Proposed

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

A public hearing will be conducted on Thursday, July 14, 2016 at 9:00 a.m. in the Board of Healing Arts Conference Room on the Lower Level 800 SW Jackson, Topeka, Kansas to review and consider the adoption and revocation of proposed regulations of the Kansas State Board of Pharmacy, on a permanent basis.

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 and revocation 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, across the street from the north entrance to the building, and across the street from the west entrance to the building. Curbs at all entrances are accessible to individuals with disabilities.

Summaries of the proposed regulations and their economic impact follow. (Note: Statements indicating that a regulation is "not anticipated to have any economic impact" are intended to indicate that no economic impact on the Kansas State Board of Pharmacy, other state agencies, state employees, or the general public has been identified.)

Copies of the regulations and economic impact statement may be viewed at http://pharmacy.ks.gov/statutes-regs/proposed-reg-changes.

K.A.R. 68-1-1b. Continuing Education for Pharmacists. This regulation is being amended to provide additional requirements for pharmacists to obtain the 30 hours of continuing education for each two-year renewal period and to provide proof of such to the Board. The amendments also create requirements for education providers and pharmacists to have continuing education approved by the Board and provide certficates of completion to pharmacists.

K.A.R. 68-1-1f. Foreign graduates. This regulation outlines the requirements, including passing the TOLFL, for graduates of foreign pharmacy programs who are seeking licensure in Kansas. The amendments update the passing scores to comply with National Board of Pharmacy standards, as well as requiring the TOEFL be internet-based.

K.A.R. 68-1-1g. Internet-based TOEFL. This regulation previously provided the requirements for foreign graduates to pass the internet-based TOEFL, and is being proposed for revocation because all requirements are being updated in proposed K.A.R. 68-1-1f.

K.A.R. 68-5-18. Pharmacy Technicians; Continuing Education. This proposed new regulation sets forth the continuing education requirements for pharmacy technicians, including obtaining 20 hours of continuing education for each two-year renewal period and providing proof of such to the Board. The proposed language also creates requirements for education providers and pharmacy technicians to have continuing education approved by the Board and provide certificates of completion to pharmacy technicians.

K.A.R. 68-7-10. Pharmacy-based drug distribution systems in long-term care facilities; emergency medication kits. This regulation is being amended to allow and regulate automated drug delivery systems in long-term care facilities.

K.A.R. 68-9-2. Automated drug delivery systems in pharmacies. This regulation is being amended to allow and regulate automated drug delivery systems in pharmacies.

K.A.R. 68-9-3. Automated drug delivery system to supply drugs for administration in certain facilities. This proposed new regulation sets forth the requirements for automated drug delivery systems in medical care facilities, institutional drug rooms, and long-term care or nursing facilities. The regulation includes duties, responsibilities and standards for the pharmacist-in-charge, regulates who may access the system, and establishes criteria for the drugs

which may be stored in an automated system and the process for tracking, monitoring, and managing such system.

K.A.R. 68-11-3. Fees for registration as a pharmacy technician or pharmacy intern. This proposed new regulation sets the fee for a pharmacy technician registration or renewal at $20, and sets the fee for a pharmacy intern registration at $20.

SUMMARY OF ECONOMIC IMPACT

It is the mission of the Board to ensure that all persons practicing pharmacy are properly licensed and registered, 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.

The Board anticipates minimal economic impact to the Board, its licensees and registrants, or Kansas pharamcies. 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. For a more detailed summary of the economic impact each specific regulation may have, see the Economic Impact Statement, provided at the website above.

Proposed

68-1-1b. Continuing ~~educational unit~~ education for pharmacists. (a)(1) ~~Ten clock-hours of continuing education approved by the board shall constitute one continuing educational unit (C.E.U.).~~ "Continuing education" shall mean an organized and systematic education experience beyond basic preparation that is designed to achieve the following:

~~(i)~~(A)(i) Increase knowledge, improve skills, or enhance the practice of pharmacy; or

~~(B)~~(ii) improve protection of the public health and welfare; and

~~(2)~~(B) ensure continued competence.

(2) "ACPE-NABP CPE monitor service" shall mean the electronic tracking service of the accreditation council for pharmacy education and the national association of boards of pharmacy for monitoring continuing education that pharmacists receive from continuing education providers.

