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Proposed

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

A public hearing will be conducted on Tuesday, October 22, 2019 at 8:00 a.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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K.A.R. 68-2-10. Cessation of operations. This regulation is being amended to require closed pharmacies to notify the Board and patients about the location and disposition of patient records, and creating requirements for pharmacies accepting records of closed pharmacies.

K.A.R. 68-7-15. Prepackaging or repackaging of oral drugs. This regulation is being amended to allow packaging of drugs dispensed or supplied by the pharmacy or any other pharmacy engaged in a shared services agreement under K.A.R. 68-7-20, and to provide necessary limitations for prepackaging and repackaging of parenteral products.

K.A.R. 68-19-1. Minimum program requirements. This regulation is being amended to require review of the Board's quarterly newsletter during the pharmacy's quarterly continuous quality improvement meetings.

K.A.R. 68-21-6. Reciprocal agreements with other states or government entities to share information. This regulation is being amended to allow the Board to share K-TRACS data with other relevant government entities that have established prescription drug monitoring programs, including the Missouri St. Louis County initiative, military health system via the department of defense, Indian health systems, and veteran health system.

K.A.R. 68-14-1. This regulation is being considered for revocation as the result of proposed amendments and additions to the remainder of Article 14 of the Board's regulations (KAR 68-14-2 through 68-14-7b).

K.A.R. 68-14-2. Definitions. This regulation is being amended to include additional definitions consistent with the Federal Drug Supply Chain Security Act (DSCSA) that shall apply to Article 14 of the Board's regulations, as well as clarify language in the Pharmacy Practice Act.

K.A.R. 68-14-3. This regulation is being considered for revocation as the result of 2017 amendments to the Pharmacy Practice Act which make the contents of this regulation duplicative of statute.

K.A.R. 68-14-4. Minimum required information for registration. This regulation is being amended to include application requirements for virtual wholesale distributors, third-party logistics providers, and outsourcing facilities. It also further clarifies the requirements for wholesale distributors, including inspection and other non-resident compliance requirements.

K.A.R. 68-14-5. Personnel. This regulation is being amended to include personnel requirements for virtual wholesale distributors, third-party logistics providers, and outsourcing facilities. It also further clarifies the requirements for maintaining training records for five years and requires outsourcing facilities to designate a pharmacist-in-charge.

K.A.R. 68-14-7. Wholesale distributors; minimum requirements for the storage and handling of prescription-only drugs and devices and for the establishment and maintenance of prescription-only drug and device distribution records. This regulation is

being amended to update the operations requirements for wholesale distributors to be consistent with the Federal Drug Supply Chain Security Act (DSCSA).

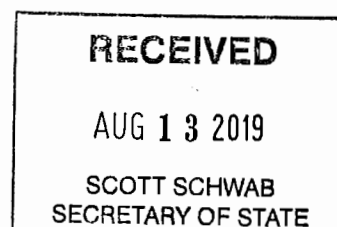
K.A.R. 68-14-7a. Third-party logistics providers; minimum requirements for operation and maintenance of records. This is a new regulation drafted to provide operational requirements for third-party logistics providers, a newly regulated category of registrants, consistent with the Federal Drug Supply Chain Security Act (DSCSA).

K.A.R. 68-14-7b. Outsourcing facilities; minimum requirements for operation and maintenance of records. This is a new regulation drafted to provide operational requirements for outsourcing facilities, a newly regulated category of registrants, consistent with the Federal Drug Supply Chain Security Act (DSCSA).

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.

DSCSA: The Board anticipates minimal economic impact to the Board, its licensees and registrants, or Kansas-registered pharmacies. Amendments will enhance business activity related to the manufacture, distribution, and compounding of prescription drugs and devices by allowing these facilities to more readily transact business with Kansas. The regulations are also designed to maintain necessary public protection mechanisms within these facilities and ensure compliance with recognized pharmacy standards. Registration and renewal application fees have been set in a separate regulation. However, fees should have a null effect on revenue and expense because the Board is merely shifting registrants from one registration category to another. 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.

