

**State of Kansas**  
**Board of Pharmacy**

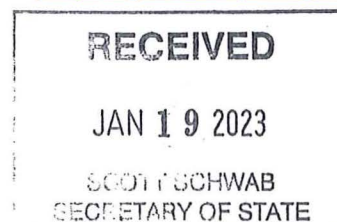
**Notice of Public Hearing on Proposed Administrative  
Regulations**

A public hearing will be conducted on Thursday, April 27, 2023, at 9:00 a.m. at the Office of Administrative Hearings, 1020 S Kansas Ave, Topeka, Kansas, to review and consider the adoption of proposed permanent regulations of the Kansas State Board of Pharmacy.

This 60-day notice of the public hearing shall constitute a public comment period for the purpose of receiving written public comments on the proposed regulations. All interested parties may submit written comments prior to the public hearing to Alexandra Blasi, Executive Secretary, 800 S.W. Jackson, Suite 1414, Topeka, Kansas 66612-1244, or by e-mail to [pharmacy@ks.gov](mailto:pharmacy@ks.gov). All interested parties will be given a reasonable opportunity to present their views orally regarding the adoption of the proposed regulations during the public hearing. In order to provide all parties an opportunity to present their views, it may be necessary to request that each participant limit any oral presentation to five minutes.

Any individual with a disability may request an accommodation in order to participate in the public hearing and may request the regulations and economic impact statements in an accessible format. Requests for accommodation to participate in the public hearing should be made at least 10 business days in advance of the hearing by contacting Alexandra Blasi, Executive Secretary, 800 S.W. Jackson, Suite 1414, Topeka, Kansas 66612-1244 or by phone at (785) 296-4056. Handicapped parking is located at the north entrance to the building. Curbs at the north entrance are accessible to individuals with disabilities.

Summaries of the proposed regulations and their economic impact follow. Copies of the regulations and economic impact statement may be viewed at <https://pharmacy.ks.gov/statutes->



[regs/proposed-changes](#). (Note: Statements indicating that “The Board anticipates that the proposed amendment/new regulation will have minor to no economic impact” are intended to indicate that no economic impact on the Board, other state agencies, state employees, or the general public have been identified.)

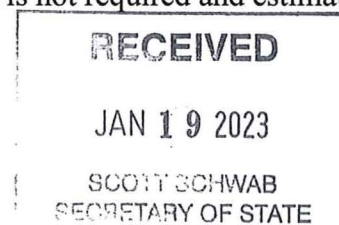
**K.A.R. 68-1-1b. Continuing education for pharmacists.** The proposed amendment to this regulation modifies the continuing education requirement for pharmacists licensed by the Board. The amendment would require pharmacists to obtain a topical one hour of continuing education provided by the Board; this hour would be counted towards the 30 clock-hour requirement. The Board would make the one-hour course available to pharmacists free of charge and anticipates the proposed amendment will have minor to no economic impact.

**K.A.R. 68-1-2a. Pharmacist-in-charge; acknowledgment; notice of designation.** The proposed amendments to this regulation clarify the process for becoming a pharmacist-in-charge (PIC), including an acknowledgment of PIC responsibilities. The amendment also updates and clarifies Board notification requirements for PICs beginning and ceasing to serve as PIC, and allows pharmacies to request a 30-day waiver for additional time to designate a new PIC. The Board anticipates that the proposed amendment will have minor to no economic impact.

**K.A.R. 68-1-9. Pharmacist-in-charge; responsibilities.** The proposed new regulation is designed to provide greater consistency and clarity of pharmacy PIC requirements and highlight practice setting variance. The proposed regulation captures general PIC responsibilities, including supervision, availability, record-keeping, resources, managing drug recalls, changing PIC, drug inventory, newsletter review, and development of pharmacy policies and procedures. The Board anticipates the proposed regulation will have minor to no economic impact.

**K.A.R. 68-2-20. Pharmacist’s function in filling a prescription.** The proposed amendments to this regulation provide consistency with updates to the Pharmacy Act, including the ability for pharmacists to fill prescriptions based on a prescriber’s telephonic consultation with a patient, which judgmental functions a pharmacist may delegate to a pharmacist intern or pharmacy technician, and which nonjudgmental functions may be delegated within certain limitations. Finally, the proposed amendments authorize an exception to the verbal patient counseling requirement in limited circumstances. The Board anticipates the proposed amendments will have minor to no economic impact.

**K.A.R. 68-7-8. Records.** The proposed amendments to this regulation are designed to allow pharmacies the ability to digitize prescription records to reduce costs associated with paper storage. Language sets forth basic requirements for ensuring accurate copies and retrievable electronic records. This amendment does not require any pharmacy to participate in digital recordkeeping. Amendments do not require record digitization and are designed to be business-friendly and allow autonomy in recordkeeping processes, while providing minimum safeguards to ensure public protection. While pharmacies that elect to engage in digitization of records may incur costs associated with electronic storage systems, this is not required and estimated



expenses are unknown to the Board. Additionally, many pharmacies may already have electronic storage systems capable of storing additional electronic records without additional expense. Pharmacies electing to participate in electronic scanning and shredding of paper records could experience decreased costs associated with physical record storage in the long-run. Since the regulation does not mandate pharmacies engage in electronic storage, no economic impact is anticipated.

**K.A.R. 68-7-11. Medical care facility pharmacy.** The proposed amendments to this regulation are designed to clarify the responsibilities of the PIC, which have been moved into new K.A.R. 68-1-9. New language outlines the requirements for pharmacies registered as medical care facilities in Kansas, including updating emergency supply labeling requirements, allowing a physician's assistant to enter the pharmacy as directed, and requiring a pharmacist to review medication orders within three days. Any economic impact will likely stem from shortening the medication order review timeline, but the Board anticipates this will be de minimus.

**K.A.R. 68-7-12. Responsibility of pharmacist-in-charge in other than a medical care facility pharmacy.** The proposed amendments to this regulation are designed to clarify the responsibilities of the PIC, which have been moved into new K.A.R. 68-1-9. The Board anticipates the proposed amendments will have minor to no economic impact.

**K.A.R. 68-7-15. Packaging of drugs or devices in advance of immediate need.** The proposed amendments to this regulation require prepackaged drugs to be packaged in a suitable container consistent with the Pharmacy Act and the State and Federal Uniform Controlled Substances Acts. The proposed amendments also require a pharmacist to verify all prepackaged drugs or devices prior to release, consistent with requirements for prescription dispensing. The Board anticipates the proposed amendment will have minor to no economic impact.

**K.A.R. 68-7-16. Labels for drugs or devices packaged in advance of immediate need.** While proposed amendments to this regulation appear vast, they are actually very minor. Language changes represent technical updates since the last revision in 1978. Substantive amendments include updating and streamlining the labeling requirement for drugs or devices packaged in advance of immediate need. This change is consistent with updates to the Pharmacy Act and the State and Federal Uniform Controlled Substances Acts. The Board anticipates that the proposed amendment will have minor to no economic impact.

**K.A.R. 68-7-19. Transfer of a refillable prescription between pharmacies.** The proposed amendments to this regulation respond to recent changes in the Pharmacy Act, which authorizes the pharmacy to transfer certain prescriptions at the patient's request and allows additional pharmacy personnel to receive and transfer such prescriptions. Amendments also update current standards and clarify the process for completing such transfers. Amendments are consistent with federal requirements and those for controlled substances, additionally updating requirements for electronic prescriptions. The Board anticipates that the proposed amendment will have minor to no economic impact but will provide substantial benefit to Kansas patients.

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**K.A.R. 68-7-20a. Delivery of prescriptions dispensed to an alternate site for administration.** The proposed new regulation addresses the practices known as “white bagging” and “brown bagging” in the pharmacy setting. The Board identified several areas for public protection, including requirements for specific communication between the pharmacies, delivery to a pharmacy versus a practitioner’s office, policies and procedures, recordkeeping, prescription tracking, patient consent, patient counseling, prescription storage in accordance with manufacturer requirements, and return of any prescription not administered to the patient. The regulation also eliminates the practice of “brown bagging” or delivering a prescription to a patient’s residence required to be administered by a healthcare provider, except in limited circumstances, and restricts prescriptions for controlled substances.

The Board is unable to quantify an economic impact. While the proposed language does create new requirements for these practices, pharmacies already have the capacity to implement compliance as the proposed regulation is closely aligned with routine prescription dispensing practices.

**K.A.R. 68-20-1. Definitions.** The proposed amendments to this regulation clarify and modify the definitions specific to the Kansas Uniform Controlled Substances Act. Amendments align with current federal requirements. The Board anticipates that the proposed amendment will have minor to no economic impact since pharmacies are already required to comply with federal law.

**K.A.R. 68-20-16. Records and inventories of registrants.** The proposed amendments to this regulation clarify and modify recordkeeping and inventory requirements for controlled substances in Kansas pharmacies. Specifically, the proposed amendments update federal regulatory sections, including drugs of concern, limit to non-liquid dosage forms, and clarify documentation requirements. Amendments align with current federal requirements. The Board anticipates that the proposed amendment will have minor to no economic impact since pharmacies are already required to comply with federal law.

**K.A.R. 68-20-18. Information concerning prescriptions.** The proposed amendments to this regulation update requirements for controlled substance medications including identifying and verifying a valid prescription, contents of a valid prescription, electronic prescriptions, transmission, and dispensing. Amendments align with current federal requirements. The Board anticipates that the proposed amendment will have minor to no economic impact since pharmacies are already required to comply with federal law.

**K.A.R. 68-20-18a. Information concerning prescriptions; recordkeeping; pharmacy prescription application.** The proposed new regulation includes requirements for controlled substance medications including supplying, dispensing, and administering these medications, and sets forth procedures and requirements for partial fills and refills, and outlines recordkeeping requirements. Language aligns with current federal requirements. The Board anticipates that the regulation will have minor to no economic impact since pharmacies are already required to comply with federal law.

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**K.A.R. 68-20-19. Controlled substances listed in schedule II.** The proposed amendments to this regulation update requirements specific to Schedule II controlled substance medications, including specific dispensing requirements, patient records, and annotations. Amendments align with current federal requirements. The Board anticipates that the proposed amendment will have minor to no economic impact since pharmacies are already required to comply with federal law.

**K.A.R. 68-20-20. Controlled substances listed in schedules III, IV, and V.** The proposed amendments to this regulation update requirements specific to Schedule III, IV, and V controlled substance medications, including specific dispensing requirements, patient records, and annotations. Amendments align with current federal requirements. The Board anticipates that the proposed amendment will have minor to no economic impact since pharmacies are already required to comply with federal law.

**K.A.R. 68-20-21. Revoked.** The proposed revocation is due to the content of the regulation being consolidated into K.A.R. 68-20-20. No economic impact.

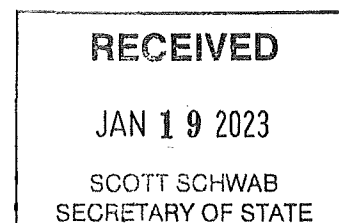
**K.A.R. 68-20-22. Selling without a prescription.** The proposed amendments to this regulation update requirements for sales of prescription-only drugs without a prescription (i.e., methamphetamine precursors). Amendments align with current federal requirements. The Board anticipates that the proposed amendment will have minor to no economic impact since pharmacies are already required to comply with federal law.

**K.A.R. 68-21-1. Definitions.** The proposed amendments update and clarify several definitions within the Prescription Drug Monitoring Program (K-TRACS) to match current pharmacy recordkeeping practices. The Prescription Monitoring Program Act was amended in 2022 and changes are reflected in this amendment. The Board anticipates that the proposed amendment will have minor to no economic impact.

**K.A.R. 68-21-2. Electronic reports.** The proposed amendment updates and clarifies when a dispenser shall file controlled substance prescriptions reports in K-TRACS, shortens the timeframe for filing, and updates requirements for requesting exemption. The Prescription Monitoring Program Act was amended in 2022 and changes are reflected in this amendment. The Board anticipates any economic impact will relate to dispensers no longer qualifying for the exemption, pharmacies changing or updating software vendor agreements, and software vendors changing how controlled substance prescriptions are reported to K-TRACS on the pharmacies' behalf. However, as vendors are likely to be multi-state vendors, they are likely already compliant with the amendment in Kansas.

**K.A.R. 68-21-3. Revoked.** This regulation is revoked as moot and in conflict with recent updates to Prescription Monitoring Program Act. No economic impact.

**K.A.R. 68-21-4. Notice of requests for information.** The proposed amendments to this regulation provide technical clarification since the regulation has not been updated since 2010. The Board anticipates no economic impact.



**K.A.R. 68-21-5. Access to program information.** The proposed amendments to this regulation clarify existing requirements for requesting data from K-TRACS. The Prescription Monitoring Program Act was amended in 2022 and changes are reflected in this amendment. The Board anticipates that the proposed amendment will have minor to no economic impact.

**K.A.R. 68-23-1. Definitions.** The proposed new regulation provides requirements for the new practice of telepharmacy as required by the Pharmacy Act. The Board anticipates no economic impact from definitions.

**K.A.R. 68-23-2. Telepharmacy outlet application; facility; managing pharmacy.** The proposed new regulation provides requirements for the new practice of telepharmacy as required by the Pharmacy Act. This regulation sets forth the requirements for pharmacy owners who wish to establish a telepharmacy outlet, including where it can be established, how many prescriptions can be dispensed from the outlet, how the outlet is to be supervised, the opportunity for the outlet to receive a waiver from the Board in certain circumstances to operate a telepharmacy, and outlet compliance.

The Board is unable to quantify an economic impact. While the proposed new regulation creates new requirements for pharmacies that wish to utilize telepharmacy, the proposed new regulation does not require pharmacies to utilize telepharmacy. Pharmacies wishing to open a telepharmacy may incur costs ranging from \$5,000 to \$25,000 for initial setup and ongoing maintenance approximating \$1,500 to \$5,000 per month.

**K.A.R. 68-23-3. Personnel, staffing, training, and supervision.** The proposed new regulation provides requirements for the new practice of telepharmacy as required by the Pharmacy Act. This regulation sets forth the requirements for the personnel who would staff the telepharmacy outlet, internal inspection, storage of drugs and devices, emergency procedures, and what constitutes direct supervision. Additional travel and coverage by a pharmacist-in-charge or supervising pharmacist that would be above and beyond routine in-person pharmacy supervision. While no additional pharmacist hours are required to operate a telepharmacy outlet, there may be a shift in the location for hours worked or those dedicated to particular tasks/functions which may have an economic impact. The Board anticipates no additional economic impact.

**K.A.R. 68-23-4. Practice of pharmacy.** The proposed new regulation provides requirements for the new practice of telepharmacy as required by the Pharmacy Act. This regulation sets forth the requirements for when a prescription may be dispensed, what tasks may be performed by pharmacist interns and pharmacy technicians, and outlet compliance.

**K.A.R. 68-23-5. Operation of telepharmacy outlet.** The proposed new regulation provides requirements for the new practice of telepharmacy as required by the Pharmacy Act. This regulation sets forth the requirements for when the telepharmacy outlet can be operated, what electronic prescription application may be utilized, where the outlet receives prescriptions and devices, what notices and licenses must be displayed, how often a pharmacist must be on site, storage of drugs and devices, recordkeeping, emergencies, and closure of the outlet.

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**K.A.R. 68-23-6. Structural, security, technology, and equipment requirements; restrictions.** The proposed new regulation provides requirements for the new practice of telepharmacy as required by the Pharmacy Act. This regulation sets forth the requirements for the security system employed by the telepharmacy outlet, plumbing and electricity, sanitation, lighting and climate, recordkeeping, and automated dispensing. Vendors and other state boards of pharmacy estimate the costs of continuous video surveillance of the telepharmacy outlet at \$20,000, and costs of ongoing maintenance and storage to range from \$300 - \$1,650 per month. The cost of a monitored alarm system is estimated under \$1,000 per year. This is also referenced in K.A.R. 68-23-2. No additional economic impact is anticipated aside and apart from routine pharmacy operation costs.

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**68-1-1b. Continuing education for pharmacists.** (a)(1) "Continuing education" shall mean an organized and systematic education experience beyond basic preparation that is designed to achieve the following:

- (A)(i) Increase knowledge, improve skills, or enhance the practice of pharmacy; or
- (ii) improve protection of the public health and welfare; and
- (B) ensure continued competence.

(2) "ACPE-NABP CPE monitor service" shall mean the electronic tracking service of the accreditation council for pharmacy education and the national association of boards of pharmacy for monitoring continuing education that pharmacists receive from continuing education providers.

(b)(1) Thirty clock-hours of continuing education shall be required for renewal of a pharmacist license during each licensure period. Continuing education clock-hours may be prorated for licensure periods that are less than biennial at a rate of 1.25 clock-hours per month.

(2) Each licensee shall complete a continuing education course consisting of one clock-hour that is provided by the board for renewal of a pharmacist license, which shall be counted toward the 30 clock-hour requirement. This paragraph shall take effect on July 1, 2023.

(c)(1) Each continuing education program shall be approved by the board. Each provider or licensee shall submit the continuing education program to the board at least 10 days in advance for consideration for approval. Each provider shall advertise the continuing education program as having only pending approval until the provider is notified of approval by the board.

(2) Continuing education programs shall not include in-service programs, on-the-job training, orientation for a job, an education program open to the general public, a

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cardiopulmonary resuscitation (CPR) course, a basic cardiac life support (BCLS) course, emergency or disaster training or direct experience at a healthcare facility under a code blue, testing out of a course, and medical school courses.

(3) Each provider shall furnish a certificate of completion to the licensee for each continuing education program that the licensee has successfully completed. Each certificate shall be in a format approved by the board and shall include the following:

- (A) The licensee's name;
- (B) the title and date of the approved continuing education program;
- (C) the name of the provider;
- (D) the number of continuing education clock-hours approved by the board;
- (E) the number of continuing education clock-hours completed by the licensee;
- (F) the approved program number issued by the board; and
- (G) the provider's dated signature, certifying program completion.

(d) Within 30 days of completion, each licensee shall submit to the board proof of completion of any approved continuing education program not reported to the ACPE-NABP CPE monitor service. No credit shall be given for any certificate of completion received by the board after the June 30 expiration date of each licensure period.

(e) A licensee shall not be allowed to carry forward excess clock-hours earned in one licensure period into the next licensure period.

(f) The required continuing education shall be obtained in the two-year licensure period ending on the June 30 expiration date of each license. (Authorized by K.S.A. 65-1630; implementing K.S.A. 2015-Supp. 65-1632; effective, E-76-31, Aug. 11, 1975; effective May 1,

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1976; amended May 1, 1978; amended May 1, 1983; amended May 1, 1986; amended May 1,  
1987; amended July 1, 1990; amended July 31, 1998; amended Oct. 20, 2006; amended April 23,  
2010; amended Aug. 19, 2016; amended P-\_\_\_\_\_.)

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**68-1-2a. Pharmacist-in-charge examination; acknowledgement; notice of**

**designation.** (a) ~~Each prospective pharmacist-in-charge shall take a pharmacy law examination administered by the board, with a passing score of at least 85%. The examination shall include the statutes and rules and regulations, both state and federal, governing the practice of pharmacy.~~

(b) Each pharmacy or registrant required to have a pharmacist-in-charge that operates for more than 30 days without a designated pharmacist-in-charge who meets the requirements of this regulation shall be deemed to be in violation of K.S.A. 65-1627(e), and amendments thereto.

(e)(b) ~~A pharmacist who has already passed the~~ Each prospective pharmacist-in-charge examination required by the board shall not be required to retake the examination upon assuming the duties of a pharmacist-in-charge but shall, at the time of assuming these duties, sign an acknowledgment that states both of the following:

(1) ~~The pharmacist is not currently prevented from performing the duties of a pharmacist-in-charge by an order of the board.~~

(2) ~~the pharmacist has reviewed the pharmacy act and the board's regulations and is aware of the responsibilities of a pharmacist-in-charge. The pharmacist-in-charge shall immediately provide this acknowledgment to the board within 30 days of assuming the duties of a pharmacist-in-charge. A copy of the acknowledgment shall be maintained at the premises where the pharmacist is functioning as a pharmacist-in-charge.~~

(c) Except as specified in subsection (d), each pharmacy owner shall submit to the board, on a form provided by the board, notice of designation of a new pharmacist-in-charge at the pharmacy or facility required to have a pharmacist-in-charge no later than 30 days after the previous pharmacist-in-charge has ceased to serve as the pharmacist-in-charge.

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(d) Any pharmacy owner that is unable to designate a new pharmacist-in-charge within 30 days may submit to the board, on a form provided by the board, a request for a 30-day extension to designate a new pharmacist-in-charge. The request shall be submitted to the board no more than 30 days after the previous pharmacist-in-charge has ceased to serve as pharmacist-in-charge and shall provide the reason for the request. (Authorized by K.S.A. 2000 2022 Supp. 65-1643 and K.S.A. 2000 Supp. 65-1627 65-1626 and K.S.A. 65-1630; implementing K.S.A. 2000 Supp. 65-1643, K.S.A. 2000 Supp. 65-1627 and K.S.A. 2000 2022 Supp. 65-1626, as amended by L. 2001, ch. 31, sec. 1 and K.S.A. 65-1637c; effective Aug. 1, 1997; amended May 31, 2002; amended P-\_\_\_\_\_.)

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**68-1-9. Pharmacist-in-charge; responsibilities.** (a) Each pharmacist-in-charge shall develop, supervise, and coordinate all pharmaceutical services performed within the pharmacy to ensure compliance with the Kansas pharmacy act, the state and federal uniform controlled substances act, the state and federal food, drug, and cosmetic act, and all applicable regulations.

(b) Each pharmacist-in-charge shall be personally available to the extent required to ensure comprehensive pharmaceutical services within the pharmacy and to develop a staff of additional licensed pharmacists and supportive personnel as necessary to serve the needs of the pharmacy. Each pharmacist-in-charge shall maintain records in the pharmacy describing the training and education regarding work functions performed by all pharmacy personnel. Each pharmacist-in-charge shall maintain in the pharmacy written procedures for the following:

- (1) Designating the person or persons functioning as pharmacy technicians and supportive personnel;
- (2) describing the job duties of all personnel;
- (3) documenting the procedural steps taken by the pharmacist-in-charge to limit the functions of all personnel to their respective pharmacy work functions; and
- (4) documenting training and related education for nondiscretionary tasks performed by pharmacy technicians.

(c) Each pharmacist-in-charge shall be responsible for direct supervision of all pharmacy personnel, for the security of the pharmacy, and for the security of all drugs in the pharmacy.

(d) Each pharmacist-in-charge shall ensure that the pharmacy maintains adequate drug information references commensurate with services offered and a current copy of the state laws and regulations listed in subsection (a).

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(e) Each pharmacist-in-charge shall be responsible for establishing a drug recall procedure that can be effectively implemented.

(f) Each pharmacist-in-charge shall be responsible for developing written procedures for maintaining records of drug distribution, prepackaging, repackaging, and compounding. Prepackaging and repackaging of drugs shall be done in accordance with K.A.R. 68-7-15 and labeled in accordance with K.A.R. 68-7-16.

(g) Each pharmacist-in-charge shall be responsible for reviewing each published board newsletter and posting the newsletter in a conspicuous area within the pharmacy until publication of the next board newsletter.

(h)(1) Each pharmacist shall submit to the board, on a form provided by the board, notice of ceasing to serve as the pharmacist-in-charge at a pharmacy or facility required to have a pharmacist-in-charge no later than five days after ceasing to serve as the pharmacist-in-charge.

(2) Each pharmacist ceasing to serve as the pharmacist-in-charge shall inventory all controlled substances and drugs of concern, as defined by K.S.A. 65-1682 and amendments thereto, in the pharmacy or facility in accordance with the inventory requirements of K.A.R. 68-20-16 no more than two days before ceasing to serve as the pharmacist-in-charge and no later than the day ceasing to serve as the pharmacist-in-charge.

(3) Each pharmacist beginning to serve as the pharmacist-in-charge shall inventory all controlled substances and drugs of concern, as defined by K.S.A. 65-1682 and amendments thereto, in the pharmacy or facility in accordance with the requirements of K.A.R. 68-20-16 after beginning to serve as the pharmacist-in-charge but no more than two days after beginning to serve as the pharmacist-in-charge. The inventory may be taken simultaneously with the previous

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pharmacist-in-charge on the last day of the previous pharmacist-in-charge if both pharmacists are present in the pharmacy, actively participate in the inventory, and sign the inventory.

(4) If a pharmacist ceasing to serve as pharmacist-in-charge is unable to complete the inventory specified in paragraph (2) of this subsection or is terminated for a suspected or known violation of the Kansas pharmacy act, the pharmacy or facility owner shall request approval from the board to designate another pharmacist to conduct the inventory. If the board approves the request, the pharmacy or facility owner may designate another pharmacist to conduct the inventory specified in paragraph (2) of this subsection within the designated time frame.

(Authorized by K.S.A. 2022 Supp. 65-1626 and K.S.A. 65-1630; implementing K.S.A. 2022 Supp. 65-1626, K.S.A. 65-1637c, K.S.A. 65-1642, and K.S.A. 65-1648; effective P-\_\_\_\_\_.  
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**68-2-20. Pharmacist's function in filling a prescription.** (a) As used in this regulation, each of the following terms shall have the meanings meaning specified in this subsection:

(1) "Authorized Prescriber" ~~shall mean~~ means a "practitioner" as defined by K.S.A. 65-1626~~(gg)~~ and amendments thereto, a "mid-level practitioner" as defined by K.S.A. 65-1626~~(ss)~~ and amendments thereto, or a person authorized to issue a prescription by the laws of another state.

(2) "Legitimate medical purpose," when used ~~in regard to~~ regarding the dispensing of a prescription drug, ~~shall mean~~ means that the prescription for the drug was issued with a valid preexisting patient-prescriber relationship rather than with a relationship established through an internet-based questionnaire, ~~an internet-based consultation, or a telephonic consultation.~~

(b) ~~These~~ Except as provided in subsection (c), judgmental functions that constitute the filling or refilling of a prescription shall be performed only by a ~~licensed~~ pharmacist or by a ~~pharmacy student or pharmacist~~ intern under the direct supervision of a licensed pharmacist and shall consist of the following steps:

- (1) Read and interpret the prescription of the prescriber;
- (2) limit any filling or refilling of a prescription to one year from the date of origin, except as provided by K.S.A. 65-1637 and K.S.A. 65-4123, and amendments thereto;
- (3) verify the compounding, counting, and measuring of ingredients and document the accuracy of the prescription;
- (4) ~~identify, in the pharmacy record, the pharmacist who verifies the accuracy of the completed prescription;~~
- (5) personally offer to counsel each patient or the patient's agent with each new

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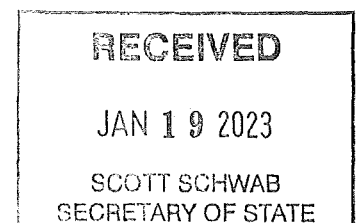
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prescription dispensed, once yearly on maintenance medications; and, if the pharmacist deems appropriate, with prescription refills in accordance with subsection ~~(e)~~(e);

~~(6)~~(5) ensure the proper selection of the prescription medications, devices, or suppliers as authorized by law;

~~(7) when supervising a pharmacy technician, delegate only nonjudgmental duties associated with the preparation of medications and conduct in-process and final checks;~~

~~(8) prohibit all other pharmacy personnel from performing those judgmental functions restricted to the pharmacist; and~~

~~(9)~~(6) interpret and verify patient medication records and perform drug regimen reviews.

(c) The pharmacist-in-charge shall prohibit all other pharmacy personnel from performing those judgmental functions restricted to the pharmacist. The following judgmental functions shall be performed only by a pharmacist and shall not be delegated:

(1) Final verification of the accuracy of a completed compound or prescription;

(2) documentation of the pharmacist's final verification in the pharmacy record; and

(3) direct supervision of a pharmacist intern or pharmacy technician.

(d) Any pharmacist may delegate nonjudgmental functions to a pharmacist intern or pharmacy technician. Each pharmacist shall conduct in-process and final checks associated with the preparation of medications, except as provided by K.A.R. 68-7-11.

(e) In order to comply with ~~paragraph~~ subsection (b)(5), the pharmacist or the ~~pharmacy student or pharmacist~~ intern under the pharmacist's direct supervision shall perform the following:

(1) Personally offer to counsel each patient or the patient's agent with each new

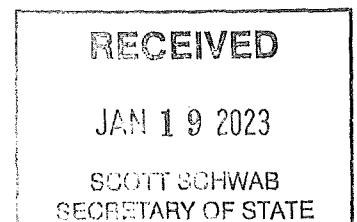
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prescription dispensed, once yearly on maintenance medications; and, if the pharmacist deems appropriate, with prescription refills. Any pharmacist may authorize an exception to the verbal counseling requirement on a case-by-case basis for the continuation of therapy prescriptions issued more frequently than once yearly;

(2) provide the verbal counseling required by this regulation in person, ~~whenever practical,~~ or by the utilization of a telephone or other communication service available to the patient or patient's agent if the prescription is not collected at the pharmacy. ~~Any pharmacist may authorize an exception to the verbal counseling requirement on a case-by-case basis for refills, maintenance medications, or continuous medications for the same patient;~~

(3) when appropriate, provide alternative forms of patient information to supplement verbal patient counseling. These supplemental forms of patient information may include written information, leaflets, pictogram labels, video programs, and auxiliary labels on the prescription vials. However, the supplemental forms of patient information shall not be used as a substitute for the verbal counseling required by this regulation;

(4) encourage proper patient drug utilization and medication administration. The pharmacist shall counsel the patient or patient's agent on those elements that, in the pharmacist's professional judgment, are significant for the patient. These elements may include the following:

- (A) The name and a description of the prescribed medication or device;
- (B) the dosage form, dosage, route of administration, and duration of therapy;
- (C) special directions and precautions for preparation, administration, and use by the patient;
- (D) common side effects, adverse effects or interactions, or therapeutic contraindications

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that could be encountered; the action required if these effects, interactions, or contraindications occur; and any activities or substances to be avoided while using the medication;

(E) techniques for self-monitoring drug therapy;

(F) proper storage requirements and disposal instructions; and

(G) action to be taken in the event of a missed dose; and

(5) expressly notify the patient or the patient's agent if a brand exchange has been exercised.

