Proposed

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

A public hearing will be conducted on Tuesday, November 27, 2018 at 1:00 p.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-

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regs/proposed-reg-changes.

**K.A.R. 68-13-1.** This regulation is being considered for revocation as the result of recent Board adoption of three new regulations governing sterile and non-sterile compounding in Kansas (KAR 68-13-2, 68-13-3, and 68-13-4). This regulation is now outdated and moot.

**K.A.R. 68-7-10. Pharmacy-based drug distribution systems in long-term care facilities; emergency mediciation kits.** This regulation is being amended to align definitions with statutory changes and allow nurses and other healing arts professionals to access automated drug delivery systems in long-term care facilities for administration of medications to patients consistent with their respective practice acts.

**K.A.R. 68-9-2. Automated drug delivery systems in pharmacies.** This regulation is being amended to align definitions with statutory changes, allow for manual overrides when systems are jammed, blocked, or malfunctioning, and allow nurses to access automated drug delivery systems for administration of medications to patients consistent with their practice act.

**K.A.R. 68-9-3. Automated drug delivery system to supply drugs for administration in certain facilities.** This regulation is being amended to align definitions with statutory changes and allow nurses and other healing arts professionals to access automated drug delivery systems in medical care facilities for administration of medications to patients consistent with their respective practice acts. In addition, the regulation is being amended to clarify the types of nursing facilities that may utilize automated drug delivery systems.

**K.A.R. 68-2-23. Notification to board; disciplinary action.** This is a new regulation that would require each owner of a Kansas-registered pharmacy to notify the board within 30 days of any denial, limitation, suspension, revocation, voluntary surrender, or other disciplinary action taken by the state of Kansas or another jurisdiction against the pharmacy, the pharmacy owner, or any application, license, registration, or permit held by the pharmacy owner.

**K.A.R. 68-7-25. Notification to board; pharmacist, pharmacy technician, or pharmacy intern.** This is a new regulation that would require either the pharmacist-in-charge or the owner of any Kansas-registered pharmacy to notify the board in writing within one day of any suspected diversion, theft, or loss of any controlled substance and provide a copy of the completed DEA-106 form.

**K.A.R. 68-20-15b. Notification to board; suspected diversion, theft, or loss of controlled substances.** This is a new regulation that would require each pharmacist, pharmacy technician, and pharmacy student to notify the board within 30 days of any criminal arrest, charge, or conviction rationally related to drugs or the practice of pharmacy, or any denial, limitation, suspension, revocation, voluntary surrender, or other disciplinary action taken by the state of Kansas or another jurisdiction against any professional or occupational application, license, registration, or permit held by the individual.

## 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.

Automation: The Board anticipates minimal economic impact to the Board, its licensees and registrants, or Kansas-registered pharamcies. Amendments will enhance business activities by allowing all healthcare practitioners to operate under the full scope of their practice act. Failure to amend the regulation could result in significant costs to establishments because personnel would be required to acquire additional training and registration. 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.

Compounding: No economic impact.

Reporting requirements: The Board anticipates minimal economic impact to the Board, its licensees and registrants, or Kansas-registered pharamcies. Many licensees and registrants are already engaging in these practices. 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. In the event of a loss or suspected theft/diversion, the Board may initiate an investigation for which the resources necessary would be difficult to estimate. Benefits to the public are significant in allowing the Board more timely notification of situations that may constitute a violation of the Kansas pharmacy practice act or the controlled substance act.

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

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**68-2-23. Notification to board; disciplinary action.** Each pharmacy owner shall notify the board in writing within 30 days of any denial, limitation, suspension, revocation, voluntary surrender, or other disciplinary action taken by the state of Kansas or another jurisdiction against the pharmacy or the pharmacy owner or any application, license, registration, or permit held by the pharmacy owner. (Authorized by K.S.A. 65-1630; implementing K.S.A. 2017 Supp. 65-1627; effective P-_____.)

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**68-7-10. Pharmacy-based drug distribution systems in long-term care facilities; emergency medication kits.** (a) Each of the following terms, as used in this regulation, shall have the meaning specified in this subsection:

(1) "Automated drug delivery system" means an automated dispensing system, as defined by K.S.A. 2017 Supp. 65-1626 and amendments thereto, that is located in a long-term care facility, uses a robotic, mechanical, or computerized device ~~that is used~~ to supply ~~drugs for administration~~ each drug to an individual licensed by the board of healing arts or the board of nursing, who shall administer the drug to a patient, and meets the requirements of K.A.R. 68-9-3.