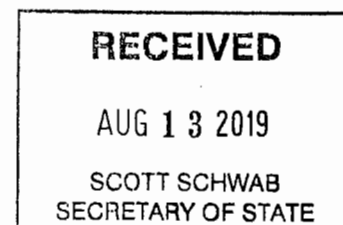


Cessation of Operations: The Board anticipates minimal economic impact to the Board, its licensees and registrants, or Kansas-registered pharmacies. Any economic impact would be specifically related to the closing pharmacy's new responsibility to notify patients of the closure and the disposition of patient records. Pharmacies are already required to maintain patient records for five years and, upon closure, are required to secure another pharmacy buyer or a permanent storage location for the files. The only new component is a notification to the patient about the disposition of the patient record. Notification may be made by mail or email, the economic effect of which may include the cost of paper, envelopes, and postage. This cost would be allocated to the closing pharmacy.

K-TRACS Interstate Data Sharing: The Board anticipates no economic impact to the Board, its licensees and registrants, or any Kansas citizen/business. The Board has data sharing capabilities and will merely expand to these other entities. If there is any economic impact, it would be related to increased data sharing and increased program utilization which could positively benefit the health of patients and Kansans. Such impact is unquantifiable.

Other Regulations: No economic impact.

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



68-2-10. Cessation of operations. ~~(a) Each registrant that~~ When any pharmacy ceases
~~operations at the particular location for which the registration was received shall, the pharmacist-~~
~~in-charge shall meet the following requirements:~~

(1) Within five days after termination of ceasing operations at that location, deliver to the
~~executive secretary of the~~ submit to the ~~board the registration and a written explanation of, on a~~
~~form provided by the board, notice of cessation of pharmacy operations, which shall include the~~
~~following:~~

(A) The date the pharmacy ceased operations;

(B) a signed statement attesting that an inventory of all controlled substances was
conducted;

(C) the location, pharmacy registration number, contact information, and manner of
disposition of the remaining stocks of drugs; and

(D) the location, pharmacy registration number, contact information, and manner of
disposition of all records required by the Kansas pharmacy practice act to be maintained; and

(2) no more than 10 days after ceasing operations at that location, notify each patient who
has received a prescription from the pharmacy within the previous two-year period, either by
U.S. mail or by electronic mail, of the cessation of operations of the pharmacy and the contact
information and location for obtaining copies of patient records.

(b) The pharmacist-in-charge of any pharmacy that acquires patient records from a
pharmacy that ceases operation shall be responsible for the preservation of the acquired records
for the remainder of the term that the records are required by the Kansas pharmacy practice act to
be preserved.

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(c) In the absence of a pharmacist-in-charge, the owner of each pharmacy shall meet the requirements of this regulation. (Authorized by K.S.A. 65-1630; implementing K.S.A. 2001 Supp. 65-1642 and K.S.A. 65-1643; effective Jan. 1, 1966; amended, E-76-31, Aug. 11, 1975; amended May 1, 1976; amended Feb. 7, 2003; amended P-_____.)

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

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

(b) Packaging shall be limited to the drugs dispensed from or supplied by the premises pharmacy or in accordance with a shared services agreement.

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

(d) 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 drug area is used for prepackaging or repackaging, the area shall be enclosed and 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.

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(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~~ dated April 1, 2016 and hereby adopted by reference.

(h) In addition to meeting the requirements of this regulation, all repackaging of sterile preparations shall meet the requirements of K.A.R. 68-13-4. (Authorized by K.S.A. 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 Dec. 15, 2017; amended P-_____.)

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68-14-1. (Authorized by K.S.A. 65-1630; implementing K.S.A. 1998 Supp. 65-1643;
effective June 15, 1992; amended March 20, 1995; amended July 30, 1999; revoked P-_____
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68-14-2. Definitions. As used in this article of the board's regulations and the pharmacy practice act, each of the following terms shall have the meaning specified in this regulation:

(a) "Blood" means whole blood collected from a single donor and processed either for transfusion or for further manufacturing.

(b) "Blood component" means that part of blood separated by physical or mechanical means.