~~(d)(f)~~ Except as required by K.S.A. 65-16,127 and amendments thereto for the dispensing of an emergency opioid antagonist, nothing in this regulation shall be construed to require a pharmacist to provide the required patient counseling if either of the following occurs:

(1) The patient or the patient's agent refuses counseling.

(2) The pharmacist, based upon professional judgment, determines that the counseling may could be detrimental to the patient's care ~~or to the relationship between the patient and the patient's prescriber.~~

~~(e)(g)~~ Each pharmacist shall make a reasonable effort to ensure that any prescription, regardless of the means of transmission, has been issued for a legitimate medical purpose by an ~~authorized~~ a prescriber. (Authorized by K.S.A. 65-1630; implementing K.S.A. ~~2008~~ 2021 Supp. 65-1626, ~~K.S.A. 2008 Supp. and~~ 65-1637; and ~~K.S.A. 2008 Supp. 65-1642~~; effective, E-77-39, July 22, 1976; effective Feb. 15, 1977; amended May 1, 1978; amended May 1, 1988; amended Nov. 30, 1992; amended March 20, 1995; amended Aug. 14, 1998; amended Dec. 27, 1999; amended Feb. 7, 2003; amended Jan. 8, 2010; amended P-\_\_\_\_\_.)

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**68-7-8. Records.** ~~Original written prescriptions shall be deemed recordation in writing by~~  
the pharmacist under the provisions of K.S.A. 65-1637 (b) (1975 Supp.) (a) Each of the  
following terms, as used in this regulation, shall have the meaning specified in this subsection:

(1) "Digital image" means the electronic record produced when a hard-copy prescription  
is scanned by a computer and converted from human-readable format to a computer-readable  
digital format and maintained as part of the prescription record in a pharmacy prescription  
application.

(2) "Electronic annotation" means a method to mark up a digital image or electronic  
prescription to allow both notes and clarifications to be added to the prescription record without  
altering the original digital image.

(b) Each pharmacy owner and pharmacist-in-charge shall keep a book or file that records  
every prescription order filled at the pharmacy.

(c)(1) A digital image of the prescription may constitute the original prescription order. A  
hard copy of the prescription order shall not be required to be maintained if all of the following  
conditions are met:

(A) The prescription is not for a controlled substance.

(B) The pharmacy prescription application can capture and store an exact and legible  
image of the original prescription.

(C) The digital image includes the front and back of the prescription and retains all colors  
and graphics on the prescription.

(D) The digital image is unalterable.

(E) The digital image and all electronic annotations are readily retrievable and can be

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immediately reproduced by the pharmacy prescription application in electronically viewable and paper formats. In lieu of reproducing the digital image in a color paper format, the digital image may be provided in color in an electronic portable document format (PDF).

(F) Policies and procedures for the use of digital images are developed and implemented to include capturing, making, storing, retrieving, and recovering digital images and electronic annotations, and destruction of the original hard-copy prescription.

(G) The pharmacy maintains a back-up copy of the digital image and all electronic annotations stored in the pharmacy prescription application and updates the back-up copy at least once every seven days.

(H) A secure destruction method is used to dispose of the hard-copy prescription to ensure privacy and confidentiality.

(2) If the pharmacy prescription application data is automatically entered by a prescription order received by electronic transmission, the automated record shall constitute the original prescription order and a hard copy shall not be required if all of the following conditions are met:

(A) The electronic prescription and its means of transmission meet all requirements of the pharmacy act of the state of Kansas and the state and federal controlled substance acts, and amendments thereto.

(B) The pharmacy prescription application can capture and store all prescription information received.

(C) The prescription information is readily retrievable, and the pharmacy prescription application can immediately reproduce all prescription information received in both

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electronically viewable and paper formats.

(D) The pharmacy maintains a back-up copy of the electronic prescription record and all electronic annotations stored in the pharmacy prescription application and updates the back-up copy at least once every seven days.

(3) Nothing in paragraph (c)(1) shall be construed as requiring a pharmacy to maintain a digital image in lieu of hard-copy prescription.

(d) Any digital image may contain electronic annotations if the original image is still available for review and the name of the individual who made the annotations is documented.

(e) The pharmacist shall ensure that each printout of a digital image provided to a patient or the patient's representative is conspicuously marked "Copy Only" or "Not Valid for Dispensing Purposes."

(f) Each pharmacy owner shall establish policies and procedures in accordance with this regulation and shall ensure that all policies and procedures comply with the pharmacy act of the state of Kansas, and amendments thereto, and the implementing regulations. Each pharmacist-in-charge shall document an annual review of the policies and procedures for compliance with the pharmacy act, and amendments thereto, and the implementing regulations.

(g) Each of the following individuals shall be responsible for ensuring that each digital image is a complete, accurate, and legible representation of the corresponding hard-copy prescription:

(1) The pharmacist, pharmacist intern, or pharmacy technician who generates the digital image;

(2) the pharmacist, pharmacist intern, or pharmacy technician who enters the prescription

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information into the pharmacy prescription application; and

(3) the pharmacist who verifies the prescription. (Authorized by K.S.A. ~~1975 Supp.~~ 65-1630; implementing K.S.A. 65-1626a, as amended by L. 2022, ch. 74, sec. 2, K.S.A. 2021 Supp. 65-1637, K.S.A. 65-1642, and K.S.A. 2021 Supp. 65-1656; effective, E-76-31, Aug. 11, 1975; effective May 1, 1976; amended P-\_\_\_\_\_.)

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**68-7-11. Medical care facility pharmacy.** The scope of pharmaceutical services within a medical care facility pharmacy shall ~~conform to~~ meet the following requirements:

(a) The pharmacist-in-charge shall be responsible for developing programs and supervising all personnel in the distribution and control of drugs and all pharmaceutical services in the medical care facility.

(b) The pharmacist-in-charge shall develop a policy and procedure manual governing the storage, control, and distribution of drugs within the medical care facility. The pharmacist-in-charge shall submit the policy and procedure manual for approval to the pharmacy and therapeutics committee or an equivalent committee governing the security, control, and distribution of drugs within the facility.

(c) The pharmacist-in-charge shall be responsible for the maintenance of all emergency medication kits.

(d) The pharmacist-in-charge shall be responsible for developing procedures for the distribution and control of drugs within the medical care facility when a pharmacist is not on the premises. These procedures shall be consistent with the following requirements:

(1) ~~Inpatient service.~~ Drugs may be obtained upon a prescriber's medication order for administration to the inpatient by a physician's assistant, designated registered professional nurse, or nurses with approval and supervision of the pharmacist-in-charge. Adequate records of these withdrawals shall be maintained.

(2) ~~Emergency outpatient service.~~

(A) An interim supply of prepackaged drugs shall be supplied to an outpatient on an emergency basis only by a designated registered professional nurse or nurses pursuant to a

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prescriber's medication order when a pharmacist is not on the premises and a prescription cannot be filled. The interim supply shall be labeled with the following information:

- (i) ~~The name, address, and telephone number of the medical care facility;~~
- (ii) ~~the name of the prescriber. The label shall include the name of the practitioner and, if involved, the name of either the physician's assistant (PA) or the advanced registered nurse practitioner (ARNP);~~
- (iii) ~~the full name of the patient;~~
- (iv) ~~the identification number assigned to the interim supply of the drug or device by the medical care facility pharmacy;~~
- (v) ~~the date the interim supply was supplied;~~
- (vi) ~~adequate directions for use of the drug or device;~~
- (vii) ~~the beyond-use date of the drug or device issued;~~
- (viii) ~~the brand name or corresponding generic name of the drug or device;~~
- (ix) ~~the name of the manufacturer or distributor of the drug or device, or an easily identified abbreviation of the manufacturer's or distributor's name;~~
- (x) ~~the strength of the drug;~~
- (xi) ~~the contents in terms of weight, measure, or numerical count; and~~
- (xii) ~~necessary auxiliary labels and storage instruction, if needed in accordance with~~

K.A.R. 68-7-14.

(B) The interim supply shall be limited in quantity to an amount sufficient to supply the outpatient's needs until a prescription can be filled. Adequate records of the distribution of the interim supply shall be maintained and shall include the following information:

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(i) The original or a copy of the prescriber's order; or, if an oral order, a written record prepared by a designated registered professional nurse or nurses that reduces the oral order to writing. The written record shall be signed by the designated registered professional nurse or nurses and the prescriber; and

(ii) the name of the patient; the date supplied; the drug or device, strength, and quantity distributed; directions for use; the prescriber's name; and, if appropriate, the DEA number.

(3) The designated registered professional nurse or nurses or physician's assistant may enter the medical care facility pharmacy and remove properly labeled pharmacy stock containers, commercially labeled packages, or properly labeled prepackaged units of drugs. The registered professional nurse or physician's assistant shall not transfer a drug from one container to another for future use, but may transfer a single dose from a stock container for immediate administration to the ultimate user.

(e) The pharmacist-in-charge of the medical care facility pharmacy shall maintain documentation of at least quarterly checks of drug records and conditions of drug storage, in all locations within the facility, including nursing stations, emergency rooms, outpatient departments, and operating suites.

(f) The pharmacist-in-charge shall participate with the pharmacy and therapeutics committee or an equivalent committee in formulating broad professional policies regarding the evaluation, appraisal, selection, procurement, storage, distribution, use, and safety procedures for drugs within the medical care facility.

(g) ~~The pharmacist in charge shall be responsible for establishing a drug recall procedure that can be effectively implemented.~~

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~~(h)(1) The pharmacist in charge shall be responsible for developing written procedures for maintaining records of drug distribution, prepackaging, and bulk compounding. Prepackaged drugs shall include the following information:~~

~~(A) The brand name or corresponding generic name of the drug;~~

~~(B) the name of the manufacturer or distributor of the drug, or an easily identified abbreviation of the manufacturer's or distributor's name;~~

~~(C) the strength of the drug;~~

~~(D) the contents in terms of weight, measure, or numerical count;~~

~~(E) the lot number; and~~

~~(F) the beyond-use date.~~

~~(2) Prepackaged drugs shall be packaged in suitable containers and shall be subject to all other provisions of the Kansas state board of pharmacy regulations under the uniform controlled substances act of the state of Kansas and under the pharmacy act of the state of Kansas. Before releasing any drugs or devices from the pharmacy, the pharmacist shall verify the accuracy of all prepackaging and the compounding of topical and oral drugs.~~

~~(i) The pharmacist in charge shall ensure that the medical care facility maintains adequate drug information references commensurate with services offered and a current copy of the Kansas pharmacy act, the Kansas uniform controlled substances act, and current regulations under both acts.~~

~~(j) The pharmacist in charge shall be responsible for pharmacist supervision of all pharmacy technicians and for confining their activities to those functions permitted by the pharmacy practice act. Records shall be maintained describing the following:~~

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~~(1) The training and related education for nondiscretionary tasks performed by pharmacy technicians; and~~

~~(2) written procedures designating the person or persons functioning as pharmacy technicians, describing the functions of the pharmacy technicians, and documenting the procedural steps taken by the pharmacist in charge to limit the functions of pharmacy technicians to nondiscretionary tasks.~~

~~(k)~~ The pharmacist-in-charge shall be responsible for establishing policies and procedures for the mixing or preparation of parenteral admixtures. Whenever drugs are added to intravenous solutions, distinctive supplemental labels shall be affixed that indicate the name and amount of the drug added, the date and the time of addition, the beyond-use date, storage instructions, and the name or initials of the person who prepared the admixture. The pharmacist-in-charge shall comply with all requirements of ~~K.A.R. 68-13-1~~ article 13 of the board's regulations. Before the parenteral admixture is released from the pharmacy, the pharmacist shall verify the accuracy of all parenteral admixtures prepared by pharmacy technicians.

~~(l)~~(h) The pharmacist shall interpret the prescriber's original order, or a direct copy of it, before the drug is distributed and shall verify that the medication order is filled in strict conformity with the direction of the prescriber. This requirement shall not preclude orders transmitted by the prescriber through electronic transmission. Variations in this procedure with "after-the-fact" review of the prescriber's original order shall be consistent with medical care facility procedures established by the pharmacist-in-charge. Each medication order shall be reviewed by a pharmacist within ~~seven~~ three days of the date it was written.

~~(m) Pharmacy services to outpatients during pharmacy hours shall be in accordance with~~

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~~the board's regulations, K.S.A. 65-1625 et seq., and K.S.A. 65-4101 et seq., and amendments thereto, governing community pharmacy practice.~~

~~(n) The pharmacist in charge shall be responsible for the security of the pharmacy, including the drug distribution systems and personnel.~~

(i)(1) When a pharmacist is on the premises but not in the pharmacy, a pharmacy technician may be in the pharmacy. A pharmacy technician shall not distribute any drug or device out of the pharmacy when a pharmacist is not physically in the pharmacy unless authorized by the pharmacist.

(2) When a pharmacist is not on the premises, no one shall be permitted in the pharmacy except the designated registered professional nurse or nurses or a physician's assistant.

~~(e) Each pharmacist in charge who will no longer be performing the functions of the pharmacist in charge position shall inventory all controlled substances in the pharmacy before leaving the pharmacist in charge position. A record of the inventory shall be maintained for at least five years.~~

~~(p) Within 72 hours after beginning to function as a pharmacist in charge, the pharmacist in charge shall inventory all controlled substances in the pharmacy. A record of the inventory shall be maintained for at least five years.~~

~~(q)(j)~~ Except with regard to drugs that have not been checked for accuracy by a pharmacist after having been repackaged, prepackaged, or compounded in a medical care facility pharmacy, a pharmacy technician in a medical care facility may check the work of another pharmacy technician in filled floor stock, a crash cart tray, a unit-dose cart, or an automated dispensing machine if the checking pharmacy technician meets each of the following criteria

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requirements:

(1) Has passed a ~~current~~ certification issued by the ~~pharmacy technician certification board or a current certification issued by any other pharmacy technician certification organization~~ examination approved by the board. ~~Any pharmacy technician certification organization may be approved by the board if the board determines that the organization has a standard for pharmacy technician certification and recertification not below that of the pharmacy technician certification board;~~

(2) has either of the following experience levels:

(A) One year of experience working as a pharmacy technician plus at least six months of experience working as a pharmacy technician in the medical care facility at which the checking will be performed; or

(B) one year of experience working as a pharmacy technician in the medical care facility at which the checking will be performed; and

(3) has successfully completed a written training program and related examination designed by the pharmacist-in-charge of the medical care facility pharmacy to demonstrate competency in accurately checking whether floor stock, a crash cart tray, and an automated dispensing machine have been properly filled. (Authorized by K.S.A. 65-1630; implementing K.S.A. ~~2008~~ 2022 Supp. 65-1626, K.S.A. ~~2008~~ Supp. 65-1642, and K.S.A. 65-1648; effective, E-77-39, July 22, 1976; effective Feb. 15, 1977; amended May 1, 1978; amended May 1, 1988; amended May 1, 1989; amended Dec. 27, 1999; amended April 28, 2000; amended July 20, 2007; amended July 16, 2010; amended P-\_\_\_\_\_.)

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**68-7-12. Responsibility of pharmacist-in-charge in other than a medical care facility pharmacy.** Each pharmacist-in-charge for premises having a pharmacy registration, other than a medical care facility pharmacy, shall be responsible for the following functions:;

(a) ~~Each pharmacist in charge shall develop, supervise, and coordinate all pharmaceutical services carried on within the pharmacy to ensure compliance with the Kansas pharmacy act, the Kansas uniform controlled substances act, federal drug laws, and all applicable regulations.~~

(b) ~~Each pharmacist in charge shall be personally available to the extent required to ensure comprehensive pharmaceutical services within the pharmacy and to develop a staff of additional licensed pharmacists and supportive personnel as necessary to serve the needs of the pharmacy. Each pharmacist in charge shall maintain records in the pharmacy describing the training and education regarding work functions performed by all pharmacy personnel. Each pharmacist in charge shall maintain in the pharmacy written procedures that address the following areas:~~

(1) ~~Designate the person or persons functioning as pharmacy technicians and supportive personnel;~~

(2) ~~describe the functions of all personnel; and~~

(3) ~~document the procedural steps taken by the pharmacist in charge to limit the functions of all personnel to their respective pharmacy work functions.~~

(e) Each pharmacist-in-charge shall develop or approve written policies and procedures for the pharmacy that meet all of the following conditions:

(1) Provide adequate accountability and control of drugs in compliance with the Kansas pharmacy act, the Kansas state and federal uniform controlled substances act, federal drug laws

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and the state and federal food, drug, and cosmetic act, and all applicable regulations are provided for; and

(2) ensure that any incident that occurs as a result of an alleged or real error in filling or dispensing a prescription or medication order is brought to the attention of the pharmacist-in-charge and completely documented in accordance with ~~the requirements of~~ K.A.R. 68-7-12b.

(3) ~~Adequate records of the pharmacy's dispensing, prepackaging, and bulk compounding actions are maintained, and all prepackaging of drugs is done in suitable containers, properly labeled in accordance with K.A.R. 68-7-16.~~

(d)(b) Each pharmacist-in-charge shall develop written procedures for maintaining records of the pharmacy's dispensing, prepackaging, and bulk compounding actions and shall ensure that prepackaged medication is packaged in suitable containers and properly labeled.

(e) ~~A pharmacist-in-charge who will no longer be performing the functions of the pharmacist-in-charge position shall inventory all controlled substances in the pharmacy before leaving the pharmacist-in-charge position. A record of the inventory shall be maintained for at least five years.~~

(f) ~~Within 72 hours after beginning to function as a pharmacist-in-charge, the pharmacist-in-charge shall inventory all controlled substances in the pharmacy. A record of the inventory shall be maintained for at least five years.~~ (Authorized by K.S.A. 65-1630 and K.S.A. 2006 Supp. 65-1643; implementing K.S.A. 2006 2022 Supp. 65-1626 and K.S.A. 2006 Supp. 65-1637; effective, E-77-39, July 22, 1976; effective Feb. 15, 1977; amended May 1, 1978; amended May 1, 1989; amended Nov. 30, 1992; amended Feb. 27, 1998; amended Dec. 27, 1999; amended Feb. 7, 2003; amended July 20, 2007; amended P-\_\_\_\_\_.)

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**68-7-15. ~~Prepackaging or repackaging~~ Packaging of drugs or devices in advance of immediate need.** All ~~prepackaging or repackaging of oral drugs or devices~~, whether in a unit-dose container or multiple-dose container, packaged in advance of immediate need shall meet the requirements of this regulation.

(a) ~~Packaging in advance of immediate need~~ shall be done by a pharmacist or under the pharmacist's direct supervision. The pharmacist shall verify and document verification of the packaged drugs or devices before the packaged drugs or devices are released from a facility registered with the board.

(b) Packaging shall be limited to the drugs or devices dispensed from or supplied by the ~~pharmacy~~ facility registered with the board or in accordance with a shared services agreement.

(c) All containers used for packaging shall preserve the stability and integrity of the drug or device. The storage conditions of each packaged drug or device shall be maintained according to the manufacturer's recommendations to preserve the stability and integrity of the drug. The ~~expiration beyond-use date assigned to each packaged drug or device~~ shall be the manufacturer's expiration date, the ~~expiration~~ maximum allowable beyond-use date for the type of packaging material used, or not more than 12 months from the date of packaging, whichever is earlier.

(d) An electronic or a written record shall be established for lot numbers for recall purposes and shall be kept readily retrievable in the facility registered with the board.

(e) If an area apart or separated from the prescription drug area is used for ~~prepackaging or repackaging~~ packaging, the area shall be enclosed and locked when a pharmacist is not in attendance in that area.

(f) In lieu of separately dispensing a drug and an ingestible event marker approved by the

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food and drug administration to monitor whether a patient is taking the drug as prescribed, any pharmacist may use an ingestible event medication adherence package pursuant to a valid prescription order or after obtaining the consent of the practitioner, caregiver, or patient.

(g) For purposes of this regulation, "ingestible event medication adherence package" shall mean an ingestible unit-dose package designed to ensure medication adherence that contains drugs from a manufacturer's original container and an ingestible event marker, as defined by 21 C.F.R. 880.6305, ~~dated April 1, 2016~~ effective February 1, 2022 and hereby adopted by reference.

(h) In addition to meeting the requirements of this regulation, all ~~repackaging~~ packaging of sterile preparations shall meet the requirements of K.A.R. 68-13-4. (Authorized by K.S.A. 65-1630; implementing K.S.A. 2022 Supp. 65-1626a and K.S.A. 65-1634; effective May 1, 1978; amended Dec. 15, 2017; amended Nov. 29, 2019; amended P-\_\_\_\_\_.)

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**68-7-16. Labels for ~~prepackaged or repackaged~~ drugs or devices packaged in advance of immediate need.** (a) ~~Labels~~ Except as specified in subsection (b), each label for ~~prepackaged and repackaged drugs~~ a drug or device packaged in advance of immediate need shall contain the following:

(a)(1) The generic name ~~with manufacturer of the drug or device and distributor's the manufacturer's name or~~. If the packaged drug or device bears a brand name, the brand name may be substituted for the generic name of the drug or device;

(b)(2) ~~the strength and quantity of the drug or device;~~

(c)(3) ~~the lot number and, date repackaged of packaging, and the person name of the individual~~ responsible for packaging;

(d)(4) ~~the expiration beyond-use date, if applicable; and~~

(e)(5) ~~necessary auxiliary labels necessary.~~

(f)(b) ~~Manufacturer~~ If the owner of a facility registered with the board maintains a record system that includes the manufacturer's name, lot numbers, date repackaged of packaging, and the person name of the individual responsible for packaging the drug or device, this information may be deleted from the label if a suitable record system is maintained to indicate them.

(Authorized by K.S.A. 1977 Supp. 65-1630; implementing K.S.A. 2022 Supp. 65-1626a and K.S.A. 65-1634; effective May 1, 1978; amended P-\_\_\_\_\_.)

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**68-7-19. Transfer of a refillable prescription between pharmacies.** (a) As used in K.S.A. 65-1656; and amendments thereto, the requested or transferring pharmacy ~~is that~~ shall mean the pharmacy ~~which that~~ has on file the original refillable prescription that the patient ~~wishes~~ wants to transfer to a second pharmacy. The dispensing or requesting pharmacy ~~is~~ shall mean the pharmacy that is wanting the information transferred from the original refillable prescription so that the patient may obtain the medication at this second pharmacy or the pharmacy receiving the transferred prescription.

(b) ~~Valid refillable prescriptions for prescription drugs not listed in schedule II of the uniform controlled substances act may be transferred either by direct communications between two licensed pharmacists from one pharmacy to another pharmacy or by a licensed pharmacist operating a suitable electronic device.~~ Before any prescription is transferred, the prescription information at the transferring pharmacy shall meet all of the following criteria conditions:

- (1) The prescription information indicates authorization for refilling by the prescriber.
- (2) The drug on the prescription information is not a schedule II controlled substance.
- (3) The number of lawfully allowable refills directed by the prescriber has not been exceeded.

(4) The maximum allowable time limit from the original dating of the prescription has not been exceeded.

(c) When a prescription on record is transferred, the following ~~record keeping~~ recordkeeping shall be required:

(1)(A) ~~If the transfer involves a noncontrolled substance, the pharmacist at The~~ transferring pharmacy shall ~~perform~~ cancel the transferred prescription by writing the word

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"void" on its face and shall record the following on the prescription:

(i) Cancel the transferred prescription by writing the word "void" on its face The name,

address, and phone number of the receiving pharmacy; and

(ii) record on the face of the prescription the name and address of the pharmacy to which

the prescription was transferred, the date of the transfer request, the full name of the pharmacist

to which the prescription was transferred, and the full name of the pharmacist transferring the

prescription the DEA registration number of the receiving pharmacy, if the drug is a schedule III,

IV, or V controlled substance;

(iii) the date of the transfer request and the date of the prescription transfer;

(iv) the first name and last name of the person providing the requested prescription

transfer information at the transferring pharmacy and, if applicable, the first name and last name

of the pharmacist supervising the transfer; and

(v) the first name and last name of the person receiving the prescription transfer

information at the requesting pharmacy and, if applicable, the first name and last name of the

pharmacist supervising the transfer.

(B) If the pharmacy from which the prescription is transferred utilizes a computerized

prescription record-keeping ~~recordkeeping~~ system adequate to do so, ~~the transferring pharmacist~~

~~may record~~ the information required by paragraphs (1)(A)(i) and (ii) this regulation shall be

documented in the computer record of the prescription ~~instead of recording the information and~~

shall not be required to be manually recorded on the face of the prescription.

(C) ~~Transferring pharmacies that have computerized record-keeping systems that permit~~

~~requesting pharmacies to electronically transfer prescriptions and prescription information from~~

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the transferring pharmacy to the requesting pharmacy shall establish procedures to permit these transfers only in instances of valid and legal requests and to insure that the prescription information required by subsection (b) is available to the requesting pharmacy at the time of the electronic transfer.

(D) If the requesting pharmacy is transferring a prescription and prescription information from another pharmacy without communicating directly with a pharmacist at the transferring pharmacy, the pharmacist at the requesting pharmacy shall insure that there is a sufficient electronic record left at the transferring pharmacy so that a pharmacist at the transferring pharmacy can comply with the record-keeping requirements of K.S.A. 65-1656, and amendments thereto, and these regulations.

(2)(A) If the transfer involves a C-III, IV, or V controlled substance, the pharmacist at the transferring pharmacy shall perform the following:

- (i) Cancel the transferred prescription by writing the word "void" on its face; and
- (ii) record on the back of the prescription the name, address, and DEA registration number of the pharmacy to which the prescription was transferred, the date of the transfer request, the full name of the pharmacist to which the prescription was transferred, and the full name of the pharmacist transferring the prescription.

(B) Transferring pharmacies that have computerized prescription record-keeping systems that permit requesting pharmacies to electronically transfer prescriptions and prescription information from the transferring pharmacy to the requesting pharmacy shall establish procedures to permit these transfers only in instances of valid and legal requests and to insure that the prescription information required by subsection (b) is available to the pharmacist at the

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~~requesting pharmacy at the time of the electronic transfer.~~

~~(C) If the requesting pharmacy is transferring a prescription and prescription information from another pharmacy without communicating directly with a pharmacist at the transferring pharmacy, the pharmacist at the requesting pharmacy shall insure that there is a sufficient electronic record left at the transferring pharmacy so that a pharmacist at the transferring pharmacy can comply with the record-keeping requirements of K.S.A. 65-1656, and amendments thereto, and these regulations.~~

(3) The prescription record at the pharmacy receiving the transferred prescription shall show the following, in addition to all other lawfully required information ~~of~~ for an original prescription:

~~(A)~~(i) The word "transfer" written on the face of the prescription record;

~~(B)~~(ii) the date ~~of original issuance and issued~~, the date of original filling, if different from ~~and~~ the issuance date of the last fill;

~~(C)~~(iii) the original number of refills authorized, and the number of remaining authorized refills, ~~and the date of last refill~~;

~~(D)~~(iv) the original prescription number;

~~(E)~~(v) the name, address, and telephone number of the transferring pharmacy, ~~and the name of the transferring pharmacist~~;

(vi) the first name and last name of the person providing the requested prescription transfer information at the transferring pharmacy and, if applicable, the first name and last name of the pharmacist supervising the transfer; and

(vii) the first name and last name of the person receiving the prescription transfer

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information at the requesting pharmacy and, if applicable, the first name and last name of the pharmacist supervising the transfer;

~~(F)(viii)~~ the name, address, and telephone number of the prescriber; and

~~(G)(ix)~~ if the transfer involves a ~~C-III~~ schedule III, IV, or V controlled substance, the DEA registration number of the prescriber and of the transferring pharmacy.

~~(4) If the transfer involves a noncontrolled substance and the pharmacy to which the prescription is transferred utilizes a computerized prescription record-keeping system adequate to do so, the receiving pharmacist may record the information required by paragraphs (3)(A) through (F) in the computer record of the prescription instead of otherwise recording the information.~~

(B) If the pharmacy receiving the prescription transfer utilizes a computerized prescription recordkeeping system adequate to do so, the information required by this regulation shall be documented in the computer record of the prescription and shall not be required to be manually recorded on the prescription.

