**State of Kansas**

**Board of Pharmacy**

**Notice of Hearing on Proposed Administrative**

**Regulations**

 A public hearing will be conducted at 9:00 a.m. Thursday, April 27, 2023, 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. The public hearing will be conducted in person and via video conferencing system. Members of the public who wish to attend the public hearing virtually must pre-register at <https://kansasag.zoom.us/meeting/register/tZcuduuhrz0pGd3f7SZjreoQ_jCw1Nn_reQ9>.

 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 SW Jackson, Suite 1414, Topeka, KS 66612-1244 or by email to 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 SW Jackson, Suite 1414, Topeka, KS 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.

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

Summaries of the proposed regulations and their economic impact follow. (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, persons subject to the proposed regulations, 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. 68-7-8. 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. 68-7-19. 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.

**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. 68-20-21. 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. 68-23-2. 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. 68-23-6. 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.

Alexandra Blasi

Executive Secretary

Board of Pharmacy