(2) "Formulary" means a prescription drug list approved by the pharmacy and therapeutics committee or an equivalent committee governing the security, control, and distribution of drugs within a long-term care facility.

(3) "Long-term care facility" means "nursing facility," as defined in K.S.A. 39-923 and amendments thereto.

(4) "Traditional system" means a drug distribution system in which the pharmacist receives a prescription order for an individual patient and fills the prescription in any manner other than packaging individual doses in unit-dose containers.

(5) "Unit-dose container" means a single-unit or multiple-unit container for articles intended for administration in single doses and directly from the container, by other than parenteral route.

(A) "Multiple-unit container" means a container that permits the withdrawal of successive portions of the contents without changing the strength, quality, or purity of the remaining portion.

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(B) "Single-unit container" means a container that is designed to hold a quantity of a drug intended for administration as a single dose promptly after the container is opened.

(6) "Unit-dose system" means a drug distribution system that is pharmacy-based and uses unit-dose containers that enable distribution of packaged doses in a manner that preserves the identity of the drug until the time of administration.

(b) Each pharmacy-based drug distribution system for a long-term care facility shall meet the following requirements:

(1) Be consistent with the medication needs of each patient;

(2) conform to all federal and state laws and regulations pertaining to pharmacies; and

(3) meet the following additional requirements:

(A) Each prescription shall be dispensed from a pharmacy within a time period that reasonably meets the needs of the patient, considering the following factors:

(i) The need for the drug as an emergency;

(ii) the availability of the drug;

(iii) the pharmacy's hours of operation; and

(iv) the stability of the drug;

(B) the supplying pharmacy shall be responsible for the safe delivery of drugs to a designated person or persons in the long-term care facility;

(C) the supplying pharmacy shall provide a method of identifying the date and quantity of medication dispensed;

(D) a patient medication profile record system shall be maintained for each long-term care facility patient serviced by the supplying pharmacy and shall contain the information necessary

to allow the pharmacist to monitor each patient's drug therapy; and

(E) each medication distribution system container shall be labeled to permit the identification of the drug therapy.

(c) Each unit-dose system shall meet the following requirements, in addition to the requirements in subsection (b):

(1) All medication shall be packaged in unit-dose containers as far as practicable and the packaging shall meet the requirements of K.A.R. 68-7-15 and 68-7-16, unless the manufacturer specifies a different type of packaging to be used to prevent adulteration as defined by K.S.A. 65-668, and amendments thereto.

(2) The pharmacist shall be responsible for filling and refilling prescriptions or prescriber's orders, or both, according to the directions of the prescriber by relying on the original prescription or prescriber's order or a copy thereof.

(3) The pharmacist shall comply with all requirements for prescription orders, including inventory and recordkeeping requirements, under the following:

(A) The Kansas uniform controlled substances act, K.S.A. 65-4101 et seq. and amendments thereto;

(B) the Kansas pharmacy act, K.S.A. 65-1625 et seq. and amendments thereto;

(C) the board's applicable regulations in articles 1 and 20; and

(D) all federal laws and regulations applicable to prescriptions or medication orders.

(4) Packaging for the unit-dose ~~dispensing~~ system shall take place at the address of the pharmacy providing the unit-dose system.

(5) Container requirements for unit-dose systems may include trays, bins, carts, and locked

cabinets if the requirements of K.A.R. 68-7-14 are met. If these options are used, all patient medication trays or drawers shall be sufficiently labeled to identify each patient.

(6) Each unit-dose system shall provide a verification check at the point of patient administration in order to ensure proper drug utilization.

(7) The delivery time-cycle or hours of exchange shall not be limited to a specific time, but shall depend upon the pharmacist's discretion, the needs of the long-term care facility, the stability of the drug, and the type of container used.

(8) The pharmacist shall have sole responsibility for dispensing under the unit-dose system.

(d)(1) Each emergency medication kit shall contain only the drugs that are generally regarded by practitioners as essential to the prompt treatment of sudden and unforeseen changes in a patient's condition that present an imminent threat to the patient's life or well-being.

(2) Each drug to be contained within an emergency medication kit shall be approved by the long-term care facility's pharmaceutical services committee or its equivalent, either of which shall be composed of at least a practitioner and a pharmacist.

(3) The pharmacist providing each emergency medication kit shall ensure that the following requirements are met:

(A) The kit shall be supplied by a pharmacist, who shall retain possession of the drug until it is administered to the patient upon the valid order of a prescriber.