(b) ~~Three C.E.U.s~~ Thirty clock-hours of continuing education shall be required for renewal of a pharmacist license during each licensure period. Continuing education clock-hours may be prorated for licensure periods that are less than biennial at a rate of ~~.125 C.E.U.s~~ 1.25 clock-hours per month.

(c)(1) ~~Each continuing education program administered by a provider approved by the accreditation council for pharmacy education (ACPE) shall be approved by the board.~~

~~(2)~~ Each continuing education program shall be ~~a program of continuing education that has been~~ approved by the board. Each provider ~~not approved by the ACPE~~ or licensee shall submit the continuing education program to the board at least ~~120~~ 10 days in advance for consideration for approval. Each provider shall advertise the continuing education program as having only pending approval until the provider is notified of approval by the board.

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(2) ~~Except for continuing education programs provided by an ACPE approved provider,~~ Continuing education programs shall not include in-service programs, on-the-job training, orientation for a job, an education program open to the general public, a cardiopulmonary resuscitation (CPR) course, a basic cardiac life support (BCLS) course, emergency or disaster training or direct experience at a healthcare facility under a code blue, testing out of a course, and medical school courses~~, and continuing medical education (CME) category 1 programs~~.

(3) ~~The criteria for continuing education specified in paragraphs (a)(1) and (2) shall be considered by the board when deciding whether to approve a continuing education program submitted by a provider not approved by the ACPE~~ Each provider shall furnish a certificate of completion to the licensee for each continuing education program that the licensee has successfully completed. Each certificate shall be in a format approved by the board and shall include the following:

(A) The licensee's name;

(B) the title and date of the approved continuing education program;

(C) the name of the provider;

(D) the number of continuing education clock-hours approved by the board;

(E) the number of continuing education clock-hours completed by the licensee;

(F) the approved program number issued by the board; and

(G) the provider's dated signature, certifying program completion.

(d) ~~Attendance at a scheduled board meeting shall be accepted by the board for C.E.U. credit according to this schedule:~~

~~(1) 0.1 C.E.U. for each two hours of attendance at a scheduled board meeting; and~~

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~~(2) a maximum of 0.8 C.E.U. for a biennial licensing period~~ Within 30 days of completion, each licensee shall submit to the board proof of completion of any approved continuing education program not reported to the ACPE-NABP CPE monitor service. No credit shall be given for any certificate of completion received by the board after the June 30 expiration date of each licensure period.

(e) ~~In each biennial licensing period, the total number of combined C.E.U. credits from attendance at programs of a provider not approved by the ACPE and from attendance at a scheduled board meeting shall not exceed 0.8 C.E.U., for purposes of meeting the continuing education requirement for license renewal.~~

~~(f)~~ A licensee shall not be allowed to carry forward excess clock-hours earned in one licensure period into the next licensure period.

(f) The required continuing education shall be obtained in the two-year licensure period ending on the June 30 expiration date of each license. (Authorized by ~~and~~ K.S.A. 65-1630; implementing K.S.A. 2015 Supp. 65-1632; effective, E-76-31, Aug. 11, 1975; effective May 1, 1976; amended May 1, 1978; amended May 1, 1983; amended May 1, 1986; amended May 1, 1987; amended July 1, 1990; amended July 31, 1998; amended Oct. 20, 2006; amended April 23, 2010; amended P-_____.)

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68-1-1f. Foreign graduates. (a) Each applicant who has graduated from a school or college of pharmacy or a pharmacy department of a university located outside of the United States or who is not a citizen of the United States shall provide proof that the applicant has reasonable ability to communicate verbally and in writing with the general public in English as specified in this regulation.

(b) Each foreign applicant shall be required to meet ~~one of~~ the ~~following~~ English language requirements for licensure under the pharmacy act of the state of Kansas:

~~(1) Pass the test of English as a foreign language (TOEFL) with a score of at least 570 and the test of spoken English (TSE) with a score of at least 50; or~~

~~(2) pass~~ by passing the internet-based ~~TOEFL (iBT) as specified in K.A.R. 68-1-1g~~ test of English as a foreign language (TOEFL iBT) with at least the following minimum scores:

(1) 22 in reading;

(2) 21 in listening;

(3) 26 in speaking; and

(4) 24 in writing. (Authorized by ~~and~~ K.S.A. 65-1630 and K.S.A. 65-1631; implementing K.S.A. 65-1631; effective May 1, 1983; amended June 6, 1994; amended March 20, 1995; amended Aug. 1, 1997; amended Oct. 20, 2006; amended P-_____.)