~~(d) If two or more Pharmacies use sharing a common electronic prescription files to maintain dispensing information and do not physically transfer prescriptions or information for dispensing purposes, all pharmacies licensed by the board that have access to these common files computerized recordkeeping system that permits the electronic transfer of prescriptions and prescription information from the transferring pharmacy to the requesting pharmacy shall be responsible to insure that at all times the common files contain at least the following information readily available to any person accessing the file be required to do the following:~~

(1) Establish procedures to permit these transfers only in instances of valid and legal

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requests;

(2) ensure that at the time of the transfer there is a sufficient electronic record left at the transferring pharmacy so that a pharmacist at the transferring pharmacy can comply with the recordkeeping requirements of K.S.A. 65-1656, and amendments thereto, and this regulation;  
and

(3) ensure that the common files contain the following information in a manner readily available to any person accessing the files:

(A) Any authorization for refilling by the prescriber;

(2)(B) an indication of whether or not the number of lawfully allowable refills authorized by the prescriber has been exceeded;

(3)(C) an indication of whether ~~or not~~ the maximum allowable time limit from the original date of the prescription has been exceeded;

(4)(D) any other information provided by the original prescription or prescription order;  
and

(5)(E) the name and address of the pharmacy last dispensing the drug pursuant to the prescription.

(e) The dispensing pharmacy shall advise the patient and notify the transferring pharmacy that the original prescription shall be canceled in the transferring pharmacy.

(f) ~~A Kansas~~ Any pharmacist may transfer a valid, refillable prescription from or to another pharmacy in or outside ~~the state of~~ Kansas. Noncontrolled substance prescriptions may be transferred more than once, but ~~C-III~~ schedule III, IV, and V controlled substance prescriptions shall not be transferred more than one time.

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(g) Drugs shall not be dispensed more frequently or in larger amounts, except as allowed by K.S.A. 65-1637 and amendments thereto, than the prescriber ordered without direct prescriber authorization by way of a new prescription order.

(h) Valid refillable prescription transfers for prescription drugs not listed in schedule II of the uniform controlled substances act may be received or transferred by a pharmacist, or a pharmacist intern under the direct supervision of a pharmacist, utilizing any of the following methods of communication:

(1) Direct verbal communication;

(2) facsimile; or

(3) automated computer software.

(i) Valid refillable prescription transfers for noncontrolled substances may be received or transferred by a pharmacy technician that has passed a national certification exam approved by the board and has been authorized by the supervising pharmacist to perform this function by means of automated computer pharmacy software or by facsimile of a transfer document created by the transferring pharmacy's prescription processing software.

(j) A pharmacy technician shall not forward or transfer an original, unfilled prescription.

(k) Any pharmacist or pharmacist intern may forward or transfer an original, unfilled prescription to a receiving pharmacy.

(l) A pharmacy shall not initiate the transfer of a prescription without authorization from the patient or the patient's caregiver.

(m) All records required by this regulation shall be kept readily retrievable for five years.

(Authorized by and implementing K.S.A. 1998 2021 Supp. 65-1656; effective March 29, 1993;

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**68-7-20a. Delivery of prescriptions dispensed to an alternate site for administration.**

(a) Any pharmacist may fill a prescription at an initiating pharmacy and cause the prescription to be delivered to a medical care facility pharmacy for preparation and administration to the patient.

The pharmacies shall either have the same owner or have a written contract specifying the services provided and the shared responsibilities of each party in complying with the pharmacy act and the implementing regulations.

(b) Each owner and pharmacist-in-charge of a pharmacy participating in providing prescription services under subsection (a) shall maintain and comply with a policies and procedures manual that includes the following:

(1) A description of how each pharmacy will comply with the pharmacy act and the board's regulations;

(2) procedures for maintaining and retrieving dispensing records that include the following:

(A) The manner in which each pharmacy will access prescription information necessary to complete assigned responsibilities;

(B) a method of recordkeeping that identifies the pharmacist responsible for dispensing the prescription and counseling the patient; and

(C) a method of recordkeeping that documents all required elements of medication preparation specified in article 13 of the board's regulations;

(3) the mechanism to track the prescription during each stage of the filling, dispensing, and delivery process;

(4) controls to protect the privacy and security of confidential records;

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(5) procedures for ensuring accuracy, security, integrity, and accountability in the delivery process;

(6) procedures and recordkeeping requirements for returning to the initiating pharmacy any unopened prescription medication not administered to the patient; and

(7) the procedure for informing and obtaining consent from the patient for using this dispensing and delivery process.

(c) Any pharmacist may fill a prescription at an initiating pharmacy and cause the prescription to be delivered to a practitioner for administration to the patient pursuant to a written agreement between the pharmacy and the practitioner that specifies the procedures for delivery and the shared responsibilities of each party in complying with the pharmacy act and the implementing regulations.

(d) Each owner and pharmacist-in-charge of a pharmacy participating in providing prescription services under subsection (c) shall maintain and comply with a policies and procedures manual that includes the following:

(1) Procedures for tracking and ensuring security, accountability, integrity, and accuracy of delivery for the dispensed prescription from the time the prescription leaves the pharmacy until the prescription is received at the practitioner's office;

(2) the procedure for providing counseling to the patient;

(3) procedures and recordkeeping requirements for returning to the initiating pharmacy any unopened prescription medication not administered to the patient;

(4) controls to protect the privacy and security of confidential records; and

(5) the procedure for informing and obtaining consent from the patient for using this

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dispensing and delivery process.

(e) Each owner and pharmacist-in-charge of a pharmacy participating in drug delivery for administration shall ensure that the following requirements are met:

(1) All prescriptions waiting to be picked up or in the process of being delivered shall be stored according to the manufacturer's requirements and the pharmacy act and the implementing regulations.

(2) A copy of the agreement shall be maintained at each participating pharmacy.

(3) The policy and procedure manual shall be maintained at each participating pharmacy.

(f) Prescriptions waiting to be administered to the patient shall be stored in a room, cabinet, cart, or other device that is locked when not in use, cannot be easily moved, and is restricted to the practitioner, pharmacist, or the designee of a practitioner or pharmacist.

(g) Each pharmacy shall be exempt from the requirements of subsections (a) through (e) if the delivery location is a pharmacy or practitioner's office, the delivery location does not routinely receive deliveries from the initiating pharmacy, and any delay in delivery could result in potential patient harm. The pharmacist responsible for filling the prescription shall meet the following requirements:

(1) Notify the medical care facility pharmacy or practitioner's office of the anticipated arrival date of the shipment, the exact address where the prescription will be shipped, the name of the patient to whom the drug is being dispensed, and any special storage requirements for the prescription;

(2) provide counseling to the patient or ensure that a process is in place for the patient to receive counseling from a practitioner or pharmacist; and

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(3) provide a procedure for returning to the initiating pharmacy any unopened prescription medication not administered to the patient.

(h) A pharmacist shall not allow to be delivered to a patient's residence a prescription that is intended to be subsequently transported by the patient or patient's agent to a medical care facility, clinic, practitioner's office, or pharmacy for administration to the patient. However, a pharmacist may allow the prescription to be delivered to a patient's residence if the patient has an inherited bleeding disorder requiring therapy to prevent or treat bleeding episodes.

(i) Prescriptions for controlled substances shall not be delivered under this regulation unless the delivery is authorized by the drug enforcement administration (DEA) and the uniform controlled substances act.

(j) All records required under this regulation shall be readily retrievable and maintained for five years at the pharmacy. (Authorized by K.S.A. 65-1630; implementing K.S.A. 65-1626a, as amended by L. 2022, ch. 74, sec. 2, K.S.A. 65-1634, K.S.A. 2021 Supp. 65-1637, K.S.A. 65-1642, and K.S.A. 2021 Supp. 65-1656; effective P-\_\_\_\_\_.)

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**68-20-1. Definitions.** ~~The following terms in this regulation shall have the meanings~~  
specified As used in this article of the board's regulations, each of the following terms shall have  
the meaning specified in this regulation:

(a) "Act" means the uniform controlled substances act of Kansas, K.S.A. 65-4101, et seq.,  
and amendments thereto;

(b) "Basic class," ~~means, as to~~ when referring to controlled substances listed in ~~schedules I~~  
~~and II~~ K.S.A. 65-4105 and K.S.A. 65-4107 and amendments thereto, means any of the following:

(1) Each of the opiates, including its isomers, esters, ethers, and salts, and salts of isomers,  
esters, and ethers, whenever the existence of ~~such~~ the isomers, esters, ethers and salts is possible  
within the specific chemical designation listed in K.S.A. 65-4105(b) and amendments thereto;

(2) each of the opium derivatives, including its salts and isomers, and salts of isomers,  
whenever the existence of ~~such~~ the salts, isomers, and salts of isomers is possible within the  
specific chemical designation listed in K.S.A. 65-4105(c) and amendments thereto;

(3) each of the hallucinogenic substances, including its salts and isomers, and salts of  
isomers, whenever the existence of ~~such~~ the salts, isomers, and salts of isomers is possible within  
the specific chemical designation listed in K.S.A. 65-4105(d) and amendments thereto;

(4) each of the following substances, whether produced directly or indirectly by extraction  
from substances of vegetable origin, ~~or~~ independently by means of chemical synthesis, or by a  
combination of extraction and chemical synthesis:

(A) Opium, including raw opium, opium extracts, opium fluid extracts, powdered opium,  
granulated opium, deodorized opium, and tincture of opium;

(B) apomorphine;

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(C) codeine;

(D) ethylmorphine;

(E) hydrocodone;

(F) hydromorphone;

(G) metopon;

(H) morphine;

(I) oxycodone;

(J) oxymorphone;

(K) thebaine;

(L) mixed alkaloid of opium listed in K.S.A. 65-4107(b)(1) and amendments thereto;

(M) cocaine; and

(N) ecgonine;

(5) each of the opiates, including its isomers, esters, ethers, and salts, whenever the existence of such the isomers, esters, ethers, and salts is possible within the specific chemical designation listed in K.S.A. 65-4107(c) and amendments thereto;

(6) methamphetamine, including its salts, isomers, and salts of isomers, when contained in any injectable liquid;

(7) amphetamine, its salts, optical isomers and salts of its optical isomers;

(8) phenmetrazine and its salts; ~~and~~ or

(9) methylphenidate.

(c) "Controlled premises" means:

~~(1) places~~ a facility registered with the board and any conveyance operated by the facility

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where controlled substances or original or copies of records or documents required under the act are kept or required to be kept; and

~~(2) places where registrants or persons who are registered under the act or who are exempted from registration under the act may lawfully hold, manufacture, distribute, dispense, administer, or otherwise dispose of controlled substances. Such places shall include factories, warehouses, establishments and conveyances.~~

(d) ~~"Secretary" means the executive secretary of the state board of pharmacy of the state of Kansas. "Drug of concern" has the meaning specified in K.S.A. 65-1682, and amendments thereto.~~

(e) ~~"Prescription" means an order for medication which that is dispensed to or for an ultimate user; but does. This term shall~~ not include an order for medication which that is dispensed for immediate administration to the ultimate user. An order for a single dose of a drug for immediate administration to a bed patient in a medical care facility shall not be construed to be a prescription.

(f) ~~"Register" and "registration" mean only registration required and permitted under the controlled substances act. K.S.A. 65-4117. "Readily retrievable" has the meaning specified in K.S.A. 65-1626 and K.S.A. 65-4101, and amendments thereto.~~

(g) ~~"Registrant" means any person who is registered pursuant to the act K.S.A. 65-4117, and amendments thereto.~~

(h) ~~"Bureau" and "BNDD" mean the bureau of narcotics and dangerous drugs.~~

(i) ~~"Preceptor" means a licensed pharmacist who has been approved, by the board, for the supervision of students who are securing the pharmaceutical experience required by law as a~~

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condition precedent to taking the examination for licensure as a pharmacist. "Secretary" means executive secretary of the Kansas state board of pharmacy.

~~(j)~~(i) Any Each term used in this article of the board's regulations that is not defined in this regulation shall have the meaning ~~as set forth~~ specified in the act. ~~To the extent definitions are not in conflict with any provision of the act, terms shall also have the meanings set forth in, the~~ Kansas pharmacy act of the state and, or the Kansas prescription monitoring program act, and amendments thereto.

~~(k)~~ This regulation shall be effective on May 1, 1989. (Authorized by and implementing K.S.A. 65-4102; ~~implementing K.S.A. 65-4101~~; effective, E-72-24, Aug. 25, 1972; effective Jan. 1, 1973; amended May 1, 1985; amended May 1, 1989; amended P-\_\_\_\_\_.)

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**68-20-16. Records and inventories of registrants.** (a) Except as provided in this regulation, each registrant shall keep records and maintain inventories in conformance with the recordkeeping and inventory requirements of 21 ~~CFR~~ C.F.R. 1304.04(a)(2), (a)(3), (f), (g), (h)(1), (h)(2), (h)(3), and (h)(4), ~~including 21 CFR 1304.04(f) as referred to by 21 CFR 1304.04(g), and 21 CFR 1304.11, as in effect on April 1, 2008~~ February 1, 2022, which are hereby adopted by reference. Except as otherwise provided in this regulation, the registrant shall maintain executed order forms and controlled substance inventories at the registered facility and keep the records on file for at least five years.

(b) After the initial inventory is taken, the registrant shall take a subsequent inventory of all controlled substances and drugs of concern on hand at least every year but no later than 375 days after the date of the previous inventory. ~~The annual inventory shall be taken at least eight months after the previous inventory~~ All controlled substances and drugs of concern shall be inventoried on the same calendar date.

(c) Each required inventory of schedule II controlled substances and ~~all products containing hydrocodone~~ nonliquid dosage forms of other controlled substances and drugs of concern shall be taken by exact count.

(d) ~~All registrants~~ Each registrant handling schedule V ~~preparations~~ controlled substances and drugs of concern shall be subjected to the same inventory and recordkeeping requirements specified in subsections (a) and (b). ~~In addition, an inventory of schedule V items shall be taken in conjunction with the required inventory requirements relating to schedules II, III, and IV.~~

(e) Each inventory of controlled substances shall be maintained in legible, hard-copy format and shall include the following:

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(1) The date the inventory was conducted;

(2) the name, license or registration number, and signature of each individual participating in the inventory; and

(3) documentation of whether the inventory was taken before the opening of business or after the close of business. If the pharmacy is open 24 hours per day and does not close, the time that the count was taken shall be documented. (Authorized by K.S.A. 65-4102, ~~as amended by L. 2009, ch. 32, sec. 54,~~ and K.S.A. 65-4121; implementing K.S.A. 65-4121; effective, E-72-24, Aug. 25, 1972; effective Jan. 1, 1973; amended May 1, 1989; amended July 31, 1998; amended Dec. 27, 1999; amended Nov. 13, 2009; amended P-\_\_\_\_\_.)

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**68-20-18. Information concerning prescriptions.** (a) ~~Persons entitled to issue prescriptions. A~~ Any prescription for a controlled substance may be filled by a pharmacist if the prescription has been issued only by a practitioner or mid-level practitioner prescriber who meets the following conditions requirements:

(1) Is legally authorized to prescribe controlled substances in Kansas or ~~any other competent jurisdiction~~ is authorized by the laws of another state; and

(2) is either registered or exempted from registration under K.S.A. 65-4116~~(d)~~ or K.S.A. 65-4117 and amendments thereto.

~~(b) Purpose of issue of prescription.~~

(1) To be ~~effective~~ valid, a prescription for a controlled substance shall be issued for a legitimate medical purpose by a ~~practitioner or mid-level practitioner prescriber~~ acting in the usual course of professional practice. The responsibility for the proper prescribing and dispensing of controlled substances shall rest with the prescriber, but a corresponding responsibility shall rest with the pharmacist who fills the prescription. The ~~person~~ individual filling an unlawful prescription, as well as the ~~person~~ individual issuing it, shall be subject to the penalties provided for violations of the provisions of the ~~controlled substance act, K.S.A. 65-4101, et. seq. and amendments thereto.~~

(2) A prescription shall not be issued in order for a ~~practitioner or mid-level practitioner to obtain controlled substances for supplying that individual or any other prescriber for the purpose of general dispensing to patients~~ pharmacist shall not fill a prescription for a controlled substance or drug of concern for office use. However, any pharmacist may document on an invoice any distribution of controlled substances or drugs of concern made to a registrant.

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(3) A prescription shall not be issued for the dispensing of narcotic drugs listed in any schedule to a narcotic drug-dependent ~~person~~ individual for the purpose of continuing dependence upon these drugs, except as allowed by 21 C.F.R. 1306.07(d), as in effect on November 2, 2020, or in the course of conducting an authorized clinical investigation in the development of a narcotic addict rehabilitation program.

(c) ~~Manner of issuance of prescriptions:~~

(1) To be valid, a prescription for a controlled substance ~~prescriptions in schedules II through V~~ shall not be issued on a prescription blank that is preprinted or rubber-stamped with the name of a propriety preparation or with the strength, quantity, or directions.

(2) ~~All written prescriptions~~ Each prescription for a controlled substance ~~substances~~ substance shall meet the following requirements:

(A) Be dated and ~~manually~~ signed on the day date issued;

(B) bear the following information:

(i) The full name, address, and DEA registration number of the ~~practitioner or mid-level practitioner~~ prescriber;

(ii) the name and address of the patient; ~~and~~

(iii) the drug name, strength, dosage form, quantity prescribed, and directions for use; and

(iv) if applicable, the identification number issued by the DEA or a written notice of action under the good faith exception pursuant to 21 C.F.R. 1301.28(e), as in effect on November 2, 2020, for a prescription for a schedule III, IV, or V narcotic drug approved by the FDA specifically for detoxification or maintenance treatment; and

(C) be written with ink, indelible pencil, or typewriter or be printed on a computer printer.

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(3) A ~~practitioner or mid-level practitioner~~ prescriber shall manually sign a paper prescription in the same manner as that individual would sign a check or legal document. Each electronic prescription shall be issued and signed in accordance with 21 C.F.R. 1311.120(b)(9) and (b)(11), 21 C.F.R. 1311.135(a) and (c), 21 C.F.R. 1311.140, and 21 C.F.R. 1311.145, as in effect on February 1, 2022, which are hereby adopted by reference.

(4) ~~The prescriptions~~ Any prescription may be prepared by a ~~secretary or an agent~~ for the signature of a ~~practitioner or mid-level practitioner~~ prescriber, but the prescriber shall be responsible if the prescription does not conform in all essential respects to the state and federal law and regulations. A corresponding liability shall rest upon the pharmacist who fills a prescription that is not prepared in the form prescribed by this regulation.

(5) ~~An~~ Each intern, resident, foreign physician, or foreign medical graduate exempted from registration under K.S.A. 65-4116(d), and amendments thereto, shall include on all prescriptions issued the registration number of the hospital or other institution and the special internal code number assigned to the intern, resident, foreign physician, or foreign medical graduate by the hospital or other institution as provided in K.A.R. 68-20-10. This requirement shall be in lieu of the registration number of the ~~practitioner~~ prescriber required by this subsection. Each prescription shall have the name of the intern, resident, foreign physician, or foreign medical graduate stamped or printed on it, as well as the signature of the ~~physician~~ prescriber.

(6) ~~An~~ Each official exempted from registration under K.A.R. 68-20-10 shall include on all prescriptions issued the official's branch of service or agency and the service identification number. This requirement shall be in lieu of the registration number of the ~~practitioner~~ prescriber otherwise required by this subsection. The service identification number for a public health

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service employee shall be that individual's social security identification number. Each prescription shall have the name of the officer stamped or printed on it, as well as the signature of the officer.

~~(d) Manner of issuance of prescriptions by facsimile.~~

~~(1)(7) Any controlled substance prescriptions prescription in schedules III through V may be issued as a paper or electronic prescription or transmitted by telephone by a prescriber or the prescriber's designated agent to a pharmacy for a patient of the prescriber. The transmitted telephone prescription may be by oral, or facsimile, or electronic transmission. Except as authorized by K.A.R. 68-2-22, each nonpaper prescription orders order shall be reduced to hard copy as soon as the order is reviewed by the pharmacist. The hard copy reduction shall include all information required by this regulation, except for the signature of the prescriber in the case of an oral transmission, and, if telephoned transmitted by other than the prescriber, shall bear the first name and last name of the person so transmitting or telephoning the prescription. Each prescription sent by facsimile transmission shall be transmitted directly from the prescriber or the prescriber's designated agent to the pharmacy and shall contain a header identifying the sender of the prescription.~~

~~(2)(8) Any controlled substance prescriptions prescription in schedule II may be transmitted by facsimile or electronic transmission from the prescriber to a pharmacy issued as a paper or electronic prescription. However, when the prescription is actually dispensed, the original written prescription that is manually signed by the prescriber shall be presented, verified against the facsimile or electronic transmission, and retained for filing. Exceptions to this subsection shall be in compliance with K.A.R. 68-20-10a. Each prescription for a schedule II~~

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controlled substance transmitted to a pharmacy by oral or facsimile transmission shall be dispensed in accordance with 21 C.F.R. 1306.11 and K.A.R. 68-20-19. Each prescription sent by facsimile transmission shall be transmitted directly from the prescriber or the prescriber's designated agent to the pharmacy and shall contain a header identifying the sender of the prescription.

(9) Any pharmacist may fill multiple prescriptions issued by a prescriber authorizing the patient to receive up to a 90-day supply of a schedule II controlled substance if all of the following conditions are met:

(A) Each separate prescription is issued for a legitimate medical purpose by a prescriber acting in the usual course of professional practice.

(B) The prescriber provides written instructions on each prescription other than the first prescription, if the prescriber intends for the first prescription to be filled immediately, indicating the earliest date on which the prescription may be filled.

(C) The prescriber concludes that providing the patient with multiple prescriptions does not create an undue risk of diversion or abuse.

(D) Each separate prescription meets all requirements for a schedule II controlled substances prescription, including being dated and signed on the date issued.

(e)(d) Persons entitled to fill prescriptions:

(1) A prescription for controlled substances shall be filled only by the following individuals:

(A)(1) A pharmacist acting in the usual course of professional practice in a registered pharmacy, hospital drug room, or other registered place of employment; or

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(B)(2) a pharmacist intern acting under the immediate personal direction and direct supervision of a licensed pharmacist.

(2) For the purposes of this regulation, an intern shall mean a prospective candidate for examination as a licensed pharmacist who is qualified to receive, and is obtaining, pharmaceutical experience as defined in K.A.R. 68-5-1.

(3) A medical care facility or other institution registered with the board shall administer or dispense directly a controlled substance listed in schedules III and IV and legend V only pursuant to a written prescription signed by the prescriber or to an order of medication made by a prescriber that is dispensed for immediate administration to the ultimate user. (Authorized by K.S.A. 1998-Supp. 65-4102; implementing K.S.A. 65-4123, as amended by L. 1999, Ch. 115, Sec. 15; effective, E-72-24, Aug. 25, 1972; effective Jan. 1, 1973; amended May 1, 1988; amended Sept. 9, 1991; amended March 29, 1993; amended March 20, 1995; amended Dec. 27, 1999; amended P-\_\_\_\_\_.)

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**68-20-18a. Information concerning prescriptions; recordkeeping; pharmacy**

**prescription application.** (a) Each controlled substance shall be supplied or dispensed directly to a patient only pursuant to a prescription issued in accordance with K.A.R. 68-20-18. Each controlled substance shall be supplied at a registered facility for immediate facility administration to the ultimate user only pursuant to a medication order.

(b) Each dispensing, partial filling, or refilling of a prescription for a controlled substance shall be entered on the back of the prescription with the date, quantity, and name or initials of the pharmacist providing the final verification.

(c) As an alternative to the procedures provided by subsection (b), a pharmacy prescription application may be used for the storage and retrieval of dispensing, refill, and partial filling information for prescription orders for controlled substances if all of the following requirements are met:

(1) Each computerized system shall provide on-line retrieval, by computer monitor display or hard-copy printout, of original prescription order, refill, and partial fill information for those prescription orders that are authorized for filling. Each display or printout of information shall include the following:

- (A) The original prescription number;
- (B) the date of issuance of the original prescription order by the prescriber;
- (C) the dates of dispensing or partial filling;
- (D) the full name and address of the patient;
- (E) the name, address, and DEA registration number of the prescriber;
- (F) the name, strength, dosage form, quantity of the controlled substance prescribed, and

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the quantity dispensed, if different from the quantity prescribed;

(G) the identification code, or name or initials of the dispensing pharmacist;

(H) the total number of refills authorized by the prescriber, if applicable and allowable; and

(I) the total number of doses dispensed to date for that prescription order.

(2) Each pharmacist who makes use of a pharmacy prescription application shall document that the information in the pharmacy prescription application is correct each time the pharmacist fills, refills, or partially fills a controlled substance.

(A) If the pharmacy prescription application produces a hard-copy printout of each day's controlled substance prescription order data, the printout shall meet the following requirements:

(i) The printout shall be verified, dated, and signed by the pharmacist who filled or partially filled the prescription order. The pharmacist shall verify that the date indicated is correct and then sign this document in the same manner as the pharmacist would sign a check or legal document.

(ii) The printout shall be provided to each pharmacy using the computerized system within 72 hours of the date on which the controlled substance was dispensed.

(iii) The printout shall be verified and signed by each pharmacist who is involved in the dispensing.

(B) In lieu of signing a hard-copy printout of each day's controlled substance prescription order data, the pharmacy owner shall maintain a bound logbook or separate file in which each pharmacist involved in the dispensing shall sign a statement, in the manner described in paragraph (c)(2)(A), each day, attesting to the fact that the information entered into the pharmacy prescription application that day has been reviewed by the pharmacist and is correct as shown.

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(3) Each pharmacy prescription application shall have the capability of producing a printout of any fill data that the facility is responsible for maintaining. Each printout shall include an audit trail for any specified strength and dosage form of any controlled substance, by brand, generic name, or both, in addition to the following:

- (A) The name of the prescriber;
- (B) the name and address of the patient;
- (C) the quantity dispensed on each fill;
- (D) the date of dispensing of each fill;
- (E) the name or identification code of the dispensing pharmacist; and
- (F) the number of the original prescription order.

(4) If a pharmacy experiences a computer system outage of the pharmacy prescription application, the pharmacy shall have an auxiliary procedure that will be used for documentation of partial fills and refills of controlled substance prescriptions. This auxiliary procedure shall ensure that partial fills or refills are authorized by the original prescription, the maximum number of dosage units or refills has not been exceeded, the prescription is still valid for partial filling or refilling, and all appropriate data is retained for on-line data entry as soon as the computer system is available for use again.

(d) All prescriptions, records, and documents required by this article of the board's regulations shall be kept readily retrievable at the registered location for five years from the date of the last filling, refilling, partial filling, or entry into the record, except that financial and shipping records may be kept at other than the registered location with approval of the DEA.

(Authorized by and implementing K.S.A. 65-4102, K.S.A. 65-4121, and K.S.A. 65-4123;

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**Proposed**

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**68-20-19. Controlled substances listed in schedule II. (a) Requirements of prescription.**

(1) A pharmacist shall dispense a controlled substance listed in schedule II, ~~which that~~ is a ~~prescription~~ prescription-only drug as ~~determined under these regulations~~, only pursuant to a ~~written signed~~ prescription ~~signed by the prescribing practitioner~~ issued in accordance with K.A.R. 68-20-18, except as provided in paragraph (a)(4) ~~of this subsection~~.

(2) ~~Any written prescriptions signed by the prescribing practitioner falling~~ A prescription under the above provisions of paragraph (a)(1) shall not be filled if ~~submitted in either of the~~ following circumstances:

(A) ~~More than six months~~ 90 days after the original date of issue appearing on the ~~written~~ prescription; or

(B) before or after any date specified on the prescription by the prescriber.

(3) ~~A prescriber may administer a controlled substance listed in schedule II in the course of professional practice without a prescription, subject to K.A.R. 68-20-18.~~

(4)(A) ~~In the case of~~ For an emergency situation, as defined by paragraph (5)(a)(4) ~~of this subsection~~, a pharmacist may dispense a controlled substance listed in schedule II upon receiving the oral authorization of a prescriber, if all of the following ~~conditions~~ requirements are met:

(i) The quantity prescribed and dispensed ~~is~~ shall be limited to the amount adequate to treat the patient during the emergency period. Dispensing beyond the emergency period shall be pursuant to a ~~written signed~~ prescription ~~signed by the prescriber~~ issued in accordance with K.A.R. 68-20-18.

(ii) The prescription shall be immediately reduced to a hard copy by the pharmacist and shall contain all information required under K.A.R. 68-20-18(e) except for the signature of the

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prescriber.

(iii) If the prescriber is not known to the pharmacist, the pharmacist shall make a reasonable effort to determine that the authorization came from the prescriber, which may include a call back to the prescriber, using the prescriber's phone number as listed in the telephone directory or other good faith efforts to ~~insure~~ ensure the prescriber's identity, or both.

(iv) Within seven days after authorizing an emergency prescription drug order, the prescriber shall cause a written or electronic prescription drug order for the emergency quantity prescribed to be delivered to the dispensing pharmacist.

(B) In addition to ~~confirming to~~ meeting the requirements of K.A.R. 68-20-18(e), the prescription drug order shall have written on its face "Authorization for Emergency Dispensing" and the date of the prescription drug order.