(B) If the kit is not in an automated drug delivery system, the kit shall be locked or sealed in a manner that indicates when the kit has been opened or tampered with.

(C) The kit shall be securely locked in a sufficiently well-constructed cabinet or cart or in an automated drug delivery system, with drugs properly stored according to the manufacturer's

recommendations. Access to the cabinet or cart shall be available only to each nurse specified by the pharmaceutical services committee or its equivalent.

(D) The kit shall have an expiration date equivalent to the earliest expiration date of the drugs within the kit, but in no event more than one year after all of the drugs were placed in the kit.

(E) Unless the kit is in an automated drug delivery system, all drugs contained within the emergency medication kit shall be returned to the pharmacy as soon as the kit has been opened, along with the prescriber's drug order for medications administered. (Authorized by K.S.A. 65-1630; implementing K.S.A. ~~2015~~ 2017 Supp. 65-1637, K.S.A. ~~2015~~ 2017 Supp. 65-1642, and K.S.A. 2017 Supp. 65-1648; effective May 1, 1978; amended May 1, 1983; amended Sept. 9, 1991; amended Aug. 19, 2016; amended P- _____.)

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**68-7-25. Notification to board; pharmacist, pharmacy technician, or pharmacy intern.** Each pharmacist, pharmacy technician, and pharmacy intern shall notify the board in writing of any of the following circumstances within 30 days of the date of occurrence:

(a) Any conduct resulting in a charge of, arrest or indictment for, plea of guilty or no contest to, diversion agreement, or suspended imposition of sentence against the registrant or licensee that would constitute any of the following:

(1) Unprofessional conduct as defined by K.S.A. 65-1626, and amendments thereto;

(2) a violation of the federal or state food, drug, and cosmetic act; or

(3) a violation of the Kansas uniform controlled substances act;

(b) any conviction of any felony against the registrant or licensee; or

(c) any denial, limitation, suspension, revocation, voluntary surrender, or other disciplinary action taken by another jurisdiction against any pharmacy, pharmacist, pharmacy intern, or pharmacy technician application, license, registration, or permit held by the registrant or licensee. (Authorized by K.S.A. 65-1630; implementing K.S.A. 2017 Supp. 65-1626, 65-1627, 65-1663, and 65-1676; effective P-_____.)

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**68-9-2. Automated drug delivery systems in pharmacies.** (a) For purposes of this regulation, "automated drug delivery system" shall mean an automated dispensing system, as defined by K.S.A. 65-1626 and amendments thereto, that is located in a Kansas pharmacy and uses a robotic, mechanical, or computerized device ~~located in a Kansas pharmacy that performs~~ to perform operations or activities other than compounding or administration, involving the storage, packaging, or labeling of, or any other step before dispensing, drugs. Each prescription medication prepared by an automated drug delivery system shall be verified and documented by a Kansas-licensed pharmacist as part of the dispensing process.

(b) A pharmacist-in-charge of any licensed pharmacy, licensed health care facility, or other location that is required to be supervised by a pharmacist-in-charge and that uses an automated drug delivery system shall perform the following before allowing the automated drug delivery system to be used:

(1) Ensure that the automated drug delivery system is in good working order and accurately selects the correct strength, dosage form, and quantity of the drug prescribed while maintaining appropriate recordkeeping and security safeguards;

(2) ensure that the automated drug delivery system has a mechanism for securing and accounting for all drugs removed from and subsequently returned to the system;

(3) ensure that the automated drug delivery system has a mechanism for securing and accounting for all wasted or discarded drugs, including a manual override for the pharmacist, pharmacy intern, or pharmacy technician to clear a jammed, blocked, or malfunctioning automated drug delivery system;

(4) ensure compliance with an ongoing continuous quality improvement program pursuant

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to K.S.A. 65-1695, and amendments thereto, or a risk management program that monitors total system performance and includes the requirement for accuracy in the drug and strength delivered;

(5) ensure that the automated drug delivery system is loaded accurately and according to the original manufacturer's storage requirements;

(6) approve and implement an operational policy that limits the personnel responsible for the loading and unloading of drugs to or from the automated drug delivery system to any of the following:

(A) A Kansas-licensed pharmacist;

(B) a Kansas-registered pharmacy intern; ~~or~~

(C) a Kansas-registered pharmacy technician; or

(D) a nurse with a license issued pursuant to K.S.A. 65-1115, and amendments thereto;

