KANSAS STATE BOARD OF PHARMACY
ECONOMIC IMPACT STATEMENT

The Kansas State Board of Pharmacy (Board) is proposing new K.A.R. 68-13-2, 68-13-3, 68-13-4, and 68-5-17 for administration of the Kansas Pharmacy Practice Act, K.S.A. 65-1625 *et seq*., and amendments to K.A.R. 68-21-7 for administration of the Kansas Prescription Monitoring Act, K.S.A. 65-1681 *et seq*.

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 and dispensing of prescription drugs, maintenance of professional practice standards, and proper manufacture, distribution, and sale of prescription and nonprescription drugs, including controlled substances and poisons. In order to attain these goals, the Board is proposing these regulatory changes to comply with professional, healthcare, and safety norms.

In all instances, 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 and thus none were considered.

COMPOUNDING

I. Summary of Proposed Regulations. K.A.R. 68-13-2, 68-13-3, and 68-13-4 are being proposed to create minimum standards for sterile and non-sterile pharmaceutical compounding in Kansas consistent with the U.S. Pharmacopeia (USP) requirements.

II. Reason(s) the Proposed Regulation Is Required, Including Whether or Not the Regulation Is Mandated by Federal Law. Implementation of these new regulations are a direct result of 2017 HB 2055, which newly defined compounding and included authority for the Board to adopt administrative rules and regulations. There are no federal requirements implicated by this regulation, but pharmaceutical compounding must also be compliant with federal law, which adopts USP standards.

III. Anticipated Economic Impact on the Board. The Board anticipates an economic impact in the form of compliance and enforcement resources. Board inspectors are required to inspect pharmacies annually, and pharmacies participating in sterile compounding will likely require a higher level of review and education. These inspections will take additional staff time to complete and may result in more disciplinary cases. In addition, Board inspectors are currently undergoing additional certification and training to ensure they are adequately equipped to conduct inspections at compounding facilities. The Board is responsible for a portion of these training costs (approximately $1,500 per person) and also receives a scholarship from the National Association of Boards of Pharmacy. The remaining Board inspector to complete training will do so in fiscal year 2019, and those costs have already been budgeted.

IV. Anticipated Financial Impact Upon Private Individuals or Businesses. Any impact on private individuals or businesses would come in the form of compliance with facility and practice standards. Pharmacies are not required to do sterile or nonsterile compounding. While

pharmacists complete training as part of their education, pharmacy technicians will need to be adequately trained, which may occur on the job or at a training facility at the expense of the pharmacy. No other economic impact is anticipated.

V. Anticipated Economic Impact Upon Other Entities or Persons. There would be no negative impact on other entities or persons. There would be a positive impact on patient safety and welfare.

PHARMACY TECHNICIAN EXAM

I. Summary of Proposed Regulations. K.A.R. 68-5-17 is proposed to identify the requirements for successful completion of the pharmacy technician certification exam. For all pharmacy technicians registered after July 1, 2017, the Board will require passing scores from the Pharmacy Technician Certification Board (PTCB) or the National Healthcareer Association (ExCPT) exams prior to the first renewal (24-26 months) of the pharmacy technician's registration.

II. Reason(s) the Proposed Regulation Is Required, Including Whether or Not the Regulation Is Mandated by Federal Law. This regulation is consistent with K.S.A. 65-1663, which requires that every pharmacy technician registered after July 1, 2017 be required to pass a certified pharmacy technician examination approved by the Board within the period of time specified by the Board after becoming registered. There are no federal requirements implicated by this regulation.

III. Anticipated Economic Impact on the Board. Though the Board does not anticipate any economic impact as a result of these changes, it is possible that a certification requirement may deter individuals from entering or remaining in the profession, the economic impact of which is unknown.

IV. Anticipated Financial Impact Upon Private Individuals or Businesses. There will be an economic impact to registered pharmacy technicians as they take the PTCB or ExCPT exams, which cost $120 on average. This cost may be passed onto the employer pharmacy if they pay for the exam on behalf of the registrant, and may result in a higher wage or earning potential for the pharmacy technician after successful passage of the exam. Failure to pass the exam may also result in termination of employment and the inability to renew the pharmacy technician registration.

V. Anticipated Economic Impact Upon Other Entities or Persons. There would be no negative impact on other entities or persons. There would be a positive impact on patient safety and welfare.

DRUGS OF CONCERN

I. Summary of Proposed Regulations. K.A.R. 68-21-7 is being amended to classify any product, compound, mixture, or preparation containing gabapentin as a drug of concern. K.A.R. 68-21-7 identifies the drugs of concern that are reported to, tracked by, and monitored through

the Kansas Prescription Monitoring Program (K-TRACS) that are not controlled substances identified in Schedules II-IV of the Kansas Controlled Substances Act.

II. Reason(s) the Proposed Regulation Is Required, Including Whether or Not the Regulation Is Mandated by Federal Law. The K-TRACS Advisory Committee recommended the Board begin tracking gabapentin in K-TRACS as a result of an increase in substance use and overdose cases in other states related to this drug, as well as the increase in the purchase and potential misuse of this medication. Gabapentin is an anticonvulsant used to control seizures, but is also commonly prescribed to treat nerve pain in adult patients suffering from diabetes, herpes, or shingles. Federal law does not mandate the proposed amendment.

III. Anticipated Economic Impact on the Board. The Board does not anticipate any economic impact. The Board contracts with Appriss Health to operate the K-TRACS clearinghouse, and they would manage any changes to the required reporting and fields, which is done without additional charge to the Board.

IV. Anticipated Financial Impact Upon Private Individuals or Businesses. The Board does not anticipate any financial impact upon other governmental agencies. The Board anticipates a financial impact to each registered Kansas pharmacy (~1,900) that must update their software to report prescriptions for gabapentin to K-TRACS, the exact amount of which is unknown to the Board. Pharmacies generally update their drug lists as changes are made to federal and local laws and the impact is minimal. The Board of Pharmacy has given impacted entities an additional 90 days to make changes to their software.

V. Anticipated Economic Impact Upon Other Entities or Persons. There would be no impact on other entities or persons.