Proposed

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

A public hearing will be conducted on Wednesday, November 8, 2017 at 8:30 a.m. in the Board of Regents Board Room at 1000 SW Jackson, Suite 520, 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 across the street from the north entrance to the building. Curbs at the north 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

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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. 68-1-3a. Qualifying pharmaceutical experience. This regulation is amended to increase the number of hours required to complete one year of experience as a pharmacy intern to 1,740 clock-hours. This change is consistent with national standards and current training requirements of the two largest pharmacist feeder schools in Kansas.

K.A.R. 68-2-20. Pharmacist function in filling a prescription. This regulation is amended to provide consistency with statutes in the Pharmacy Practice Act. Pharmacists may only fill prescriptions written by practitioners or mid-level practitioners that would have commensurate prescribing authority if licensed or registered in Kansas. Additional amendments allow dispensing of a prescription drug based on a prescription that may have been issued based on a practitioner's telephonic consultation with a patient, in response to chapter 34, section 6 of the 2017 Kansas session laws.

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

K.A.R. 68-7-15. Prepackaging or repackaging of drugs. This regulation is amended to allow pharmacists to dispense and repackage prescribed medications in conjunction with an ingestible event marker designed to ensure medication adherence.

K.A.R. 68-7-20. Shared services. This regulation is amended to require a pharmacy participating in shared services to be actively engaged in operating their pharmacy.

K.A.R. 68-11-2. Fees. This regulation is amended to include application and renewal fees for new registration/permit categories, including third-party logistics providers, outsourcing facilities or virtual outsourcing facilities, repackagers, and automated dispensing systems consistent with new federal and state facility licensure categories. In addition, the application and renewal fee for retail dealers is being rounded to the nearest dollar amount ($10).

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 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-registered 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.

68-1-3a. Qualifying pharmaceutical experience. (a) Pharmaceutical experience that qualifies as one year of experience shall consist of ~~1,500~~ 1,740 clock-hours as a pharmacy student or registered intern while being supervised by a preceptor. A preceptor may supervise at any time no more than two individuals who are pharmacy students or interns. All hours worked when the pharmacy student or intern is in regular attendance at an approved school of pharmacy and during vacation times and other times when the pharmacy student or intern is enrolled but not in regular attendance at an approved school of pharmacy may be counted as qualified hours. However, not more than 60 hours of work shall be acquired in any one week.

(b) No time may accrue to a pharmacy student before acceptance in an approved school of pharmacy or before being registered as an intern with the board. However, any foreign pharmacy graduate who has passed equivalent examinations as specified in K.A.R. 68-1-1f and K.A.R. 68-1-1h may apply for registration as an intern.

(c) Once registered as an intern, the intern shall complete all required hours within six years.

(d) Reciprocity shall not be denied to any applicant who is otherwise qualified and who meets either of the following conditions:

(1) Has met the internship requirements of the state from which the applicant is reciprocating; or

(2) has at least one year of experience as a registered pharmacist. (Authorized by K.S.A. 65-1630; implementing K.S.A. 65-1631; effective, E-76-31, Aug. 11, 1975; effective May 1, 1976; amended May 1, 1983; amended May 1, 1985; amended May 31, 2002; amended Jan. 14, 2005; amended Oct. 23, 2009; amended P-_____.)

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68-2-20. Pharmacist's function in filling a prescription. (a) As used in this regulation, each of the following terms shall have the ~~meanings~~ meaning specified in this subsection:

(1) "Authorized prescriber" shall mean a "practitioner" ~~as defined by K.S.A. 65-1626(gg) and amendments thereto, a~~ or "mid-level practitioner" as defined by K.S.A. 65-1626~~(ss)~~ and amendments thereto~~,~~ or a person authorized to issue a prescription by the laws of another state who would have commensurate prescribing authority if licensed or registered in Kansas.

(2) "Legitimate medical purpose," when used in regard to the dispensing of a prescription drug, shall mean that the prescription for the drug was issued with a valid preexisting patient-prescriber relationship rather than with a relationship established through an internet-based questionnaire~~,~~ or an internet-based consultation~~, or a telephonic consultation~~.