(7) at the location of the automated drug delivery system, maintain a current list of those approved individuals who are authorized to unload any drug from the automated drug delivery system;

(8) approve and implement security measures that meet the requirements of all applicable state and federal laws and regulations in order to prevent unauthorized individuals from accessing or obtaining drugs;

(9) preapprove all individuals who are authorized to unload any drug from the automated drug delivery system;

(10) ensure that all drugs loaded in the automated drug delivery system are packaged in the manufacturer's ~~sealed~~ original packaging or in repackaged containers, in compliance with

K.A.R. 68-7-15 and K.A.R. 68-7-16, or in containers with the lot number and expiration date tracked by the automated drug delivery system;

(11) provide the board with prior written notice of the installation or removal of the automated drug delivery system; and

(12) ensure that a system of preventive maintenance and sanitation for the automated drug delivery system is established and followed. (Authorized by K.S.A. 65-1630; implementing K.S.A. ~~2015~~ 2017 Supp. 65-1637 and 65-1642; effective July 6, 2001; amended Feb. 7, 2003; amended Aug. 19, 2016; amended P- _____.)

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**68-9-3. Automated drug delivery system to supply drugs for administration in certain facilities.** (a) Each of the following terms, as used in this regulation, shall have the meaning specified in this subsection:

(1) "Automated drug delivery system" means an automated dispensing system, as defined by K.S.A. 2017 Supp. 65-1626 and amendments thereto, that is located in a facility outside of a managing pharmacy and uses a robotic, mechanical, or computerized device ~~that is used in a facility outside of a pharmacy for supplying drugs for administration~~ to supply each drug to an individual licensed by the board of healing arts or the board of nursing, who shall administer the drug to a patient.

(2) "Facility" means any of the following:

(A) A medical care facility, as defined in K.S.A. 65-1626 and amendments thereto;

(B) an institutional drug room, as defined in K.S.A. 65-1626 and amendments thereto; or

(C) a long-term care facility, which shall mean any of the following:

(i) A nursing facility, as defined in K.S.A. 39-923 and amendments thereto;

(ii) a nursing facility for mental health, as defined in K.S.A. 39-923 and amendments thereto; or

(iii) any other type of adult care home, as defined in K.S.A. 39-923 and amendments thereto, that is not specified in paragraphs (a)(2)(C)(i) and (ii) and, after submitting an application, is approved by the board for an automated drug delivery system.

(3) "Managing pharmacy" means a pharmacy located in Kansas.

(4) "Pharmacist-in-charge" means the pharmacist-in-charge of the managing pharmacy.

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(b) Before the initial stocking and use of an automated drug delivery system to supply drugs for administration, the pharmacist-in-charge shall meet the following requirements:

(1) Provide the board with at least 14-day prior written notice, on a form provided by the board; and

(2) ensure that all necessary licenses, registrations, and authorizations, including a drug enforcement administration registration if supplying controlled substances, have been obtained.

(c) The pharmacist-in-charge shall consult with the pharmacy and therapeutics committee or an equivalent committee in establishing the criteria and process for determining a formulary of approved drugs that may be stored in the automated drug delivery system.

(d) A bar code verification, electronic verification, or similar verification process shall be utilized to ensure the correct selection of drugs placed or to be placed into each automated drug delivery system. The utilization of a bar code, electronic verification, or similar verification process shall require an initial quality assurance validation, followed by a quarterly assurance review by a pharmacist.

(e) The pharmacist-in-charge shall ensure that a policy exists requiring that if, at the time of loading any controlled substance, a discrepancy in the count of that drug in the automated drug delivery system exists, the discrepancy is immediately reported to the pharmacist-in-charge.

Whenever the pharmacist-in-charge becomes aware of a discrepancy regarding the count of a controlled substance in the automated drug delivery system, the pharmacist-in-charge shall be responsible for reconciliation of the discrepancy or proper reporting of the loss.