(c) "Common ownership and control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, by contract, or otherwise by other means.

(d) "Drug sample" means a unit of a prescription-only drug that is not intended to be sold, is intended to promote the sale of the drug, and is distributed on a gratuitous basis.

(e) "Device" has the meaning specified in K.S.A. 65-656, and amendments thereto.

(f) "Emergency medical reasons" shall include transfers of prescription-only drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage, except that the gross dollar value of these transfers shall not exceed five percent of the total prescription-only drug sales revenue of either the transferor or transferee pharmacy during any period of 12 consecutive months.

(g) "Excursion" means a deviation from the range of temperatures specified by the manufacturer for storage or transport of a prescription-only drug or device based on stability data.

(~~f~~)(h) "Intracompany sales" ~~means~~ and "intracompany distribution" mean any transaction or transfer between any division, subsidiary, parent, affiliated, or related company under the

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common ownership and control of a corporate entity.

~~(g)~~(i) "Primary owner" means any person owning or controlling more than 50 percent of the wholesaler's business.

(j) "Room temperature" means a temperature that is maintained thermostatically and meets the following requirements:

(1) Encompasses the usual and customary working environment of 20° to 25°C (68° to 77°F);

(2) results in a mean kinetic temperature calculated to be not more than 25°C (77°F); and

(3) allows for excursions between 15° and 30°C (59° to 86°F) experienced in facilities, such that the allowable calculated mean kinetic temperature remains in the allowed range.

(k) "Virtual wholesale distribution" means arranging for the distribution of a drug or device, which may include taking actual possession of the drug or device and shall include contracting with another entity for the distribution, purchase, and sale of the drug or device.

(l) "Virtual wholesale distributor" means a business entity that arranges for the distribution of a drug or device, with or without taking actual possession of the drug or device, and contracts with others for the distribution, purchase, and sale.

~~(h)~~(m) "Wholesale distribution" means distribution of prescription-only drugs or devices to persons other than a consumer or patient and shall include virtual wholesale distribution and virtual wholesale distributors, but this term shall not include ~~any~~ either of the following:

(1) Intracompany sales;

~~(2) the purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a drug for its own use from the group purchasing~~

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organization or from other hospitals or health care entities that are members of these organizations;

(3) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug by a charitable organization described in section 501(c)(3) of the U.S. internal revenue code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;

(4) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug among hospitals or other health care entities that are under common control;

(5) the sale, purchase, or trade of a drug or an offer to sell, purchase, or trade a drug for emergency medical reasons;

(6) the sale, purchase, or trade of a drug; an offer to sell, purchase, or trade a drug; or the dispensing of a drug pursuant to a prescription;

(7) The distribution of drug samples by manufacturers' representatives or distributors' representatives of the authorized distributor of record, in accordance with 21 U.S.C. 353; or

(8)(2) the sale, purchase, or trade of blood and blood components intended for transfusion.

(i) "Wholesale distributor" means anyone doing business in this state and engaging in wholesale distribution of prescription only drugs, including the following:

(1) Manufacturers;

(2) repackers;

(3) own-label distributors;

(4) private-label distributors;

(5) jobbers;

(6) brokers;

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~~(7) warehouses, including manufacturers' and distributors' warehouses, chain drug
warehouses, and wholesale drug warehouses;~~

~~(8) independent wholesale drug traders; and~~

~~(9) retail pharmacies that conduct wholesale distributions. (Authorized by and
implementing K.S.A. 65-1630; implementing K.S.A. 65-1626, as amended by L. 2019, ch. 52,
sec. 7, K.S.A. 65-1643, K.S.A. 65-1655, K.S.A. 65-1655a, and K.S.A. 65-1655b; effective June
15, 1992; amended July 23, 1999; amended P-_____.)~~

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68-14-3. (Authorized by and implementing K.S.A. 1998 Supp. 65-1655 and 65-1643;
effective June 15, 1992; amended July 23, 1999; revoked P-_____.)

