Proposed

State of Kansas
Board of Pharmacy

Notice of Public Hearing on Proposed Administrative Regulation

A public hearing will be conducted on Wednesday, December 11, 2024, at 8:30 a.m. at the Board of Healing Arts Conference Room on the Lower Level of 800 SW Jackson, Topeka, Kansas, to review and consider the adoption of the proposed permanent regulation 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 regulation. All interested parties may submit written comments prior to the public hearing to Alexandra Blasi, Executive Secretary, 800 SW 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 regulation 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 regulation and economic impact statement 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, 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.

A summary of the proposed regulation and its economic impact follows. Copies of the

regulation and economic impact statement may be viewed at:

www.pharmacy.ks.gov/legal/proposed-state-reg-changes.

K.A.R. 68-7-20a. Delivery of prescriptions dispensed to an alternate site for administration. The proposed regulation addresses an area of pharmacy practice that regulations have previously been silent on, but recent amendments to the Kansas Pharmacy Act regarding prescription delivery have created the need for regulatory guidance. The regulation governs several areas for public protection, including requirements for policies and procedures, notifications, drug storage during delivery, returning drugs to the originating pharmacy, and delivery time. The proposed regulation addresses the practice known as "white bagging" in the pharmacy setting. White bagging refers to the process where health insurers cover essential patient-specific medications contingent upon the medication being distributed from a third-party pharmacy to an administration site for administering. The top patient conditions for which hospitals see white bagging used are auto-immune conditions and cancer. The Board anticipates that the proposed regulation will have minor to no negative economic impact and will help prevent medication waste.

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

(a) Definitions. Each of the following terms shall have the meaning specified in this regulation:

(1) "Administering facility" means a registered administering facility or a non-registered administering facility.

(2) "Non-registered administering facility" means a facility that is not registered with the board and is authorized to administer prescription-only drugs under the direction of a practitioner or mid-level practitioner.

(3) "Registered administering facility" means a facility registered with the board that is authorized to administer prescription-only drugs pursuant to state or federal authority.

(b) Any pharmacist may fill a prescription at an originating pharmacy and cause the prescription to be delivered to an administering facility for preparation and administration to the patient.

(c) Each owner and pharmacist-in-charge of an originating pharmacy participating in drug delivery for administration under subsection (b) shall maintain and comply with a policies and procedures manual that includes the following:

(1) Maintaining and retrieving dispensing records that include the following:

(A) The manner in which the 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;

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(2) the mechanism for the administering facility to track the prescription during each stage of the delivery process;

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

(4) Ensuring accuracy, security, integrity, and accountability in the delivery process from the time the prescription leaves the originating pharmacy until the prescription is received by staff at the administering facility;

(5) Recordkeeping requirements for handling any unopened prescription medication not administered to the patient; and

(6) Informing and obtaining consent from the patient for using this dispensing and delivery process.

(d) Each owner and pharmacist-in-charge of an originating pharmacy participating in drug delivery for administration under subsection (b) shall ensure that the following requirements are met:

(1) Each prescription waiting to be picked up or in the process of being delivered to the administering facility shall be stored according to the manufacturer's requirements and relevant laws and regulations.

(2) The pharmacist responsible for filling the prescription shall meet the following requirements:

(A) Notify the administering facility of the anticipated arrival date of the shipment to the administering facility, 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;

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

(C) provide a procedure for returning to the originating pharmacy any unopened prescription medication not administered to the patient; and

(D) coordinate the preparation and delivery of the materials needed by the administering facility to administer the dispensed prescription.

(3) Each prescription shall be scheduled for delivery during the administering facility's normal business day unless otherwise agreed upon by the administering facility.

(e) Prescriptions for controlled substances shall not be delivered under this regulation unless the delivery is in compliance with state and federal law.

(f) Each owner and pharmacist-in-charge of a registered administering facility participating in drug delivery for administration under subsection (b) shall ensure each prescription waiting to be administered to the patient shall be stored according to the manufacturer's requirements and relevant laws and regulations 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 their designee.

(g) A pharmacist shall only allow a prescription to be returned to stock at either the originating pharmacy or the registered administering facility by agreement with the originating pharmacy if it meets the following requirements:

(1) The prescription was delivered to a registered administering facility pursuant to subsection (b); and

(2) the prescription is unopened, unadulterated, and was continuously maintained in

accordance with the manufacturer's requirements and relevant laws and regulations.

(h) 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. 2023 Supp. 65-1626a, K.S.A. 65-1634, K.S.A. 2023 Supp. 65-1637, K.S.A. 65-1642, and K.S.A. 2023 Supp. 65-1656; effective P-_____.)

Proposed

Kansas Administrative Regulations
Economic Impact Statement (EIS)

Kansas Board of Pharmacy	Bradford DeYoung	785-608-2722
Agency	Agency Contact	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 or more in implementation and compliance costs that are reasonably expected to be incurred by or passed along to businesses, local governmental units and individuals as a result of the proposed rule and regulation over the initial five-year period following adoption of such rule(s) and regulation(s) (as calculated in Section III, F)?