(f) The pharmacist-in-charge shall be responsible for the following:

(1) Controlling access to the automated drug delivery system;

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(2) maintaining policies and procedures for the following:

(A) Operating the automated drug delivery system;

(B) providing prior training and authorization of personnel who are authorized to remove any drug from the automated drug delivery system;

(C) maintaining, at the location of the automated drug delivery system, a list of those individuals who are authorized to remove any drug from the automated drug delivery system;

(D) maintaining patient services whenever the automated drug delivery system is not operating; and

(E) defining a procedure for a pharmacist to grant access to the drugs in the automated drug delivery system;

(3) securing the automated drug delivery system;

(4) ensuring that each patient receives the pharmacy services necessary for appropriate pharmaceutical care;

(5) ensuring that the automated drug delivery system maintains the integrity of the information in the system and protects patient confidentiality;

(6) ensuring compliance with all requirements for packaging and labeling each medication pursuant to K.A.R. 68-7-15 and K.A.R. 68-7-16, unless the medication is already packaged in the manufacturer's ~~sealed~~ original container or in repackaged containers;

(7) ensuring that a system of preventive maintenance and sanitation exists and is implemented for the automated drug delivery system;

(8) ensuring that a policy exists for securing and accounting for all drugs that are wasted or discarded from the automated drug delivery system;

(9) ensuring that inspections are conducted and documented at least monthly to ensure the accuracy of the contents of the automated drug delivery system; and

(10) ensuring the accurate loading and unloading of the automated drug delivery system by approving and implementing an operational policy that limits the personnel responsible for the loading and unloading of the automated drug delivery system to a Kansas-licensed pharmacist or ~~either~~ any of the following, each of whom shall be under the supervision of a Kansas-licensed pharmacist:

(A) A Kansas-registered pharmacy intern; ~~or~~

(B) a Kansas-registered pharmacy technician; or

(C) a nurse with a license issued pursuant to K.S.A. 65-1115, and amendments thereto.

(g) A pharmacist shall comply with the medication order review and verification requirements specified in K.A.R. 68-7-11.

(h) Except in the event of a sudden and unforeseen change in a patient's condition that presents an imminent threat to the patient's life or well-being, any authorized individual at a facility may distribute patient-specific drugs utilizing an automated drug delivery system without verifying each individual drug selected or packaged by the automated drug delivery system only if both of the following conditions are met:

(1) The initial medication order has been reviewed and approved by a pharmacist.

(2) The drug is distributed for subsequent administration by a health care professional permitted by Kansas law to administer drugs.

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(i) The pharmacist-in-charge shall be responsible for establishing a continuous quality improvement program for the automated drug delivery system. This program shall include written procedures for the following:

(1) Investigation of any medication error related to drugs supplied or packaged by the automated drug delivery system;

(2) review of any discrepancy or transaction reports and identification of patterns of inappropriate use of or access to the automated drug delivery system; and

(3) review of the operation of the automated drug delivery system.

(j) The pharmacist-in-charge shall ensure that the managing pharmacy maintains, in a readily retrievable manner and for at least five years, the following records related to the automated drug delivery system:

(1) Transaction records for all drugs or devices supplied by the automated drug delivery system; and

(2) any report or analysis generated as part of the continuous quality improvement program.

(k) A Kansas-registered pharmacy technician ~~or~~, a Kansas-registered pharmacy intern, or a nurse with a license issued pursuant to K.S.A. 65-1115, and amendments thereto, who the pharmacist-in-charge has determined is properly trained may be authorized by that pharmacist-in-charge to perform the functions of loading and unloading an automated drug delivery system utilizing a bar code verification, electronic verification, or similar verification process as specified in subsection (d).

(l) If any drug has been removed from the automated drug delivery system, that drug shall not be replaced into the automated drug delivery system unless either of the following conditions is met:

(1) The drug's purity, packaging, and labeling have been examined according to policies and procedures established by the pharmacist-in-charge to determine that the reuse of the drug is appropriate.

(2) The drug is one of the specific drugs, including multidose vials, that have been exempted by the pharmacy and therapeutics committee or an equivalent committee.

(m) Upon the removal of any automated drug delivery system, the pharmacist-in-charge shall provide the board with notification, on a form provided by the board. (Authorized by K.S.A. 65-1630; implementing K.S.A. ~~2015~~ 2017 Supp. 65-1637, ~~K.S.A. 2015 Supp.~~ 65-1642, and ~~K.S.A.~~ 65-1648; effective Aug. 19, 2016; amended P-_____.)

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**68-13-1.** (Authorized by K.S.A. 65-1630; implementing K.S.A. 2001 Supp. 65-1642; effective May 1, 1988; amended Feb. 7, 2003; revoked P- _____.)

