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. 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 roll 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 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 is currently working on amendments to 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.services in the fom of telepharmacy or secure vending machines, increse in the prevalence and oversight of sterile and nonsterily 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.

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Performance Measures

Outcome Measures	*Goal*	*FY 2019 Actuals*	*FY 2020 Actuals*	*FY 2021 Actuals*	*FY 2022 Previous Est.*	*FY 2022 Actuals*	*FY 2023 Est.*	*FY 2024 Est.*	*3- yr. Avg.*
1. Percentage of initial applications processed within 30 days of receipt during the previous fiscal year	A	78.70%	79.96%	64.21%	75.00%	77.95%	75%	75%	74.04%
2. Percentage of initial applications processed within 30 days of completion during previous fiscal year	A	100.00%	95.37%	74.21%	85.00%	97.20%	87%	87%	88.93%
3. Percentage of initial applications for military service members or spouses processed within 15 days of completion during the previous fiscal year	A				90.00%	100.00%	95%	95%	100%
4. Percentage of online renewals for previous fiscal year	A	97.80%	89.40%	98.80%	98.90%	99.20%	99%	99%	95.80%

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5. Number of CE courses approved for previous fiscal year	A	81	60	54	60	62	60	60	59
Output Measures									
6. Number of complaints received during calendar year	B	41	109	165	100	70	125	125	115
7. Number of compliance investigations conducted during calendar year	B	581	532	541	350	335	500	500	469
8. Number of applications or renewals referred to compliance division during calendar year	B	278	236	318	250	232	250	250	262
9. Number of denied applications during calendar year	B	86	40	110	50	61	50	50	70
10. Number of revoked licensees/registrants during calendar year	B	106	54	38	75	19	35	35	37
11. Number of other disciplinary actions during calendar year	B	248	215	118	250	146	175	175	160
Additional Measures as Necessary									
12. Pecentage of resident pharmacy inspections conducted within past 24 months	B	98.1%	92.8%	80.5%	93.5%	99.1%	94.0%	94.0%	90.8%
13. Percentage of other facility resident inspections conducted within past 36 months	B	78.7%	73.3%	82.5%	80.5%	86.0%	85.0%	85.0%	80.6%
14. Percentage of investigations completed within nine months during calendar year	B	97.2%	98.5%	97.8%	95.0%	100.0%	95.0%	95.0%	98.8%

Funding

Funding Source	*FY 2019 Actuals*	*FY 2020 Actuals*	*FY 2021 Actuals*	*FY 2022 Approved*	*FY 2022 Actuals*	*FY 2023 Est.*	*FY 2024 Est.*	*3-yr. Avg.*
State General Fund	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Non-SGF State Funds	1,318,556	1,393,000	1,348,845	2,223,372	1,538,844	2,412,768	2,482,235	1,426,896
Federal Funds	-	-	-	-	-	-	-	-
Total	$ 1,318,556	$ 1,393,000	$ 1,348,845	$ 2,223,372	$ 1,538,844	$ 2,412,768	$ 2,482,235	$ -
FTE	12.0	12.0	12.5	13.0	13.0	14.0	14.0	14.0

Drug Monitoring Program

Consequences of Not Funding this Program

Misuse abuse and diversion of controlled substances and drugs of concern

Statutory Basis		Mandatory vs. Discretionary	MOE/Match Rqt.	Priority Level
Specific	KSA 65-1625 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.

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Performance Measures

Outcome Measures	*Goal*	*FY 2019 Actuals*	*FY 2020 Actuals*	*FY 2021 Actuals*	*FY 2022 Previous Est.*	*FY 2022 Actuals*	*FY 2023 Est.*	*FY 2024 Est.*	*3- yr. Avg.*
1. Number of registered K-TRACS Prescribers	A	10,481	10,829	9,438	9,500	10,572	10,600	10,700	10,280
2. Number of registered K-TRACS pharmacists	A	4,367	3,395	3,809	3,820	3,629	3,650	3,700	3,611
3. Number of Active Integrations	A	144	179	179		282	290	295	213
4. Annual program costs per K-TRACS user	A	$12.37	$31.84	$14.66	$15.89	$16.89	$17.24	$72.93	$21.13
5. Annual program costs per K-TRACS patient	A	$0.22	$0.55	$0.26	$0.27	$0.29	$0.21	$0.87	0.37
6. Annual Program costs per K-TRACS prescription	A	$0.03	$0.08	$0.04	$0.04	$0.04	$0.04	$0.16	0.05
Output Measures									
7. Number of K-TRACS queries	A	2,105,100	2,407,981	2,855,531	21,000,000	5,295,053	5,300,000	5,350,000	3,519,522
8. Percentage of Registered Users	A	50%	50%	52%		55%	55%	55%	52%
9. Percentage of Registered Users	A	61%	53%	48%		46%	50%	50%	49%
Additional Measures as Necessary									
10. Number of connected states	B	32	37	37	37	37	38	38	37
11. Number of Threshhold Patients	B	167	97	88	85	30	25	25	72
12. Number of Clinical Alerts	B	-	191,484	188,984	188,000	186,239	184,376	182,532	188,902

Funding

Funding Source	*FY 2019 Actuals*	*FY 2020 Actuals*	*FY 2021 Actuals*	*FY 2022 Approved*	*FY 2022 Actuals*	*FY 2023 Est.*	*FY 2024 Est.*	*3-yr. Avg.*
State General Fund	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Non-SGF State Funds	183,737	452,870	217,604	210,454	223,719	244,836	1,035,660	298,064
Federal Funds	856,480	899,396	1,277,940	1,703,940	1,427,483	1,372,640	730,070	1,201,606
Total	$ 1,040,217	$ 1,352,266	$ 1,495,544	$ 1,914,394	$ 1,651,202	$ 1,617,476	$ 1,765,730	$ 1,499,671
FTE	3.0	6.0	6.0	6.0	6.0	5.0	5.0	5.0