☐ Yes If "Yes," then the agency shall not adopt the rule(s) and regulation(s) until the rule(s) and regulation(s) has been ratified by the Legislature with a bill, unless the proposed rule(s) and regulation(s) are: 1) mandated by the federal government as a requirement for participating in or implementing a federally subsidized or assisted program, as described in K.S.A. 77-416(b)(1)(B), and amendments thereto; 2) temporary rule(s) and regulation(s) adopted pursuant to K.S.A. 77-722, and amendments thereto; or 3) rules and regulations adopted pursuant to K.S.A. 2-3710 (Kansas Agricultural Remediation Board). Continue to fill out the remaining EIS form to be included with the regulation packet in the review process to the Department of Administration and the Attorney General. The submitted EIS will be independently analyzed by the Division of the Budget for 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. The submitted EIS will be analyzed by the Division of the Budget for approval.

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Section I

Analysis, brief description, and cost and benefit quantification of the proposed rule(s) and regulation(s). If the approach chosen by the Kansas agency to address the policy issue is different from that utilized by agencies of contiguous states or of the federal government, the economic impact statement shall include an explanation of why the Kansas agency's rule and regulation differs.

K.A.R. 68-7-20a addresses the practice known as "white bagging" in the pharmacy setting. The top patient conditions for which hospitals see white bagging used are auto-immune conditions and cancer, both high-risk and high-burden conditions. Kansas pharmacy regulations have previously been silent on this topic, but recent amendments to the Kansas Pharmacy Act regarding prescription delivery have created the need for regulatory guidance. The Board worked with administering facilities, chain pharmacies, pharmacy benefit managers, the hospital association, the pharmacist association, and other stakeholders to draft this regulation over the course of several working meetings. In doing so, the Board identified several areas for public protection, including requirements for policies and procedures, notifications, drug storage during delivery, returning drugs to the originating pharmacy, and delivery time. Such hazards to patient safety have been reported to the Board and verified through investigation of current practices.

The Board anticipates that the proposed regulation will have no costs related to shipping, tracking packages, and ensuring delivery within normal operating hours of administering facilities. During the preliminary rulemaking process, stakeholders indicated that packages are already shipped using common carriers, and tracking is already available to the originating pharmacy. The regulation will require the originating pharmacy to share this tracking information with the administering facility – this should not have an economic impact on facilities as it can be accomplished by any means of communication within the normal course of pharmacy business. Additionally, no specific pharmacy personnel are required to perform this task, so it may be handled by non-pharmacy support staff. An originating pharmacy may employ more complex tracking mechanisms at their discretion. While engaging with stakeholders, the Board inquired about costs associated with the regulation and the feedback the Board received was that the costs were acceptable. However, no stakeholder volunteered exact cost estimates even after being asked.

The Board also anticipates that the proposed regulation will have no costs related to originating pharmacies maintaining policies and procedures that ensure the accuracy, security, integrity, and accountability in the delivery process from the time the prescription leaves the originating pharmacy until the prescription is received by staff at the administering facility. The Board anticipates that this requirement will reduce overall drug waste. In a survey completed by the Kansas Hospital Association, hospital pharmacy respondents indicated white bagging medications can be shipped to their pharmacies as low as 1-3 times per year or as frequently as 1-3 times per week. White bagging medications are used for a myriad of conditions, including auto-immune, cancer, blood and brain disorders, and asthma. Almost 50% of responding pharmacists indicated they have had to dispose of medications received through white bagging, resulting in significant waste. The Pharmaceutical Care Management Association provided the Board with a report from The Moran Company from 2018 which identified a significant mark-up on prescription drugs provided by hospitals above those of specialty pharmacies through white bagging. Therefore, ensuring a safe and effective process for white bagging should help eliminate unnecessary waste, risks associated with mismanaged medications, and additional costs to patients and payors (including Medicare and Medicaid) from replaced medications.

The Board is aware that past prescription waste related to these expensive medications has ranged from $10,000 - 100,000+ annually per administering facility. The Board anticipates that additional benefits include greater patient safety and providing greater transparency in the prescription delivery and administration process for originating pharmacies, administering facilities, and patients.

Section II

Explain whether the proposed rule and regulation is mandated by federal law as a requirement for participating in or implementing a federally subsidized or assisted program and whether the proposed rules and regulations exceed the requirements of applicable federal law.

Regulation is not mandated by the federal government.

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 restriction on current business activities. Previous regulation drafts on this topic elicited comments from stakeholders suggesting prior language created a "de facto ban on the practice of white bagging." As that was never the Board's intention, the Board specifically worked with stakeholders to craft a careful balance of regulatory requirements aimed at minimizing cost and regulatory burden, while decreasing the significant risk to patients and prescription waste from past complaints and practices. As a result, the current proposed regulation will not act as a "de facto ban on the practice of white bagging."