(C) The written or electronic prescription drug order shall be delivered to the pharmacist in person within seven days of authorization or, if the written prescription is delivered by mail, it shall be postmarked within the seven-day period.

(D) Upon receipt, the dispensing pharmacist shall attach this written prescription drug order to the pharmacist's record of the emergency prescription drug order. For each electronic prescription, the dispensing pharmacist shall annotate the record of the electronic prescription with the original authorization and date of the oral order.

(E) The pharmacist shall notify the nearest office of the U.S. drug enforcement administration (DEA) if the prescribing practitioner fails to deliver a written or electronic prescription drug order to the pharmacist. Failure of the pharmacist to ~~do so~~ notify the DEA shall void the authority conferred by this ~~paragraph~~ regulation to dispense without a written or

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electronic prescription of a prescriber.

(5)(4) For the purposes of authorizing a prescription of any controlled substance listed in schedule II of the federal or state uniform controlled substances act, the term "emergency situation" ~~means those situations~~ shall mean any situation in which the prescriber determines the following:

(A) That immediate administration of the controlled substance is necessary for proper treatment of the intended ultimate user;

(B) that no appropriate alternative treatment is available, including administration of a drug that is not a controlled substance under schedule II of the act; and

(C) that it is not reasonably possible for the prescriber to provide a written prescription to be presented, before dispensing, to the pharmacist dispensing the substance.

~~(b) A medical care facility or other institution registered with the board shall administer or dispense a controlled substance listed in schedule II only pursuant to a written prescription signed by the prescriber or to an order for medication made by a prescriber that is dispensed for immediate administration to the ultimate user.~~

~~(c) Partial filling of prescriptions.~~ The partial filling of a prescription for any controlled substance listed in schedule II shall be permissible, only as provided in this subsection.

(1) Whenever the pharmacist is unable to supply the full quantity called for in a written, electronic, or emergency prescription and the pharmacist makes a notation of the quantity supplied on the face of the written prescription or, written record of the emergency prescription, or electronic prescription record, the pharmacist shall perform the following:

(A) Fill the remaining portion of the prescription within 72 hours of the first partial filling

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or, if the remaining portion cannot be filled within the 72-hour period, the pharmacist shall notify the prescriber of the situation; and

(B) supply no further quantity beyond 72 hours without a new prescription.

(2) ~~Whenever written,~~ Prescriptions for schedule II controlled substances for patients in a long-term care facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness may be filled in partial quantities, including individual dosage units, as provided in this subsection. The pharmacist shall record on the prescription whether the patient is "terminally ill" or an "LTCF patient."

(A) ~~For each partial filling, the dispensing pharmacist shall record on the back of the prescription, or on another appropriate, uniformly maintained, and readily retrievable record, the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist.~~

(B) The total quantity of schedule II controlled substances dispensed in all partial fillings shall not exceed the total quantity prescribed.

(C)(B) These schedule II prescriptions shall be valid for partial filling for a period not to exceed 60 days from the issue date of the prescription unless terminated sooner by the discontinuance of medication.

(3) Any prescription for a schedule II controlled substance may be partially filled at the request of the patient or the prescriber who wrote the prescription. The pharmacist shall not fill or partially fill any remaining portions of the prescription more than 30 days after the date the prescription was written, except as provided by paragraphs (b)(1) and (2). The total quantity of schedule II controlled substances dispensed in all partial fillings shall not exceed the total

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quantity prescribed.

~~(d)(c) Labeling of substances. The Each~~ pharmacist filling a written or emergency prescription for a controlled substance listed in schedule II shall ~~affix~~ ensure that a label that meets the requirements of K.A.R. 68-7-14 and 21 C.F.R. 290.5 is affixed to the package showing the following information:

- ~~(1) The date the prescription was filled;~~
- ~~(2) the name, address, and telephone number of the pharmacy dispensing the prescription;~~
- ~~(3) the serial number of the prescription;~~
- ~~(4) the full name of the patient;~~
- ~~(5) the name of the practitioner and either the physician's assistant (PA) or the advanced registered nurse practitioner (ARNP);~~
- ~~(6) the directions for use and cautionary statements, if any, contained in the prescription or required by law;~~
- ~~(7) the brand name or corresponding generic name of the prescription medication;~~
- ~~(8) the manufacturer or distributor of the prescription medication, or an easily identified abbreviation of the manufacturer's or distributor's name;~~
- ~~(9) the expiration date of the prescription medication dispensed, if applicable.~~

~~(e) Filing of prescriptions.~~

~~(1)(d)~~ All written prescriptions, electronic prescriptions, and written records of emergency prescriptions shall be kept in accordance with K.A.R. 68-20-16.

~~(2) All written or emergency prescriptions for a controlled substance listed in schedule II shall be cancelled on the face of the prescription with the name of the pharmacist filling that~~

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prescription.

(3) All written or emergency prescriptions for controlled substances listed in schedule II and filled by a pharmacy intern shall be cancelled on the face of the prescription with the names of the pharmacy intern and preceptor authorizing the filling of that prescription. (Authorized by and K.S.A. 65-4102; implementing K.S.A. ~~1998 Supp. 65-4102~~ 2022 Supp. 65-4107, K.S.A. 65-4121, and K.S.A. 65-4123, as amended by L. 1999, Ch. 115, Sec. 15; effective, E-72-24, Aug. 25, 1972; effective Jan. 1, 1973; amended Sept. 9, 1991; amended March 29, 1993; amended March 20, 1995; amended Feb. 5, 1999; amended Dec. 27, 1999; amended P-\_\_\_\_\_.

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**68-20-20. Controlled substances listed in schedules III and, IV, and V. (a)**

**Requirements of prescription:**

(1) A pharmacist may dispense any controlled substance listed in schedule III, IV, or V that is a prescription ~~prescription-only~~ drug as determined under the federal food, drug, and cosmetic act, pursuant only to a written prescription signed by a prescriber, or an oral prescription made by a prescriber, and promptly reduced to writing by the pharmacist containing all information required under K.A.R. 68-20-18(c), except for the signature of the prescriber issued in accordance with K.A.R. 68-20-18.

(2) A prescriber may administer any controlled substance listed in schedule III, IV, or V in the course of the practitioner's professional practice without a prescription, subject to K.A.R. 68-20-18.

(3) A medical care facility registered with the board may administer or dispense directly, but shall not prescribe, any controlled substance listed in schedule III, IV, or V only pursuant to a written prescription signed by the prescriber, or to an order for medication made by a prescriber for immediate administration to the ultimate user.

**(b) Filling of prescriptions:**

(1) Each refilling of a prescription shall be entered on the back of a prescription, with the following additional information:

(A) The date of refilling or dispensing;

(B) the amount dispensed; and

(C) the name or initials of the dispensing pharmacist or pharmacist intern.

(2) Additional quantities of controlled substances listed in schedules schedule III or, IV, or

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V may be authorized by a prescriber through an oral refill authorization transmitted to the pharmacist if all of the following conditions are met:

~~(A)~~(1) The total quantity authorized, including the amount of the original prescription, does not exceed five refills or extend beyond six months from the date of issue of the original prescription.

~~(B)~~(2) The pharmacist obtaining the oral authorization records on the reverse of the original prescription the following:

~~(i)~~(A) The date;

~~(ii)~~(B) the quantity of refill;

~~(iii)~~(C) the number of additional refills authorized; and

~~(iv)~~(D) the initials of the pharmacist who received the authorization from the prescriber.

~~(C)~~(3) The quantity of each additional refill authorized is equal to or less than the quantity authorized for the initial filling of the original prescription.

~~(D)~~(4) The prescriber executes a new prescription as provided in K.A.R. 68-20-18 for any additional quantities beyond the five-refill, six-month limitation.

(5) The authorization of additional quantities is documented by either of the methods specified in K.A.R. 68-20-18a.

~~(3) As an alternative to the procedures provided by paragraph (b)(2), an automated data processing system may be used for the storage and retrieval of refill information for prescription orders for controlled substances in schedule III and IV, if all of the following requirements are met:~~

~~(A) Any such proposed computerized system shall provide on-line retrieval, via CRT~~

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~~display or hard-copy printout, of original prescription order information for those prescription orders that are currently authorized for refilling. This shall include the following:~~

- ~~(i) The original prescription number;~~
- ~~(ii) the date of issuance of the original prescription order by the prescriber;~~
- ~~(iii) the full name and address of the patient;~~
- ~~(iv) the name, address, and DEA registration number of the prescriber;~~
- ~~(v) the name, strength, dosage form, quantity of the controlled substance prescribed, and the quantity dispensed, if different from the quantity prescribed; and~~
- ~~(vi) the total number of refills authorized by the prescriber.~~

~~(B) Any such proposed computerized system shall also provide on-line retrieval, via CRT display or hard-copy printout, of the current refill history for schedule III or IV controlled substance prescription orders that have been authorized for refill during the past six months. This refill history shall include the following information:~~

- ~~(i) The name of the controlled substance;~~
- ~~(ii) the date of refill;~~
- ~~(iii) the quantity dispensed;~~
- ~~(iv) the identification code, or name or initials of the dispensing pharmacist for each refill;~~

and

- ~~(v) the total number of refills dispensed to date for that prescription order.~~

~~(C) Documentation that the refill information entered into the computer each time a pharmacist refills an original prescription order for a schedule III or IV controlled substance is correct shall be provided by the individual pharmacist who makes use of such a system. If this~~

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~~system provides a hard copy printout of each day's controlled substance prescription order refill data, that printout shall be verified, dated, and signed by the individual pharmacist who refilled the prescription order. The individual pharmacist shall verify that the date indicated is correct and then sign this document in the same manner as the pharmacist would sign a check or legal document. This document shall be maintained in a separate file at the pharmacy for five years from the dispensing date. This printout of the day's controlled substance prescription order refill data shall be provided to each pharmacy using the computerized system within 72 hours of the date on which the refill was dispensed. This document shall be verified and signed by each pharmacist who is involved with the dispensing. In lieu of such a printout, the pharmacy shall maintain a bound logbook, or separate file, in which each individual pharmacist involved in the dispensing shall sign a statement, in the manner previously described, each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by the pharmacist and is correct as shown. This book or file shall be maintained at the pharmacy employing the system for five years after the date of dispensing the appropriately authorized refill.~~

~~(D) Any such computerized system shall have the capability of producing a printout of any refill data that the user pharmacy is responsible for maintaining. This shall include a refill by-refill audit trail for any specified strength and dosage form of any controlled substance, by brand, generic name, or both. This printout shall include the following:~~

- ~~(i) The name of the prescriber;~~
- ~~(ii) the name and address of the patient;~~
- ~~(iii) the quantity dispensed on each refill;~~

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~~(iv) the date of dispensing for each refill;~~

~~(v) the name or identification code of the dispensing pharmacist; and~~

~~(vi) the number of the original prescription order.~~

~~(E) In any central computerized system employed by a user pharmacy, the central recordkeeping location shall be capable of sending the printout to the pharmacy within 48 hours, and if an authorized agent of the board requests a copy of this printout from the user pharmacy, it shall, if requested to do so by the agent, verify the printout transmittal capability of its system by documentation.~~

~~(F) If a pharmacy that employs such a computerized system experiences system downtime, the pharmacy shall have an auxiliary procedure that will be used for documentation of refills of schedule III and IV controlled substance prescription orders. This auxiliary procedure shall insure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data is retained for on-line data entry as soon as the computer system is available for use again.~~

~~(4) When filing refill information for original prescription orders for schedule III or IV controlled substances, a pharmacy may use one of the two systems described in paragraphs (2) or (3) of this subsection.~~

~~(5) In the case of medical care facilities registered with the board, all requirements specified in paragraphs (b)(1), (2), and (3) above shall be maintained in the medication records or other readily retrievable records regularly maintained by the medical care facility.~~

~~(c) Partial filling of prescriptions. A prescription for a controlled substance listed in schedule III, IV, or V may be partially filled if all of the following conditions are met:~~

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(1) Each partial filling is recorded in the same manner as that for a refilling.

(2) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.

(3) ~~Except for a controlled substance listed in schedule V,~~ No dispensing occurs after six months after the date on which the prescription was issued.

(d) ~~Labeling of substances. The~~ Each pharmacist filling a prescription for a controlled substance listed in schedule III ~~or~~, IV, or V shall ~~affix to the package~~ ensure that a label showing the following:

~~(1) The pharmacy name and address;~~

~~(2) the serial number of the prescription;~~

~~(3) the date of initial filling;~~

~~(4) the name of the patient;~~

~~(5) the name of the prescriber issuing the prescription;~~

~~(6) the directions for use; and~~

~~(7) cautionary statements, if any, contained in the prescription as required by law, except as provided in 21 CFR 1306.24 as in effect on April 1, 1999, which is hereby adopted by reference meeting the requirements of K.A.R. 68-7-14 is affixed to the package.~~

(e) ~~Filing prescriptions.~~ All prescriptions for controlled substances listed in schedules III, IV, and V shall be kept in accordance with K.A.R. 68-20-16. (Authorized by ~~and~~ K.S.A. 65-4102 and K.S.A. 65-4121; implementing K.S.A. ~~1998 Supp.~~ 65-4102, K.S.A. 65-4121, and K.S.A. 65-4123; effective, E-73-24, Aug. 25, 1972; effective Jan. 1, 1973; amended May 1, 1983; amended April 30, 1990; amended Aug. 4, 2000; amended P-\_\_\_\_\_.)

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**68-20-21.** (Authorized by K.S.A. 1998 Supp. 65-4113; effective, E-72-24, Aug. 25, 1972;  
effective Jan. 1, 1973; amended Dec. 27, 1999; revoked P-\_\_\_\_\_.)

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**68-20-22. Dispensing Selling without a prescription.** A Any controlled substance listed in ~~schedule V and a controlled substance listed in schedule II, III or, IV which, or V~~ that is not a ~~prescription~~ prescription-only drug as determined under the federal food, drug, and cosmetic act, may be ~~dispensed~~ sold by a pharmacist without a prescription to a purchaser at retail, ~~provided~~ that if all of the following conditions are met:

(a) The sale of any substance that is a methamphetamine precursor is made in accordance with K.S.A. 65-16,102, and amendments thereto, and with 21 C.F.R. 1314.20, 21 C.F.R. 1314.25, 21 C.F.R. 1314.30, 21 C.F.R. 1314.100, and 21 C.F.R. 1314.105 as in effect on August 31, 2022.

(b) The sale of any substance that is not a methamphetamine precursor meets all of the following conditions:

(1) ~~such dispensing~~ Approval of the sale is made only by a pharmacist ~~as that term is defined by the pharmacy act of the state of Kansas and not by a non-pharmacist~~ nonpharmacist employee, even if under the supervision of a pharmacist ~~(although after the pharmacist has fulfilled his or her professional and legal responsibilities set forth in this act, the actual cash, credit transaction, or delivery, may be completed by a nonpharmacist.~~

(b)(2) The pharmacist does not sell at retail more than 240 cc (8 ounces) of any such controlled substance containing opium, nor or more than 120 cc (4 ounces); of any other such controlled substance nor to the same purchaser in any 48-hour period.

(3) The pharmacist does not sell at retail more than forty-eight (48) dosage units of any such controlled substance containing opium, nor or more than twenty-four (24) dosage units of any other such controlled substance may be dispensed at retail to the same purchaser in any

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~~given forty-eight (48) hour~~ 48-hour period.

(e)(4) The purchaser is at least ~~eighteen (18)~~ years of age.

(d)(5) The pharmacist requires every purchaser of a controlled substance ~~under this section~~  
~~not known to him or her~~ to furnish suitable identification (~~including~~ that includes proof of age  
~~where appropriate~~).

(e)(6) The pharmacist maintains a bound record book for the dispensing of controlled  
substances ~~under this section is maintained by the pharmacist, which.~~ The record book shall  
contain the name and address of the purchaser, the name and quantity of controlled substance  
purchased, the date of each purchase, and the name or initials of the pharmacist who ~~dispensed~~  
approved the sale of the substance to the purchaser. ~~(The record book shall be maintained in~~  
~~accordance with the record keeping requirements of the uniform controlled substances act of the~~  
~~state of Kansas);~~ kept readily retrievable at the registered location for five years.

(f)(c) A prescription is not required for ~~distribution or~~ dispensing of the substance pursuant  
to any other federal, state, or local law. (Authorized by K.S.A. 65-16,106; implementing K.S.A.  
1977 Supp. 65-4116 65-16,102 and 65-16,104; effective May 1, 1978; amended P-  
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**68-21-1. Definitions.** As used in ~~these~~ this article of the board's regulations, each of the following terms shall have the ~~meanings~~ meaning specified in this regulation:

(a) "Authentication" means the provision of information, an electronic device, or a certificate by the board or its designee to a ~~dispenser or prescriber requester~~ requester that allows the ~~dispenser or prescriber requester~~ requester to electronically access prescription monitoring information. The authentication may include the provision of a user name, a password, or an electronic identification device or certificate.

(b) "DEA" means the drug enforcement administration of the United States department of justice.

(c) "Dispenser identification number" means the ~~drug enforcement administration (DEA)~~ number ~~if available or, If a DEA number is not available~~ issued to the dispenser, the dispenser identification number means the national provider identifier (NPI) number or the Kansas license number.

~~(e)~~(d) "Drug enforcement administration number" means a unique registration number issued to an a practitioner authorized ~~prescriber of~~ by the DEA to prescribe controlled substances ~~by the drug enforcement administration, United States department of justice.~~

~~(d)~~(e) "National provider identifier" and "NPI" mean a unique 10-digit number issued by the national provider identifier registry and used to identify each ~~health care provider~~ practitioner whose services are authorized by medicaid or medicare.

~~(e)~~(f) "Patient identification number" means that patient's unexpired temporary or permanent driver's license number ~~or, state-issued identification card number, or pharmacy system-generated identification number.~~ If the patient does not have one of those numbers, the

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dispenser shall use the patient's insurance identification number. If the patient does not have an insurance identification number, the dispenser shall use the patient's first, middle, and last initials, followed by the patient's eight-digit birth date. The patient identification number shall not include a social security number.

(f) ~~"Prescriber identification number" means the DEA number if available or, if not available, the NPI.~~

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

(h) "Report" means a compilation of data concerning a dispenser, patient, drug of concern, or scheduled substance as defined in K.S.A. 65-1682(g), and amendments thereto.

(i) ~~"Stakeholder" means a person, group, or organization that could be affected by the program's actions, objectives, and policies.~~

(j)(h) "Valid photographic identification" means any of the following:

(1) ~~An unexpired permanent or temporary driver's license, state identification card, or instruction permit issued by any U.S. state or Canadian province;~~

(2) ~~an unexpired state identification card issued by any U.S. state or Canadian province;~~

(3) ~~an unexpired official passport issued by any nation;~~

(4)(3) ~~an unexpired a United States armed forces military identification card issued to any active duty, reserve, or retired member and the member's dependents;~~

(5) ~~an unexpired merchant marine identification card issued by the United States coast guard; or~~

(6) ~~an unexpired state liquor control identification card issued by the liquor control authority of any U.S. state or Canadian province; or~~

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(7)(4) an unexpired enrollment identification card issued by the governing authority of a federally recognized United States Indian tribe located in Kansas, if the enrollment card incorporates security features comparable to those used by the Kansas department of revenue for drivers' licenses.

(k)(i) "Zero report" means an electronic data submission reflecting no dispensing activity for a given period.

~~This regulation shall take effect 90 days after publication in the Kansas register.~~

(Authorized by K.S.A. 65-1692; implementing K.S.A. 2013 2022 Supp. 65-1682; effective Oct. 15, 2010; amended Aug. 13, 2014; amended P-\_\_\_\_\_.)

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**68-21-2. Electronic reports.** (a)(1) Except as specified in subsections (d) and (e), each dispenser shall file a report with the board for each scheduled substances, ~~as defined in K.S.A. 65-1682(g) and amendments thereto,~~ substance and any drugs drug of concern dispensed sold in this state Kansas or to an address in this state Kansas. This report shall be submitted ~~within 24 hours of~~ by the end of the next business day from the time day that the substance drug is dispensed sold, unless the board grants an extension as specified in subsection (d).

(2)(b) Except as specified in subsections (c), (d), and (e), each dispenser that does not dispense scheduled substances, ~~as defined in K.S.A. 65-1682(g) and amendments thereto,~~ or any drugs of concern in this state Kansas or to an address in this state Kansas during the reporting period specified in paragraph subsection (a)(1) shall file a zero report with the board. Each zero report shall meet the following requirements:

(A) ~~Cover not more than a seven-day period in which no such drugs were dispensed; and~~

(B) be filed ~~the~~ by the end of the next business day following the end of the period covered by the zero report.

(b) ~~In addition to the requirements of K.S.A. 65-1683 and amendments thereto, each dispenser shall submit the prescriber's name, the patient's telephone number, and the number of refills for the dispensed drug on the report to the board. As an alternative to reporting the dispenser identification number, any dispenser may report the pharmacy DEA number.~~

(c) Any dispenser that meets the following conditions may submit a written request to the board for an exemption from subsection (b):

(1) The dispenser does not monthly dispense more than 10 prescriptions for scheduled substances and drugs of concern in Kansas or to an address in Kansas.

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(2) The dispenser is unable to automate submission of a zero report.

(d) Any medical care facility, as defined by K.S.A. 65-1626 and amendments thereto, may submit a written request to the board for an exemption from subsections (a) and (b) if the medical care facility provides an interim supply of a scheduled substance or drug of concern to an outpatient on an emergency basis and the interim quantity does not exceed a 48-hour supply and, as described in K.A.R. 68-7-11(d)(2)(B), is limited to an amount sufficient to supply the outpatient's needs until a prescription can be filled in accordance with K.A.R. 68-7-11. This exemption shall apply only to the outpatient emergency interim supply of drugs and not to other outpatient dispensing or supply activities of the medical care facility.

(e) Any dispenser that does not dispense scheduled substances or drugs of concern in Kansas or to an address in Kansas may submit a written request to the board for an exemption from subsections (a) and (b) if both of the following conditions are met:

(1) The dispenser has submitted the required reports for at least three months or has provided three months of dispensing records to the board.

(2) The request is accompanied by the following:

(A) If the dispenser is a nonresident pharmacy, a list of states in which the pharmacy is registered;

(B) the current prescription monitoring program reporting status in each state in which the dispenser is registered; and

(C) a copy of any written reprimand, censure, or other disciplinary action related to prescription monitoring program reporting that the dispenser has had in any state, district, or territory.

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(f) Each dispenser or pharmacy that no longer meets the criteria for exemption specified in subsection (c), (d), or (e) shall notify the board and begin submitting reports within seven days.

(g) Each exemption issued by the board shall expire annually on August 31.

(h) Except as specified in K.A.R. 68-21-3, each report required to be submitted pursuant to subsection (a) shall be submitted by secure file transfer protocol in the electronic format established by the American society for automation in pharmacy, dated no earlier than 2007 2020, version 4, release 1 2b.

~~(d) An extension may be granted by the board to a dispenser for the submission of any report required to be submitted pursuant to subsection (a) if both of the following conditions are met:~~

~~(1)(A) The dispenser suffers a mechanical or electronic failure; or~~

~~(B) the dispenser cannot meet the deadline established by subsection (a) because of circumstances beyond the dispenser's control.~~

~~(2) The dispenser files a written application for extension on a form provided by the board within 24 hours of discovery of the circumstances necessitating the extension request or on the next day the board's administrative office is open for business.~~

~~(e) An extension for the filing of a report shall be granted to a dispenser if the board is unable to receive electronic reports submitted by the dispenser.~~

~~(f) Each dispenser that is registered or licensed to dispense scheduled substances, as defined in K.S.A. 65-1682(g) and amendments thereto, or any drugs of concern in this state or to an address in this state but does not dispense any of these drugs shall notify the board in writing~~

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~~that the dispenser will not be reporting to the board. If the dispenser begins dispensing scheduled substances, as defined in K.S.A. 65-1682(g) and amendments thereto, or any drugs of concern in this state or to an address in this state, the dispenser shall notify the board of this fact and shall begin submitting reports to the board pursuant to this regulation.~~

(i) Each dispenser shall correct any reporting error within seven days of discovering the error or being notified of the error by the board or the board's designee.

~~This regulation shall take effect 90 days after publication in the Kansas register.~~

(Authorized by K.S.A. 2013 Supp. ~~65-1683~~ and 65-1692; implementing K.S.A. 2013 2022 Supp. 65-1683; effective Oct. 15, 2010; amended April 15, 2011; amended Aug. 13, 2014; amended P-\_\_\_\_\_.)

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**Proposed**

**68-21-3.** (Authorized by K.S.A. 2009 Supp. 65-1692; implementing K.S.A. 2009 Supp. 65-1683; effective Oct. 15, 2010; revoked P-\_\_\_\_\_.)

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**68-21-4. Notice of requests for information.** Each dispenser who may access information maintained by the board on each drug of concern and ~~schedule II through IV drug~~ scheduled substance dispensed to one of the dispenser's patients for the purpose of providing medical or pharmaceutical care shall notify the patient of this access to ~~prescription monitoring~~ program information by performing either of the following:

(a) Posting an easily viewable sign at the place where prescription orders are issued or accepted for dispensing; or

(b) providing written material about the dispenser's access to ~~prescription monitoring~~ program information. (Authorized by K.S.A. 2009 ~~Supp.~~ 65-1692; implementing K.S.A. 2009 ~~Supp.~~ 65-1685, as amended by L. 2022, ch. 74, sec. 5; effective Oct. 15, 2010; amended P-\_\_\_\_\_.)

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**68-21-5. Access to program information.** All requests for, uses of, and disclosures of prescription monitoring information by authorized persons shall meet the requirements of K.S.A. 65-1685, and amendments thereto, and this article.

(a) By patients or patient's personal representative.

(1) Any patient or that patient's personal representative patient's designee may obtain a report listing all program information that pertains to the patient, in accordance with this regulation and K.S.A. 65-1685 and amendments thereto.

(2) Each patient or the patient's personal representative seeking access to the information described in paragraph (a)(1) shall submit by submitting a written request for information in person to the board on a form provided by the board. The written request shall be in a format established by the board and, which shall include the following elements:

(A)(1) The patient's name and, if applicable, the full name of the patient's personal representative designee;

(B)(2) the patient's residential address and, if applicable, the complete residential address of the patient's personal representative designee;

(C)(3) the patient's telephone number, if any, and, if applicable, the telephone number of the personal representative patient's designee; and

(D)(4) the time period for which information is being requested;

(3)(5) the patient or the patient's personal representative shall produce two forms of a copy of a valid photographic identification before obtaining access to the patient's information obtained by the program. of the patient or the patient's personal representative shall allow photocopying of the identification. designee; and

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~~(4)(6) Before access to the patient's information obtained by the program is given, one of the following shall be produced if the requester is not the patient:~~

~~(A) For a personal representative, an official attested copy of the judicial order granting authority to gain access to the health care records of the patient;~~

~~(B) for a parent of a minor child, a certified copy of the birth certificate of the minor child or other official documents establishing, a copy of official documents establishing either legal guardianship; or~~

~~(C) for a person holding power of attorney, the original document establishing the power of attorney.~~

~~(5) The patient's personal representative shall allow the photocopying of the documents described in this subsection.~~

~~(6) The patient authorization may be verified by the board by any reasonable means before providing the information to the personal representative.~~

~~(b) By dispensers.~~

~~(1) Any practitioner, dispenser, or delegate may obtain any program information relating to a patient of the dispenser for the purpose of providing pharmaceutical care to that patient, in accordance with this regulation and K.S.A. 65-1685, and amendments thereto. The information shall be provided in a format established by the board, which may include delivery by electronic means, facsimile transmission, or telephone.~~

~~(2) Each dispenser who seeks access to the information described in paragraph (b)(1) shall submit a written, by submitting an electronic request to the board by mail, hand delivery, or electronic means in a manner established by the board, using authentication. If the authentication~~

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~~is lost or missing or the security of the authentication is compromised, the dispenser shall cause the board to be notified by telephone and in writing as soon as reasonably possible. Information regarding more than one patient may be submitted in a single request.~~

Each request shall be submitted in a format established by the board and shall include the following elements for each patient:

(A) The patient's first name and birth date last name;

(B) ~~if known to the dispenser, the patient's address and telephone number~~ date of birth;

and

(C) the time period for which information is being requested;

~~(D) the dispenser's name;~~

~~(E) if applicable, the name and address of the dispenser's pharmacy;~~

~~(F) the dispenser identification number; and~~

~~(G) the dispenser's signature.~~

~~(3)(2) The authentication and identity of the practitioner, dispenser, or delegate shall be verified by the board before allowing access to any prescription monitoring program information. If the authentication is lost or missing or if the security of the authentication is compromised, the practitioner, dispenser, or delegate shall notify the board in writing as soon as possible.~~

~~(c) By prescribers:~~

~~(1) Any prescriber or health care practitioner authorized by a prescriber may obtain any program information relating to a patient under the prescriber's care, in accordance with this regulation and K.S.A. 65-1685 and amendments thereto. The information shall be provided in a~~

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~~format established by the board, which may include delivery by electronic means, facsimile, or telephone.~~

~~(2) Each prescriber or health care practitioner authorized by a prescriber who seeks access to program information shall submit a written request to the board by mail, hand delivery, or electronic means in a manner established by the board, using authentication. If the authentication is lost or missing or the security of the authentication is compromised, the prescriber shall cause the board to be notified by telephone and in writing as soon as reasonably possible. Information regarding more than one patient may be submitted in a single request.~~

~~Each request shall be submitted in a format established by the board and shall include the following elements for each patient:~~

- ~~(A) The patient's name and birth date;~~
- ~~(B) if known to the prescriber, the patient's address and telephone number;~~
- ~~(C) the time period for which information is being requested;~~
- ~~(D) the prescriber's name;~~
- ~~(E) the name and address of the prescriber's medical practice;~~
- ~~(F) the prescriber identification number; and~~
- ~~(G) the prescriber's signature.~~

~~(3) The authentication and identity of the dispenser shall be verified before allowing access to any program information.~~

~~(d) By director or board investigator of a health professional licensing, certification, or regulatory agency or entity.~~

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(1) In conjunction with an active investigation, any director or board investigator designated representative of a health professional licensing, certification, or regulatory agency or entity charged with administrative oversight of practitioners or dispensers may obtain any program information needed in carrying out that individual's business, in accordance with this regulation and K.S.A. 65-1685 and amendments thereto. The information shall be provided in a format established by the board, which may include delivery by electronic means, facsimile, or telephone.