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**68-20-15b. Notification to board; suspected diversion, theft, or loss of controlled substances.** Either the pharmacist-in-charge or the pharmacy owner shall notify the board in writing within one day of any suspected diversion, theft, or loss of any controlled substance and, upon completion, shall provide the board with a copy of the completed DEA 106 form issued by the U.S. department of justice. (Authorized by K.S.A. 2017 Supp. 65-4102; implementing K.S.A. 65-4117; effective P-_____.)

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# Kansas Administrative Regulations
# Economic Impact Statement
# For the Kansas Division of the Budget

| Kansas Board of Pharmacy | Alexandra Blasi | 785-296-8419 |
|---|---|---|
| Agency | Agency Contact | Contact Phone Number |

68-2-23, 68-20-15b, 68-7-25
K.A.R. Number(s)

Submit a hard copy of the proposed rule(s) and regulation(s) and any external documents that the proposed rule(s) and regulation(s) would adopt, along with the following to: Division of the Budget
900 SW Jackson, Room 504-N
Topeka, KS 66612

## I. Brief description of the proposed rule(s) and regulation(s).

K.A.R. 68-2-23 is a new regulation that would require each owner of a Kansas-registered pharmacy to notify the board within 30 days of any denial, limitation, suspension, revocation, voluntary surrender, or other disciplinary action taken by the state of Kansas or another jurisdiction against the pharmacy, the pharmacy owner, or any application, license, registration, or permit held by the pharmacy owner.

K.A.R. 68-20-15b is a new regulation that would require either the pharmacist-in-charge or the owner of any Kansas-registered pharmacy to notify the board in writing within one day of any suspected diversion, theft, or loss of any controlled substance and provide a copy of the completed DEA-106 form.

K.A.R. 68-7-25 is a new regulation that would require each pharmacist, pharmacy technician, and pharmacy student to notify the board within 30 days of any criminal arrest, charge, or conviction rationally related to drugs or the practice of pharmacy, or any denial, limitation, suspension, revocation, voluntary surrender, or other disciplinary action taken by the state of Kansas or another jurisdiction against any professional or occupational application, license, registration, or permit held by the individual.

## II. Statement by the agency if the rule(s) and regulation(s) is mandated by the federal government and a statement if approach chosen to address the policy issue is different from that utilized by agencies of contiguous states or the federal government. *(If the approach is different, then include a statement of why the Kansas rule and regulation proposed is different)*

The regulations are not mandated by the federal government. This approach is consistent with notification requirements for the majority of state boards of pharmacy, the National Association of Boards of Pharmacy model act, and other Kansas regulatory agencies.

## III. Agency analysis specifically addressing following:

### A. The extent to which the rule(s) and regulation(s) will enhance or restrict business activities and growth;

The regulations should not have any impact on business growth. Pharmacy activities may be impacted slightly by the notification requirements associated with the facilities, but only if the triggering factual scenarios occur. Impact is very minor.

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**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 would be affected by the proposed rule and regulation and on the state economy as a whole;**

Pharmacies may elect to update policy and procedure manuals or create a standardized format for reporting to the Board. Costs would be limited to the staff time associated with generating the required reports to the Board and responding to any resulting investigation initiated by the Board.

In the event of a loss or suspected theft/diversion of a controlled substance, the Board may initiate an investigation which may include an on-site inspection of the facility and its records. This may generate costs for the pharmacy in the form of staff time, but costs are difficult to estimate because they can vary greatly depending on the facts. Ultimately, a minor loss is unlikely to result in financial impact, whereas a major diversion of controlled substances could include a lengthy investigation and potential disciplinary action, including a fine of up to $5,000 per violation of the pharmacy practice act.

No other economic impact is anticipated.

**C. Businesses that would be directly affected by the proposed rule and regulation;**

Pharmacies, Hospitals, and other facilities that employ licensed pharmacists and registered students or technicians.

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

The benefit is significant because these regulations allow the Board to receive more timely notification of situations that may constitute a violation of the Kansas pharmacy practice act or the controlled substance act. Currently, the Board only receives information at the time of renewal unless the individual or facility elects to notify the Board. By receiving more timely notification, the Board can investigate and initiate necessary disciplinary action sooner, thereby more readily protecting Kansas citizens.

**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;**

K.A.R. 68-2-23 and 68-7-25 allow 30 days for notification to the Board. This is longer than some agencies (10-15 days) and provides a more reasonable timetable for licensees.

K.A.R. 68-20-15b requires an immediate notification to the Board, but then allows time for the pharmacy to complete their investigation into the suspected theft, loss, or diversion and merely provide a copy to the Kansas Board of the document already prepared for the federal government (DEA-106). This avoids duplication of efforts.