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68-14-4. Minimum required information for registration. (a) Each wholesale distributor, virtual wholesale distributor, third-party logistics provider, or outsourcing facility shall provide the board with the following minimum information as part of the registration requirements described in K.S.A. 65-1645, and amendments thereto, and as part of any renewal of any registration:

- (1) The name, ~~full~~ commercial business address, and telephone number of the registrant;
- (2) each trade or business name used by the registrant;
- (3) the address, telephone number, and name of the contact person for each facility used by the registrant for the storage, handling, and distribution of prescription-only drugs or devices;
- (4) the type of ownership or operation, including partnership, corporation, or sole proprietorship; ~~and~~
- (5) the name of each owner, operator, ~~or both~~ facility manager, and designated representative of the registrant, including the following:
 - (A) If a person, the name, address, and date of birth of the person;
 - (B) if a partnership, the name, address, and date of birth of each partner, and the name of the partnership;
 - (C) if a corporation, the name ~~and~~, title, address, and date of birth of each corporate officer and director, the corporate name, and the name of the state of incorporation; and
 - (D) if a sole proprietorship, the ~~full~~ name, address, and date of birth of the sole proprietor and the name of the business entity;
- (6) a list of all states where the registrant is registered as a wholesale distributor, virtual wholesale distributor, third-party logistics provider, or outsourcing facility;

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(7) a copy of any current DEA registration;

(8) all disciplinary actions or sanctions by any state or federal agency against the registrant or any principal, owner, director, officer, facility manager, or designated representative thereof;

(9) if the facility is located outside of Kansas, a record of the following:

(A) A current registration in the state where the registrant is located;

(B) a satisfactory inspection conducted within the previous 36-month period by the registering entity of the state where the registrant is located. If no such inspection record is readily available, the record of a satisfactory inspection conducted at the expense of the registrant within the previous 36-month period by a third party recognized by the board to inspect may be accepted; and

(C) a designated resident agent in Kansas for service of process, the record of whom shall also be on file with the secretary of state; and

(10) if the registrant is an outsourcing facility, a record of the following:

(A) A current outsourcing facility registration from the food and drug administration (FDA); and

(B) a current inspection report from an FDA inspection conducted within the previous 24-month period that indicates compliance with the requirements of the federal food, drug and cosmetic act, including guidance documents and current good manufacturing practices established by the FDA. If no such inspection record is readily available, the record of a satisfactory inspection conducted at the expense of the registrant within the previous 36-month period by a third party recognized by the board to inspect may be accepted.

(b) A single registration may be issued by the board for any business entity operating more

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~~than one facility within this state, or for a parent entity with divisions, subsidiaries, affiliate companies, or some combination of these within this state when operations are conducted at more than one location and there exists joint ownership and control among all the entities~~ Each registrant shall provide the board with a surety bond that meets the requirements of 21 U.S.C. 360ccc-2.

(c) Each registrant shall provide and maintain, in readily retrievable form, a list of all manufacturers, wholesale distributors, third-party logistics providers, outsourcing facilities, and dispensers with which the registrant is transacting business.

(d) Each registrant shall submit revised information requested by subsection (a) within 30 days after any change in that information. (Authorized by K.S.A. 65-1630; implementing K.S.A. 1998-Supp. 65-1643, K.S.A. 65-1645 and, K.S.A. 65-1655, K.S.A. 65-1655a, and K.S.A. 65-1655b; effective June 15, 1992; amended July 23, 1999; amended P-_____.)

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68-14-5. Personnel. ~~As a condition for receiving and retaining a wholesale distributor registration, the~~ (a) Each wholesale distributor registrant, virtual wholesale distributor registrant, third-party logistics registrant, or outsourcing facility registrant shall require each person employed in any ~~prescription-only drug~~ wholesale distribution, virtual wholesale distribution, third-party logistics, or outsourcing activity to have, or any combination of these activities, to receive education, training, and experience, ~~or any combination of these,~~ sufficient for that person to perform the assigned functions in a manner providing assurance that the drug product quality, safety, and security will at all times be maintained as required by law. Each registrant shall maintain records of the training, education, and experience for five years.