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68-1-1g. (Authorized by and implementing K.S.A. 65-1631; effective Oct. 20, 2006; revoked P-_____.)

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68-5-18. Pharmacy technicians; continuing education. (a)(1) "Continuing education" shall mean an organized and systematic education experience beyond basic preparation that is designed to achieve the following:

(A)(i) Increase knowledge, improve skills, or enhance the practice of pharmacy; or

(ii) improve protection of the public health and welfare; and

(B) ensure continued competence.

(2) "ACPE-NABP CPE monitor service" shall mean the electronic tracking service of the accreditation council for pharmacy education and the national association of boards of pharmacy for monitoring continuing education that pharmacy technicians receive from continuing education providers.

(b) Twenty clock-hours of continuing education shall be required for renewal of a pharmacy technician registration during each registration period. Continuing education clock-hours may be prorated for registration periods that are less than biennial at a rate of 0.8 clock-hours per month.

(c)(1) Each continuing education program shall be approved by the board. Each provider or registrant shall submit the continuing education program to the board at least 10 days in advance for consideration for approval. Each provider shall advertise the continuing education program as having only pending approval until the provider is notified of approval by the board.

(2) Continuing education programs shall not include in-service programs, on-the-job training, orientation for a job, an education program open to the general public, a cardiopulmonary resuscitation (CPR) course, a basic cardiac life support (BCLS) course, emergency or disaster training or direct experience at a healthcare facility under a code blue, testing out of a course, and medical school courses.

(3) Each provider shall furnish a certificate of completion to the pharmacy technician for each continuing education program that the registrant has successfully completed. Each certificate shall be in a format approved by the board and shall include the following:

(A) The registrant's name;

(B) the title and date of the approved continuing education program;

(C) the name of the provider;

(D) the number of continuing education clock-hours approved by the board;

(E) the number of continuing education clock-hours completed by the registrant;

(F) the approved program number issued by the board; and

(G) the provider's dated signature, certifying program completion.

(d) Within 30 days of completion, each pharmacy technician shall submit to the board proof of completion of any approved continuing education program not reported to the ACPE-NABP CPE monitor service. No credit shall be given for any certificate of completion received by the board after the October 31 expiration date of each registration period.

(e) A licensee shall not be allowed to carry forward excess clock-hours earned in one registration period into the next registration period.

(f) The required continuing education shall be obtained in the two-year registration period ending on the October 31 expiration date of each registration. (Authorized by K.S.A. 65-1630 and K.S.A. 2015 Supp. 65-1663; implementing K.S.A. 2015 Supp. 65-1663; effective P-_____.)

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

(1) ~~"Adult care home" has the same meaning as set forth in K.S.A. 39-923.~~ "Automated drug delivery system" means a robotic, mechanical, or computerized device that is used to supply drugs for administration 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.

(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.

~~(2)~~(6) "Unit-dose system" means a drug distribution system ~~which~~ that is pharmacy-based and ~~which~~ 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.

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~~(3) "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.~~

~~(4) "Unit dose container" means a single or multiple unit container for articles intended for administration in single doses, directly from the container, by other than parenteral route.~~

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

~~(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.~~

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

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

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

(3) ~~conform to~~ meet the following additional requirements:

(A) ~~All prescriptions (unit dose or traditional)~~ Each prescription shall be dispensed from a pharmacy within a ~~reasonable length of~~ time ~~after the medication is ordered.~~ 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 ~~adult care home.~~ 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 ~~adult care home~~ 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) ~~All~~ each medication distribution system ~~containers~~ container shall be labeled to permit the identification of the drug therapy.

(c) ~~All~~ Each unit-dose ~~drug distribution systems~~ system shall meet the following requirements, in addition to the ~~above~~ requirements~~, conform to the following requirements~~ in subsection (b):

(1) All medication shall be packaged in unit-dose containers as far as practicable~~,~~ and the packaging shall ~~conform to the provisions~~ meet the requirements of K.A.R. 68-7-15 and 68-7-16.