**F. An estimate, expressed as a total dollar figure, of the total annual implementation and compliance costs that are reasonably expected to be incurred by or passed along to business, local governments, or members of the public.**

$0

Proposed

**An estimate, expressed as a total dollar figure, of the total implementation and compliance costs that are reasonably expected to be incurred by or passed along to business, local governments, or members of the public.**

$0

**Do the above total implementation and compliance costs exceed $3.0 million over any two-year period?**

YES ☐ NO ☒

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

Many pharmacies and licensees are already engaged in this practice to comply with other state and federal laws. Costs of implementation are negligible because of the current tracking systems and requirements already in existence in pharmacies. Free options are available to licensees for notification to the Board (email, fax, in person).

**Prior to the submission or resubmission of the proposed rule(s) and regulation(s), did the agency hold a public hearing if the total implementation and compliance costs exceed $3.0 million over any two-year period 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.**

YES ☐ NO ☒

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.**

No impact.

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

The Board consulted other state boards of pharmacy, other Kansas regulatory boards, and the National Association of Boards of Pharmacy to craft these requirements. Board staff (licensed pharmacists) also reviewed the requirements. No public impact is anticipated.

I. **For environmental rule(s) and regulation(s) describe the costs that would likely accrue if the proposed rule(s) and regulation(s) are not adopted, as well as the persons would bear the costs and would be affected by the failure to adopt the rule(s) and regulation(s).**

Not environmental.

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Division of the Budget

Proposed

# Kansas Administrative Regulations
# Economic Impact Statement
# For the Kansas Division of the Budget

| Kansas Board of Pharmacy | Alexandra Blasi | 785-296-8419 |
|---|---|---|
| Agency | Agency Contact | Contact Phone Number |

68-7-10, 68-9-2, 68-9-3
K.A.R. Number(s)

Submit a hard copy of the proposed rule(s) and regulation(s) and any external documents that the proposed rule(s) and regulation(s) would adopt, along with the following to: Division of the Budget
900 SW Jackson, Room 504-N
Topeka, KS 66612

**I. Brief description of the proposed rule(s) and regulation(s).**

KAR 68-7-10 is being amended to align definitions with statutory changes and allow nurses and other healing arts professionals to access automated drug delivery systems in long-term care facilities for administration of medications to patients consistent with their respective practice acts.

K.A.R. 68-9-2 is being amended to align definitions with statutory changes, allow for manual overrides when systems are jammed, blocked, or malfunctioning, and allow nurses to access automated drug delivery systems for administration of medications to patients consistent with their practice act.

K.A.R. 68-9-3 is being amended to align definitions with statutory changes and allow nurses and other healing arts professionals to access automated drug delivery systems in medical care facilities for administration of medications to patients consistent with their respective practice acts. In addition, the regulation is being amended to clarify the types of nursing facilities that may utilize automated drug delivery systems.

**II. Statement by the agency if the rule(s) and regulation(s) is mandated by the federal government and a statement if approach chosen to address the policy issue is different from that utilized by agencies of contiguous states or the federal government.** ***(If the approach is different, then include a statement of why the Kansas rule and regulation proposed is different)***

The content of these regulations are not mandated by the federal government. This approach is consistent with other states and this language was inadvertently omitted from the previously adopted version (2016). Access for these individuals is consistent with their respective practice acts and standard of practice. Such changes are made in consultation with the respective regulatory agencies.

**III. Agency analysis specifically addressing following:**

**A. The extent to which the rule(s) and regulation(s) will enhance or restrict business activities and growth;**

Amendments will enhance business activities by allowing all licensed and registered healthcare practitioners to operate under the full scope of their practice act without unnecessary or inadvertent limitations with regard to automated dispensing machines in healthcare facilities.

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**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 would be affected by the proposed rule and regulation and on the state economy as a whole;**

No economic impact. Amendments are consistent with current standards of practice and within the existing scope of other Kansas practice acts.

**C. Businesses that would be directly affected by the proposed rule and regulation;**

Long-term care facilities, pharmacies, and medical care facilities.

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

Amendments will allow nurses and other named healthcare personnel to access automated dispensing systems consistent with current standards of practice. Failure to amend the regulation would result in significant costs to establishments because personnel would be required to acquire additional training and registration as a pharmacy technician with the Board of Pharmacy to access such systems ($20 per 2-yr registration, cost of completing 20 hours continuing education each biennial renewal period, and passage of the pharmacy technician certification exam), or facilities would be forced to hire additional workers to complete these tasks – pharmacists, pharmacy students, or pharmacy technicians.