(b) Each wholesale distributor registrant, virtual wholesale distributor registrant, or third-party logistics provider registrant shall designate an individual as the facility manager, who shall be responsible for all aspects of the registrant's operation.

(c) Each outsourcing facility registrant shall designate a pharmacist-in-charge, as defined by K.S.A. 65-1626 and amendments thereto, who shall be responsible for all aspects of the registrant's operation. (Authorized by and implementing K.S.A. 65-1630; implementing K.S.A. 1998 Supp. 65-1655, K.S.A. 65-1655a, and K.S.A. 65-1655b; effective June 15, 1992; amended July 23, 1999; amended P-_____.)

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68-14-7. Wholesale distributors; minimum requirements for the storage and handling of prescription-only drugs and devices and for the establishment and maintenance of prescription-only drug and device distribution records. Each wholesale distributor registrant shall meet the following minimum requirements for the storage and handling of prescription-only drugs and devices, and for the establishment and maintenance of prescription-only drug and device distribution records by ~~wholesale distributors~~ the registrant and ~~their~~ its officers, agents, representatives, and employees:

(a) Facilities. Each facility at which prescription-only drugs and devices are stored, warehoused, handled, held, offered, marketed, transported from, or displayed shall meet the following requirements:

(1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(2) have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(3) have a quarantine area for storage of prescription-only drugs and devices that are outdated, damaged, deteriorated, misbranded, ~~or~~ adulterated, counterfeit, or suspected of being counterfeit, or that are in immediate or sealed, secondary containers that have been opened or deemed unfit for distribution;

(4) be maintained in a clean and orderly condition; ~~and~~

(5) be free from infestation by insects, rodents, birds, or vermin of any kind;

(6) be a commercial location and not a personal dwelling or residence;

(7) have sufficient storage space to maintain records of all transactions for at least five

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years; and

(8) be in a location separate from any other wholesale distributor or pharmacy registered by the board or another state.

(b) Security.

(1) Each facility used for wholesale ~~drug~~ distribution shall be secure from unauthorized entry.

(A) Access from outside the premises shall be kept to a minimum and be well controlled.

(B) The outside perimeter of the premises shall be well lighted.

(C) Entry into areas where prescription-only drugs or devices are held shall be limited to authorized personnel.

(2) Each facility shall be equipped with an alarm system to detect entry after hours.

(3) Each facility shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(4) Each registrant shall ensure adequate accountability and control of all controlled substances in compliance with the Kansas uniform controlled substances act, federal drug laws, and all applicable regulations.

(5) Each registrant shall verify that all persons or entities who undertake, either directly or by any other arrangement, to transport prescription-only drugs or devices on behalf of the registrant ensure security.

(c) Storage. All prescription-only drugs and devices shall be stored at appropriate

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temperatures and under appropriate conditions in accordance with ~~requirements, if any, in the~~ labeling manufacturer's recommendations to preserve the stability of these drugs and devices, or with requirements in the 1995 edition of the United States pharmacopeia/national formulary (USP/NF), ~~which is adopted by reference.~~

(1) If no storage requirements are established for a prescription-only drug or device, the drug or device may be held at "controlled" room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(2) Appropriate manual, electromechanical, or electronic temperature and humidity-recording equipment, devices, logs, or a combination of these ~~methods~~ means shall be utilized to document proper storage of prescription-only drugs and devices at least once during each 24-hour period.

(3) The ~~record-keeping~~ recordkeeping requirements in subsection (f) ~~of this regulation~~ shall be followed for all stored prescription-only drugs and devices.

(d) Examination of materials.

(1) Upon receipt, each outside shipping container shall be visually examined ~~for identity to~~ identify and to prevent the acceptance of ~~contaminated~~ prescription-only drugs or ~~prescription-only drugs~~ devices that are contaminated or otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment shall be carefully inspected ~~for identity of~~ to identify the prescription-only ~~drug products~~ drugs or devices and to ensure that there is no delivery of

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prescription-only drugs or devices that have been damaged in storage or held under improper conditions.

