KANSAS STATE BOARD OF PHARMACY
ECONOMIC IMPACT STATEMENT

The Kansas State Board of Pharmacy (Board) is proposing amendments to the following regulations: K.A.R. 68-1-3a, 68-2-20, 68-7-12a, 68-7-15, 68-7-20, and 68-11-2; for the administration of the Kansas Pharmacy Practice Act, K.S.A. 65-1625 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.

QUALIFYING PHARMACEUTICAL EXPERIENCE

I. Summary of Proposed Regulations. K.A.R. 68-1-3a is being amended to increase the number of hours required to complete one year of experience as a pharmacy intern to 1,740 clock-hours. This change is consistent with national standards and current training requirements of the two largest pharmacist feeder schools in Kansas.

II. Reason(s) the Proposed Regulation Is Required, Including Whether or Not the Regulation Is Mandated by Federal Law. The Board is required to adopt regulations to specify the education requirements for pharmacists in accordance with K.S.A. 65-1631. There are no federal requirements implicated by this regulation.

III. Anticipated Economic Impact on the Board. No changes in costs or fees are anticipated by the Board, nor any impact on application processing as a result of the amendment.

IV. Anticipated Financial Impact Upon Private Individuals or Businesses. Though the amendment increases the number of hours required for pharmacy interns in achieving the requisite education to qualify for a pharmacist license in Kansas, this change is consistent with national trends, other state requirements, and the majority of pharmacy interns are already required to complete 1,740 clock-hours of pharmaceutical experience in attaining their graduate degree. No impact on private citizens or businesses 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.
PHARMACIST FUNCTION IN FILLING A PRESCRIPTION

I. Summary of Proposed Regulations. K.A.R. 68-2-20 is being amended to provide consistency with statutes in the Pharmacy Practice Act. First, pharmacists may only fill prescriptions written by practitioners or mid-level practitioners that would have commensurate prescribing authority if licensed or registered in Kansas. Additional amendments allow dispensing of a prescription drug based on a prescription that may have been issued based on a practitioner’s telephonic consultation with a patient.

II. Reason(s) the Proposed Regulation Is Required, Including Whether or Not the Regulation Is Mandated by Federal Law. The Board’s first amendment is consistent with K.S.A. 65-1626 and 65-1637, which do not allow pharmacists to fill prescriptions written by pharmacists who may have prescribing authority in other states, or other healthcare practitioners that may have prescribing authority in other states. The amendment regarding telephonic consultation is made in response to chapter 34, section 6 of the 2017 Kansas session laws, which states: “Nothing contained in the pharmacy act of the state of Kansas shall require an in-person examination or encounter between a person licensed to practice medicine and surgery and the patient prior to a pharmacist filling or refilling any prescription.” There are no federal requirements implicated by this regulation.

III. Anticipated Economic Impact on the Board. The Board does not anticipate any economic impact as a result of these changes.

IV. Anticipated Financial Impact Upon Private Individuals or Businesses. Any impact to private individuals may be related to the cost of obtaining another prescription from a person authorized to prescribe in Kansas or the decreased cost of obtaining a prescription from a practitioner as a result of a telephonic encounter. There may be an impact to pharmacists or pharmacies who are reviewing these prescriptions, but that would be difficult to estimate or quantify. Any impact to other businesses would be unknown to the Board.

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

NON-RESIDENT PHARMACIES

I. Summary of Proposed Regulations. K.A.R. 68-7-12a is being amended to require each non-resident pharmacy to designate a pharmacist-in-charge (PIC), which, by definition, must be licensed as a pharmacist in the state of Kansas and to require all practicing pharmacists employed by or under contract with the non-resident pharmacy to be licensed in the state where that pharmacist is practicing. In addition, each non-resident pharmacy will be required to provide the Board with a satisfactory inspection conducted within the previous 12-month period by the non-resident pharmacy’s state board of pharmacy. If none is available, the non-resident pharmacy may, at their expense, contract with a Board-approved third party for an inspection.

II. Reason(s) the Proposed Regulation Is Required, Including Whether or Not the Regulation Is Mandated by Federal Law. The Board is amending this regulation to ensure
public safety and the ability of the Board to properly regulate and discipline non-resident pharmacies and the pharmacist responsible for that facility (PIC). While the Board allows non-resident pharmacies to provide services to Kansans, it is difficult for the Board to ensure quality and compliance due to the facility location. Therefore, the Board must rely on the non-resident state board of pharmacy to properly inspect and report issues. However, some state boards may be unable or unwilling to meet these requirements, so the Board offers an additional inspection option. Additionally, requiring the PIC to be licensed in Kansas allows the Board to regulate that pharmacist in cases of non-compliance. There are no federal requirements implicated by this regulation.