(b) Those judgmental functions that constitute the filling or refilling of a prescription shall be performed only by a licensed pharmacist or by a pharmacy student or intern under the direct supervision of a licensed pharmacist and shall consist of the following steps:

(1) Read and interpret the prescription of the prescriber;

(2) limit any filling or refilling of a prescription to one year from the date of origin, except as provided by K.S.A. 65-1637 and amendments thereto;

(3) verify the compounding, counting, and measuring of ingredients and document the accuracy of the prescription;

(4) identify, in the pharmacy record, the pharmacist who verifies the accuracy of the completed prescription;

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(5) personally offer to counsel each patient or the patient's agent with each new prescription dispensed, once yearly on maintenance medications, and, if the pharmacist deems appropriate, with prescription refills in accordance with subsection (c);

(6) ensure the proper selection of the prescription medications, devices, or suppliers as authorized by law;

(7) when supervising a pharmacy technician, delegate only nonjudgmental duties associated with the preparation of medications and conduct in-process and final checks;

(8) prohibit all other pharmacy personnel from performing those judgmental functions restricted to the pharmacist; and

(9) interpret and verify patient medication records and perform drug regimen reviews.

(c) In order to comply with paragraph (b)(5), the pharmacist or the pharmacy student or intern under the pharmacist's supervision shall perform the following:

(1) Personally offer to counsel each patient or the patient's agent with each new prescription dispensed, once yearly on maintenance medications, and, if the pharmacist deems appropriate, with prescription refills;

(2) provide the verbal counseling required by this regulation in person, whenever practical, or by the utilization of a telephone service available to the patient or patient's agent. Any pharmacist may authorize an exception to the verbal counseling requirement on a case-by-case basis for refills, maintenance medications, or continuous medications for the same patient;

(3) when appropriate, provide alternative forms of patient information to supplement verbal patient counseling. These supplemental forms of patient information may include written information, leaflets, pictogram labels, video programs, and auxiliary labels on the prescription

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vials. However, the supplemental forms of patient information shall not be used as a substitute for the verbal counseling required by this regulation;

(4) encourage proper patient drug utilization and medication administration. The pharmacist shall counsel the patient or patient's agent on those elements that, in the pharmacist's professional judgment, are significant for the patient. These elements may include the following:

(A) The name and a description of the prescribed medication or device;

(B) the dosage form, dosage, route of administration, and duration of therapy;

(C) special directions and precautions for preparation, administration, and use by the patient;

(D) common side effects, adverse effects or interactions, or therapeutic contraindications that could be encountered; the action required if these effects, interactions, or contraindications occur; and any activities or substances to be avoided while using the medication;

(E) techniques for self-monitoring drug therapy;

(F) proper storage requirements; and

(G) action to be taken in the event of a missed dose; and

(5) expressly notify the patient or the patient's agent if a brand exchange has been exercised.

(d) Nothing in this regulation shall be construed to require a pharmacist to provide the required patient counseling if either of the following occurs:

(1) The patient or the patient's agent refuses counseling.

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(2) The pharmacist, based upon professional judgment, determines that the counseling may be detrimental to the patient's care or to the relationship between the patient and the patient's prescriber.

(e) Each pharmacist shall make a reasonable effort to ensure that any prescription, regardless of the means of transmission, has been issued for a legitimate medical purpose by an authorized prescriber. (Authorized by K.S.A. 65-1630; implementing K.S.A. ~~2008~~ 2016 Supp. 65-1626, as amended by L. 2017, ch. 34, sec. 1, and K.S.A. ~~2008~~ 2016 Supp. 65-1637, ~~and K.S.A. 2008 Supp. 65-1642~~ as amended by L. 2017, ch. 34, sec. 6; effective, E-77-39, July 22, 1976; effective Feb. 15, 1977; amended May 1, 1978; amended May 1, 1988; amended Nov. 30, 1992; amended March 20, 1995; amended Aug. 14, 1998; amended Dec. 27, 1999; amended Feb. 7, 2003; amended Jan. 8, 2010; amended P-_____.)

Proposed

68-7-12a. Nonresident pharmacies. ~~(a)~~ Each nonresident ~~pharmacies~~ pharmacy shall meet the ~~following~~ requirements of this regulation to be and remain registered in Kansas by the board.