(2) Each director or board investigator of a licensing board with jurisdiction over a dispenser or prescriber who seeks access to program information shall submit for a practitioner licensed or regulated by the agency or for a patient by submitting a written request by mail, facsimile, or electronic means to a location specified by the board. The written request shall contain a statement of facts from which the board can make a determination of reasonable cause for the request, on a form provided by the board.

(1) If the request is for program information related to a practitioner, the request shall include the following:

(A) The requestor's name and agency;

(B) the practitioner's name;

(C) the practitioner's DEA number, if issued to the practitioner;

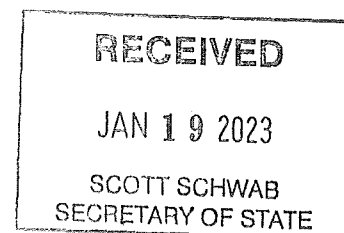
(D) the practitioner's NPI number, if issued to the practitioner; and

(E) the time period for which information is being requested.

(2) If the request is for program information related to a patient, the request shall include the following:

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(A) The requestor's name and agency;

(B) the patient's first name and last name;

(C) the patient's date of birth; and

(D) the time period for which information is being requested.

(e) By local, state, and federal law enforcement or prosecutorial officials;

(1) Any local, state, or federal law enforcement officer or prosecutorial official may obtain any program information as required for an ongoing case, in accordance with this regulation and K.S.A. 65-1685 and amendments thereto. The information shall be provided in a format established by the board, which may include delivery by electronic means, facsimile, or telephone.

(2) Each local, state, or federal law enforcement officer or prosecutorial official who seeks access to program information shall register with the board. Once registration is approved, the requester may submit a written request by mail, facsimile, or electronic means to the board. All requests for, uses of, and disclosures of prescription monitoring information by authorized persons under this subsection shall meet the requirements of K.S.A. 65-1685 (e)(4), and amendments thereto.

(f) By the Kansas health policy authority for purposes of the Kansas medicaid and state children's health insurance program (SCHIP).

(1) An authorized representative of the Kansas health policy authority may obtain any program information regarding medicaid or SCHIP program recipients, in accordance with this regulation and K.S.A. 65-1685 and amendments thereto. The information shall be provided in a format established by the board.

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(2) Each authorized representative of the Kansas health policy authority seeking program information regarding medicaid or SCHIP program recipients who seeks access to program information shall submit a request to the board.

(g) By any other state's prescription monitoring program.

(1) Any authorized representative from any other state's prescription monitoring program may obtain any program information for requests from within that state that do not violate the authentication and security provisions of the prescription monitoring program act, in accordance with this regulation and K.S.A. 65-1685 and amendments thereto. The information shall be provided in a format established by the board, which may include delivery by electronic means, facsimile, or telephone.

(2) Any authorized representative from another state's prescription monitoring program seeking access to program information shall first establish a data-sharing agreement with the board in which the states agree to share prescription monitoring information with one another. The agreement shall specify what information will be made available and to whom, how requests will be made, how quickly requests will be processed, and in which format the information will be provided.

(h) By public or private entities for statistical, research, or educational purposes.

(1) Any public or private entity may obtain program information, in accordance with this regulation and K.S.A. 65-1685(d) and amendments thereto. The information shall be provided in a format established by the board.

(2) Each public or private entity who seeks access to program information shall submit a written request by mail, facsimile, or electronic means to the board. The written request shall

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~~contain a statement of facts from which the board can make a determination of reasonable cause for the request.~~

(d) Any designated representative from the department of health and environment, an overdose fatality review board established by the state, or an impaired provider program for practitioners may obtain program information related to a patient in accordance with K.S.A. 65-1685, and amendments thereto, by submitting an electronic written request to the board in a manner established by the board, using authentication. The request shall include the following:

(1) The patient's first name and last name;

(2) the patient's date of birth; and

(3) the time period for which information is being requested. (Authorized by K.S.A. 2009 Supp. 65-1692; implementing K.S.A. 2009 Supp. 65-1685, as amended by L. 2022, ch. 74, sec. 5; effective Oct. 15, 2010; amended P-\_\_\_\_\_.)

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Article 23. Telepharmacy

**68-23-1. Definitions.** Each of the following terms, as used in this article of the board's regulations, shall have the meaning specified in this regulation:

(a) "Community mental health center" has the meaning specified in K.S.A. 39-2002, and amendments thereto.

(b) "Dispensing threshold" means a dispensation average of 65 prescriptions per day per quarter. The average shall be calculated by dividing the total number of prescriptions dispensed by the number of days the telepharmacy outlet was open during the quarter. Each quarter shall consist of January 1 through March 31, April 1 through June 30, July 1 through September 30, and October 1 through December 31 of each year.

(c) "Federally qualified health center" means a center that meets the requirements for federal funding under the federal public health service act, 42 U.S.C. § 1396d, as in effect on March 15, 2022, and that has been designated as a "federally qualified health center" by the federal government.

(d) "Indigent health care clinic" has the meaning specified in K.S.A. 75-6102, and amendments thereto.

(e) "Pharmacy prescription application" has the meaning specified in K.S.A. 65-1626, and amendments thereto.

(f) "Telepharmacy" has the meaning specified in K.S.A. 2022 Supp. 65-16,130, and amendments thereto.

(g) "Telepharmacy outlet" has the meaning specified in K.S.A. 2022 Supp. 65-16,130, and

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amendments thereto.

(h) "Telepharmacy system" means an electronic system that links a managing pharmacy to a telepharmacy outlet. (Authorized by K.S.A. 2022 Supp. 65-16,130; implementing K.S.A. 2022 Supp. 65-1626 and 65-16,130; effective P-\_\_\_\_\_.)

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**68-23-2. Telepharmacy outlet application; facility; managing pharmacy.** Each owner and each pharmacist-in-charge shall ensure that the telepharmacy outlet meets the requirements of this article of the board's regulations to be registered and to remain registered with the board.

(a) Application.

(1) The owner of the telepharmacy outlet or the owner's authorized representative shall apply for registration and renewal on forms approved by the board. The owner of the telepharmacy outlet shall pay an annual pharmacy registration fee as specified in K.A.R. 68-11-2.

(2) Each owner that receives, maintains, or dispenses controlled substances shall obtain a registration from the DEA and provide a copy of the valid registration to the board.

(3) Upon receipt of a completed application, both the owner or the owner's authorized representative and the pharmacist-in-charge may be required to meet with the board or the board's representative.

(b) Location and delivery.

(1)(A) Except as specified in paragraph (b)(1)(B), each telepharmacy outlet shall meet the following requirements at the time of application:

(i) Be at least 20 miles from any registered pharmacy; and

(ii) not be in a county that contains a city or municipality with a population greater than 50,000 individuals.

(B) Any telepharmacy outlet may be located in any of the following:

(i) A community mental health center;

(ii) an indigent health care clinic; or

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(iii) a federally qualified health center.

(2) Each telepharmacy outlet shall be fewer than 50 miles from the managing pharmacy.

(3) Any telepharmacy outlet may dispense prescriptions by delivery or mail carrier within 20 miles of the telepharmacy outlet.

(4) For purposes of this regulation, miles shall be calculated by the most direct driving route.

(c) Dispensing threshold.

(1) The telepharmacy outlet owner shall notify the board in writing no more than five days after exceeding the dispensing threshold.

(2) No more than 30 days after exceeding the dispensing threshold, a pharmacist shall be physically present at the telepharmacy outlet when it is open.

(3) After demonstrating two consecutive quarters of operating under the dispensing threshold, the telepharmacy outlet owner may submit to the board a written request for the telepharmacy outlet to be open while a pharmacist is not physically present at the telepharmacy outlet.

(d) Managing pharmacy.

(1) Any managing pharmacy may supervise no more than two telepharmacy outlets.

(2) No telepharmacy outlet may serve as a managing pharmacy for another telepharmacy outlet.

(e) Exemption or waiver. Any telepharmacy outlet owner may submit a written request to the board for an exemption from or waiver of the requirements of this article of the board's regulations, except for the requirements of subsection (b). The following factors shall be

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considered by the board or the board's designee in determining whether to grant an exemption or waiver:

(1) The number of prescriptions dispensed or reasonably expected to be dispensed by the telepharmacy outlet;

(2) the number of patients served or reasonably expected to be served by the telepharmacy outlet;

(3) the education, experience, and training of any pharmacy personnel physically present at the telepharmacy outlet or supervising from the managing pharmacy;

(4) the prescription drugs or devices received, stored, and dispensed at the telepharmacy outlet;

(5) medical necessity;

(6) the effect on the health and welfare of persons in Kansas;

(7) any circumstance that makes a requirement unreasonable or unnecessarily burdensome; and

(8) any event that directly resulted from the occurrence of natural causes outside the control of the telepharmacy outlet or managing pharmacy.

(f) Compliance. Except as specified in this article of the board's regulations, each telepharmacy outlet owner and each pharmacist-in-charge shall ensure that the telepharmacy outlet meets the requirements of a pharmacy specified in the pharmacy act of the state of Kansas and amendments thereto, the uniform controlled substances act and amendments thereto, and the implementing regulations. (Authorized by and implementing K.S.A. 2022 Supp. 65-16,130; effective P-\_\_\_\_\_.)

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**68-23-3. Personnel, staffing, training, and supervision.** (a) Each telepharmacy outlet owner shall designate a pharmacist-in-charge, as defined by K.S.A. 65-1626 and amendments thereto, who shall also be the pharmacist-in-charge of the managing pharmacy.

(b) Except for the provisions of K.A.R. 68-7-13, the pharmacist-in-charge shall comply with all requirements of a pharmacist-in-charge specified in the pharmacy act of the state of Kansas, and amendments thereto, and the implementing regulations.

(c) The pharmacist-in-charge shall ensure that the telepharmacy outlet is open only when the supervising pharmacist is physically present at the managing pharmacy or is physically present at the telepharmacy outlet.

(d) The pharmacist-in-charge shall ensure that documentation of training and qualifications is maintained at the telepharmacy outlet and the managing pharmacy for all personnel working in the prescription area of the telepharmacy outlet, including proof that all personnel meet the requirements of subsection (g).

(e) The pharmacist-in-charge shall establish policies and procedures for the telepharmacy outlet and managing pharmacy. The policies and procedures shall include the following:

(1) Self-inspection criteria for the telepharmacy outlet; and

(2) a plan for continuation of pharmaceutical services for patients at the telepharmacy outlet in case of emergency, telepharmacy system outage, unavailability of video surveillance, temporary closure, or interruption of services, including a plan for the arrival of necessary pharmacy personnel at the telepharmacy outlet or the delivery of necessary supplies or equipment to the telepharmacy outlet within a reasonable period of time.

(f) The pharmacist-in-charge shall ensure that a pharmacist conducts an on-site, monthly

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self-inspection of the telepharmacy outlet no more than 31 days after the previous self-inspection. The pharmacist conducting the self-inspection shall compile a report at the time of self-inspection, which shall include the name and license number of the pharmacist, the date and time the self-inspection was conducted, the items reviewed, the findings, and, as needed, a corrective action plan. Each report shall be maintained at the telepharmacy outlet in a readily retrievable manner for five years. Each self-inspection shall include the pharmacist's review and evaluation of the following:

- (1) Audit and reconciliation of all inventories of controlled substances and drugs of concern;
- (2) audit of the electronic keypad or other electronic entry system and all related records;
- (3) verification that the continuous video surveillance system is functioning and recordings are maintained and available for at least 60 days following the date of the recording;
- (4) the number of prescriptions filled during the preceding 30 days;
- (5) the number of hours when a pharmacist was physically present at the telepharmacy outlet during the preceding 30 days;
- (6) compliance with policies and procedures for the telepharmacy outlet;
- (7) compliance with an ongoing continuous quality improvement program pursuant to K.S.A. 65-1695 and amendments thereto, review of incident reports, and necessary training or education of pharmacy personnel in response to any incident;
- (8) records of the receipt and disbursement of prescription drugs to monitor for diversion, theft, or loss;
- (9) inspection of drug supplies and storage areas to ensure the removal and quarantine of

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outdated drugs and devices;

(10) inspection of stock drug supplies and storage areas to ensure that the drugs are maintained in a manner to prevent diversion, theft, or loss and to maintain the integrity of the drugs; and

(11) verification that the temperature and humidity of storage areas for the stored drugs, devices, and equipment are maintained in accordance with the manufacturer's or distributor's recommendations.

(g) Whenever a pharmacist is not physically present at the telepharmacy outlet, one of the following individuals shall be authorized to be in the prescription area of the telepharmacy outlet while the telepharmacy outlet is open:

(1) A pharmacy technician who has the following education, experience, and training:

(A) At least one year of experience as a pharmacy technician in a retail pharmacy located in Kansas in the two years preceding the date the pharmacy technician begins working at the telepharmacy outlet;

(B) at least 160 hours of training either with the current pharmacist-in-charge or the pharmacist-in-charge's designee;

(C) documentation of passing a certification examination approved by the board in accordance with K.A.R. 68-5-17;

(D) a score of at least 85 percent on the telepharmacy outlet examination administered by the board;

(E) understanding of the telepharmacy outlet policies and procedures; and

(F) demonstrated proficiency in operating the telepharmacy system and pharmacy

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prescription application used by the telepharmacy outlet; or

(2) a pharmacist intern who has completed at least two years of pharmacy school and has demonstrated proficiency in operating the telepharmacy system and pharmacy prescription application used by the telepharmacy outlet. Any pharmacist intern may perform only the duties of a pharmacy technician. Hours worked in a telepharmacy outlet shall not be counted as the qualifying pharmaceutical experience required by K.A.R. 68-1-3a.

(h) When calculating the ratio of pharmacy technicians to pharmacists in accordance with K.A.R. 68-5-16, the following requirements shall apply:

(1) If a pharmacist is not present at the telepharmacy outlet, each pharmacy technician or pharmacist intern at the telepharmacy outlet shall be included in the ratio calculated for the supervising pharmacist at the managing pharmacy.

(2) If a pharmacist is present at the telepharmacy outlet, each pharmacy technician or pharmacist intern at the telepharmacy outlet shall be included in the ratio calculated for the pharmacist present at the telepharmacy outlet.

(i) The pharmacist-in-charge shall maintain a list of all pharmacy technicians and pharmacist interns authorized to work at the telepharmacy outlet. The list shall be maintained at the telepharmacy outlet and the managing pharmacy.

(j) Any clerk, cashier, or delivery driver may be present at the telepharmacy outlet. However, none of these individuals shall have access to the prescription area of the telepharmacy outlet.

(k) Unless a pharmacist is physically present at the telepharmacy outlet, each pharmacy technician or pharmacist intern at the telepharmacy outlet shall be under continuous electronic

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supervision by a supervising pharmacist physically present at the managing pharmacy. Except to turn on the relevant technology, no pharmacy technician or pharmacist intern shall be allowed in the prescription area of the telepharmacy outlet unless the pharmacy technician or pharmacist intern is under continuous electronic supervision.

(1) Electronic supervision conducted in accordance with this article of the board's regulations shall constitute direct supervision. (Authorized by and implementing K.S.A. 2022 Supp. 65-16,130; effective P-\_\_\_\_\_.)

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**68-23-4. Practice of pharmacy.** (a) Each prescription to be dispensed by a telepharmacy outlet shall be reviewed by a pharmacist after being filled but before being dispensed. The pharmacist shall perform prescription utilization review, prescription verification, and final verification. If the pharmacist is not physically present at the telepharmacy outlet, the final verification shall require using the telepharmacy system to verify the source container, prescription medication, and prescription label against the prescription order.

(b) A pharmacy technician or pharmacist intern shall not compound a sterile preparation or nonsterile preparation unless a pharmacist is physically present at the telepharmacy outlet.

(c) Any pharmacy technician or pharmacist intern may reconstitute commercially available oral or topical medications according to manufacturer directions, for dispensing at a telepharmacy outlet. Each reconstituted drug shall be visually verified by the pharmacist before dispensing.

(d) An immunization shall not be administered to any individual at a telepharmacy outlet unless a pharmacist is physically present.

(e) Except as specified in this article of the board's regulations, pharmacy personnel at the telepharmacy outlet shall not participate in shared services as defined by K.A.R. 68-7-20.

(f) Each pharmacist, pharmacy technician, or pharmacist intern filling a prescription at a telepharmacy outlet shall ensure that a label meeting the requirements of K.A.R. 68-7-14 is affixed to the package and includes the names, addresses, and phone numbers of the following:

- (1) The telepharmacy outlet; and
- (2) the managing pharmacy.

(g) A pharmacist shall counsel each patient or the patient's agent in accordance with

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**Proposed**

K.A.R. 68-23-4  
p. 2

K.A.R. 68-2-20. Each refusal of counseling by the patient shall be made directly to the pharmacist. (Authorized by and implementing K.S.A. 2022 Supp. 65-16,130; effective P-\_\_\_\_\_.)

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**68-23-5. Operation of telepharmacy outlet.** Each telepharmacy outlet shall be operated in accordance with the following requirements:

(a) The telepharmacy outlet shall not open any earlier than 15 minutes after the managing pharmacy has opened and shall close at least 15 minutes before the managing pharmacy closes.

(b) The telepharmacy outlet shall use a pharmacy prescription application under common control with the managing pharmacy or shall provide the managing pharmacy with total and remote access to the pharmacy prescription application. When using a pharmacy prescription application under common control, the prescriptions filled at the telepharmacy outlet shall be distinguishable from those prescriptions filled at any other location.

(c) The telepharmacy outlet shall receive all prescription drugs and devices directly from the managing pharmacy or a wholesale distributor registered with the board. All prescription drugs and devices shall be received from the managing pharmacy or the wholesale distributor in the prescription area of the telepharmacy outlet. The telepharmacy outlet shall not distribute drugs or devices except to the managing pharmacy.

(d) The telepharmacy outlet shall prominently display the following, in a location visible to the public:

- (1) A copy of the current pharmacy registration from the board;
- (2) a copy of the current license renewal certificate of the pharmacist-in-charge;
- (3) a copy of the current registration of each pharmacy technician or pharmacist intern working at the telepharmacy outlet;
- (4) a copy of the current license of each pharmacist providing patient counseling or other pharmacy services for the telepharmacy outlet; and

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(5) a sign posted in the prescription drop-off area informing the public that the pharmacy is a telepharmacy outlet supervised by a pharmacist at the managing pharmacy and including the name, location, and phone number of the managing pharmacy.

(e) A pharmacist shall be physically present at the telepharmacy outlet at least eight hours each month.

(f) Except as authorized by the board in writing, the owner and the pharmacist-in-charge shall transfer all remaining inventory and records to the managing pharmacy upon ceasing the operations of the telepharmacy outlet.

(g) If the managing pharmacy ceases to meet the requirements in the pharmacy act of the state of Kansas and amendments thereto and the implementing regulations, the telepharmacy outlet shall cease operations in accordance with K.A.R. 68-2-10.

(h) All prescription drugs or devices, including prescriptions that have been filled but not dispensed to a patient, shall be stored in the prescription area of the telepharmacy outlet.

(i) If the operation of the telepharmacy system is interrupted or the telepharmacy system malfunctions, the telepharmacy outlet shall immediately close. No prescription shall be dispensed during the interruption or while the telepharmacy system is malfunctioning, and pharmacy personnel shall post a sign at the entrance to the telepharmacy outlet stating that the telepharmacy outlet is closed and estimating a date and time for resumption of services.

(j) The telepharmacy outlet shall maintain a perpetual inventory or continuous count of any controlled substances and drugs of concern, as defined by K.S.A. 65-1682 and amendments thereto, at the telepharmacy and shall electronically submit dispensing reports to the board in accordance with the Kansas prescription monitoring program act, and amendments thereto, and

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**Proposed**

K.A.R. 68-23-5  
p. 3

the implementing regulations. (Authorized by and implementing K.S.A. 2022 Supp. 65-16,130;  
effective P-\_\_\_\_\_.)

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**68-23-6. Structural, security, technology, and equipment requirements; restrictions.**

(a) The owner and the pharmacist-in-charge of each telepharmacy outlet shall ensure that the prescription area of the telepharmacy outlet meets the following requirements:

(1) Is restricted to authorized pharmacy personnel and is inaccessible to the public. If an authorized pharmacy technician, pharmacist intern, or pharmacist is not present, the prescription area shall be completely enclosed and secured with suitable locks and a monitored alarm system capable of detecting unauthorized entry;

(2) includes an electronic keypad or other electronic entry system into the prescription area that requires and records the unique identification code of each individual accessing the telepharmacy outlet, including the date and time of access. Complete access records shall be maintained for at least five years beyond the date of access;

(3) contains sufficient fixtures, equipment, and supplies consistent with the nature and scope of practice for the telepharmacy outlet;

(4) includes a sink with plumbing for hot and cold running water and sewer connections;

(5) is free from infestation by insects, rodents, birds, or vermin of any kind; and

(6) in all areas where drugs and devices are stored, is dry, well-lighted, well-ventilated, and maintained at temperatures and humidity levels to preserve the stability of the drugs and devices before dispensing as specified in the "United States pharmacopeia," USP-NF 2022, issue 1, as in effect on May 1, 2022, and the manufacturer's or distributor's recommendations.

(b) All pharmacy personnel shall maintain prescription and other patient information in a manner that protects the integrity and confidentiality of the information.

(c) Each telepharmacy outlet shall be connected to the managing pharmacy using a

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telepharmacy system that meets the following minimum requirements:

(1) Each telepharmacy system shall provide built-in safeguards relating to verification of the accuracy of the dispensing processes, drug utilization review, and electronic patient counseling services, including the use of the following types of technology:

(A) Audio and video;

(B) barcode technology at the telepharmacy outlet to verify the accuracy of each drug and each device before dispensing;

(C) electronic recording and storage of the digital image of the dispensed drug or device that is used by the pharmacist during final verification; and

(D) storage and forwarding of all data, images, and video for future review.

(2) Each telepharmacy system shall be configured and equipped to maintain optimal operation and be secure from unauthorized access.

(d) Each telepharmacy outlet owner shall maintain the continuous video surveillance and recordings required in this article of the board's regulations for at least 60 days following the date of the recording.

(e) Each telepharmacy outlet owner shall have technology in place to prevent a drug or device from being sold, dispensed, or delivered to a patient before a pharmacist has performed the final verification of the accuracy of the prescription and released the drug or device for sale, dispensing, or delivery from the telepharmacy outlet.

(f) Each pharmacy prescription application shall record the name of each pharmacist responsible for verification of the prescription and the name of each pharmacy technician and pharmacist intern assisting with the dispensing or sale of the prescription.

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(g) The loading of each automated dispensing system shall be completed using barcode technology.

(h) A telepharmacy outlet shall not manage an automated dispensing system in a long-term care facility. (Authorized by and implementing K.S.A. 2022 Supp. 65-16,130; effective

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## Kansas Administrative Regulations Economic Impact Statement (EIS)

Kansas Board of Pharmacy  
Agency

Alexandra Blasi  
Agency Contact

785-296-4056  
Contact Phone Number

68-1-1b  
K.A.R. Number(s)

☒ Permanent    ☐ Temporary

Is/Are the proposed rule(s) and regulation(s) mandated by the federal government as a requirement for participating in or implementing a federally subsidized or assisted program?

- ☐ Yes    If yes, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration and the Attorney General. Budget approval is not required; however, the Division of the Budget will require submission of a copy of the EIS at the end of the review process.
- ☒ No    If no, do the total annual implementation and compliance costs for the proposed rule(s) and regulation(s), calculated from the effective date of the rule(s) and regulation(s), exceed \$1.0 million over any two-year period through June 30, 2024, or exceed \$3.0 million over any two-year period on or after July 1, 2024 (as calculated in Section III, F)?
- ☐ Yes    If yes, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration, the Attorney General, AND the Division of the Budget. The regulation(s) and the EIS will require Budget approval.
- ☒ No    If no, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration and the Attorney General. Budget approval is not required; however, the Division of the Budget will require submission of a copy of the EIS at the end of the review process.

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## Section I

Brief description of the proposed rule(s) and regulation(s).

K.A.R. 68-1-1b concerns continuing education for pharmacists licensed by the Kansas Board of Pharmacy. A change to this regulation is proposed to include a topical requirement for pharmacists to obtain 1 hour of continuing education provided by the Board during each two-year renewal cycle, which shall be counted toward their 30-hour total requirement.

## Section II

Statement by the agency if the rule(s) and regulation(s) exceed the requirements of applicable federal law, and a statement if the approach chosen to address the policy issue(s) is different from that utilized by agencies of contiguous states or the federal government. *(If the approach is different or exceeds federal law, then include a statement of why the proposed Kansas rule and regulation is different.)*

Regulations are not mandated by the federal government. Proposed amendments are consistent with neighboring states and recent changes to Board of Healing Arts continuing education requirements.

## Section III

Agency analysis specifically addressing the following:

- A. The extent to which the rule(s) and regulation(s) will enhance or restrict business activities and growth;

The proposed regulations would neither enhance nor restrict business activities and growth for pharmacies and dispensing physicians.

- B. The economic effect, including a detailed quantification of implementation and compliance costs, on the specific businesses, sectors, public utility ratepayers, individuals, and local governments that would be affected by the proposed rule(s) and regulation(s) and on the state economy as a whole;

None. The Board anticipates using the KsTRAIN platform and using existing staff and resources to build and update the one-hour continuing education course every two years. The Board will not charge any fee for completion of the course.

- C. Businesses that would be directly affected by the proposed rule(s) and regulation(s);  
Kansas pharmacists

- D. Benefits of the proposed rule(s) and regulation(s) compared to the costs;  
Enhance pharmacists' knowledge of pharmacy law, ethics and clinical tools.

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- E. Measures taken by the agency to minimize the cost and impact of the proposed rule(s) and regulation(s) on business and economic development within the State of Kansas, local government, and individuals;

The Board anticipates using the Ks TRAIN platform and using existing staff and resources to build and update the one-hour continuing education course every two years. The Board will not charge any fee for completion of the course.

- F. An estimate of the total annual implementation and compliance costs that are reasonably expected to be incurred by or passed along to businesses, local governments, or members of the public.

*Note: Do not account for any actual or estimated cost savings that may be realized.*

Costs to Affected Businesses – \$0

Costs to Local Governmental Units – \$0

Costs to Members of the Public – \$0

**Total Annual Costs – \$0**

(sum of above amounts)

Give a detailed statement of the data and methodology used in estimating the above cost estimate.

No costs or charges. Reviewed regulations with pharmacy stakeholders.

- ☐ Yes     If the total implementation and compliance costs exceed \$1.0 million over any two-year period through June 30, 2024, or exceed \$3.0 million over any two-year period on or after July 1, 2024, and prior to the submission or resubmission of the proposed rule(s) and regulation(s), did the agency hold a public hearing to find that the estimated costs have been accurately determined and are necessary for achieving legislative intent? If applicable, document when the public hearing was held, those in attendance, and any pertinent information from the hearing.
- ☐ No
- ☒ Not Applicable

If applicable, click here to enter public hearing information.

Provide an estimate to any changes in aggregate state revenues and expenditures for the implementation of the proposed rule(s) and regulation(s), for both the current fiscal year and next fiscal year.

None

Provide an estimate of any immediate or long-range economic impact of the proposed rule(s) and regulation(s) on any individual(s), small employers, and the general public. If no dollar estimate can be given for any individual(s), small employers, and the general public, give specific reasons why no estimate is possible.

None

- G. If the proposed rule(s) and regulation(s) increases or decreases revenues of cities, counties or school districts, or imposes functions or responsibilities on cities, counties or school districts that will

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increase expenditures or fiscal liability, describe how the state agency consulted with the League of Kansas Municipalities, Kansas Association of Counties, and/or the Kansas Association of School Boards.

Not applicable

- H. Describe how the agency consulted and solicited information from businesses, associations, local governments, state agencies, or institutions and members of the public that may be affected by the proposed rule(s) and regulation(s).