III. Anticipated Economic Impact on the Board. The Board currently registers 935 non-resident pharmacies in 46 states, including California, Washington, North Dakota, Texas, Florida, and Maine. This measure protects the public and allows continued interstate pharmacy services, while conserving state personnel and resources that would otherwise need to be employed to inspect non-resident facilities. Requiring the PIC be a licensed pharmacist in Kansas may increase the Board’s number of licensed pharmacists, but the exact increase is difficult to estimate. If each non-resident pharmacy had their PIC become licensed in Kansas, the Board would see an increase in revenue of approximately $59,840 for the first year, and $112,200 for each subsequent biannual renewal.

IV. Anticipated Financial Impact Upon Private Individuals or Businesses. The impact to non-resident pharmacies would be minimal if they were able to obtain a satisfactory inspection from their resident state board of pharmacy and are approximated at $1,900 - $4,500 per year for a Board-approved third party inspection depending on the size, location, and functions of the non-resident pharmacy. The impact to PICs at non-resident pharmacies would be $64 for an initial pharmacist application for licensure by reciprocity and $120 for each subsequent biannual renewal.

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

PREPACKAGING OR REPACKAGING OF DRUGS

I. Summary of Proposed Regulations. K.A.R. 68-7-15 is being amended to allow pharmacists to dispense and repackage prescribed medications in conjunction with an ingestible event marker designed to ensure medication adherence.

II. Reason(s) the Proposed Regulation Is Required, Including Whether or Not the Regulation Is Mandated by Federal Law. The Board is amending this regulation to allow FDA-approved technology in the pharmacy setting in an effort to encourage and assist with patient medication adherence.

III. Anticipated Economic Impact on the Board. The Board does not anticipate any economic impact.
IV. Anticipated Financial Impact Upon Private Individuals or Businesses. The economic impact to patients, their prescribers, and their pharmacists is unknown. However, it is anticipated that repackaging this FDA-approved, prescribed device, with the prescribed medication may positively influence health outcomes.

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

**SHAREDSERVICES**

I. Summary of Proposed Regulations. K.A.R. 68-7-20 is being amended to require a pharmacy participating in shared services to be actively engaged in operating their pharmacy.

II. Reason(s) the Proposed Regulation Is Required, Including Whether or Not the Regulation Is Mandated by Federal Law. The Board is amending this regulation to protect the public from misrepresentation from pharmacies “in name only” that purport to fill, verify, and dispense their own prescriptions, but in actuality only operate a shell pharmacy that relies on another off-site pharmacy to perform its filling, verification, and dispensing functions, and then merely change the prescription labeling to reflect their pharmacy name. Therefore, the Board is requiring the requesting pharmacy to actively be engaged in the practice of pharmacy in order to utilize shared services.

III. Anticipated Economic Impact on the Board. Any economic impact to the Board will be the result of time and resources spent reviewing applications, complaints, and inspecting pharmacies utilizing shared services.

IV. Anticipated Financial Impact Upon Private Individuals or Businesses. Any economic impact to pharmacies would be unknown to the Board. No impact is anticipated for private individuals or other businesses.

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

**FEES**

I. Summary of Proposed Regulations. K.A.R. 68-11-2 is being amended to include application and renewal fees for new registration/permit categories including third-party logistics providers, outsourcing facilities or virtual outsourcing facilities, repackagers, and automated dispensing systems. In addition, the application and renewal fee for retail dealers is being rounded to the nearest dollar amount ($10).

II. Reason(s) the Proposed Regulation Is Required, Including Whether or Not the Regulation Is Mandated by Federal Law. The Board is amending this regulation to set fees for new registration/permit categories set forth by chapter 34, section 10 of the 2017 Kansas session laws, which was a direct response to the Federal Drug Supply Chain Security Act
(DSCSA), 21 U.S.C. 351 et seq. The Board is amending the retail dealer fee for convenience and ease of processing.

**III. Anticipated Economic Impact on the Board.** No revenue is anticipated from new fees because facilities fitting new registration/permit types are already registered with the Board under a different registration type. However, the Board will devote staff time and resources to identification of relevant facilities and notification about re-registration requirements. The Board plans to make this change during facility renewals to eliminate duplicate work and will be absorbed by current staff. Therefore, no fiscal impact is anticipated. Increasing retail dealer fees by $0.40 will increase Board revenue approximately $620 per year.

**IV. Anticipated Financial Impact Upon Private Individuals or Businesses.** As stated above, no expense is anticipated for new fees because facilities fitting new registration/permit types are already registered with the Board under a different registration type. Any impact to those facilities will be related to staff time necessary to re-register the facility when prompted by the Board. The impact for retail dealers will be $0.40 per year. No other impact on private citizens, businesses, or other entities is anticipated.

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