KBOP Regulatory Program

Consequences of Not Funding this Program

Potential for harm to the public resulting from: 1) No oversight of pharmacies and other drug facilities (registrants) administering, dispensing, or shipping drugs in Kansas, or pharmacy personnel (licensees). 2) Lack of compliance with pharmacy practice standards including sterile compounding.

Statutory Basis	Mandatory vs. Discretionary	MOE/Match Rqt.	Priority Level
Specific KSA 65-1625 et seq	Mandatory	No	1

Program Goals

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

B. Compliance – Facilitate compliance with, foster respect and appreciation for, and educate on Kansas statutes, rules, and regulation 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.

Program History

Regulation of the manufacture, sale, and distribution of drugs and poisons began in Kansas with the passage of enabling legislation in 1885. 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. Most states, including Kansas, have enacted their own version of the controlled substance act based on the federal provisions.

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, and shifting the roll of boards of pharmacy to a standard of care instead of a prescriptive model.

The Board recently has adopted regulations to address the increased compounding of pharmaceuticals, reporting of theft/loss of controlled substances, increasing the pharmacist to pharmacy technician ratio, and requirements for pharmacy closure to protect patient records and continuity of care. 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.

Performance Measures

Outcome Measures	*Goal*	*FY 2019*	*FY 2020*	*FY 2021*	*3- yr. Avg.*	*FY 2022*	*FY 2023*
1. Percentage of initial	A	78.70%	79.96%	64.21%	0.7429	75%	77%
2. Percentage of initial	A	100.00%	95.37%	74.21%	0.8986	85%	87%
3. Percentage of online renewals for previous fiscal year	A	97.80%	98.40%	98.80%	98.3%	98.9%	99.0%
4. Number of CE courses	A	81	60	54	65	60	60

		Cal 2019	*Cal 2020*	*Cal 2021*	*Cal 2022*	*Cal 2023*	*Cal 2024*
6. Number of complaints	B	41	109	86	79	100	100
7. Number of compliance	B	581	532	313	475	350	350
8. Number of applications or	B	278	236	227	247	250	250
9. Number of denied	B	86	40	48	58	50	50
10. Number of revoked	B	106	54	14	58	75	75
11. Number of other disciplinary	B	248	215	98	187	250	250
		FY 2019	*FY 2020*	*FY 2021*	*3- yr. Avg.*	*FY 2022*	*FY 2023*
12. Pecentage of resident	B	98.1%	92.8%	80.5%	90.4%	93.5%	94.0%
13. Percentage of other facility	B	78.7%	73.3%	82.5%	78.2%	80.5%	81.0%
14. Percentage of investigations	B	97.2%	98.5%	98.3%	98.0%	95.0%	95.0%

Funding

Funding Source		*FY 2018*	*FY 2019*	*FY 2020*	*FY 2021*	*FY 2022*	*FY 2023*
State General Fund		$ -	$ -	$ -	$ -	$ -	$ -
Non-SGF State Funds		$ 1,281,651	$ 1,318,556	$ 1,393,000	$ 1,348,845	$ 2,223,372	$ 2,130,878
Federal Funds		-	-	-	-	-	-
Total		$ 1,281,651	$ 1,318,556	$ 1,393,000	$ 1,348,845	$ 2,223,372	$ 2,130,878

KBOP Drug Monitoring Program

Consequences of Not Funding this Program

Misuse, abuse and diversion of controlled substances and drugs of concern.

Statutory Basis	Mandatory vs.	MOE/Match Rqt.	Priority Level
Specific K.S.A. 65-1681 et seq	Mandatory	No	1

Program Goals

A. Track prescriber, dispenser, and patient information for all scheduled substances and drugs of concern dispensed in Kansas or to an address in Kansas

B. Prevent abuse, misuse, and diversion of controlled substances and drugs of concern, while ensuring continued access for legitimate medical use.

Program History

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. Kansas has now joined 54 other states and U.S. districts/territories in using a PDMP in an effort to reduce the diversion and improper use of controlled substances and drugs of concern, while ensuring continued availability of these medications for legitimate use. K-TRACS includes all retail and outpatient dispensing records for any controlled substance or drug of concern dispensed in or into Kansas. The only exception is for quantities dispensed in the emergency room for 48 hours or less. If a prescriber or a pharmacist has a concern about a patient, he/she can look up the patient's prescription history in K-TRACS. Because K-TRACS is a real-time, web-based system, patient information can be obtained instantly from any location at any time with the proper login credentials. Prescribers and pharmacists must register for K-TRACS through the Board prior to utilizing the system. Each dispensing pharmacy is required to post a notice to patients about the availability and reporting of this information. Law enforcement and other state agencies have limited access to the program, but may request records with proper legal authority. In 2012, medical examiners were permitted access to 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 collaborates with KDHE to transmit such de-identified data and cooperatively employs a grant-funded epidemiologist to analyze K-TRACS data and identify trends.

Performance Measures

Outcome Measures	*Goal*	*FY 2019*	*FY 2020*	*FY 2021*	*3- yr. Avg.*	*FY 2022*	*FY 2023*
1. Number of registered K-	A	10,481	10,829	9,438	10,249	9,500	9,550
2. Number of registered K-	A	4,367	3,395	3,809	3,857	3,820	3,840
3. Number of K-TRACS queries	A	9,755,080	17,605,322	20,837,950	16,066,117	21,000,000	22,000,000
4. Annual Program Costs per K-	A	$ 12.37	$ 31.84	$ 14.66	$ 19.62	$ 15.89	$ 89.17
5. Annual Program Costs per K-	A	$ 0.22	$ 0.55	$ 0.26	$ 0.34	$ 0.27	$ 1.51
6. Annual Program Costs per K-	A	$ 0.03	$ 0.08	$ 0.04	$ 0.05	$ 0.04	$ 0.23
7. Number of connected states	B	32	37	37	35	37	37
8. Number of Threshold Patients	B	167	97	88	117	85	80
9. Number of Clinical Alert	B		191,484	188,984	190,234	188,000	188,000

Funding

Funding Source	*FY 2018*	*FY 2019*	*FY 2020*	*FY 2021*	*FY 2022*	*FY 2023*
State General Fund	$ -	$ -	$ -	$ -	$ -	$ -
Non-SGF State Funds	156,400	183,737	452,870	217,604	210,454	1,181,191
Federal Funds	775,834	856,480	899,396	1,277,940	1,703,940	518,301
Total	$ 932,234	$ 1,040,217	$ 1,352,266	$ 1,495,544	$ 1,914,394	$ 1,699,492