

State of Kansas
Board of Pharmacy
Notice of Hearing on Proposed Administrative Regulations

A public hearing will be conducted on Tuesday, October 22, 2019 at 8:00 a.m. in the Board of Healing Arts Board Room at 800 SW Jackson, Lower Level, 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. 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 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 <http://pharmacy.ks.gov/statutes->

[regs/proposed-reg-changes.](#)

K.A.R. 68-2-10. Cessation of operations. This regulation is being amended to require closed pharmacies to notify the Board and patients about the location and disposition of patient records, and creating requirements for pharmacies accepting records of closed pharmacies.

K.A.R. 68-7-15. Prepackaging or repackaging of oral drugs. This regulation is being amended to allow packaging of drugs dispensed or supplied by the pharmacy or any other pharmacy engaged in a shared services agreement under K.A.R. 68-7-20, and to provide necessary limitations for prepackaging and repackaging of parenteral products.

K.A.R. 68-19-1. Minimum program requirements. This regulation is being amended to require review of the Board's quarterly newsletter during the pharmacy's quarterly continuous quality improvement meetings.

K.A.R. 68-21-6. Reciprocal agreements with other states or government entities to share information. This regulation is being amended to allow the Board to share K-TRACS data with other relevant government entities that have established prescription drug monitoring programs, including the Missouri St. Louis County initiative, military health system via the department of defense, Indian health systems, and veteran health system.

K.A.R. 68-14-1. This regulation is being considered for revocation as the result of proposed amendments and additions to the remainder of Article 14 of the Board's regulations (KAR 68-14-2 through 68-14-7b).

K.A.R. 68-14-2. Definitions. This regulation is being amended to include additional definitions consistent with the Federal Drug Supply Chain Security Act (DSCSA) that shall apply to Article 14 of the Board's regulations, as well as clarify language in the Pharmacy Practice Act.

K.A.R. 68-14-3. This regulation is being considered for revocation as the result of 2017 amendments to the Pharmacy Practice Act which make the contents of this regulation duplicative of statute.

K.A.R. 68-14-4. Minimum required information for registration. This regulation is being amended to include application requirements for virtual wholesale distributors, third-party logistics providers, and outsourcing facilities. It also further clarifies the requirements for wholesale distributors, including inspection and other non-resident compliance requirements.

K.A.R. 68-14-5. Personnel. This regulation is being amended to include personnel requirements for virtual wholesale distributors, third-party logistics providers, and outsourcing facilities. It also further clarifies the requirements for maintaining training records for five years and requires outsourcing facilities to designate a pharmacist-in-charge.

K.A.R. 68-14-7. Wholesale distributors; minimum requirements for the storage and handling of prescription-only drugs and devices and for the establishment and maintenance of prescription-only drug and device distribution records. This regulation is

being amended to update the operations requirements for wholesale distributors to be consistent with the Federal Drug Supply Chain Security Act (DSCSA).

K.A.R. 68-14-7a. Third-party logistics providers; minimum requirements for operation and maintenance of records. This is a new regulation drafted to provide operational requirements for third-party logistics providers, a newly regulated category of registrants, consistent with the Federal Drug Supply Chain Security Act (DSCSA).

K.A.R. 68-14-7b. Outsourcing facilities; minimum requirements for operation and maintenance of records. This is a new regulation drafted to provide operational requirements for outsourcing facilities, a newly regulated category of registrants, consistent with the Federal Drug Supply Chain Security Act (DSCSA).

SUMMARY OF ECONOMIC IMPACT

It is the mission of the Board to ensure that all persons practicing pharmacy are properly licensed and registered, and to ensure compliance with Kansas statutes regarding proper compounding, storage, and dispensing of prescription drugs, maintenance of professional standards, and proper manufacture, distribution, and sale of prescription and nonprescription drugs. Thus, the Board is proposing these regulatory changes.

DSCSA: The Board anticipates minimal economic impact to the Board, its licensees and registrants, or Kansas-registered pharmacies. Amendments will enhance business activity related to the manufacture, distribution, and compounding of prescription drugs and devices by allowing these facilities to more readily transact business with Kansas. The regulations are also designed to maintain necessary public protection mechanisms within these facilities and ensure compliance with recognized pharmacy standards. Registration and renewal application fees have been set in a separate regulation. However, fees should have a null effect on revenue and expense because the Board is merely shifting registrants from one registration category to another. The Board does not anticipate any financial impact upon other governmental agencies, and the Board is unaware of any less costly or less intrusive methods to achieve the stated purposes.

Cessation of Operations: The Board anticipates minimal economic impact to the Board, its licensees and registrants, or Kansas-registered pharmacies. Any economic impact would be specifically related to the closing pharmacy's new responsibility to notify patients of the closure and the disposition of patient records. Pharmacies are already required to maintain patient records for five years and, upon closure, are required to secure another pharmacy buyer or a permanent storage location for the files. The only new component is a notification to the patient about the disposition of the patient record. Notification may be made by mail or email, the economic effect of which may include the cost of paper, envelopes, and postage. This cost would be allocated to the closing pharmacy.

K-TRACS Interstate Data Sharing: The Board anticipates no economic impact to the Board, its licensees and registrants, or any Kansas citizen/business. The Board has data sharing capabilities and will merely expand to these other entities. If there is any economic impact, it would be related to increased data sharing and increased program utilization which could positively benefit the health of patients and Kansans. Such impact is unquantifiable.

Other Regulations: No economic impact.

For a more detailed summary of the economic impact each specific regulation may have, see the Economic Impact Statements, provided at the website above.