**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;**

None – no cost in implementing regulation amendments.

**F. An estimate, expressed as a total dollar figure, of the total annual implementation and compliance costs that are reasonably expected to be incurred by or passed along to business, local governments, or members of the public.**

$0

**An estimate, expressed as a total dollar figure, of the total implementation and compliance costs that are reasonably expected to be incurred by or passed along to business, local governments, or members of the public.**

$0

**Do the above total implementation and compliance costs exceed $3.0 million over any two-year period?**

YES ☐ NO ☒

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

Amendments are consistent with current practices. No costs. Any impact from these amendments is expected to positively impact patients and facilities.

**Prior to the submission or resubmission of the proposed rule(s) and regulation(s), did the agency hold a public hearing if the total implementation and compliance costs exceed $3.0 million over any two-year period 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.**

YES ☐ NO ☒

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.**

No such impact.

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

The Board utilized its pharmacy technician/rural nurse task force composed of pharmacists, pharmacy technicians, and nurses from all over the state in addition to representatives from the relevant Kansas regulatory agencies. The task force met three different times to discuss and consider these changes. The Board also reviewed and discussed the draft amendments.

I. **For environmental rule(s) and regulation(s) describe the costs that would likely accrue if the proposed rule(s) and regulation(s) are not adopted, as well as the persons would bear the costs and would be affected by the failure to adopt the rule(s) and regulation(s).**

Not an environmental rule/reg.

# Kansas Administrative Regulations
# Economic Impact Statement
# For the Kansas Division of the Budget

Proposed

| Kansas Board of Pharmacy | Alexandra Blasi | 785-296-8419 |
|---|---|---|
| Agency | Agency Contact | Contact Phone Number |

68-13-1
K.A.R. Number(s)

Submit a hard copy of the proposed rule(s) and regulation(s) and any external documents that the proposed rule(s) and regulation(s) would adopt, along with the following to: Division of the Budget
900 SW Jackson, Room 504-N
Topeka, KS 66612

**I. Brief description of the proposed rule(s) and regulation(s).**

KAR 68-13-1 is being considered for revocation as the result of recent Board adoption of three new regulations governing sterile and non-sterile compounding in Kansas (KAR 68-13-2, 68-13-3, and 68-13-4). This regulation is now outdated and moot.

**II. Statement by the agency if the rule(s) and regulation(s) is mandated by the federal government and a statement if approach chosen to address the policy issue is different from that utilized by agencies of contiguous states or the federal government.** ***(If the approach is different, then include a statement of why the Kansas rule and regulation proposed is different)***

The content of this regulation is not mandated by the federal government. This approach is consistent with other states.

**III. Agency analysis specifically addressing following:**

**A. The extent to which the rule(s) and regulation(s) will enhance or restrict business activities and growth;**

The revocation will not impact business activities or growth.

**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 would be affected by the proposed rule and regulation and on the state economy as a whole;**

No economic impact. Revocation is consistent with the newly adopted compounding regulations.

**C. Businesses that would be directly affected by the proposed rule and regulation;**

Pharmacies

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

No cost or benefit involved with revocation.

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**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;**

None – no cost of implementation.

**F. An estimate, expressed as a total dollar figure, of the total annual implementation and compliance costs that are reasonably expected to be incurred by or passed along to business, local governments, or members of the public.**

$0

**An estimate, expressed as a total dollar figure, of the total implementation and compliance costs that are reasonably expected to be incurred by or passed along to business, local governments, or members of the public.**

$0

**Do the above total implementation and compliance costs exceed $3.0 million over any two-year period?**

YES ☐ NO ☒

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

None.

**Prior to the submission or resubmission of the proposed rule(s) and regulation(s), did the agency hold a public hearing if the total implementation and compliance costs exceed $3.0 million over any two-year period 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.**

YES ☐ NO ☒

**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.**

No such impact.

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

The Board utilized its compounding task force composed of Kansas pharmacists to craft new compounding regulations that necessitate revocation of this regulation. The task force met for more than ten years.

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**I. For environmental rule(s) and regulation(s) describe the costs that would likely accrue if the proposed rule(s) and regulation(s) are not adopted, as well as the persons would bear the costs and would be affected by the failure to adopt the rule(s) and regulation(s).**

Not an environmental rule/reg.