The Board provided an opportunity for comments on proposed draft regulations and solicited feedback from all pharmacy stakeholder organizations prior to routing the regulations through the administrative review process. The Board is working through a multi-year plan to review and revise all adopted regulations for necessary updates.

#### Section IV

Does the Economic Impact Statement involve any environmental rule(s) and regulation(s)?

- ☐ Yes If yes, complete the remainder of Section IV.  
☒ No If no, skip the remainder of Section IV.

- A. Describe the capital and annual costs of compliance with the proposed rule(s) and regulation(s), and the persons who would bear the costs.

Click here to enter agency response.

- B. Describe the initial and annual costs of implementing and enforcing the proposed rule(s) and regulation(s), including the estimated amount of paperwork, and the state agencies, other governmental agencies, or other persons who would bear the costs.

Click here to enter agency response.

- C. Describe the costs that would likely accrue if the proposed rule(s) and regulation(s) are not adopted, as well as the persons who would bear the costs and would be affected by the failure to adopt the rule(s) and regulation(s).

Click here to enter agency response.

- D. Provide a detailed statement of the data and methodology used in estimating the costs used.

Click here to enter agency response.

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## Kansas Administrative Regulations Economic Impact Statement (EIS)

Kansas Board of Pharmacy  
Agency

Alexandra Blasi  
Agency Contact

785-296-8419 (direct)  
Contact Phone Number

68-1-2a  
K.A.R. Number(s)

☒ Permanent    ☐ Temporary

Is/Are the proposed rule(s) and regulation(s) mandated by the federal government as a requirement for participating in or implementing a federally subsidized or assisted program?

☐ Yes    If yes, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration and the Attorney General. Budget approval is not required; however, the Division of the Budget will require submission of a copy of the EIS at the end of the review process.

☒ No    If no, do the total annual implementation and compliance costs for the proposed rule(s) and regulation(s), calculated from the effective date of the rule(s) and regulation(s), exceed \$1.0 million over any two-year period through June 30, 2024, or exceed \$3.0 million over any two-year period on or after July 1, 2024 (as calculated in Section III, F)?

☐ Yes    If yes, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration, the Attorney General, AND the Division of the Budget. The regulation(s) and the EIS will require Budget approval.

☒ No    If no, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration and the Attorney General. Budget approval is not required; however, the Division of the Budget will require submission of a copy of the EIS at the end of the review process.

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## Section I

Brief description of the proposed rule(s) and regulation(s).

Amendments to this regulation clarify the process for becoming a pharmacist-in-charge (PIC), including an acknowledgement of the responsibilities. The timeline is updated and clarified for providing notice to the Board for beginning or ceasing to serve as a Kansas PIC, as well as the process for pharmacies to request a 30-day waiver for additional time to designate a new PIC.

## Section II

Statement by the agency if the rule(s) and regulation(s) exceed the requirements of applicable federal law, and a statement if the approach chosen to address the policy issue(s) is different from that utilized by agencies of contiguous states or the federal government. *(If the approach is different or exceeds federal law, then include a statement of why the proposed Kansas rule and regulation is different.)*

Regulations are not mandated by the federal government. Proposed amendments are consistent with neighboring states.

## Section III

Agency analysis specifically addressing the following:

- A. The extent to which the rule(s) and regulation(s) will enhance or restrict business activities and growth;

Minimal business impact is anticipated. The codified waiver provisions should enhance the ability of pharmacies to operate with their current pharmacist staff while seeking a replacement PIC.

- B. The economic effect, including a detailed quantification of implementation and compliance costs, on the specific businesses, sectors, public utility ratepayers, individuals, and local governments that would be affected by the proposed rule(s) and regulation(s) and on the state economy as a whole;

None

- C. Businesses that would be directly affected by the proposed rule(s) and regulation(s);

Pharmacies registered in Kansas

- D. Benefits of the proposed rule(s) and regulation(s) compared to the costs;

No costs. The codified waiver provisions should enhance the ability of pharmacies to operate with their current pharmacist staff while seeking a replacement PIC.

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- E. Measures taken by the agency to minimize the cost and impact of the proposed rule(s) and regulation(s) on business and economic development within the State of Kansas, local government, and individuals;

The Board already utilizes electronic forms for the PIC changes and provides the option to make this change through the online licensing software for which all licensees and registrants have credentials and free access.

- F. An estimate of the total annual implementation and compliance costs that are reasonably expected to be incurred by or passed along to businesses, local governments, or members of the public.

*Note: Do not account for any actual or estimated cost savings that may be realized.*

Costs to Affected Businesses – \$0

Costs to Local Governmental Units – \$0

Costs to Members of the Public – \$0

**Total Annual Costs – \$0**

(sum of above amounts)

Give a detailed statement of the data and methodology used in estimating the above cost estimate.

Reviewed regulations with pharmacy stakeholders

- ☐ Yes If the total implementation and compliance costs exceed \$1.0 million over any two-year period through June 30, 2024, or exceed \$3.0 million over any two-year period on or after July 1, 2024, and prior to the submission or resubmission of the proposed rule(s) and regulation(s), did the agency hold a public hearing to find that the estimated costs have been accurately determined and are necessary for achieving legislative intent? If applicable, document when the public hearing was held, those in attendance, and any pertinent information from the hearing.
- ☐ No
- ☒ Not Applicable

If applicable, click here to enter public hearing information.

Provide an estimate to any changes in aggregate state revenues and expenditures for the implementation of the proposed rule(s) and regulation(s), for both the current fiscal year and next fiscal year.

None

Provide an estimate of any immediate or long-range economic impact of the proposed rule(s) and regulation(s) on any individual(s), small employers, and the general public. If no dollar estimate can be given for any individual(s), small employers, and the general public, give specific reasons why no estimate is possible.

None

- G. If the proposed rule(s) and regulation(s) increases or decreases revenues of cities, counties or school districts, or imposes functions or responsibilities on cities, counties or school districts that will increase expenditures or fiscal liability, describe how the state agency consulted with the League of

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Kansas Municipalities, Kansas Association of Counties, and/or the Kansas Association of School Boards.

Not applicable

- H. Describe how the agency consulted and solicited information from businesses, associations, local governments, state agencies, or institutions and members of the public that may be affected by the proposed rule(s) and regulation(s).

The Board provided an opportunity for comments on proposed draft regulations and solicited feedback from all pharmacy stakeholder organizations prior to routing the regulations through the administrative review process. The Board is working through a multi-year plan to review and revise all adopted regulations for necessary updates.

#### Section IV

Does the Economic Impact Statement involve any environmental rule(s) and regulation(s)?

- ☐ Yes If yes, complete the remainder of Section IV.  
☒ No If no, skip the remainder of Section IV.

- A. Describe the capital and annual costs of compliance with the proposed rule(s) and regulation(s), and the persons who would bear the costs.

Click here to enter agency response.

- B. Describe the initial and annual costs of implementing and enforcing the proposed rule(s) and regulation(s), including the estimated amount of paperwork, and the state agencies, other governmental agencies, or other persons who would bear the costs.

Click here to enter agency response.

- C. Describe the costs that would likely accrue if the proposed rule(s) and regulation(s) are not adopted, as well as the persons who would bear the costs and would be affected by the failure to adopt the rule(s) and regulation(s).

Click here to enter agency response.

- D. Provide a detailed statement of the data and methodology used in estimating the costs used.

Click here to enter agency response.

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# Kansas Administrative Regulations Economic Impact Statement (EIS)

Kansas Board of Pharmacy  
Agency

Alexandra Blasi  
Agency Contact

785-296-8419 (direct)  
Contact Phone Number

68-1-2a  
K.A.R. Number(s)

☒ Permanent      ☐ Temporary

Is/Are the proposed rule(s) and regulation(s) mandated by the federal government as a requirement for participating in or implementing a federally subsidized or assisted program?

☐ Yes      If yes, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration and the Attorney General. Budget approval is not required; however, the Division of the Budget will require submission of a copy of the EIS at the end of the review process.

☒ No      If no, do the total annual implementation and compliance costs for the proposed rule(s) and regulation(s), calculated from the effective date of the rule(s) and regulation(s), exceed \$1.0 million over any two-year period through June 30, 2024, or exceed \$3.0 million over any two-year period on or after July 1, 2024 (as calculated in Section III, F)?

☐ Yes      If yes, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration, the Attorney General, AND the Division of the Budget. The regulation(s) and the EIS will require Budget approval.

☒ No      If no, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration and the Attorney General. Budget approval is not required; however, the Division of the Budget will require submission of a copy of the EIS at the end of the review process.

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## Section I

Brief description of the proposed rule(s) and regulation(s).

Amendments to this regulation clarify the process for becoming a pharmacist-in-charge (PIC), including an acknowledgement of the responsibilities. The timeline is updated and clarified for providing notice to the Board for beginning or ceasing to serve as a Kansas PIC, as well as the process for pharmacies to request a 30-day waiver for additional time to designate a new PIC.

## Section II

Statement by the agency if the rule(s) and regulation(s) exceed the requirements of applicable federal law, and a statement if the approach chosen to address the policy issue(s) is different from that utilized by agencies of contiguous states or the federal government. *(If the approach is different or exceeds federal law, then include a statement of why the proposed Kansas rule and regulation is different.)*

Regulations are not mandated by the federal government. Proposed amendments are consistent with neighboring states.

## Section III

Agency analysis specifically addressing the following:

- A. The extent to which the rule(s) and regulation(s) will enhance or restrict business activities and growth;
- Minimal business impact is anticipated. The codified waiver provisions should enhance the ability of pharmacies to operate with their current pharmacist staff while seeking a replacement PIC.
- B. The economic effect, including a detailed quantification of implementation and compliance costs, on the specific businesses, sectors, public utility ratepayers, individuals, and local governments that would be affected by the proposed rule(s) and regulation(s) and on the state economy as a whole;
- None
- C. Businesses that would be directly affected by the proposed rule(s) and regulation(s);
- Pharmacies registered in Kansas
- D. Benefits of the proposed rule(s) and regulation(s) compared to the costs;
- No costs. The codified waiver provisions should enhance the ability of pharmacies to operate with their current pharmacist staff while seeking a replacement PIC.

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- E. Measures taken by the agency to minimize the cost and impact of the proposed rule(s) and regulation(s) on business and economic development within the State of Kansas, local government, and individuals;

The Board already utilizes electronic forms for the PIC changes and provides the option to make this change through the online licensing software for which all licensees and registrants have credentials and free access.

- F. An estimate of the total annual implementation and compliance costs that are reasonably expected to be incurred by or passed along to businesses, local governments, or members of the public.

*Note: Do not account for any actual or estimated cost savings that may be realized.*

Costs to Affected Businesses – \$0

Costs to Local Governmental Units – \$0

Costs to Members of the Public – \$0

**Total Annual Costs – \$0**

(sum of above amounts)

Give a detailed statement of the data and methodology used in estimating the above cost estimate.

Reviewed regulations with pharmacy stakeholders

- ☐ Yes      If the total implementation and compliance costs exceed \$1.0 million over any two-year period through June 30, 2024, or exceed \$3.0 million over any two-year period on or after July 1, 2024, and prior to the submission or resubmission of the proposed rule(s) and regulation(s), did the agency hold a public hearing to find that the estimated costs have been accurately determined and are necessary for achieving legislative intent? If applicable, document when the public hearing was held, those in attendance, and any pertinent information from the hearing.
- ☐ No
- ☒ Not Applicable

If applicable, click here to enter public hearing information.

Provide an estimate to any changes in aggregate state revenues and expenditures for the implementation of the proposed rule(s) and regulation(s), for both the current fiscal year and next fiscal year.

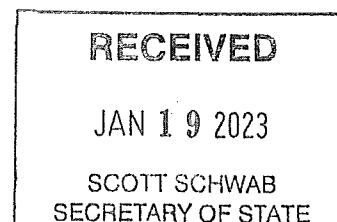
None

Provide an estimate of any immediate or long-range economic impact of the proposed rule(s) and regulation(s) on any individual(s), small employers, and the general public. If no dollar estimate can be given for any individual(s), small employers, and the general public, give specific reasons why no estimate is possible.

None

- G. If the proposed rule(s) and regulation(s) increases or decreases revenues of cities, counties or school districts, or imposes functions or responsibilities on cities, counties or school districts that will increase expenditures or fiscal liability, describe how the state agency consulted with the League of

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Kansas Municipalities, Kansas Association of Counties, and/or the Kansas Association of School Boards.

Not applicable

- H. Describe how the agency consulted and solicited information from businesses, associations, local governments, state agencies, or institutions and members of the public that may be affected by the proposed rule(s) and regulation(s).

The Board provided an opportunity for comments on proposed draft regulations and solicited feedback from all pharmacy stakeholder organizations prior to routing the regulations through the administrative review process. The Board is working through a multi-year plan to review and revise all adopted regulations for necessary updates.

## Section IV

Does the Economic Impact Statement involve any environmental rule(s) and regulation(s)?

☐ Yes If yes, complete the remainder of Section IV.

☒ No If no, skip the remainder of Section IV.

- A. Describe the capital and annual costs of compliance with the proposed rule(s) and regulation(s), and the persons who would bear the costs.

[Click here to enter agency response.](#)

- B. Describe the initial and annual costs of implementing and enforcing the proposed rule(s) and regulation(s), including the estimated amount of paperwork, and the state agencies, other governmental agencies, or other persons who would bear the costs.

[Click here to enter agency response.](#)

- C. Describe the costs that would likely accrue if the proposed rule(s) and regulation(s) are not adopted, as well as the persons who would bear the costs and would be affected by the failure to adopt the rule(s) and regulation(s).

[Click here to enter agency response.](#)

- D. Provide a detailed statement of the data and methodology used in estimating the costs used.

[Click here to enter agency response.](#)

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**SCOTT SCHWAB  
SECRETARY OF STATE**

# Kansas Administrative Regulations Economic Impact Statement (EIS)

Kansas Board of Pharmacy  
Agency

Alexandra Blasi  
Agency Contact

785-296-8419 (direct)  
Contact Phone Number

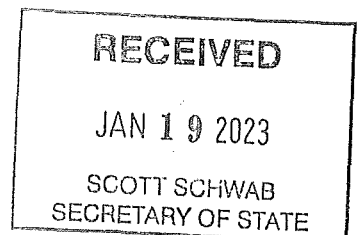
68-1-9, 68-7-11, 68-7-12  
K.A.R. Number(s)

☒ Permanent    ☐ Temporary

Is/Are the proposed rule(s) and regulation(s) mandated by the federal government as a requirement for participating in or implementing a federally subsidized or assisted program?

- ☐ Yes    If yes, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration and the Attorney General. Budget approval is not required; however, the Division of the Budget will require submission of a copy of the EIS at the end of the review process.
- ☒ No    If no, do the total annual implementation and compliance costs for the proposed rule(s) and regulation(s), calculated from the effective date of the rule(s) and regulation(s), exceed \$1.0 million over any two-year period through June 30, 2024, or exceed \$3.0 million over any two-year period on or after July 1, 2024 (as calculated in Section III, F)?
- ☐ Yes    If yes, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration, the Attorney General, AND the Division of the Budget. The regulation(s) and the EIS will require Budget approval.
- ☒ No    If no, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration and the Attorney General. Budget approval is not required; however, the Division of the Budget will require submission of a copy of the EIS at the end of the review process.

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## Section I

Brief description of the proposed rule(s) and regulation(s).

Adoption of new KAR 68-1-9 and proposed amendments to KAR 68-7-11 and 68-7-12 are designed to provide greater consistency in the requirements for the pharmacy's designated pharmacist-in-charge (PIC), and highlight differences related to any practice setting nuances. KAR 68-1-9 now captures all general responsibilities of the PIC, including supervision, availability, record-keeping, resources, managing drug recalls, changing PIC, drug inventory, newsletter review, and development of policies and procedures for the pharmacy. KAR 68-7-11 is specific to requirements for pharmacies registered as medical care facilities in Kansas. Additional proposed amendments to this regulation include updating emergency supply labeling requirements, allowing a physician's assistant to enter the pharmacy as directed, and requiring pharmacist review of certain medication orders within three days (previously seven). KAR 68-7-12 is specific to requirements for the PIC of a pharmacy that is not a medical care facility. Proposed amendments to this regulation eliminate language moved to new KAR 68-1-9.

## Section II

Statement by the agency if the rule(s) and regulation(s) exceed the requirements of applicable federal law, and a statement if the approach chosen to address the policy issue(s) is different from that utilized by agencies of contiguous states or the federal government. *(If the approach is different or exceeds federal law, then include a statement of why the proposed Kansas rule and regulation is different.)*

Regulations are not mandated by the federal government. Proposed amendments are consistent with neighboring states and current standards of pharmacy practice.

## Section III

Agency analysis specifically addressing the following:

- A. The extent to which the rule(s) and regulation(s) will enhance or restrict business activities and growth;

Minimal business impact is anticipated. The requirement for pharmacist review of medication orders within three days is a shortened timeline, but decreases the risk of harm to the patient by reducing the number of days allotted for review. This should not restrict business activity or growth.

- B. The economic effect, including a detailed quantification of implementation and compliance costs, on the specific businesses, sectors, public utility ratepayers, individuals, and local governments that would be affected by the proposed rule(s) and regulation(s) and on the state economy as a whole;

None

- C. Businesses that would be directly affected by the proposed rule(s) and regulation(s);

Pharmacies registered in Kansas

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## D. Benefits of the proposed rule(s) and regulation(s) compared to the costs;

Benefits are related to the clarity provided to licensees and registrants in reading and understanding Kansas regulations and Board expectations. The benefit of decreasing the timeline for pharmacist review of medication orders should increase patient safety but cannot be quantified.

## E. Measures taken by the agency to minimize the cost and impact of the proposed rule(s) and regulation(s) on business and economic development within the State of Kansas, local government, and individuals;

The Board has attempted to clarify and simplify language where possible, and eliminate any unnecessary requirements.

## F. An estimate of the total annual implementation and compliance costs that are reasonably expected to be incurred by or passed along to businesses, local governments, or members of the public.

*Note: Do not account for any actual or estimated cost savings that may be realized.*

Costs to Affected Businesses – \$0

Costs to Local Governmental Units – \$0

Costs to Members of the Public – \$0

**Total Annual Costs – \$0**

(sum of above amounts)

Give a detailed statement of the data and methodology used in estimating the above cost estimate.

Reviewed regulations with pharmacy stakeholders

- ☐ Yes    If the total implementation and compliance costs exceed \$1.0 million over any two-year period through June 30, 2024, or exceed \$3.0 million over any two-year period on or after July 1, 2024, and prior to the submission or resubmission of the proposed rule(s) and regulation(s), did the agency hold a public hearing to find that the estimated costs
- ☐ No
- ☒ Not Applicable    have been accurately determined and are necessary for achieving legislative intent? If applicable, document when the public hearing was held, those in attendance, and any pertinent information from the hearing.

If applicable, click here to enter public hearing information.

Provide an estimate to any changes in aggregate state revenues and expenditures for the implementation of the proposed rule(s) and regulation(s), for both the current fiscal year and next fiscal year.

None

Provide an estimate of any immediate or long-range economic impact of the proposed rule(s) and regulation(s) on any individual(s), small employers, and the general public. If no dollar estimate can be given for any individual(s), small employers, and the general public, give specific reasons why no estimate is possible.

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**SCOTT SCHWAB  
SECRETARY OF STATE**

None

- G. If the proposed rule(s) and regulation(s) increases or decreases revenues of cities, counties or school districts, or imposes functions or responsibilities on cities, counties or school districts that will increase expenditures or fiscal liability, describe how the state agency consulted with the League of Kansas Municipalities, Kansas Association of Counties, and/or the Kansas Association of School Boards.

Not applicable

- H. Describe how the agency consulted and solicited information from businesses, associations, local governments, state agencies, or institutions and members of the public that may be affected by the proposed rule(s) and regulation(s).

The Board provided an opportunity for comments on proposed draft regulations and solicited feedback from all pharmacy stakeholder organizations prior to routing the regulations through the administrative review process. The Board is working through a multi-year plan to review and revise all adopted regulations for necessary updates.

#### Section IV

Does the Economic Impact Statement involve any environmental rule(s) and regulation(s)?

- ☐ Yes If yes, complete the remainder of Section IV.  
☒ No If no, skip the remainder of Section IV.

- A. Describe the capital and annual costs of compliance with the proposed rule(s) and regulation(s), and the persons who would bear the costs.

Click here to enter agency response.

- B. Describe the initial and annual costs of implementing and enforcing the proposed rule(s) and regulation(s), including the estimated amount of paperwork, and the state agencies, other governmental agencies, or other persons who would bear the costs.

Click here to enter agency response.

- C. Describe the costs that would likely accrue if the proposed rule(s) and regulation(s) are not adopted, as well as the persons who would bear the costs and would be affected by the failure to adopt the rule(s) and regulation(s).

Click here to enter agency response.

- D. Provide a detailed statement of the data and methodology used in estimating the costs used.

Click here to enter agency response.

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SCOTT SCHWAB  
SECRETARY OF STATE

## Kansas Administrative Regulations Economic Impact Statement (EIS)

Kansas Board of Pharmacy  
Agency

Alexandra Blasi  
Agency Contact

785-296-8419 (direct)  
Contact Phone Number

68-7-8  
K.A.R. Number(s)

☒ Permanent    ☐ Temporary

Is/Are the proposed rule(s) and regulation(s) mandated by the federal government as a requirement for participating in or implementing a federally subsidized or assisted program?

- ☐ Yes    If yes, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration and the Attorney General. Budget approval is not required; however, the Division of the Budget will require submission of a copy of the EIS at the end of the review process.
- ☒ No    If no, do the total annual implementation and compliance costs for the proposed rule(s) and regulation(s), calculated from the effective date of the rule(s) and regulation(s), exceed \$1.0 million over any two-year period through June 30, 2024, or exceed \$3.0 million over any two-year period on or after July 1, 2024 (as calculated in Section III, F)?
- ☐ Yes    If yes, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration, the Attorney General, AND the Division of the Budget. The regulation(s) and the EIS will require Budget approval.
- ☒ No    If no, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration and the Attorney General. Budget approval is not required; however, the Division of the Budget will require submission of a copy of the EIS at the end of the review process.

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## Section I

Brief description of the proposed rule(s) and regulation(s).

K.A.R. 68-7-8 is being amended to allow pharmacies to digitize prescription records to reduce costs associated with paper storage. Amendments do not require any pharmacy to participate in scanning/shredding paper documents but set forth requirements for pharmacies that elect to engage in this process.

## Section II

Statement by the agency if the rule(s) and regulation(s) exceed the requirements of applicable federal law, and a statement if the approach chosen to address the policy issue(s) is different from that utilized by agencies of contiguous states or the federal government. *(If the approach is different or exceeds federal law, then include a statement of why the proposed Kansas rule and regulation is different.)*

Regulations are not mandated by the federal government. Proposed amendments are consistent with neighboring states and current standards of pharmacy practice.

## Section III

Agency analysis specifically addressing the following:

- A. The extent to which the rule(s) and regulation(s) will enhance or restrict business activities and growth;

The Board anticipates that this will allow pharmacies greater flexibility in recordkeeping and storage by utilizing digitization for the recordkeeping process. Amendments do not require digitization and are designed to be business-friendly and allow autonomy in recordkeeping processes, while providing minimum safeguards to ensure public protection.

- B. The economic effect, including a detailed quantification of implementation and compliance costs, on the specific businesses, sectors, public utility ratepayers, individuals, and local governments that would be affected by the proposed rule(s) and regulation(s) and on the state economy as a whole;

No quantifiable costs based on requirements of regulation. While pharmacies that elect to engage in digitization of records may incur costs associated with electronic storage systems, this is not required and estimated expenses are unknown to the Board. Additionally, many pharmacies may already have electronic storage systems capable of storing additional electronic records without additional expense. Pharmacies electing to participate in electronic scanning and shredding of paper records could experience decreased costs associated with physical record storage in the long-run. The Board does not anticipate additional expenses related to compliance or pharmacy inspection.

- C. Businesses that would be directly affected by the proposed rule(s) and regulation(s);

Pharmacies registered in Kansas.

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- D. Benefits of the proposed rule(s) and regulation(s) compared to the costs;  
Benefits include allowing pharmacies to digitize their records which may reduce storage costs to pharmacies. The Board anticipates pharmacies may take advantage of these amendments, but does not require pharmacies to make any changes to their current practices or recordkeeping processes.
- E. Measures taken by the agency to minimize the cost and impact of the proposed rule(s) and regulation(s) on business and economic development within the State of Kansas, local government, and individuals;  
Board is attempted to minimize any fiscal impact by not requiring pharmacies participate in scanning and shredding paper records. However, regulation is being amended at the request of several pharmacies and pharmacy owners interested in participating. Consistent with pharmacy practice of recordkeeping. Language borrowed from other state boards of pharmacy.
- F. An estimate of the total annual implementation and compliance costs that are reasonably expected to be incurred by or passed along to businesses, local governments, or members of the public.  
*Note: Do not account for any actual or estimated cost savings that may be realized.*

Costs to Affected Businesses – \$0  
Costs to Local Governmental Units – \$0  
Costs to Members of the Public – \$0  
**Total Annual Costs – \$0**  
(sum of above amounts)

Give a detailed statement of the data and methodology used in estimating the above cost estimate.

Reviewed regulation with pharmacy stakeholders.

- ☐ Yes If the total implementation and compliance costs exceed \$1.0 million over any two-year period through June 30, 2024, or exceed \$3.0 million over any two-year period on or after July 1, 2024, and prior to the submission or resubmission of the proposed rule(s) and regulation(s), did the agency hold a public hearing to find that the estimated costs have been accurately determined and are necessary for achieving legislative intent? If applicable, document when the public hearing was held, those in attendance, and any pertinent information from the hearing.
- ☐ No
- ☒ Not Applicable

If applicable, click here to enter public hearing information.

Provide an estimate to any changes in aggregate state revenues and expenditures for the implementation of the proposed rule(s) and regulation(s), for both the current fiscal year and next fiscal year.

None

Provide an estimate of any immediate or long-range economic impact of the proposed rule(s) and regulation(s) on any individual(s), small employers, and the general public. If no dollar estimate

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can be given for any individual(s), small employers, and the general public, give specific reasons why no estimate is possible.

None

- G. If the proposed rule(s) and regulation(s) increases or decreases revenues of cities, counties or school districts, or imposes functions or responsibilities on cities, counties or school districts that will increase expenditures or fiscal liability, describe how the state agency consulted with the League of Kansas Municipalities, Kansas Association of Counties, and/or the Kansas Association of School Boards.

Not applicable.

- H. Describe how the agency consulted and solicited information from businesses, associations, local governments, state agencies, or institutions and members of the public that may be affected by the proposed rule(s) and regulation(s).

The Board provided an opportunity for comments on proposed draft regulations and solicited feedback from all pharmacy stakeholder organizations prior to routing the regulation through the administrative review process. The Board is working through a multi-year plan to review and revise all adopted regulations for necessary updates.

## Section IV

Does the Economic Impact Statement involve any environmental rule(s) and regulation(s)?

- ☐ Yes If yes, complete the remainder of Section IV.  
☒ No If no, skip the remainder of Section IV.

- A. Describe the capital and annual costs of compliance with the proposed rule(s) and regulation(s), and the persons who would bear the costs.

Click here to enter agency response.

- B. Describe the initial and annual costs of implementing and enforcing the proposed rule(s) and regulation(s), including the estimated amount of paperwork, and the state agencies, other governmental agencies, or other persons who would bear the costs.

Click here to enter agency response.

- C. Describe the costs that would likely accrue if the proposed rule(s) and regulation(s) are not adopted, as well as the persons who would bear the costs and would be affected by the failure to adopt the rule(s) and regulation(s).

Click here to enter agency response.

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D. Provide a detailed statement of the data and methodology used in estimating the costs used.

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## Kansas Administrative Regulations Economic Impact Statement (EIS)

Kansas Board of Pharmacy  
Agency

Alexandra Blasi  
Agency Contact

785-296-8419 (direct)  
Contact Phone Number

68-2-20  
K.A.R. Number(s)

☒ Permanent    ☐ Temporary

Is/Are the proposed rule(s) and regulation(s) mandated by the federal government as a requirement for participating in or implementing a federally subsidized or assisted program?

- ☐ Yes    If yes, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration and the Attorney General. Budget approval is not required; however, the Division of the Budget will require submission of a copy of the EIS at the end of the review process.
- ☒ No    If no, do the total annual implementation and compliance costs for the proposed rule(s) and regulation(s), calculated from the effective date of the rule(s) and regulation(s), exceed \$1.0 million over any two-year period through June 30, 2024, or exceed \$3.0 million over any two-year period on or after July 1, 2024 (as calculated in Section III, F)?
- ☐ Yes    If yes, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration, the Attorney General, AND the Division of the Budget. The regulation(s) and the EIS will require Budget approval.
- ☒ No    If no, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration and the Attorney General. Budget approval is not required; however, the Division of the Budget will require submission of a copy of the EIS at the end of the review process.

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**Section I**

Brief description of the proposed rule(s) and regulation(s).