(a)(1) Each pharmacy shall be currently licensed or registered in good standing in the state in which it is located.

(2) Each practicing pharmacist ~~dispensing drugs into Kansas~~ employed by or under contract with the pharmacy shall be licensed as a pharmacist in the state where the pharmacist practices.

(3) Each pharmacy shall provide and maintain, in readily retrievable form, the record of a satisfactory inspection conducted within the previous 12-month period by the licensing entity of the state where the pharmacy is located. If no such inspection record is readily available, the record of a satisfactory inspection conducted at the expense of the pharmacy within the previous 12-month period by a third party recognized by the board to inspect may be accepted.

~~(b)~~(4) ~~A pharmacist licensed in the state where the pharmacist practices~~ Each pharmacy shall designate a pharmacist-in-charge, as defined by K.S.A. 65-1626 and amendments thereto, who shall be named in the application ~~as the pharmacy's responsible pharmacist, who~~ and who shall be responsible for receiving communications from the board.

~~(1)~~(A) ~~That pharmacist~~ The pharmacist-in-charge shall timely respond to any lawful request for information from the board or law enforcement authorities.

~~(2)~~(B) ~~That pharmacist~~ The pharmacist-in-charge shall be responsible for receiving and maintaining publications distributed by the board.

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~~(3) If at any time the pharmacist so designated leaves the employment of the pharmacy, the owner or the owner's authorized representative of the pharmacy shall promptly notify the board and designate another pharmacist to perform this function.~~

~~(c)~~(b) The owner or the owner's authorized representative of the nonresident pharmacy shall apply for registration and renewal on forms approved by the board. The information reasonably necessary to carry out the provisions of K.S.A. 65-1657 and amendments thereto, including the name, address, and position of each officer and director of a corporation or of the owners if the pharmacy is not a corporation, ~~may~~ shall be required by the board.

~~(d)~~(c) An exemption for registration may be granted by the board under K.S.A. 65-1657 and amendments thereto, upon application by any nonresident pharmacy that confines its dispensing activity to isolated transactions. The following shall be considered to determine whether to grant an exemption:

(1) The number of prescriptions dispensed or reasonably expected to be dispensed into Kansas;

(2) the number of patients served or reasonably expected to be served in Kansas;

(3) any efforts to promote the pharmacy's services in Kansas;

(4) any contract between the pharmacy and either an employer or organization to provide pharmacy services to employees or other beneficiaries in Kansas;

(5) medical necessity;

(6) the effect on the health and welfare of persons in Kansas; and

(7) any other relevant matters.

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~~(e)~~(d) The pharmacy owner shall pay an annual registration fee as ~~set forth~~ specified in K.A.R. 68-11-2.

~~(f)~~(e) The pharmacy records of drugs dispensed to Kansas addresses shall be maintained so that the records are readily retrievable upon request. These records shall be made available for inspection by the board or by Kansas law enforcement authorities upon request.

~~(g)~~(f) The pharmacy shall maintain an incoming toll-free telephone number for use by Kansas customers to facilitate personal communication with a pharmacist with access to patient records.

(1) This service shall be available during normal business hours for ~~a minimum of~~ at least 40 hours and six days per week.

(2) This telephone number and any others available for use shall be printed on each container of drugs dispensed in Kansas.

(3) The toll-free number shall have a sufficient number of extensions to provide reasonable access to incoming callers.

~~(h)~~(g) Generic drugs shall be dispensed into Kansas only pursuant to K.S.A. 65-1637~~(a)~~, and amendments thereto.

~~(i)~~(h) The facilities and records of the pharmacy shall be subject to inspection by the board. Satisfactory ~~inspection reports~~ inspections conducted within the previous 12-month period by the licensing entity ~~using similar standards~~ of the state where the pharmacy is located or a third party recognized by the board to inspect may be accepted in lieu of inspection by the board.

~~(j)~~(i) Each owner or owner's authorized representative of the nonresident pharmacy either doing business in Kansas ~~by~~ or providing pharmacy services, dispensing, ~~and~~ or either delivering

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or causing to be delivered prescription drugs to Kansas consumers shall designate a resident agent in Kansas for service of process and file this information with the secretary of state. (Authorized by and implementing K.S.A. ~~2001~~ 2016 Supp. 65-1657; effective March 29, 1993; amended March 20, 1995; amended Feb. 7, 2003; amended P-_____.)