(3)(A) No registrant shall engage in the wholesale distribution of prescription-only drugs or devices that are purchased or received from pharmacies or practitioners or from wholesale distributors that obtained the drugs or devices from pharmacies or practitioners.

(B) Any registrant may receive for redistribution prescription-only drugs or devices returned from pharmacies or practitioners that were distributed by the registrant. Before redistribution, the registrant shall examine the prescription-only drug or device to ensure that it has not been opened or used. If the prescription-only drug or device has been opened, it shall be quarantined and physically separated from other prescription-only drugs or devices until the prescription-only drug or device is destroyed.

(C) Any registrant that also operates as a reverse logistics provider or returns processor may receive prescription-only drugs or devices for destruction from pharmacies and practitioners regardless of where the drugs or devices are obtained. Each registrant shall maintain documentation for the disposition of prescription-only drugs or devices sent for destruction with proof of destruction, including a certificate of destruction, for inventory accountability and shall maintain records documenting any return to the supplier.

(4) ~~The record-keeping~~ recordkeeping requirements in subsection (f) ~~of this regulation~~ shall be followed for all incoming and outgoing prescription-only drugs or devices.

(e) Returned, damaged, and outdated prescription-only drugs or devices.

(1) Prescription-only drugs or devices that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription-

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only drugs and devices until they are destroyed or returned to their supplier.

(2) ~~Any~~ Each prescription-only ~~drugs~~ drug or device whose immediate or sealed outer or sealed secondary ~~containers have~~ container has been opened or used shall be identified as such, and shall be quarantined and physically separated from other prescription-only drugs or devices until ~~they are~~ the drug or device is either destroyed or returned to the supplier.

(3) If the conditions under which a prescription-only drug or device has been returned cast doubt on the drug's or device's safety, identity, strength, quality, or purity, then the drug or device shall be destroyed or returned to the supplier, unless examination, testing, or other investigations prove that the drug or device meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether or not the conditions under which a drug or device has been returned cast doubt on the drug's or device's safety, identity, strength, quality, or purity, the ~~wholesale distributor~~ registrant shall consider, among other factors, the conditions under which the drug or device has been held, stored, or shipped before or during its return and the condition of the drug or device and its container, carton, or labeling, as a result of storage or shipping.

(4) The ~~record-keeping~~ recordkeeping requirements in subsection (f) ~~of this regulation~~ shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription-only drugs or devices.

(f) ~~Record-keeping~~ Recordkeeping.

(1) Each ~~wholesale distributor~~ registrant shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription-only drugs and devices. These records shall include the following information:

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(A) The source of the drugs and devices, including the name and principal address of the seller or transferor, and the address of the location from which the drugs or devices were shipped;

(B) the identity and quantity of the drugs and devices received and either distributed or disposed of; and

(C) the dates of receipt and either distribution or other disposition of the drugs and devices.

(2) Each record related to the wholesale distribution of prescription-only drugs or devices, including invoices of purchase or sale, packing slips, and shipment records, shall accurately reflect the name of the registrant as that name appears on the registration issued by the board.

(3) Inventories and records shall be made available for inspection and photocopying by an authorized federal, state, or local law enforcement agency official representative of the board for five years following disposition of the prescription-only drugs or devices.

(3) (4) Records described in this regulation that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by an authorized official of a federal, state, or local law enforcement agency representative of the board.

(5) Each registrant shall post all current federal and state registrations in a conspicuous place.

(g) Written policies and procedures. Each ~~wholesale distributor~~ registrant shall establish, maintain, and adhere to written policies and procedures concerning the receipt, security, storage,

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inventory, and distribution of prescription-only drugs and devices, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. In addition, each ~~wholesale distributor~~ registrant shall establish, maintain, and adhere to the following written policies and procedures:

(1) A procedure by which the oldest approved stock of a prescription-only drug ~~product or device~~ is distributed first. The procedure may permit deviation from this requirement, if the deviation is temporary and appropriate to meet the needs of the receiving facility;

(2) a procedure to be followed for handling recalls and withdrawals of prescription-only drugs and devices. This procedure shall be adequate to deal with recalls and withdrawals due to any of the following:

(A) Any action initiated at the request of the food and drug administration or other federal, state, or local law enforcement or other government agency, including the board;

(B) any voluntary action by the manufacturer to remove defective or potentially defective drugs or devices from the market; or

(C) any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design;

(3) a procedure to ensure that wholesale distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency; and

(4) a procedure to ensure that ~~any~~ all outdated prescription-only drugs or devices ~~shall be~~ are segregated from other drugs or devices and either returned to the manufacturer or destroyed.