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

(3) The pharmacist shall comply with all requirements for prescription orders, including inventory and ~~record-keeping~~ 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. ~~65-1601~~ 65-1625 et seq. and amendments thereto;

(C) the board's applicable regulations in ~~K.A.R. 68-20-1 et seq. and K.A.R. 68-1-1 et seq.~~ articles 1 and 20; and

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

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

(5) Container requirements for unit-dose ~~distribution~~ systems may include trays, bins, carts, and locked cabinets if the requirements of K.A.R. 68-7-14 are ~~complied with~~ met. If these options are used, all patient medication trays or drawers shall be sufficiently labeled to identify ~~the~~ each patient.

(6) Each unit-dose ~~distribution~~ system shall provide a verification check at the point of patient administration in order to ~~insure~~ 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 ~~adult care home~~ long-term care facility, the stability of the drug, and the type of container used.

(8) The pharmacist ~~or a pharmacy intern under the direct supervision of a pharmacist~~ shall have sole responsibility for dispensing under the unit-dose system.

(d) ~~Emergency medication kits.~~

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

(2) ~~Drugs~~ Each drug to be contained within an emergency medication ~~kits~~ kit shall be approved by the ~~adult care home~~ 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 ~~conform to~~ ensure that the following requirements are met:

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(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 ~~proper~~ valid order of a ~~practitioner~~ prescriber.

(B) If the kit is not in an automated drug delivery system, the kit shall be locked or sealed in a manner that ~~obviously reveals~~ 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 ~~and~~ 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 ~~the~~ each nurse ~~or nurses as determined~~ 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 ~~is~~ has been opened, along with the ~~practitioner's~~ prescriber's drug order for medications administered. (Authorized by ~~and~~ K.S.A. 65-1630; implementing K.S.A. 2015 Supp. 65-1637, K.S.A. 2015 Supp. 65-1642, and K.S.A. 65-1648; effective May 1, 1978; amended May 1, 1983; amended Sept. 9, 1991; amended 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 ~~include any~~ mean a robotic, mechanical ~~system~~, or computerized device located in a Kansas pharmacy that performs operations or activities other than compounding or administration, ~~relative to~~ involving the storage, packaging, or labeling of, or any other step before dispensing, ~~or distribution of~~ drugs~~, in situations in which the drug is not reviewed by a Kansas-licensed pharmacist after it leaves the mechanical system and before it is dispensed, distributed, or administered~~. 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 ~~be responsible to take~~ perform the following ~~steps~~ 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 ~~dispenses~~ selects the correct strength, dosage form, and quantity of the drug prescribed while maintaining appropriate recordkeeping and security safeguards;

(2) ensure that the automated ~~pharmacy~~ 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 ~~pharmacy~~ drug delivery system has a mechanism for securing and accounting for all wasted or discarded drugs;

(4) ~~implement a documented and~~ ensure compliance with an ongoing continuous quality ~~assurance~~ improvement program pursuant 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;

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(5) ensure that the automated drug delivery system is ~~stocked~~ loaded accurately and according to ~~established and written policies and procedures~~ the original manufacturer's storage requirements;

~~(6) ensure that the use of the automated drug delivery system maintains patient confidentiality;~~

~~(7)~~(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 ~~a Kansas-licensed pharmacist or to~~ any of the following~~, each of whom shall be under the pharmacist's direct supervision~~:

(A) A ~~pharmacy student~~ Kansas-licensed pharmacist;

(B) a Kansas-registered pharmacy intern; or

(C) a Kansas-registered pharmacy technician;

(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 ~~comply with~~ 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 ~~remove~~ unload any drug ~~and maintain, at the location of~~ from the automated drug delivery system~~, a list of those approved individuals~~;

(10) ~~ensure the accuracy of the automated drug delivery system's collection, control, and maintenance of all transaction information needed to track the movement of drugs into and out of the system for security, accuracy, and accountability; and~~ 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;

(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.

~~(c) 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 be responsible to ensure all of the following:~~

~~(1) The drugs within the automated drug delivery system are inspected on site by a Kansas licensed pharmacist or by any of the following, each of whom shall be under the pharmacist's direct supervision:~~

~~(A) A pharmacy student;~~

~~(B) a pharmacy intern; or~~

~~(C) a pharmacy technician. These inspections shall be conducted at least monthly to ensure accuracy of contents.~~

~~(2) All drugs placed within the device are packaged in the manufacturer's sealed original packaging or in repackaged containers, in compliance with the requirements of K.A.R. 68-7-15 and K.A.R. 68-7-16. However, the dispensing container shall not be required to be labeled as specified in K.A.R. 68-7-14 if the dispensing container is utilized for a registered patient of the licensed health care facility and for immediate administration.~~