68-7-15. Prepackaging or repackaging of drugs. All prepackaging or repackaging of drugs, whether in a unit-dose container or multiple-dose container, shall ~~conform to the following:~~ meet the requirements of this regulation.

(a) Packaging in advance of immediate need shall be done by a pharmacist or under ~~his or her~~ the pharmacist's direct supervision.

(b) ~~This~~ Packaging shall be limited to the drugs ~~to be~~ dispensed from the premises.

(c) ~~Proper~~ All containers used for packaging and the storage conditions shall be maintained ~~so as~~ according to the manufacturer's recommendations to preserve the stability of the drug ~~as recommended by the manufacturer~~. The expiration date shall be the manufacturer's expiration date or not more than 12 months from the date of packaging, whichever is earlier.

(d) ~~A proper control system~~ An electronic or a written record shall be established for lot numbers for recall purposes.

(e) If an area apart or separated from the prescription area is used for prepackaging or repackaging, ~~such~~ the area ~~must~~ shall be enclosed and ~~secured (~~locked~~)~~ when a pharmacist is not in attendance in that area.

(f) In lieu of separately dispensing a drug and an ingestible event marker approved by the food and drug administration to monitor whether a patient is taking the drug as prescribed, any pharmacist may use an ingestible event medication adherence package pursuant to a valid prescription order or after obtaining the consent of the practitioner, caregiver, or patient.

(g) For purposes of this regulation, "ingestible event medication adherence package" shall mean an ingestible unit-dose package designed to ensure medication adherence that contains drugs from a manufacturer's original container and an ingestible event marker, as

defined by 21 C.F.R. 880.6305, in effect on April 1, 2016 and hereby adopted by reference.

(Authorized by K.S.A. ~~1977 Supp.~~ 65-1630; implementing K.S.A. 2016 Supp. 65-1626, as amended by L. 2017, ch. 34, sec. 1, K.S.A. 2016 Supp. 65-1626a, and K.S.A. 65-1634; effective May 1, 1978; amended P-_____.)

Proposed

68-7-20. Shared services. (a)(1) "Order" ~~means~~ shall mean either of the following:

(A) A prescription order as defined in K.S.A. 65-1626, and amendments thereto; or

(B) a medication order as defined in K.A.R. 68-5-1.

(2) "Shared order filling" ~~means~~ shall mean the following:

(A) Preparing, packaging, compounding, or labeling an order, or any combination of these functions, by a person authorized by the pharmacy act to do so and located at a pharmacy on behalf of and at the request of another pharmacy; and

(B) returning the filled order to the requesting pharmacy for delivery to the patient or patient's agent or, at the request of the requesting pharmacy, directly delivering the filled order to the patient.

(3) "Shared order processing" ~~means~~ shall mean the following order-processing functions that are performed by a person authorized by the pharmacy act and located at a pharmacy, on behalf of and at the request of another pharmacy:

(A) Interpreting and entering the order; and

(B) performing drug utilization reviews, claims adjudication, refill authorizations, or therapeutic interventions, or any combination of these functions.

(4) "Shared services" ~~means~~ shall mean shared order filling or shared order processing, or both.

(b) Each pharmacy participating in shared services shall be registered by the board as either a resident or a ~~non-resident~~ nonresident pharmacy.

(c) Pharmacies may provide or utilize shared services functions only if the pharmacies involved meet the following requirements:

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(1) Share a common electronic file or appropriate technology to allow access to sufficient information necessary to fill, refill, or perform shared services in conformance with the pharmacy act and the board's regulations; and

(2)(A) Have the same owner; or

(B) have a written contract outlining the services provided and the shared responsibilities of each party in complying with the pharmacy act and the board's regulations.

