%	97.68%	97%	97%

Percentage of initial applications for military service members or spouses processed within 15 days of completion during the previous fiscal year				100%	94.74%	90%	90%
Percentage of online renewals for previous fiscal year*	97.80%	98.40%	98.80%	99.20%	99.52%	99.00%	99.00%
Number of CE courses approved for previous fiscal year	81	60	54	62	73	70	70

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.

Narrative Information—DA 400

Division of the Budget — Agency Board of Pharmacy

State of Kansas — Program Agency Operations

Statistics for Licensing and Registration

		FY14	FY15	FY16	FY17	FY18	FY19	FY20	FY21	FY22	FY23
Individuals											
	Intern/Student	1,171	1,165	1,158	1,134	1,086	1,000	1,049	1,006	947	892
	Pharmacists	5,228	5,197	5,364	5,705	6,783	6,500	7,632	7,694	7,967	8,244
	Technicians	7,242	7,377	7,600	8,049	8,000	8,050	7,566	7,570	7,726	7,858
Facilities											
	Ambulance	174	161	173	180	183	175	182	190	196	196
	Analytical Lab	30	26	29	32	32	29	34	33	35	36
	County Health, Family Planning	113	103	105	103	103	98	105	114	117	117
	Distributor	1,074	1,043	1,100	1,171	1,197	1,125	1,138	960	969	971
	Distributor (non-prescription)	106	107	110	102	108	97	76	80	90	74
	Durable Medical Equipment	475	421	438	457	422	427	431	441	445	452
	Institutional Drug Room	80	55	56	56	49	52	72	74	74	79
	Manufacturer	13	13	15	16	15	16	17	459	572	620
	Outsourcing Facility							26	34	38	40
	Pharmacy (Resident)	907	901	924	922	935	921	918	905	913	911
	Pharmacy (Non-Resident)	842	839	960	992	982	616	667	716	771	785
	Research &Teaching	105	90	99	127	119	100	126	108	104	101
	Retail Dealer	1,514	1,528	1,515	1,541	1,616	1,600	1,625	1,664	1,716	1,739
	Sample Distributor	52	44	41	42	31	31	21	23	32	34
	Third-Party Logistics Provider							105	155	197	228
	Third-Party Logistics Provider (non-prescription)							25	37	42	46

Narrative Information—DA 400

Division of the Budget — Agency Board of Pharmacy

State of Kansas — Program Agency Operations

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 complete an examination, accept responsibility for the pharmacy, 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.

Narrative Information—DA 400

Division of the Budget — Agency Board of Pharmacy

State of Kansas — Program Agency Operations

Performance Measures for Regulatory Program: Compliance

Compliance Performance Measures	2018	2019	2020	2021	2022	2023ytd	2024est	2025est
Number of complaints received during calendar year	151	41	109	165	115	112	125	125
Number of compliance investigations conducted during calendar year	838	581	532	541	599	568	500	500
Number of applications or renewals referred to compliance division during calendar year	346	278	236	318	477	305	250	250
Number of denied applications during calendar year	93	86	40	110	72	49	50	50
Number of revoked licensees/registrants during calendar year	187	106	54	38	22	61	50	50
Number of other disciplinary actions during calendar year	260	248	215	118	181	342	200	200
Pecentage of resident pharmacy inspections conducted within past 24 months	94.4%	98.1%	92.8%	80.5%	93.4%	90.1%	90.0%	90.0%
Percentage of other facility resident inspections conducted within past 36 months	81.2%	78.7%	73.3%	82.5%	94.8%	94.5%	85.0%	85.0%
Percentage of investigations completed within nine months during calendar year	94.6%	97.2%	98.5%	97.8%	95.3%	100.0%	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 seven investigators for additional review. Investigation information includes data for all 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.

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 five 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.

Narrative Information—DA 400

Division of the Budget — Agency Board of Pharmacy

State of Kansas — Program Agency Operations

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 FY2023, 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.

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. The program averages 140 new user registrations each month.

	2018	2019	2020	2021	2022	2023	2024est	2025est
Registered Prescribers	9973	10481	10829	9438	10572	10548	10700	10800
Registered Dispensers	4044	4367	3395	3809	3629	3782	3800	3850
Total	14017	14848	14224	13247	14201	14330	14500	14650

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

K-TRACS averaged approximately 431,000 patient queries per month in the 2nd quarter of 2023. 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. In 2022, approximately 87% of patient searches were conducted through integrated systems. K-TRACS anticipates 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	2024est
Integrated Searches	1,169,807	1,567,170	2,117,550	4,510,561	5,196,401	4,800,000
Web Searches	935,293	840,811	737,981	784,492	760,761	765,000
Total	2,105,100	2,407,981	2,855,531	5,295,053	5,957,162	5,565,000

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	2024est
Number of Active Integrations	144	179	179	282	331	364

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

	2019	2020	2021	2022	2023	2024est
Percent of Registered Prescribers Conducting Patient Searches	50%	50%	52%	55%	59%	60%
Percent of Registered Dispensers Conducting Patient Searches	61%	53%	48%	46%	49%	51%

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 37 states, districts and territories, including most Midwest states and the Military Health System.