This regulation is being amended to provide consistency with statutes in the Pharmacy Practice Act. First, pharmacists may fill prescriptions issued based on a practitioner's telephonic consultation with a patient. Second, the Board is updating regulations based on current pharmacy practice standards. Proposed amendments clarify which judgmental functions which may not be delegated by a pharmacist to a pharmacist intern or pharmacy technician, and that nonjudgmental functions may be delegated within certain limitations. Proposed amendments also authorize an exception to the verbal patient counseling requirement in limited circumstances.

**Section II**

Statement by the agency if the rule(s) and regulation(s) exceed the requirements of applicable federal law, and a statement if the approach chosen to address the policy issue(s) is different from that utilized by agencies of contiguous states or the federal government. *(If the approach is different or exceeds federal law, then include a statement of why the proposed Kansas rule and regulation is different.)*

Regulations are not mandated by the federal government but are consistent with federal requirements related to controlled substances prescriptions. Proposed amendments are consistent with neighboring states and current standards of pharmacy practice.

**Section III**

Agency analysis specifically addressing the following:

- A. The extent to which the rule(s) and regulation(s) will enhance or restrict business activities and growth;

Minimal business impact is anticipated. Outlining which functions may or may not be delegated in the pharmacy should provide clarity and eliminate confusion, and is designed to increase discretion provided to pharmacists in completing their work and supervising pharmacy personnel. This should enhance pharmacy business activity.

- B. The economic effect, including a detailed quantification of implementation and compliance costs, on the specific businesses, sectors, public utility ratepayers, individuals, and local governments that would be affected by the proposed rule(s) and regulation(s) and on the state economy as a whole;

None

- C. Businesses that would be directly affected by the proposed rule(s) and regulation(s);

Pharmacies registered in Kansas

- D. Benefits of the proposed rule(s) and regulation(s) compared to the costs;

Benefits are related to the autonomy and discretion provided to supervising pharmacists.

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- E. Measures taken by the agency to minimize the cost and impact of the proposed rule(s) and regulation(s) on business and economic development within the State of Kansas, local government, and individuals;

The Board has attempted to clarify and simplify language where possible, and eliminate any unnecessary requirements.

- F. An estimate of the total annual implementation and compliance costs that are reasonably expected to be incurred by or passed along to businesses, local governments, or members of the public.

*Note: Do not account for any actual or estimated cost savings that may be realized.*

Costs to Affected Businesses – \$0

Costs to Local Governmental Units – \$0

Costs to Members of the Public – \$0

**Total Annual Costs – \$0**

(sum of above amounts)

Give a detailed statement of the data and methodology used in estimating the above cost estimate.

Reviewed regulations with pharmacy stakeholders

- ☐ Yes If the total implementation and compliance costs exceed \$1.0 million over any two-year period through June 30, 2024, or exceed \$3.0 million over any two-year period on or after July 1, 2024, and prior to the submission or resubmission of the proposed rule(s) and regulation(s), did the agency hold a public hearing to find that the estimated costs have been accurately determined and are necessary for achieving legislative intent? If applicable, document when the public hearing was held, those in attendance, and any pertinent information from the hearing.
- ☐ No
- ☒ Not Applicable

If applicable, click here to enter public hearing information.

Provide an estimate to any changes in aggregate state revenues and expenditures for the implementation of the proposed rule(s) and regulation(s), for both the current fiscal year and next fiscal year.

None

Provide an estimate of any immediate or long-range economic impact of the proposed rule(s) and regulation(s) on any individual(s), small employers, and the general public. If no dollar estimate can be given for any individual(s), small employers, and the general public, give specific reasons why no estimate is possible.

None

- G. If the proposed rule(s) and regulation(s) increases or decreases revenues of cities, counties or school districts, or imposes functions or responsibilities on cities, counties or school districts that will increase expenditures or fiscal liability, describe how the state agency consulted with the League of

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Kansas Municipalities, Kansas Association of Counties, and/or the Kansas Association of School Boards.

Not applicable

- H. Describe how the agency consulted and solicited information from businesses, associations, local governments, state agencies, or institutions and members of the public that may be affected by the proposed rule(s) and regulation(s).

The Board provided an opportunity for comments on proposed draft regulations and solicited feedback from all pharmacy stakeholder organizations prior to routing the regulations through the administrative review process. The Board is working through a multi-year plan to review and revise all adopted regulations for necessary updates.

#### Section IV

Does the Economic Impact Statement involve any environmental rule(s) and regulation(s)?

- ☐ Yes If yes, complete the remainder of Section IV.  
☒ No If no, skip the remainder of Section IV.

- A. Describe the capital and annual costs of compliance with the proposed rule(s) and regulation(s), and the persons who would bear the costs.

Click here to enter agency response.

- B. Describe the initial and annual costs of implementing and enforcing the proposed rule(s) and regulation(s), including the estimated amount of paperwork, and the state agencies, other governmental agencies, or other persons who would bear the costs.

Click here to enter agency response.

- C. Describe the costs that would likely accrue if the proposed rule(s) and regulation(s) are not adopted, as well as the persons who would bear the costs and would be affected by the failure to adopt the rule(s) and regulation(s).

Click here to enter agency response.

- D. Provide a detailed statement of the data and methodology used in estimating the costs used.

Click here to enter agency response.

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## Kansas Administrative Regulations Economic Impact Statement (EIS)

Kansas Board of Pharmacy  
Agency

Alexandra Blasi  
Agency Contact

785-296-8419 (direct)  
Contact Phone Number

68-7-15  
K.A.R. Number(s)

☒ Permanent    ☐ Temporary

Is/Are the proposed rule(s) and regulation(s) mandated by the federal government as a requirement for participating in or implementing a federally subsidized or assisted program?

- ☐ Yes    If yes, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration and the Attorney General. Budget approval is not required; however, the Division of the Budget will require submission of a copy of the EIS at the end of the review process.
- ☒ No    If no, do the total annual implementation and compliance costs for the proposed rule(s) and regulation(s), calculated from the effective date of the rule(s) and regulation(s), exceed \$1.0 million over any two-year period through June 30, 2024, or exceed \$3.0 million over any two-year period on or after July 1, 2024 (as calculated in Section III, F)?
- ☐ Yes    If yes, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration, the Attorney General, AND the Division of the Budget. The regulation(s) and the EIS will require Budget approval.
- ☒ No    If no, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration and the Attorney General. Budget approval is not required; however, the Division of the Budget will require submission of a copy of the EIS at the end of the review process.

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## Section I

Brief description of the proposed rule(s) and regulation(s).

K.A.R. 68-7-15 is being amended to require prepackaged drugs be packaged in suitable containers consistent with the Kansas Pharmacy Practice Act and the State and Federal Uniform Controlled Substances Acts. Proposed amendments also require a pharmacist verify all prepackaged drugs or devices prior to release, consistent with requirements for prescription dispensing.

## Section II

Statement by the agency if the rule(s) and regulation(s) exceed the requirements of applicable federal law, and a statement if the approach chosen to address the policy issue(s) is different from that utilized by agencies of contiguous states or the federal government. *(If the approach is different or exceeds federal law, then include a statement of why the proposed Kansas rule and regulation is different.)*

Regulations are not mandated by the federal government. Proposed amendments are consistent with neighboring states and current standards of pharmacy practice.

## Section III

Agency analysis specifically addressing the following:

- A. The extent to which the rule(s) and regulation(s) will enhance or restrict business activities and growth;

The Board anticipates no impact on business activities or growth.

- B. The economic effect, including a detailed quantification of implementation and compliance costs, on the specific businesses, sectors, public utility ratepayers, individuals, and local governments that would be affected by the proposed rule(s) and regulation(s) and on the state economy as a whole;

None

- C. Businesses that would be directly affected by the proposed rule(s) and regulation(s);

Pharmacies registered in Kansas

- D. Benefits of the proposed rule(s) and regulation(s) compared to the costs;

These amendments are designed to protect patients from medication errors. These are current requirements for dispensing but increases in emergency medication supply (not dispensing) have necessitated this update. Costs would be related to pharmacist review time and cannot be quantified by the Board.

- E. Measures taken by the agency to minimize the cost and impact of the proposed rule(s) and regulation(s) on business and economic development within the State of Kansas, local government, and individuals;

Consistent with pharmacy practice in dispensing medications. No additional or different requirements.

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- F. An estimate of the total annual implementation and compliance costs that are reasonably expected to be incurred by or passed along to businesses, local governments, or members of the public.  
*Note: Do not account for any actual or estimated cost savings that may be realized.*

Costs to Affected Businesses – \$0

Costs to Local Governmental Units – \$0

Costs to Members of the Public – \$0

**Total Annual Costs – \$0**  
 (sum of above amounts)

Give a detailed statement of the data and methodology used in estimating the above cost estimate.

Reviewed regulations with pharmacy stakeholders

- ☐ Yes If the total implementation and compliance costs exceed \$1.0 million over any two-year period through June 30, 2024, or exceed \$3.0 million over any two-year period on or after July 1, 2024, and prior to the submission or resubmission of the proposed rule(s) and regulation(s), did the agency hold a public hearing to find that the estimated costs have been accurately determined and are necessary for achieving legislative intent? If applicable, document when the public hearing was held, those in attendance, and any pertinent information from the hearing.
- ☐ No
- ☒ Not Applicable

If applicable, click here to enter public hearing information.

Provide an estimate to any changes in aggregate state revenues and expenditures for the implementation of the proposed rule(s) and regulation(s), for both the current fiscal year and next fiscal year.

None

Provide an estimate of any immediate or long-range economic impact of the proposed rule(s) and regulation(s) on any individual(s), small employers, and the general public. If no dollar estimate can be given for any individual(s), small employers, and the general public, give specific reasons why no estimate is possible.

None

- G. If the proposed rule(s) and regulation(s) increases or decreases revenues of cities, counties or school districts, or imposes functions or responsibilities on cities, counties or school districts that will increase expenditures or fiscal liability, describe how the state agency consulted with the League of Kansas Municipalities, Kansas Association of Counties, and/or the Kansas Association of School Boards.

Not applicable

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- H. Describe how the agency consulted and solicited information from businesses, associations, local governments, state agencies, or institutions and members of the public that may be affected by the proposed rule(s) and regulation(s).

The Board provided an opportunity for comments on proposed draft regulations and solicited feedback from all pharmacy stakeholder organizations prior to routing the regulations through the administrative review process. The Board is working through a multi-year plan to review and revise all adopted regulations for necessary updates.

#### Section IV

Does the Economic Impact Statement involve any environmental rule(s) and regulation(s)?

- ☐ Yes If yes, complete the remainder of Section IV.  
☒ No If no, skip the remainder of Section IV.

- A. Describe the capital and annual costs of compliance with the proposed rule(s) and regulation(s), and the persons who would bear the costs.

Click here to enter agency response.

- B. Describe the initial and annual costs of implementing and enforcing the proposed rule(s) and regulation(s), including the estimated amount of paperwork, and the state agencies, other governmental agencies, or other persons who would bear the costs.

Click here to enter agency response.

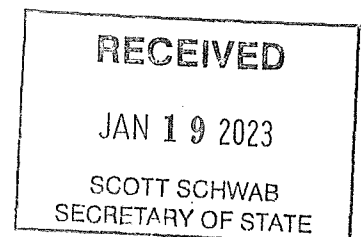
- C. Describe the costs that would likely accrue if the proposed rule(s) and regulation(s) are not adopted, as well as the persons who would bear the costs and would be affected by the failure to adopt the rule(s) and regulation(s).

Click here to enter agency response.

- D. Provide a detailed statement of the data and methodology used in estimating the costs used.

Click here to enter agency response.

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# Kansas Administrative Regulations Economic Impact Statement (EIS)

Kansas Board of Pharmacy  
Agency

Alexandra Blasi  
Agency Contact

785-296-8419 (direct)  
Contact Phone Number

68-7-16  
K.A.R. Number(s)

☒ Permanent ☐ Temporary

Is/Are the proposed rule(s) and regulation(s) mandated by the federal government as a requirement for participating in or implementing a federally subsidized or assisted program?

- ☐ Yes If yes, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration and the Attorney General. Budget approval is not required; however, the Division of the Budget will require submission of a copy of the EIS at the end of the review process.
- ☒ No If no, do the total annual implementation and compliance costs for the proposed rule(s) and regulation(s), calculated from the effective date of the rule(s) and regulation(s), exceed \$1.0 million over any two-year period through June 30, 2024, or exceed \$3.0 million over any two-year period on or after July 1, 2024 (as calculated in Section III, F)?
- ☐ Yes If yes, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration, the Attorney General, AND the Division of the Budget. The regulation(s) and the EIS will require Budget approval.
- ☒ No If no, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration and the Attorney General. Budget approval is not required; however, the Division of the Budget will require submission of a copy of the EIS at the end of the review process.

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**Section I**

Brief description of the proposed rule(s) and regulation(s).

K.A.R. 68-7-16 is being amended to provide labeling information for drugs or devices packaged in advance of immediate need consistent with the Kansas Pharmacy Practice Act and the State and Federal Uniform Controlled Substances Acts. Regulation has not been updated since 1978 so significant technical changes were required.

**Section II**

Statement by the agency if the rule(s) and regulation(s) exceed the requirements of applicable federal law, and a statement if the approach chosen to address the policy issue(s) is different from that utilized by agencies of contiguous states or the federal government. *(If the approach is different or exceeds federal law, then include a statement of why the proposed Kansas rule and regulation is different.)*

Regulations are not mandated by the federal government. Proposed amendments are consistent with neighboring states and current standards of pharmacy practice.

**Section III**

Agency analysis specifically addressing the following:

- A. The extent to which the rule(s) and regulation(s) will enhance or restrict business activities and growth;

The Board anticipates no impact on business activities or growth.

- B. The economic effect, including a detailed quantification of implementation and compliance costs, on the specific businesses, sectors, public utility ratepayers, individuals, and local governments that would be affected by the proposed rule(s) and regulation(s) and on the state economy as a whole;

None

- C. Businesses that would be directly affected by the proposed rule(s) and regulation(s);

Pharmacies registered in Kansas

- D. Benefits of the proposed rule(s) and regulation(s) compared to the costs;

These amendments are designed to protect patients and ensure proper labeling of medications. All elements should be currently required, and no costs are anticipated.

- E. Measures taken by the agency to minimize the cost and impact of the proposed rule(s) and regulation(s) on business and economic development within the State of Kansas, local government, and individuals;

Consistent with pharmacy practice in dispensing medications. No additional or different requirements.

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Revised 05/03/2022

- F. An estimate of the total annual implementation and compliance costs that are reasonably expected to be incurred by or passed along to businesses, local governments, or members of the public.  
*Note: Do not account for any actual or estimated cost savings that may be realized.*

Costs to Affected Businesses – \$0

Costs to Local Governmental Units – \$0

Costs to Members of the Public – \$0

**Total Annual Costs – \$0**  
 (sum of above amounts)

Give a detailed statement of the data and methodology used in estimating the above cost estimate.

Reviewed regulations with pharmacy stakeholders

- ☐ Yes If the total implementation and compliance costs exceed \$1.0 million over any two-year period through June 30, 2024, or exceed \$3.0 million over any two-year period on or after July 1, 2024, and prior to the submission or resubmission of the proposed rule(s) and regulation(s), did the agency hold a public hearing to find that the estimated costs have been accurately determined and are necessary for achieving legislative intent? If applicable, document when the public hearing was held, those in attendance, and any pertinent information from the hearing.
- ☐ No
- ☒ Not Applicable

If applicable, click here to enter public hearing information.

Provide an estimate to any changes in aggregate state revenues and expenditures for the implementation of the proposed rule(s) and regulation(s), for both the current fiscal year and next fiscal year.

None

Provide an estimate of any immediate or long-range economic impact of the proposed rule(s) and regulation(s) on any individual(s), small employers, and the general public. If no dollar estimate can be given for any individual(s), small employers, and the general public, give specific reasons why no estimate is possible.

None

- G. If the proposed rule(s) and regulation(s) increases or decreases revenues of cities, counties or school districts, or imposes functions or responsibilities on cities, counties or school districts that will increase expenditures or fiscal liability, describe how the state agency consulted with the League of Kansas Municipalities, Kansas Association of Counties, and/or the Kansas Association of School Boards.

Not applicable

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- H. Describe how the agency consulted and solicited information from businesses, associations, local governments, state agencies, or institutions and members of the public that may be affected by the proposed rule(s) and regulation(s).

The Board provided an opportunity for comments on proposed draft regulations and solicited feedback from all pharmacy stakeholder organizations prior to routing the regulations through the administrative review process. The Board is working through a multi-year plan to review and revise all adopted regulations for necessary updates.

## Section IV

Does the Economic Impact Statement involve any environmental rule(s) and regulation(s)?

- ☐ Yes If yes, complete the remainder of Section IV.  
☒ No If no, skip the remainder of Section IV.

- A. Describe the capital and annual costs of compliance with the proposed rule(s) and regulation(s), and the persons who would bear the costs.

Click here to enter agency response.

- B. Describe the initial and annual costs of implementing and enforcing the proposed rule(s) and regulation(s), including the estimated amount of paperwork, and the state agencies, other governmental agencies, or other persons who would bear the costs.

Click here to enter agency response.

- C. Describe the costs that would likely accrue if the proposed rule(s) and regulation(s) are not adopted, as well as the persons who would bear the costs and would be affected by the failure to adopt the rule(s) and regulation(s).

Click here to enter agency response.

- D. Provide a detailed statement of the data and methodology used in estimating the costs used.

Click here to enter agency response.

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## Kansas Administrative Regulations Economic Impact Statement (EIS)

Kansas Board of Pharmacy  
Agency

Alexandra Blasi  
Agency Contact

785-296-8419 (direct)  
Contact Phone Number

68-7-19  
K.A.R. Number(s)

☒ Permanent    ☐ Temporary

Is/Are the proposed rule(s) and regulation(s) mandated by the federal government as a requirement for participating in or implementing a federally subsidized or assisted program?

- ☐ Yes    If yes, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration and the Attorney General. Budget approval is not required; however, the Division of the Budget will require submission of a copy of the EIS at the end of the review process.
- ☒ No    If no, do the total annual implementation and compliance costs for the proposed rule(s) and regulation(s), calculated from the effective date of the rule(s) and regulation(s), exceed \$1.0 million over any two-year period through June 30, 2024, or exceed \$3.0 million over any two-year period on or after July 1, 2024 (as calculated in Section III, F)?
- ☐ Yes    If yes, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration, the Attorney General, AND the Division of the Budget. The regulation(s) and the EIS will require Budget approval.
- ☒ No    If no, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration and the Attorney General. Budget approval is not required; however, the Division of the Budget will require submission of a copy of the EIS at the end of the review process.

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**SCOTT SCHWAB  
SECRETARY OF STATE**

## Section I

Brief description of the proposed rule(s) and regulation(s).

Proposed amendments to KAR 68-7-19 respond to recent changes in the Pharmacy Practice Act authorizing the pharmacy to transfer certain prescriptions at the request of the patient, and allowing additional pharmacy personnel to receive and transfer such prescriptions. Amendments also update to current standards and clarify the process for completing such transfers. Amendments are consistent with federal requirements and those for controlled substances, and update requirements for electronic prescriptions which are used more widely and sometimes required under Kansas law.

## Section II

Statement by the agency if the rule(s) and regulation(s) exceed the requirements of applicable federal law, and a statement if the approach chosen to address the policy issue(s) is different from that utilized by agencies of contiguous states or the federal government. *(If the approach is different or exceeds federal law, then include a statement of why the proposed Kansas rule and regulation is different.)*

Regulations are not mandated by the federal government but are consistent with federal requirements related to controlled substances prescriptions. Proposed amendments are consistent with neighboring states and current standards of pharmacy practice.

## Section III

Agency analysis specifically addressing the following:

- A. The extent to which the rule(s) and regulation(s) will enhance or restrict business activities and growth;

Amendments should enhance pharmacy business practice by providing more flexibility and responsiveness to patient requests for prescription transfers, and clarifying the authority and process.

- B. The economic effect, including a detailed quantification of implementation and compliance costs, on the specific businesses, sectors, public utility ratepayers, individuals, and local governments that would be affected by the proposed rule(s) and regulation(s) and on the state economy as a whole;

None

- C. Businesses that would be directly affected by the proposed rule(s) and regulation(s);

Pharmacies registered in Kansas

- D. Benefits of the proposed rule(s) and regulation(s) compared to the costs;

Benefits are related to the clarity provided to licensees and registrants in reading and understanding Kansas regulations and Board expectations, as well as the increased flexibility provided to patients who may wish to have their prescriptions transferred to another pharmacy. Updates decrease the necessity for patients to seek new prescriptions from their healthcare providers prior to dispensing at a new or different pharmacy of the patient's choice.

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- E. Measures taken by the agency to minimize the cost and impact of the proposed rule(s) and regulation(s) on business and economic development within the State of Kansas, local government, and individuals;

The Board has attempted to clarify and simplify language where possible, and eliminate any unnecessary requirements. Additionally, the Board has worked to ensure consistency with all federal requirements.

- F. An estimate of the total annual implementation and compliance costs that are reasonably expected to be incurred by or passed along to businesses, local governments, or members of the public.

*Note: Do not account for any actual or estimated cost savings that may be realized.*

Costs to Affected Businesses – \$0

Costs to Local Governmental Units – \$0

Costs to Members of the Public – \$0

**Total Annual Costs – \$0**

(sum of above amounts)

Give a detailed statement of the data and methodology used in estimating the above cost estimate.

Reviewed regulations with pharmacy stakeholders

- ☐ Yes If the total implementation and compliance costs exceed \$1.0 million over any two-year period through June 30, 2024, or exceed \$3.0 million over any two-year period on or after July 1, 2024, and prior to the submission or resubmission of the proposed rule(s) and regulation(s), did the agency hold a public hearing to find that the estimated costs have been accurately determined and are necessary for achieving legislative intent? If applicable, document when the public hearing was held, those in attendance, and any pertinent information from the hearing.
- ☐ No
- ☒ Not Applicable

If applicable, click here to enter public hearing information.

Provide an estimate to any changes in aggregate state revenues and expenditures for the implementation of the proposed rule(s) and regulation(s), for both the current fiscal year and next fiscal year.

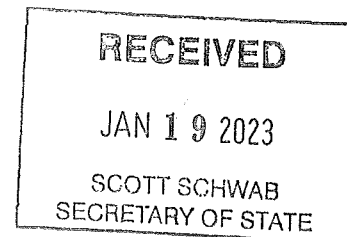
None

Provide an estimate of any immediate or long-range economic impact of the proposed rule(s) and regulation(s) on any individual(s), small employers, and the general public. If no dollar estimate can be given for any individual(s), small employers, and the general public, give specific reasons why no estimate is possible.

None

- G. If the proposed rule(s) and regulation(s) increases or decreases revenues of cities, counties or school districts, or imposes functions or responsibilities on cities, counties or school districts that will

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increase expenditures or fiscal liability, describe how the state agency consulted with the League of Kansas Municipalities, Kansas Association of Counties, and/or the Kansas Association of School Boards.

Not applicable

- H. Describe how the agency consulted and solicited information from businesses, associations, local governments, state agencies, or institutions and members of the public that may be affected by the proposed rule(s) and regulation(s).

The Board provided an opportunity for comments on proposed draft regulations and solicited feedback from all pharmacy stakeholder organizations prior to routing the regulations through the administrative review process. The Board is working through a multi-year plan to review and revise all adopted regulations for necessary updates.

#### Section IV

Does the Economic Impact Statement involve any environmental rule(s) and regulation(s)?

- ☐ Yes If yes, complete the remainder of Section IV.  
☒ No If no, skip the remainder of Section IV.

- A. Describe the capital and annual costs of compliance with the proposed rule(s) and regulation(s), and the persons who would bear the costs.

Click here to enter agency response.

- B. Describe the initial and annual costs of implementing and enforcing the proposed rule(s) and regulation(s), including the estimated amount of paperwork, and the state agencies, other governmental agencies, or other persons who would bear the costs.

Click here to enter agency response.

- C. Describe the costs that would likely accrue if the proposed rule(s) and regulation(s) are not adopted, as well as the persons who would bear the costs and would be affected by the failure to adopt the rule(s) and regulation(s).

Click here to enter agency response.

- D. Provide a detailed statement of the data and methodology used in estimating the costs used.

Click here to enter agency response.

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## Kansas Administrative Regulations Economic Impact Statement (EIS)

Kansas Board of Pharmacy  
Agency

Alexandra Blasi  
Agency Contact

785-296-8419 (direct)  
Contact Phone Number

68-7-20a  
K.A.R. Number(s)

☒ Permanent    ☐ Temporary

Is/Are the proposed rule(s) and regulation(s) mandated by the federal government as a requirement for participating in or implementing a federally subsidized or assisted program?

- ☐ Yes    If yes, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration and the Attorney General. Budget approval is not required; however, the Division of the Budget will require submission of a copy of the EIS at the end of the review process.
- ☒ No    If no, do the total annual implementation and compliance costs for the proposed rule(s) and regulation(s), calculated from the effective date of the rule(s) and regulation(s), exceed \$1.0 million over any two-year period through June 30, 2024, or exceed \$3.0 million over any two-year period on or after July 1, 2024 (as calculated in Section III, F)?
- ☐ Yes    If yes, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration, the Attorney General, AND the Division of the Budget. The regulation(s) and the EIS will require Budget approval.
- ☒ No    If no, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration and the Attorney General. Budget approval is not required; however, the Division of the Budget will require submission of a copy of the EIS at the end of the review process.

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## Section I

Brief description of the proposed rule(s) and regulation(s).

This proposed new regulation addresses the practices known as “white bagging” and “brown bagging” the pharmacy setting. Pharmacy regulations have previously been silent on this topic but recent amendments to the Kansas Pharmacy Act regarding prescription delivery have allowed for regulatory guidance. The Board received complaints and several suggestions from hospital pharmacies handling administration of specialty prescriptions dispensed by specialty pharmacies in Kansas. The Board identified several areas for public protection including requirements for specific communication between the pharmacies, delivery to a pharmacy versus a practitioner’s office, policies and procedures, recordkeeping, prescription tracking, patient consent, patient counseling, prescription storage in accordance with manufacturer requirements, and returning any prescription not administered to the patient. The regulation also eliminates the practice of “brown bagging” or delivering a prescription to patient’s residence that is required to be administered by a healthcare provider, except in limited circumstances, and restricts prescriptions for controlled substances.

## Section II

Statement by the agency if the rule(s) and regulation(s) exceed the requirements of applicable federal law, and a statement if the approach chosen to address the policy issue(s) is different from that utilized by agencies of contiguous states or the federal government. *(If the approach is different or exceeds federal law, then include a statement of why the proposed Kansas rule and regulation is different.)*

Regulations are not mandated by the federal government but are consistent with federal requirements relating to controlled substances prescriptions. Proposed language is consistent with states that have provided guidance on these topics (specifically Virginia, Louisiana, and Arkansas) and current standards of pharmacy practice. Recordkeeping, labeling, storage, and other similar requirements are taken directly from other areas of the Kansas Pharmacy and regulations adopted thereunder.

## Section III

Agency analysis specifically addressing the following:

- A. The extent to which the rule(s) and regulation(s) will enhance or restrict business activities and growth;

The Board expects this new regulation to clarify requirements for participating pharmacies and provide sufficient protections for patients receiving specialty prescriptions for direct administration. While proposed language does create additional requirements and criteria for pharmacies to be able to engage in white bagging, the Board was careful to balance these limitations with the significant risk to patients in the event of noncompliance. Such hazards have been reported to the Board and verified through investigation of white bagging and brown bagging practices, as evidenced in other states identified above.

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- B. The economic effect, including a detailed quantification of implementation and compliance costs, on the specific businesses, sectors, public utility ratepayers, individuals, and local governments that would be affected by the proposed rule(s) and regulation(s) and on the state economy as a whole;

The Board is unable to quantify an economic impact. While proposed language does create new requirements for these practices, pharmacies already have the capacity to comply as they are closely aligned with routine prescription dispensing practices.

- C. Businesses that would be directly affected by the proposed rule(s) and regulation(s);

Pharmacies, medical care facilities, and practitioner's offices registered in Kansas.

- D. Benefits of the proposed rule(s) and regulation(s) compared to the costs;

Benefits are related to the ability to ensure that prescriptions are delivered safely and directly to appropriate facilities that may administer the prescription to the patient. Any costs are significantly outweighed by the benefit to Kansas patients receiving specialty medications for direct administration.

- E. Measures taken by the agency to minimize the cost and impact of the proposed rule(s) and regulation(s) on business and economic development within the State of Kansas, local government, and individuals;

The Board believes that this regulation will have a minimal impact on Kansas business and economic development, and will instead allow for greater transparency and public protection in an existing and growing pharmacy practice.

- F. An estimate of the total annual implementation and compliance costs that are reasonably expected to be incurred by or passed along to businesses, local governments, or members of the public.

*Note: Do not account for any actual or estimated cost savings that may be realized.*

Costs to Affected Businesses – \$0

Costs to Local Governmental Units – \$0

Costs to Members of the Public – \$0

**Total Annual Costs – \$0**

(sum of above amounts)

Give a detailed statement of the data and methodology used in estimating the above cost estimate.

Reviewed regulation with pharmacy stakeholders and received positive feedback and appreciation for the Board's swift response to a new and growing issue.