(d) ~~Pharmacies~~ Each pharmacy engaged in shared services shall meet the following requirements:

(1) Maintain records identifying, individually for each order processed, the name of each pharmacist, technician, pharmacy student, and intern who took part in the drug utilization review, refill authorization, or therapeutic intervention functions performed at that pharmacy;

(2) maintain records identifying, individually for each order filled or dispensed, the name of each pharmacist, technician, pharmacy student, and intern who took part in the filling, dispensing, and counseling functions performed at that pharmacy;

(3) report to the board ~~as soon as practical~~ within 30 days the results of any disciplinary action taken by another state's pharmacy board ~~involving shared services~~;

(4) maintain a mechanism for tracking the order during each step of the processing and filling procedures performed at the pharmacy;

(5) maintain a mechanism to identify on the prescription label all pharmacies involved in filling the order;

(6) provide for adequate security to protect the confidentiality and integrity of patient information; and

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(7) be able to obtain for inspection any required record or information within 72 hours of any request by a board representative.

(e) Each pharmacy providing or utilizing shared services shall adopt and maintain a joint policies and procedures manual that meets both of the following ~~criteria~~ conditions:

(1) The manual describes how compliance with the pharmacy act and the board's regulations will be accomplished while engaging in shared services.

(2) A copy of the manual is maintained in each pharmacy.

(f) Nothing in this regulation shall prohibit an individual pharmacist licensed in Kansas who is an employee of or under contract with the pharmacy from accessing the pharmacy's electronic database from inside or outside the pharmacy and performing the order-processing functions permitted by the pharmacy act and the board's regulations, if both of the following conditions are met:

(1) The pharmacy establishes controls to protect the privacy and security of confidential records.

(2) None of the database is duplicated, downloaded, or removed from the pharmacy's electronic database.

(g) Nothing in this regulation shall permit a pharmacy, physician, physician assistant, or mid-level practitioner to utilize shared services to operate a requesting pharmacy that is not actively engaged in the practice of pharmacy. (Authorized by K.S.A. 65-1630 and K.S.A. 65-1656; implementing K.S.A. ~~2006~~ 2016 Supp. 65-1626(~~ee~~), as amended by L. ~~2007~~ 2017, ch. ~~177~~ 34, sec. ~~30 and L. 2007, ch. 195, sec. 34~~ 1, K.S.A. 2016 Supp. 65-1626a, K.S.A. ~~2006~~ 2016 Supp. 65-1637, as amended by L. ~~2007~~ 2017, ch. ~~19~~ 34, sec. ~~1~~ 6, K.S.A. ~~2006~~ 2016 Supp. 65-

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1642, as amended by L. 2017, ch. 34, sec. 8, and K.S.A. 65-1656; effective April 16, 2004; amended April 18, 2008; amended P-_____.)

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68-11-2. Fees for premises and service registrations and permits. (a) Pharmacy registration fees shall be as follows:

(1) Each new pharmacy registration shall be $112.00.

(2) Each renewal pharmacy registration shall be $100.00.

(b) Manufacturer registration fees shall be as follows:

(1) Each new manufacturer registration shall be $240.00.

(2) Each renewal manufacturer registration shall be $240.00.

(c) Wholesaler distributor registration fees shall be as follows:

(1) Each new wholesaler distributor registration shall be $240.00.

(2) Each renewal wholesaler distributor registration shall be $240.00.

(3) For each ~~wholesaler~~ wholesale distributor who deals exclusively in nonprescription drugs, the registration fee shall be $40.00.

(4) For each wholesale distributor who deals exclusively in nonprescription drugs, the renewal fee shall be $40.00.

(d) For each institutional drug room or veterinary medical teaching hospital pharmacy, registration fees shall be as follows:

(1) Each new registration shall be $20.00.

(2) Each renewal registration shall be $16.00.

(e) ~~Other~~ Retail dealer permit fees shall be as follows:

(1) Each new retail dealer permit shall be ~~$9.60~~ $10.00.

(2) Each renewal retail dealer permit shall be $10.00.

(f) Each special auction permit shall be $28.00.

~~(3)~~(g) Sample distribution fees shall be as follows:

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(1) Each new sample distribution permit shall be $24.00.

(2) Each renewal sample distribution permit shall be $24.00.

~~(f)~~(h) For each place of business that sells durable medical equipment, ~~the~~ registration ~~fee~~ fees shall be as follows:

(1) Each new registration shall be $240.00.