This procedure shall provide for written documentation of the disposition of outdated

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prescription-only drugs and devices. This documentation shall be maintained for five years after disposition of the outdated prescription-only drugs or devices; and

(5) a procedure to ensure that prescription-only drugs and devices are distributed only to registered entities with the authority to possess prescription-only drugs or devices in Kansas and to maintain documentation of this authority as part of the distribution record.

(h) Responsible persons. Each ~~wholesale distributor~~ registrant shall establish and maintain lists a list of officers, directors, managers, and other persons in charge of wholesale prescription-only drug and device distribution, storage, and handling, including a description of their duties and a summary of their qualifications. This list shall be made available for inspection by the board.

(i) Compliance with federal, state, and local law.

(1) Each ~~wholesale distributor~~ registrant that deals in controlled substances shall register with the ~~drug enforcement administration~~ DEA.

(2) Each ~~wholesale distributor~~ registrant shall permit the board's authorized personnel and authorized federal, state, and local law enforcement officials to enter and inspect the distributor's registrant's premises and delivery vehicles, and to audit the records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

(3) ~~These officials shall be required to show appropriate identification before being permitted access to wholesale distributors' premises and delivery vehicles~~ Each registrant shall operate in accordance with the requirements of 21 U.S.C. 353, 21 U.S.C. 360eee-1, 21 U.S.C. 360eee-2, and any implementing regulation.

(j) Salvaging and reprocessing. Each ~~wholesale distributor~~ registrant shall be subject to the

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provisions of any applicable federal, state, or local laws or regulations that relate to prescription-only drug ~~product~~ or device salvaging or reprocessing. (Authorized by K.S.A. 65-1630 ~~and~~; implementing K.S.A. 65-1634 and K.S.A. 65-1655; effective June 15, 1992; amended July 23, 1999; amended P-_____.)

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68-14-7a. Third-party logistics providers; minimum requirements for operation and maintenance of records. Each third-party logistics provider registrant shall meet the following minimum requirements for operation and the maintenance of records:

(a) Facilities. Each facility at which a third-party logistics provider is located shall meet the following requirements:

- (1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
- (2) have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
- (3) have a quarantine area for storage of prescription-only drugs and devices that are outdated, damaged, deteriorated, misbranded, adulterated, counterfeit, or suspected of being counterfeit or that are in immediate or sealed, secondary containers that have been opened or deemed unfit for distribution;
- (4) be maintained in a clean and orderly condition;
- (5) be free from infestation by insects, rodents, birds, or vermin of any kind;
- (6) be in a location separate from any pharmacy registered by the board or another state;
- (7) be a commercial location and not a personal dwelling or residence; and
- (8) have sufficient storage space to maintain records of all shipments pertaining to third-party logistics for at least five years.

(b) Security.

(1) Each facility used for third-party logistics shall be secure from unauthorized entry.

(A) Access from outside the premises shall be kept to a minimum and be well controlled.

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(B) The outside perimeter of the premises shall be well lighted.

(C) Entry into areas where prescription-only drugs or devices are held shall be limited to authorized personnel.

(2) Each facility shall be equipped with an alarm system to detect entry after hours.

(3) Each facility shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(c) Storage. All prescription-only drugs and devices shall be stored at appropriate temperatures and under appropriate conditions in accordance with manufacturer's recommendations to preserve the stability of these drugs and devices.

(1) If no storage requirements are established for a prescription-only drug or device, the drug or device may be held at room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(2) Appropriate manual, electromechanical, or electronic temperature and humidity-recording equipment, devices, logs, or a combination of these means shall be utilized to document proper storage of prescription-only drugs and devices at least once during each 24-hour period.