~~(3) At the time of loading any controlled substance, the count of that drug in the automated drug delivery system is correct, or any discrepancy is immediately reported to the pharmacist in charge, who shall be responsible for reconciliation of the discrepancy or proper reporting of the loss.~~ (Authorized by K.S.A. 65-1630; implementing ~~K.S.A. 2001 Supp. 65-1626, as amended by L. 2002, ch. 25, sec. 2~~

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K.S.A. 2015 Supp. 65-1637 and 65-1642; effective July 6, 2001; amended Feb. 7, 2003; 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 a robotic, mechanical, or computerized device that is used in a facility outside of a pharmacy for supplying drugs for administration.

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

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

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

(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.

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(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;

(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

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(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 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.

(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.

(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 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 Supp. 65-1637, K.S.A. 2015 Supp. 65-1642, and K.S.A. 65-1648; effective P-_____.)

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Proposed

68-11-3. Fees for registration as a pharmacy technician or pharmacy intern. The following fees shall be paid to the board:

(a) Each applicant for initial registration as a pharmacy technician shall pay a fee of $20.00.

(b) Each registered pharmacy technician shall pay a renewal fee of $20.00.

(c) Each applicant for a pharmacy intern registration shall pay a fee of $20.00.

(Authorized by K.S.A. 65-1630, K.S.A. 2015 Supp. 65-1663, and K.S.A. 2015 Supp. 65-1676; implementing K.S.A. 2015 Supp. 65-1663 and 65-1676; effective P-_____.)

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Proposed

KANSAS STATE BOARD OF PHARMACY
ECONOMIC IMPACT STATEMENT

The Kansas State Board of Pharmacy (Board) is proposing new regulations K.A.R. 68-5-18, 68-9-3, and 68-11-3, amended regulations K.A.R. 68-1-1b, 68-1-1f, 68-7-10, and 68-9-2, and revoking K.A.R. 68-1-1g, 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, 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.

CONTINUING EDUCATION

I. Summary of Proposed Regulations.

K.A.R. 68-1-1b. Continuing Education for Pharmacists. This regulation is being amended to provide additional requirements for pharmacists to obtain the 30 hours of continuing education for each two-year renewal period and to provide proof of such to the Board. The amendments also create requirements for education providers and pharmacists to have continuing education approved by the Board and provide certificates of completion to pharmacists.

K.A.R. 68-5-18. Pharmacy Technicians; Continuing Education. This proposed new regulation sets forth the continuing education requirements for pharmacy technicians, including obtaining 20 hours of continuing education for each two-year renewal period and providing proof of such to the Board. The proposed language also creates requirements for education providers and pharmacy technicians to have continuing education approved by the Board and provide certificates of completion to pharmacy technicians.

II. Reason or Reasons 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 continuing education requirements for pharmacists and pharmacy technicians in accordance with K.S.A. 65-1632 and 65-1663, respectively. There are no federal requirements implicated by this regulation.

III. Anticipated Economic Impact on the Board. The Board does not charge any fee for the approval of continuing education courses so that will not impact the Board. Courses that have been approved by the Accreditation Council for Pharmacy will automatically be integrated into the Board's licensing system and require no additional work for Board staff. Any economic

impact will be related to general licensing record updates and document processing and storage. Costs to the Board might appear in the form of administrative staff time and will likely be offset by the Board's ongoing implementation of a more efficient licensing system.

IV. Anticipated Financial Impact Upon Private Individuals or Businesses. Pharmacists and pharmacy technicians may experience an impact in their time related to providing proof of their education to the Board. However, courses that have been approved by the Accreditation Council for Pharmacy will automatically be integrated into the Board's licensing system and require no additional work for pharmacists or pharmacy technicians. The Board does not charge any fee for the approval of continuing education courses so there is no anticipated economic impact for continuing education providers, pharmacists, pharmacies or pharmacy technicians. Businesses (including pharmacies) or pharmacy technicians may be impacted by the number of hours required to complete the continuing education, in addition to costs of taking any course, though many free courses are available both in-person and online. No other impact on private citizens or businesses is anticipated.

VI. 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.

AUTOMATION

I. Summary of Proposed Regulations.

K.A.R. 68-7-10. Pharmacy-Based Drug Distribution Systems in Long-Term Care Facilities; Emergency Medication Kits. This regulation is being amended to allow and regulate automated drug delivery systems in long-term care facilities.