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

Narrative Information—DA 400

Division of the Budget — Agency Board of Pharmacy

State of Kansas — Program Agency Operations

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	2024est
Number of Threshold Patients	85	38	34	30	44	35
Rate of multiple provider episodes for prescription opioids per 100,000 Kansas residents	6	3.5	2.9	1.5	1.7	1.5

Narrative Information—DA 400

Division of the Budget — Agency Board of Pharmacy

State of Kansas — Program Agency Operations

NPLEx

1. Register dispensers in the NPLEx electronic logging system

2. Track the number of purchases for non-prescription products containing PSE ingredients

3. Track the number of sales blocked for exceeding legal limits

TRANSACTION SUMMARY STATISTICS (2023)

	JAN	FEB	MAR	APR	MAY	JUN	JUL	TOTAL
PURCHASES	37,737	37,123	40,473	39,975	37,910	31,138	29,023	**253,379**
BLOCKS	1,318	1,244	1,431	1,609	1,562	1,359	1,252	**9,775**
GRAMS SOLD	83,621	82,543	95,339	97,008	92,323	76,132	71,285	**598,251**
BOXES SOLD	39,594	38,919	42,397	41,915	39,743	32,769	30,456	**265,793**
GRAMS BLOCKED	5,287	3,802	4,621	5,299	5,035	4,398	4,060	**32,502**
BOXES BLOCKED	1,566	1,448	1,652	1,852	1,831	1,572	1,418	**11,339**
AVG GRAMS PER BOX BLOCKED	3.38	2.63	2.80	2.86	2.75	2.80	2.86	**2.87**

PHARMACY PARTICIPATION STATISTICS (Jul 2023)

Enabled Pharmacies	554
Pharmacies Submitting a Transaction	488
Pharmacies Logging in Without a Transaction	0
Inactive Pharmacies	66
Pharmacy Participation for Jul	88.09%

The tables above represent the transaction summary statistics from NPLEx for products containing methamphetamine precursors, such as pseudoephedrine (i.e., Sudafed, Zyrtec D, and Claritin D), and pharmacy submissions during a sample month (August 2023).

Enhancement Requests for FY2025:

Pay Plan Supplemental Change Package:

Per the direction of Division of Budget, the Board is requesting a supplemental change package of $74,739 to offset the state employee pay plan approved by the 2023 Legislature, giving employees a 5% salary increase. Although the action increased the FY 2024 expenditure limitation, the Legislature did not include the expenditure limitation increase for FY 2025.

Compliance Staff:

New 1.0 FTE for FY2025:

The Board is requesting a supplemental package totaling $151,715 for FY2025 to fund an additional 1.0 FTE for an Assistant Director position within the Compliance division. The Board currently employs a Director of Compliance who is responsible for the oversight of the division and supervision of five full-time inspectors. The volume of work assigned to the Compliance team over the past ten years has increased substantially due in part to the rising practice of sterile and nonsterile compounding, as well as the increase in complaints, investigations, and impaired practitioners. Complex investigations often require multiple inspectors and/or a supervisor to ensure that the Board can adequately manage the facility personnel and space, collect evidence, and complete the investigation within a reasonable period of time. Over the last two years, such investigations and resultant disciplinary actions have taken multiple months of an inspectors' time, but sometimes result in probationary fees which will help offset this additional expenditure. In addition, the Board is utilizing an inspector to provide subject matter expertise to the Attorney for regulation review and provide support for pharmacy and statewide emergency declarations. In consideration of the long-term health of the Compliance division and succession planning, the Board believes that adding an Assistant Director position would be beneficial. The position would support the Director of Compliance, relieve certain specialized duties (as mentioned above) from the inspectors to improve their workload, provide training to inspectors and staff, and be the natural successor to the Director upon any change in personnel. Therefore, the Board requests an additional 1.0 FTE for an Assistant Director of Compliance position beginning in FY 2025.

Hospitality:

The Board is also requesting an enhancement of the official hospitality fund in the amount of $500 for FY2025. The Board primarily uses the hospitality fund to pay for lunches during regular in-person Board meetings in Topeka and quarterly staff in-service meetings, which average

$300 per meal. The last increase to this fund was requested in FY2020 and does not adequately cover costs associated with increased food costs due to inflation. According to the U.S. Bureau of Labor Statistics, food prices have increased 19.6% since June 2020. In addition, costs are heightened by the need to provide individual servings instead of buffet meals due to the public health risk and dietary restrictions of Board and staff members.