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 will be affected by the proposed rule(s) and regulation(s) and on the state economy as a whole;

Based on pharmacy stakeholder feedback, the Board anticipates that the regulation's costs will be absorbed into existing pharmacy operations and will not incur additional separate costs. During meetings with administering facilities, chain pharmacies, pharmacy benefit managers, the hospital association, the pharmacist association, and other stakeholders, the Board was able to gain glimpses into how much a "wasted" drug could cost; however, the Board was not provided with any short term or long term projected costs for the proposed regulation as it is currently written. The proposed language creates new requirements for the practice of delivering prescription medications to an administering facility for direct administration to the patient. Additionally, the proposed regulation does not require pharmacies or administering facilities to participate in this practice. Pharmacies that do wish to participate already have the capacity to comply as they are closely aligned with routine prescription dispensing practices.

The Board also narrowly tailored the regulation to only those facilities under the jurisdiction of the Board of Pharmacy. Therefore, this regulation will have no impact on any facility or practitioner not registered with the Board (i.e., practitioner office, physician, infusion center, etc.).

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

Pharmacies and medical care facilities (e.g., hospitals). Specifically, only facilities registered with the Board that are authorized to dispense or administer prescription-only drugs pursuant to state or federal authority.

Specialty pharmacies located in Kansas: 3

Specialty pharmacies outside of Kansas shipping into Kansas: 15
Administering facilities located in Kansas: ~180

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

The Board anticipates that benefits include ensuring that prescriptions are delivered safely and directly to appropriate facilities that may administer the prescription to the patient in a timely and safe manner. Additionally, transparency in the process of delivering prescription medications required to be administered to patients in a medical care setting is imperative and requires regulatory oversight to ensure patient safety. Unlike oral medications, medications compounded and prepared for administration directly into the human body are more volatile and have a much higher risk for the patient if not handled and stored correctly.

The Board is aware that in 2023 many administering facilities stopped accepting delivery of prescriptions for administration altogether due to patient safety concerns, prescription waste, and lack of regulatory oversight. With the proposed regulation, facilities that previously stopped participating indicated they may be able to reengage in this practice. If administering facilities refuse to accept these medications for patient administration, patients will be required to travel further distances from their home and/or away from their regular healthcare provider community to receive medication; a net negative to patient care and access to care.

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 hosted multiple meetings and requested feedback from the aforementioned stakeholders prior to moving the proposed regulation through the administrative rule making process. Meetings were open for participation from anyone in attendance. This resulted in the proposed regulation taking a substantially different form than the 2023 proposed version. The proposed version of the regulation has the support of all participating stakeholders. The information the Board has received indicates that the regulation provides minor adjustments to existing pharmacy practices but substantial benefit.

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 individuals. *Note: Do not account for any actual or estimated cost savings that may be realized. Implementation and compliance costs determined shall be those additional costs reasonably expected to be incurred and shall be separately identified for the affected businesses, local governmental units, and individuals.*

Costs to Affected Businesses – $0

Costs to Local Governmental Units – $0

Costs to Individuals – $0

Total Annual Costs – $0
(sum of above amounts)

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

The Kansas Board of Pharmacy reviewed the proposed regulation with the aforementioned stakeholders before moving the regulations through the administrative rule making process. The Kansas Board of Pharmacy requested that each stakeholder provide a cost estimates for implementation of the regulation. No cost estimates were provided.

☐ Yes
☐ No
☒ Not Applicable

If the total implementation and compliance costs exceed $1.0 million or more in implementation and compliance costs over the initial five-year period following adoption of such rule(s) and regulation(s) that are reasonably expected to be incurred by or passed along to businesses, local governmental units and individuals as a result of the proposed rule and regulation, 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.

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 are no anticipated changes in state revenue or expenditures as a result of the adoption of the regulations. There are no anticipated revenues or expenditures to special revenue funds (including the Pharmacy Fee Fund).

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.

The Board anticipates that there will be no economic impact on small employers (independent pharmacies) or large employers (PBMs, specialty chain pharmacies, and medical care facilities (hospitals)).

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.

The amendment will have no effect on cities, counties, or school districts.

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

The Kansas Board of Pharmacy met with and reviewed the proposed regulation with the aforementioned stakeholders multiple times before moving the regulations through the administrative rule making process. The Kansas Board of Pharmacy requests that each stakeholder provides a cost estimate for the regulation. At this time, the Board has not received any short term or long term cost estimates from this regulation. The information the Board has received indicates that the any costs will be absorbed by the pharmacy in the regular course of business.

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 individuals or entities who would bear the costs.

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 individuals who will bear the costs.

C. Describe the costs that would likely accrue if the proposed rule(s) and regulation(s) are not adopted, the individuals or entities who will bear the costs and who will be affected by the failure to adopt the rule(s) and regulation(s).

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

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