K.A.R. 68-9-2. Automated drug delivery systems in pharmacies. This regulation is being amended to allow and regulate automated drug delivery systems in pharmacies.

K.A.R. 68-9-3. Automated drug delivery system to supply drugs for administration in certain facilities. This proposed new regulation sets forth the requirements for automated drug delivery systems in medical care facilities, institutional drug rooms, and long-term care or nursing facilities. The regulation includes duties, responsibilities and standards for the pharmacist-in-charge, regulates who may access the system, and establishes criteria for the drugs which may be stored in an automated system and the process for tracking, monitoring, and managing such system.

II. Reason or Reasons the Proposed Regulation Is Required, Including Whether or Not the Regulation Is Mandated by Federal Law. The Board is amending and adopting these regulations to respond to increasing demands and trends in automation in the various pharmacy settings. New language creates specific requirements for human oversight, maintenance, accountability and access. There are no federal requirements implicated by this regulation.

III. Anticipated Economic Impact on the Board. The Board has three licensed pharmacy inspectors and two pharmacy compliance inspectors that conduct regular inspections of pharmacies and other facilities, including automation standards and practices. While there may be some cost to the Board in terms of time and resources of inspectors educating licensees about changes, these are normal and anticipated updates that should not have an impact on the Board's budget or expenditures. Costs will likely be offset by the Board's ongoing implementation of a more efficient and real-time inspection system.

IV. Anticipated Financial Impact Upon Private Individuals or Businesses. Pharmacists and pharmacies may experience an impact in time related to implementation and meeting the new requirements. However, cost and time savings through pharmacy automation is significant, which has been demonstrated in state pilot projects. Additionally, error rates are often lower in automated processes, which create fewer complaints and incidents requiring additional time and resources. No other impact on private citizens or businesses is anticipated.

VI. 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.

FEES

I. Summary of Proposed Regulations. K.A.R. 68-11-3. Fees for registration as a pharmacy technician or pharmacy intern. This proposed new regulation sets the fee for a pharmacy technician registration or renewal at $20, and sets the fee for a pharmacy intern registration at $20.

II. Reason or Reasons the Proposed Regulation Is Required, Including Whether or Not the Regulation Is Mandated by Federal Law. The Board is proposing this regulation for two reasons. First, though these fees reflect current pharmacy technician fees, this is not reflected in any regulation adopted by the Board, as required by K.S.A. 65-1663. Second, the Board currently requires no fee for pharmacy intern registration, which is creating an unmet financial burden for the agency despite the Board's statutory authority to charge a one-time fee for this six-year registration. There are no federal requirements implicated by this regulation.

III. Anticipated Economic Impact on the Board. The Board currently processes over 250 pharmacy intern applications per year. Pharmacy intern applications are the most time-intensive for Board staff, both when they are received and throughout the six-year life of the registration. Currently, the Board charges a minimum $20 fee for all other license types, but charges nothing to pharmacy interns. Instituting a $20 fee would increase Board revenues by approximately $5,200 per fiscal year. Aside from revenue processing time, there would be no additional cost to the Board.

IV. Anticipated Financial Impact Upon Private Individuals or Businesses. Pharmacy interns would be required to pay a one-time $20 fee for a six-year registration. No other impact on private citizens, businesses, or other entities is anticipated.

FOREIGN GRADUATES

I. Summary of Proposed Regulations.

K.A.R. 68-1-1f. Foreign graduates. This regulation outlines the requirements, including passing the test of English as a foreign language (TOEFL), for graduates of foreign pharmacy programs who are seeking licensure in Kansas. The amendments update the passing scores to comply with National Board of Pharmacy standards, as well as requiring the TOEFL be internet-based.

K.A.R. 68-1-1g. Internet-based TOEFL. This regulation previously provided the requirements for foreign graduates to pass the internet-based TOEFL, and is being proposed for revocation because all requirements are being updating into proposed K.A.R. 68-1-1f.

II. Reason or Reasons the Proposed Regulation Is Required, Including Whether or Not the Regulation Is Mandated by Federal Law. The Board is amending and revoking these regulations to match the current National Association of Boards of Pharmacy standards for passage of the TOEFL, and to remove old requirements for non-internet-based testing, which is no longer available.

III. Anticipated Economic Impact. The Board does not anticipate any financial impact.