Narrative Information—DA 400

Division of the Budget — Agency Board of Pharmacy

State of Kansas — Program Agency Operations

Overview of Agency Budget at Each Request Level – FY2024:

The proposed budget for Fiscal Year 2024 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;
- 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 FY2024 is $4,320,655 with $3,378,261 funded from the fee fund, $200,000 from the K-TRACS fund, $99,352 from the KDHE grant, $486,186 from the 2020 Harold Rogers grant, $119,356 from the SAMHSA grant, and $37,500 from the American Rescue Plan Act (ARPA) State Relief Fund.

Salaries and Wages FY2024. In FY2024, the Board requests to fund 19 full-time staff persons. Two of the 19 full-time staff are temporary, grant funded positions. The Board's adjusted budget request for salaries and benefits for FY2024 is $1,876,927 with $1,544,489 funded from the fee fund, $80,647 from the K-TRACS fund, $165,683 from the 2020 Harold Rogers grant, and $86,108 from the SAMHSA grant.

Contractual Services FY2024. The agency's major expenditures in this category are for rent; licensing software; K-TRACS AWARxE™ software; communication expenses; agency copier contract; 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 FY2024 adjusted budget request for contractual services is $2,368,828 with $1,761,372 from the fee fund, $119,353 from the K-TRACS fund for the K-TRACS AWARxE™ base software cost, $99,352 from the KDHE grant, $318,503 from the 2020 Harold Rogers grant, $32,748 from the SAMHSA grant, and $37,500 from the ARPA grant. Because federal grant funding has not yet been awarded, the Board's contractual service request for FY2024 from the fee fund includes $779,760 to continue the K-TRACS special software programs, namely INTEGRx8, the technology system that integrates K-TRACS data into electronic health record systems for prescribers and pharmacists in Kansas.

Commodities FY2024. The agency's major expenditures in this category include office supplies and equipment, computer systems, gasoline, and parts and supplies for the Board's seven vehicles. The Board's total FY2024 adjusted budget request for commodities is $44,300 with $41,800 funded from fee fund, $2,000 from the 2020 Harold Rogers grant, and $500 from the SAMHSA grant.

Capital Outlay FY2024. Expenditures in this category include office equipment, furniture, and vehicles. The Board's total FY2024 adjusted budget request for capital outlay is $28,600 all from fee funds.

Hospitality FY2024. The Board's base budget request for hospitality for FY2024 is $2,000.

Narrative Information—DA 400

Division of the Budget — Agency Board of Pharmacy

State of Kansas — Program Agency Operations

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;
- 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 $4,058,714 with $3,692,553 funded from the fee fund, $200,000 from the K-TRACS fund, $46,886 from the 2020 Harold Rogers grant, and $119,275 from the SAMHSA grant.

Salaries and Wages FY2025. In FY2025, the Board requests to fund 21 full-time staff persons. This includes the 20 staff persons budgeted in FY2024 plus a supplemental request for the 1.0 FTE Assistant Director of Compliance position discussed earlier. The supplemental package totals $151,715 and will be funded by the fee fund. The 2020 Harold Rogers grant award expires September 30, 2024, and, therefore, the grant will only cover applicable positions for the first three months of the fiscal year. Salaries for these positions for the remaining nine months will be covered by the K-TRACS fund and the SAMHSA grant. The Board's total FY2025 adjusted budget request for salaries is $2,025,210 with $1,693,153 funded from the fee fund, $191,500 from the K-TRACS fund, $41,291 from the 2020 Harold Rogers grant, and $99,266 from the SAMHSA grant.

Contractual Services FY2025. The agency's major expenditures in this category are for rent; licensing software; K-TRACS AWARxE™ software; communication expenses; agency copier contract; 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 $1,924,904 with $1,891,300 from fee funds, $8,500 from the K-TRACS fund for the K-TRACS AWARxE™ base software cost, $5,595 from the 2020 Harold Rogers grant, and $19,509 from the SAMHSA grant. Because federal grant funding has not yet been awarded, the Board's contractual service request for FY2025 from the fee fund includes $831,914 to continue the K-TRACS special software programs, namely INTEGRx8, the technology system that integrates K-TRACS data into electronic health record systems for prescribers and pharmacists in Kansas.

Commodities FY2025. The agency's major expenditures in this category include office supplies and equipment, computer systems, gasoline, and parts and supplies for the Board's seven vehicles. The Board's total FY2025 adjusted budget request for commodities is $45,000 with $44,500 funded from fee fund and $500 from the SAMHSA grant.

Capital Outlay FY2025. Expenditures in this category include office equipment, furniture, and vehicles. The Board's total FY2025 adjusted budget request for capital outlay is $61,100 all from fee funds.

Hospitality FY2025. The Board's base budget request for hospitality for FY2025 is $2,000. As explained earlier, the Board is requesting an enhancement of the hospitality fund in the amount of $500 to cover increased food costs for Board meetings and in-service staff meetings. The adjusted budget request for FY2025 for hospitality is $2,500.