(2) Each renewal registration shall be $240.00.

(i) Third-party logistics provider registration fees shall be as follows:

(1) Each new third-party logistics provider registration shall be $240.00.

(2) Each renewal third-party logistics provider registration shall be $240.00.

(3) For each third-party logistics provider who deals exclusively in nonprescription drugs, the registration fee shall be $40.00.

(4) For each third-party logistics provider who deals exclusively in nonprescription drugs, the renewal fee shall be $40.00.

(j) For each outsourcing facility or virtual outsourcing facility, registration fees shall be as follows:

(1) Each new registration shall be $240.00.

(2) Each renewal registration shall be $240.00.

(k) Repackager registration fees shall be as follows:

(1) Each new registration shall be $240.00.

(2) Each renewal registration shall be $240.00.

(l) For each place of business that operates an automated dispensing system for patient medication administration, registration fees shall be as follows:

(1) Each new registration shall be $20.00.

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(2) Each renewal registration shall be $20.00. (Authorized by K.S.A. 65-1630 and K.S.A. ~~2013~~ 2016 Supp. 65-1645, as amended by L. 2017, ch. 34, sec. 10; implementing K.S.A. ~~2013~~ 2016 Supp. 65-1645, as amended by L. 2017, ch. 34, sec. 10; effective May 1, 1983; amended May 1, 1988; amended June 6, 1994; amended Feb. 7, 2003; amended Oct. 24, 2008; amended May 30, 2014; amended P-_____.)

KANSAS STATE BOARD OF PHARMACY
ECONOMIC IMPACT STATEMENT

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

It is the mission of the Board to ensure that all persons practicing pharmacy are properly licensed and registered, and to ensure compliance with Kansas statutes regarding proper compounding and dispensing of prescription drugs, maintenance of professional practice standards, and proper manufacture, distribution, and sale of prescription and nonprescription drugs, including controlled substances and poisons. In order to attain these goals, the Board is proposing these regulatory changes to comply with professional, healthcare, and safety norms.

In all instances, the Board does not anticipate any financial impact upon other governmental agencies, and the Board is unaware of any less costly or less intrusive methods to achieve the stated purposes and thus none were considered.

QUALIFYING PHARMACEUTICAL EXPERIENCE

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

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

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

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

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

PHARMACIST FUNCTION IN FILLING A PRESCRIPTION

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

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

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

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

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

NON-RESIDENT PHARMACIES

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

II. Reason(s) the Proposed Regulation Is Required, Including Whether or Not the Regulation Is Mandated by Federal Law. The Board is amending this regulation to ensure

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public safety and the ability of the Board to properly regulate and discipline non-resident pharmacies and the pharmacist responsible for that facility (PIC). While the Board allows non-resident pharmacies to provide services to Kansans, it is difficult for the Board to ensure quality and compliance due to the facility location. Therefore, the Board must rely on the non-resident state board of pharmacy to properly inspect and report issues. However, some state boards may be unable or unwilling to meet these requirements, so the Board offers an additional inspection option. Additionally, requiring the PIC to be licensed in Kansas allows the Board to regulate that pharmacist in cases of non-compliance. There are no federal requirements implicated by this regulation.

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

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

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

PREPACKAGING OR REPACKAGING OF DRUGS

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

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

III. Anticipated Economic Impact on the Board. The Board does not anticipate any economic impact.

IV. Anticipated Financial Impact Upon Private Individuals or Businesses. The economic impact to patients, their prescribers, and their pharmacists is unknown. However, it is anticipated that repackaging this FDA-approved, prescribed device, with the prescribed medication may positively influence health outcomes.

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

SHARED SERVICES

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

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

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

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

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

FEES

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

II. Reason(s) the Proposed Regulation Is Required, Including Whether or Not the Regulation Is Mandated by Federal Law. The Board is amending this regulation to set fees for new registration/permit categories set forth by chapter 34, section 10 of the 2017 Kansas session laws, which was a direct response to the Federal Drug Supply Chain Security Act

(DSCSA), 21 U.S.C. 351 *et seq*. The Board is amending the retail dealer fee for convenience and ease of processing.

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

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

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