- ☐ Yes If the total implementation and compliance costs exceed \$1.0 million over any two-year period through June 30, 2024, or exceed \$3.0 million over any two-year period on or after July 1, 2024, and prior to the submission or resubmission of the proposed rule(s) and regulation(s), did the agency hold a public hearing to find that the estimated costs have been accurately determined and are necessary for achieving legislative intent? If applicable, document when the public hearing was held, those in attendance, and any pertinent information from the hearing.
- ☐ No
- ☒ Not Applicable

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If applicable, click here to enter public hearing information.

Provide an estimate to any changes in aggregate state revenues and expenditures for the implementation of the proposed rule(s) and regulation(s), for both the current fiscal year and next fiscal year.

None

Provide an estimate of any immediate or long-range economic impact of the proposed rule(s) and regulation(s) on any individual(s), small employers, and the general public. If no dollar estimate can be given for any individual(s), small employers, and the general public, give specific reasons why no estimate is possible.

None

- G. If the proposed rule(s) and regulation(s) increases or decreases revenues of cities, counties or school districts, or imposes functions or responsibilities on cities, counties or school districts that will increase expenditures or fiscal liability, describe how the state agency consulted with the League of Kansas Municipalities, Kansas Association of Counties, and/or the Kansas Association of School Boards.

Not applicable.

- H. Describe how the agency consulted and solicited information from businesses, associations, local governments, state agencies, or institutions and members of the public that may be affected by the proposed rule(s) and regulation(s).

The Board provided an opportunity for comments on proposed draft regulations and solicited feedback from all pharmacy stakeholder organizations prior to routing the regulation through the administrative review process. The Board is working through a multi-year plan to review and revise all adopted regulations for necessary updates.

#### Section IV

Does the Economic Impact Statement involve any environmental rule(s) and regulation(s)?

- ☐ Yes If yes, complete the remainder of Section IV.  
☒ No If no, skip the remainder of Section IV.

- A. Describe the capital and annual costs of compliance with the proposed rule(s) and regulation(s), and the persons who would bear the costs.

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- B. Describe the initial and annual costs of implementing and enforcing the proposed rule(s) and regulation(s), including the estimated amount of paperwork, and the state agencies, other governmental agencies, or other persons who would bear the costs.

[Click here to enter agency response.](#)

- C. Describe the costs that would likely accrue if the proposed rule(s) and regulation(s) are not adopted, as well as the persons who would bear the costs and would be affected by the failure to adopt the rule(s) and regulation(s).

[Click here to enter agency response.](#)

- D. Provide a detailed statement of the data and methodology used in estimating the costs used.

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## Kansas Administrative Regulations Economic Impact Statement (EIS)

Kansas Board of Pharmacy  
Agency

Alexandra Blasi  
Agency Contact

785-296-8419 (direct)  
Contact Phone Number

68-20-1, 68-20-16, 68-20-18, 68-20-18a, 68-20-19, 68-20-20, 68-20-21, 68-20-22

☒ Permanent ☐

Temporary

K.A.R. Number(s)

Is/Are the proposed rule(s) and regulation(s) mandated by the federal government as a requirement for participating in or implementing a federally subsidized or assisted program?

- ☒ Yes If yes, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration and the Attorney General. Budget approval is not required; however, the Division of the Budget will require submission of a copy of the EIS at the end of the review process.
- ☐ No If no, do the total annual implementation and compliance costs for the proposed rule(s) and regulation(s), calculated from the effective date of the rule(s) and regulation(s), exceed \$1.0 million over any two-year period through June 30, 2024, or exceed \$3.0 million over any two-year period on or after July 1, 2024 (as calculated in Section III, F)?
- ☐ Yes If yes, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration, the Attorney General, AND the Division of the Budget. The regulation(s) and the EIS will require Budget approval.
- ☐ No If no, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration and the Attorney General. Budget approval is not required; however, the Division of the Budget will require submission of a copy of the EIS at the end of the review process.

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## Section I

Brief description of the proposed rule(s) and regulation(s).

KAR 68-20-1 includes amendments to the definitions section for the article of regulations specific to the Kansas Uniform Controlled Substances Act.

KAR 68-20-16 includes amendments to the record-keeping and inventory requirements for controlled substances in Kansas pharmacies. Specifically, proposed amendments update federal regulatory sections, include drugs of concern, limit to non-liquid dosage forms, and clarify documentation requirements.

KAR 68-20-18, 68-20-18a, 68-20-19, and 68-20-20 include amendments for prescriptions for controlled substances and pharmacist review and dispensing of such prescriptions. The Board is updating requirements for supplying, dispensing, and administering these medications, sets forth procedures and requirements for partial fills and refills, and outlines record-keeping requirements. Certain sections distinguish between the requirements for different schedules of controlled substances medications (i.e., II, III, IV, and V). Amendments also address requirements for handling electronic prescriptions. KAR 68-20-21 is proposed for revocation because the content was consolidated and moved into KAR 68-20-20.

KAR 68-20-22 includes amendments to the requirements for sales of prescription-only drugs (i.e., methamphetamine precursors).

All proposed amended regulations include updates to federal regulatory sections and alignment with federal requirements for written and electronic prescriptions.

## Section II

Statement by the agency if the rule(s) and regulation(s) exceed the requirements of applicable federal law, and a statement if the approach chosen to address the policy issue(s) is different from that utilized by agencies of contiguous states or the federal government. *(If the approach is different or exceeds federal law, then include a statement of why the proposed Kansas rule and regulation is different.)*

Yes, the federal government mandates pharmacy compliance with similar federal regulations. Proposed Kansas regulation revisions are consistent with federal requirements related to controlled substance orders, prescriptions, and sales. Proposed amendments are consistent with neighboring states and current standards of pharmacy practice.

## Section III

Agency analysis specifically addressing the following:

- A. The extent to which the rule(s) and regulation(s) will enhance or restrict business activities and growth;

Minimal business impact is anticipated. All amendments are consistent with current federal requirements. In addition, alignment with federal standards allows pharmacies increased flexibility, especially with regard to electronic prescriptions and partial fills. This should enhance pharmacy operations.

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- B. The economic effect, including a detailed quantification of implementation and compliance costs, on the specific businesses, sectors, public utility ratepayers, individuals, and local governments that would be affected by the proposed rule(s) and regulation(s) and on the state economy as a whole;  
None
- C. Businesses that would be directly affected by the proposed rule(s) and regulation(s);  
Pharmacies registered in Kansas
- D. Benefits of the proposed rule(s) and regulation(s) compared to the costs;  
Changes are necessitated by current federal requirements. Thus, the benefit of alignment outweighs the costs of noncompliance with federal law or confusion for pharmacists in meeting two distinct standards.
- E. Measures taken by the agency to minimize the cost and impact of the proposed rule(s) and regulation(s) on business and economic development within the State of Kansas, local government, and individuals;  
The Board has attempted to clarify and simplify language where possible, and eliminate any unnecessary requirements. Steps are taken to shift record-keeping and storage requirements to electronic format wherever possible.
- F. An estimate of the total annual implementation and compliance costs that are reasonably expected to be incurred by or passed along to businesses, local governments, or members of the public.  
*Note: Do not account for any actual or estimated cost savings that may be realized.*

Costs to Affected Businesses – \$0

Costs to Local Governmental Units – \$0

Costs to Members of the Public – \$0

**Total Annual Costs – \$0**  
(sum of above amounts)

Give a detailed statement of the data and methodology used in estimating the above cost estimate.

Reviewed regulations with pharmacy stakeholders

- ☐ Yes    If the total implementation and compliance costs exceed \$1.0 million over any two-year period through June 30, 2024, or exceed \$3.0 million over any two-year period on or after July 1, 2024, and prior to the submission or resubmission of the proposed rule(s) and regulation(s), did the agency hold a public hearing to find that the estimated costs have been accurately determined and are necessary for achieving legislative intent? If applicable, document when the public hearing was held, those in attendance, and any pertinent information from the hearing.
- ☐ No
- ☒ Not Applicable

If applicable, click here to enter public hearing information.

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Provide an estimate to any changes in aggregate state revenues and expenditures for the implementation of the proposed rule(s) and regulation(s), for both the current fiscal year and next fiscal year.

None

Provide an estimate of any immediate or long-range economic impact of the proposed rule(s) and regulation(s) on any individual(s), small employers, and the general public. If no dollar estimate can be given for any individual(s), small employers, and the general public, give specific reasons why no estimate is possible.

None

- G. If the proposed rule(s) and regulation(s) increases or decreases revenues of cities, counties or school districts, or imposes functions or responsibilities on cities, counties or school districts that will increase expenditures or fiscal liability, describe how the state agency consulted with the League of Kansas Municipalities, Kansas Association of Counties, and/or the Kansas Association of School Boards.

Not applicable

- H. Describe how the agency consulted and solicited information from businesses, associations, local governments, state agencies, or institutions and members of the public that may be affected by the proposed rule(s) and regulation(s).

The Board provided an opportunity for comments on proposed draft regulations and solicited feedback from all pharmacy stakeholder organizations prior to routing the regulations through the administrative review process. The Board is working through a multi-year plan to review and revise all adopted regulations for necessary updates.

## Section IV

Does the Economic Impact Statement involve any environmental rule(s) and regulation(s)?

- ☐ Yes If yes, complete the remainder of Section IV.  
☒ No If no, skip the remainder of Section IV.

- A. Describe the capital and annual costs of compliance with the proposed rule(s) and regulation(s), and the persons who would bear the costs.

Click here to enter agency response.

- B. Describe the initial and annual costs of implementing and enforcing the proposed rule(s) and regulation(s), including the estimated amount of paperwork, and the state agencies, other governmental agencies, or other persons who would bear the costs.

Click here to enter agency response.

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- C. Describe the costs that would likely accrue if the proposed rule(s) and regulation(s) are not adopted, as well as the persons who would bear the costs and would be affected by the failure to adopt the rule(s) and regulation(s).

[Click here to enter agency response.](#)

- D. Provide a detailed statement of the data and methodology used in estimating the costs used.

[Click here to enter agency response.](#)

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## Kansas Administrative Regulations Economic Impact Statement (EIS)

Kansas Board of Pharmacy  
Agency

Alexandra Blasi  
Agency Contact

785-296-4056  
Contact Phone Number

68-21-1 through 68-21-5  
K.A.R. Number(s)

☒ Permanent    ☐ Temporary

Is/Are the proposed rule(s) and regulation(s) mandated by the federal government as a requirement for participating in or implementing a federally subsidized or assisted program?

- ☐ Yes    If yes, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration and the Attorney General. Budget approval is not required; however, the Division of the Budget will require submission of a copy of the EIS at the end of the review process.
- ☒ No    If no, do the total annual implementation and compliance costs for the proposed rule(s) and regulation(s), calculated from the effective date of the rule(s) and regulation(s), exceed \$1.0 million over any two-year period through June 30, 2024, or exceed \$3.0 million over any two-year period on or after July 1, 2024 (as calculated in Section III, F)?
- ☐ Yes    If yes, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration, the Attorney General, AND the Division of the Budget. The regulation(s) and the EIS will require Budget approval.
- ☒ No    If no, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration and the Attorney General. Budget approval is not required; however, the Division of the Budget will require submission of a copy of the EIS at the end of the review process.

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## Section I

Brief description of the proposed rule(s) and regulation(s).

K.A.R. 68-21-1 through 68-21-5 provide requirements for the Kansas prescription monitoring program (K-TRACS). Changes to these regulations are necessary after recent updates to the Prescription Monitoring Program statutes (K.S.A. 65-1681 et seq.) effective July 1, 2022. Proposed amendments update definitions; revise reporting exemption requirements for different facility types and pharmacy practice models; update reporting standards to be consistent with current information technology and standards of practice; remove waiver provisions related to non-electronic report submissions; revise requirements and procedures for authorized individuals who are authorized to receive program information pursuant to the statutes; and update language for consistency.

## Section II

Statement by the agency if the rule(s) and regulation(s) exceed the requirements of applicable federal law, and a statement if the approach chosen to address the policy issue(s) is different from that utilized by agencies of contiguous states or the federal government. *(If the approach is different or exceeds federal law, then include a statement of why the proposed Kansas rule and regulation is different.)*

Regulations are not mandated by the federal government. Proposed regulations are consistent with other state prescription monitoring programs and are consistent with the requirements set by Kansas statute.

## Section III

Agency analysis specifically addressing the following:

- A. The extent to which the rule(s) and regulation(s) will enhance or restrict business activities and growth;

The proposed regulations would neither enhance nor restrict business activities and growth for pharmacies and dispensing physicians.

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- B. The economic effect, including a detailed quantification of implementation and compliance costs, on the specific businesses, sectors, public utility ratepayers, individuals, and local governments that would be affected by the proposed rule(s) and regulation(s) and on the state economy as a whole;

Most of the regulatory changes will have no economic impact. Some economic impact may result from amendments to K.A.R. 68-21-2. Software vendors that support dispensers (mainly pharmacies) may need to make changes to how/when they report information on behalf of pharmacies to the Kansas prescription monitoring program. Pharmacies have contracts with their software vendors that require the vendors to be compliant with all state rules and regulations. It is anticipated that costs incurred by the vendors to conform to the new program rules will be covered within existing contractual relationships as part of annual software maintenance. However, it is anticipated that dispensers would incur indirect costs of annual increases to their maintenance contracts to cover costs associated with these required changes.

Amendments to K.A.R. 68-21-2 would require pharmacies and dispensing physicians to report prescriptions to K-TRACS based on the date a prescription was sold, which is usually determined from the integration of a point-of-sale system. Point-of-sale systems are estimated to cost \$8,000 to \$13,000. There are approximately 19 Kansas pharmacies and dispensing physicians without this technology currently (which comprises 3% of all Kansas pharmacies and dispensing physicians reporting to K-TRACS). All other dispensers already meet amended requirements. The Board plans to work directly with these 19 dispensers to ensure compliance with minimum necessary changes. The maximum impact to one of the 19 non-compliant facilities would be \$13,000.

- C. Businesses that would be directly affected by the proposed rule(s) and regulation(s);  
Dispensers (pharmacies and dispensing physicians)
- D. Benefits of the proposed rule(s) and regulation(s) compared to the costs;

These regulations reflect changes to the K-TRACS program and to prescription monitoring programs over the past decade. The proposed regulations will create efficiencies in compliance monitoring by streamlining requirements and conforming to updated PDMP reporting standards. These requirements will also ensure high data quality to PDMP end users. The proposed regulations also clearly outline information access guidelines for greater transparency and compliance.

- E. Measures taken by the agency to minimize the cost and impact of the proposed rule(s) and regulation(s) on business and economic development within the State of Kansas, local government, and individuals;

The Board has attempted to clarify and simplify language where possible, and eliminate any unnecessary requirements. K.S.A. 65-1683 provides statutory exemptions to program reporting requirements. The proposed regulations include additional exemption provisions, including one for dispensers with low volumes of prescriptions and software lacking the

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ability to comply with the regulations. K-TRACS also intends to publish a complete set of guidelines for changes to reporting requirements for pharmacies and vendors at one time so the changes can be made all at once, which should help reduce the time and resources needed to implement the changes.

- F. An estimate of the total annual implementation and compliance costs that are reasonably expected to be incurred by or passed along to businesses, local governments, or members of the public.

*Note: Do not account for any actual or estimated cost savings that may be realized.*

Costs to Affected Businesses – \$247,000

Costs to Local Governmental Units – \$0

Costs to Members of the Public – \$0

**Total Annual Costs – \$247,000**

(sum of above amounts)

Give a detailed statement of the data and methodology used in estimating the above cost estimate.

If all pharmacies and dispensing physicians currently lacking the ability to report a sold date to K-TRACS (19) needed to purchase a point-of-sale system in order to do so, then those dispensers may incur a cost of \$8,000 to \$13,000 per system, which would equal \$247,000 based on max estimates.

Other indirect costs of escalating annual maintenance costs from software vendors to dispensers is difficult to calculate based on the number of vendors in the marketplace and variability of their operations, features and fee structures. Anticipated costs should be negligible.

- ☐ Yes      If the total implementation and compliance costs exceed \$1.0 million over any two-year period through June 30, 2024, or exceed \$3.0 million over any two-year period on or after July 1, 2024, and prior to the submission or resubmission of the proposed rule(s) and regulation(s), did the agency hold a public hearing to find that the estimated costs have been accurately determined and are necessary for achieving legislative intent? If applicable, document when the public hearing was held, those in attendance, and any pertinent information from the hearing.
- ☐ No
- ☒ Not Applicable

If applicable, click here to enter public hearing information.

Provide an estimate to any changes in aggregate state revenues and expenditures for the implementation of the proposed rule(s) and regulation(s), for both the current fiscal year and next fiscal year.

There is no anticipated change in state revenues and expenditures as a result of implementation of the proposed regulations.

Provide an estimate of any immediate or long-range economic impact of the proposed rule(s) and regulation(s) on any individual(s), small employers, and the general public. If no dollar estimate can be given for any individual(s), small employers, and the general public, give specific reasons why no estimate is possible.

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It is anticipated dispensers may incur indirect costs as a result of implementation of the proposed regulations. These indirect costs may appear in the form of annual increases to software maintenance contracts that dispensers have with their vendors, who are contracted to help the dispenser remain in compliance with state regulations. There are numerous vendors that dispensers may use, and each vendor charges a different price for software maintenance based on a variety of factors within the dispenser's practice. It would be difficult to determine if increases in annual maintenance costs were directly attributable to the implementation of the proposed regulations, and it would be difficult to determine those costs across a multitude of vendors. Costs are anticipated to be negligible.

- G. If the proposed rule(s) and regulation(s) increases or decreases revenues of cities, counties or school districts, or imposes functions or responsibilities on cities, counties or school districts that will increase expenditures or fiscal liability, describe how the state agency consulted with the League of Kansas Municipalities, Kansas Association of Counties, and/or the Kansas Association of School Boards.

There is no impact from the proposed regulations on cities, counties or school districts.

- H. Describe how the agency consulted and solicited information from businesses, associations, local governments, state agencies, or institutions and members of the public that may be affected by the proposed rule(s) and regulation(s).

The Board provided an opportunity for comments and discussion on draft regulations, and solicited feedback from pharmacists and stakeholder groups such as the Kansas Pharmacists Association prior to routing through the administrative rulemaking process. Feedback indicated annual maintenance contracts would encompass most of costs associated with the changes. K-TRACS also discussed the implementation of the requirement to report prescriptions based on the date a prescription was sold with other prescription drug monitoring programs who have made similar regulation changes to incorporate the use of sold date in reporting. Other state programs provided perspective on costs incurred by their dispensers to make changes in their states.

#### Section IV

Does the Economic Impact Statement involve any environmental rule(s) and regulation(s)?

- ☐ Yes If yes, complete the remainder of Section IV.  
☒ No If no, skip the remainder of Section IV.

- A. Describe the capital and annual costs of compliance with the proposed rule(s) and regulation(s), and the persons who would bear the costs.

[Click here to enter agency response.](#)

- B. Describe the initial and annual costs of implementing and enforcing the proposed rule(s) and regulation(s), including the estimated amount of paperwork, and the state agencies, other governmental agencies, or other persons who would bear the costs.

[Click here to enter agency response.](#)

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- C. Describe the costs that would likely accrue if the proposed rule(s) and regulation(s) are not adopted, as well as the persons who would bear the costs and would be affected by the failure to adopt the rule(s) and regulation(s).

[Click here to enter agency response.](#)

- D. Provide a detailed statement of the data and methodology used in estimating the costs used.

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# Kansas Administrative Regulations Economic Impact Statement (EIS)

Kansas Board of Pharmacy  
Agency

Alexandra Blasi  
Agency Contact

785-296-8419 (direct)  
Contact Phone Number

68-23-1, 68-23-2, 68-23-3, 68-23-4, 68-23-5, 68-23-6  
K.A.R. Number(s)

☒ Permanent    ☐ Temporary

Is/Are the proposed rule(s) and regulation(s) mandated by the federal government as a requirement for participating in or implementing a federally subsidized or assisted program?

- ☐ Yes    If yes, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration and the Attorney General. Budget approval is not required; however, the Division of the Budget will require submission of a copy of the EIS at the end of the review process.
- ☒ No    If no, do the total annual implementation and compliance costs for the proposed rule(s) and regulation(s), calculated from the effective date of the rule(s) and regulation(s), exceed \$1.0 million over any two-year period through June 30, 2024, or exceed \$3.0 million over any two-year period on or after July 1, 2024 (as calculated in Section III, F)?
- ☐ Yes    If yes, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration, the Attorney General, AND the Division of the Budget. The regulation(s) and the EIS will require Budget approval.
- ☒ No    If no, continue to fill out the remaining form to be included with the regulation packet submitted in the review process to the Department of Administration and the Attorney General. Budget approval is not required; however, the Division of the Budget will require submission of a copy of the EIS at the end of the review process.

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## Section I

Brief description of the proposed rule(s) and regulation(s).

K.A.R. 68-23-1 through 68-23-6 are proposed to provide requirements for the new practice of telepharmacy in Kansas. As required by new K.S.A. 65-16,130, the proposed regulations outline definitions, as well as the requirements for the registration application and renewal; restrictions on the location, delivery, managing pharmacy, and dispensing threshold; criteria for exemption or waiver; practice of telepharmacy; management of controlled substances and drugs of concern; operations; personnel, staffing, training, and supervision; and structural, security, technology, and equipment requirements.

## Section II

Statement by the agency if the rule(s) and regulation(s) exceed the requirements of applicable federal law, and a statement if the approach chosen to address the policy issue(s) is different from that utilized by agencies of contiguous states or the federal government. *(If the approach is different or exceeds federal law, then include a statement of why the proposed Kansas rule and regulation is different.)*

Regulations are not mandated by the federal government. Proposed regulations are consistent with other state models and the requirements set by Kansas statute.

## Section III

Agency analysis specifically addressing the following:

- A. The extent to which the rule(s) and regulation(s) will enhance or restrict business activities and growth;

The Board anticipates that proposed regulations will enhance pharmacy business activity and flexibility, and provide greater access to pharmaceutical services for patients.

Restrictions on the location of the telepharmacy outlet and delivery radius (K.A.R. 68-23-2) may limit telepharmacy outlet operations but only based on the presence and availability of existing and operational pharmacies in the area. Furthermore, location restrictions do not apply to community mental health centers, federally qualified health clinics, or indigent health care clinics. Restrictions on managing pharmacies ensure a supervising pharmacist is available to handle any situation and can reach the telepharmacy outlet quickly in-person, if necessary.

Other restrictions on any business activities would be related to the financial burden of implementing telepharmacy software and equipment (K.A.R. 68-23-6). However, these requirements are consistent with routine pharmacy operations.

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Business activity may also be restricted by requiring minimum qualifications, training, and experience from telepharmacy outlet personnel. Therefore, they are reasonable and consistent to protect the public welfare.

- B. The economic effect, including a detailed quantification of implementation and compliance costs, on the specific businesses, sectors, public utility ratepayers, individuals, and local governments that would be affected by the proposed rule(s) and regulation(s) and on the state economy as a whole;

Any economic impact different from that related to routine operation of a pharmacy would be related to the telepharmacy outlet's costs for the following:

1. The cost of implementation and monthly maintenance of telepharmacy outlet software and equipment. Vendors and other state boards of pharmacy estimate the costs of implementation to range from \$5,000 - \$25,000 for initial setup (equipment, support, software, installation, etc.), and costs of ongoing maintenance to range from \$200 - \$1,000 per month (software, operation, electronic storage).
2. The cost of continuous video surveillance of the telepharmacy outlet, which would depend on the software vendor, hours of operation, amount of video storage required, etc. Vendors and other state boards of pharmacy estimate the costs of implementation at \$20,000, and costs of ongoing maintenance and storage to range from \$300 - \$1,650 per month.
3. The cost of a monitored alarm system, which is estimated under \$1,000 per year.
4. Additional travel and coverage by a pharmacist-in-charge or supervising pharmacist that would be above and beyond routine in-person pharmacy supervision. While no additional pharmacist hours are required to operate a telepharmacy outlet, there may be a shift in the location for hours worked or those dedicated to particular tasks/functions.

While the telepharmacy outlet may have revenue limitations based on the maximum average quarterly prescriptions dispensed (dispensing threshold), the pharmacy could elect to exceed the threshold by adding an in-person pharmacist. The regulation allows for this to be somewhat fluid on a quarterly basis with proper notification and approval from the Board.

Note: There is no mandate that any business operate a telepharmacy outlet or that any pharmacist serve as a pharmacist-in-charge or supervising pharmacist.

- C. Businesses that would be directly affected by the proposed rule(s) and regulation(s);

Pharmacies registered in Kansas

- D. Benefits of the proposed rule(s) and regulation(s) compared to the costs;

In 2018, the Board commenced a pilot project allowing for the operation of a telepharmacy outlet in the state of Kansas. Telepharmacy allows a pharmacist to conduct their review, supervision, verification, and patient counseling responsibilities virtually, while a pharmacy technician or pharmacist intern 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

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pilot has been operational for 3+ years, demonstrating success and no increased risk to the public.

The National Association of Boards of Pharmacy (NABP) added telepharmacy to the Model Act in 2006 and more than 25 states have adopted telepharmacy laws or regulations, including Nebraska, Colorado, and Texas. The proposed regulations provide appropriate protections and requirements for proper administration and use of these systems, establish criteria for safe operation, compliance, and evaluation, and create the potential for increased patient/consumer access to pharmacy services, especially in rural or underserved areas.

While operational service and equipment requirements may be higher than a traditional pharmacy, costs are reduced by not requiring the staffing of an in-person supervising pharmacist.

- E. Measures taken by the agency to minimize the cost and impact of the proposed rule(s) and regulation(s) on business and economic development within the State of Kansas, local government, and individuals;

Utilization of existing Board forms, resources, and processes. Proposed regulations for telepharmacy outlets deviate as minimally as possible from existing pharmacy requirements in Kansas.

- F. An estimate of the total annual implementation and compliance costs that are reasonably expected to be incurred by or passed along to businesses, local governments, or members of the public.

*Note: Do not account for any actual or estimated cost savings that may be realized.*

Costs to Affected Businesses – \$10k to 40k for one-time implementation for each telepharmacy outlet; \$1200-\$3500 per month for ongoing telepharmacy systems maintenance

Costs to Local Governmental Units – \$0

Costs to Members of the Public – \$0

**Total Annual Costs** – \$10k to 40k one-time; \$14k-\$42k ongoing  
(sum of above amounts)

Give a detailed statement of the data and methodology used in estimating the above cost estimate.

Review of other state board of pharmacy fiscal and economic statements related to rule adoption. Review of software and industry vendor costs.

- ☐ Yes      If the total implementation and compliance costs exceed \$1.0 million over any two-year period through June 30, 2024, or exceed \$3.0 million over any two-year period on or after July 1, 2024, and prior to the submission or resubmission of the proposed rule(s) and regulation(s), did the agency hold a public hearing to find that the estimated costs
- ☐ No
- ☒ Not

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Applicable have been accurately determined and are necessary for achieving legislative intent? If applicable, document when the public hearing was held, those in attendance, and any pertinent information from the hearing.

If applicable, click here to enter public hearing information.

Provide an estimate to any changes in aggregate state revenues and expenditures for the implementation of the proposed rule(s) and regulation(s), for both the current fiscal year and next fiscal year.

None

Provide an estimate of any immediate or long-range economic impact of the proposed rule(s) and regulation(s) on any individual(s), small employers, and the general public. If no dollar estimate can be given for any individual(s), small employers, and the general public, give specific reasons why no estimate is possible.

Not quantifiable. The goal of allowing telepharmacy operations is to provide increased access to pharmacy services in Kansas. However, the nature of the allowance is that the Board does not know if/when any telepharmacy will be operational in Kansas or what actual fiscal impact there may be.

- G. If the proposed rule(s) and regulation(s) increases or decreases revenues of cities, counties or school districts, or imposes functions or responsibilities on cities, counties or school districts that will increase expenditures or fiscal liability, describe how the state agency consulted with the League of Kansas Municipalities, Kansas Association of Counties, and/or the Kansas Association of School Boards.

Not applicable.

- H. Describe how the agency consulted and solicited information from businesses, associations, local governments, state agencies, or institutions and members of the public that may be affected by the proposed rule(s) and regulation(s).

Proposed regulations are based on similar state models, as well as comments and feedback from pharmacy stakeholders and telepharmacy organizations. The Board's pilot project is ongoing after 3+ years in operation and the Kansas Pharmacists Association's hosting of a telepharmacy workgroup that informed Board actions and proposed regulations. Any member of the public was invited to participate in providing feedback to the Board on draft regulations.

## Section IV

Does the Economic Impact Statement involve any environmental rule(s) and regulation(s)?

- ☐ Yes If yes, complete the remainder of Section IV.  
☒ No If no, skip the remainder of Section IV.

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Click here to enter agency response.

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- C. Describe the costs that would likely accrue if the proposed rule(s) and regulation(s) are not adopted, as well as the persons who would bear the costs and would be affected by the failure to adopt the rule(s) and regulation(s).

Click here to enter agency response.

- D. Provide a detailed statement of the data and methodology used in estimating the costs used.

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