(3) The recordkeeping requirements in subsection (f) shall be followed for all stored prescription-only drugs and devices.

(d) Examination of materials.

(1) Upon receipt, each outside shipping container shall be visually examined to identify and

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to prevent the acceptance of prescription-only drugs or devices that are contaminated or otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment shall be carefully inspected to identify the prescription-only drugs or devices and to ensure that there is no delivery of prescription-only drugs or devices that have been damaged in storage or held under improper conditions.

(3) The recordkeeping requirements in subsection (f) shall be followed for all incoming and outgoing prescription-only drugs or devices.

(e) Returned, damaged, and outdated prescription-only drugs or devices.

(1) Prescription-only drugs or devices that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription-only drugs and devices until they are destroyed or returned to their supplier.

(2) Each prescription-only drug or device whose immediate or sealed outer or sealed secondary container has been opened or used shall be identified as such and shall be quarantined and physically separated from other prescription-only drugs and devices until the drug or device is either destroyed or returned to the supplier.

(3) If the conditions under which a prescription-only drug or device has been returned cast doubt on the drug's or device's safety, identity, strength, quality, or purity, then the drug or device shall be destroyed or returned to the supplier, unless examination, testing, or other investigations prove that the drug or device meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether or not the conditions under which a drug or device has been returned cast doubt on the drug's or device's safety, identity, strength, quality, or

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purity, the registrant shall consider, among other factors, the conditions under which the drug or device has been held, stored, or shipped before or during its return and the condition of the drug or device and its container, carton, or labeling, as a result of storage or shipping.

(4) The recordkeeping requirements in subsection (f) shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription-only drugs or devices.

(f) Recordkeeping.

(1) Each registrant shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription-only drugs and devices. These records shall include the following information:

(A) The source of the drugs and devices, including the name and principal address of the seller or transferor, and the address of the location from which the drugs or devices were shipped;

(B) the identity and quantity of the drugs and devices received and either distributed or disposed of; and

(C) the dates of receipt and either distribution or other disposition of the drugs and devices.

(2) Inventories and records shall be made available for inspection and photocopying by an authorized representative of the board for five years following disposition of the prescription-only drugs or devices.

(3) The records described in this regulation that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from the inspection site and not electronically retrievable shall be made available for inspection within

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two working days of a request by an authorized representative of the board.

(4) Each registrant shall post all current federal and state registrations in a conspicuous place.

(g) Written policies and procedures. Each registrant shall establish, maintain, and adhere to written policies and procedures concerning the receipt, security, storage, inventory, and distribution of prescription-only drugs and devices, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. In addition, each registrant shall establish, maintain, and adhere to the following written policies and procedures:

(1) A procedure by which the oldest approved stock of a prescription-only drug or device is distributed first. The procedure may permit deviation from this requirement, if the deviation is temporary and appropriate to meet the needs of the receiving facility;

(2) a procedure to be followed for handling recalls and withdrawals of prescription-only drugs and devices. This procedure shall be adequate to deal with recalls and withdrawals due to any of the following:

(A) Any action initiated at the request of the food and drug administration or other federal, state, or local law enforcement or other government agency, including the board;

(B) any voluntary action by the manufacturer to remove defective or potentially defective drugs or devices from the market; or

(C) any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design;

(3) a procedure to ensure that the registrant prepares for, protects against, and handles any

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crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency;

(4) a procedure to ensure that all outdated prescription-only drugs or devices are segregated from other drugs and devices and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription-only drugs or devices. Each registrant shall maintain this documentation for five years after disposition of each outdated prescription-only drug or device; and

(5) a procedure to ensure that prescription-only drugs and devices are sold only to registered entities with the authority to possess prescription-only drugs or devices in Kansas and to maintain documentation of this authority as part of the distribution record.

(h) Responsible persons. Each registrant shall establish and maintain a list of officers, directors, managers, and other persons in charge of prescription-only drug and device distribution, storage, and handling, including a description of their duties and a summary of their qualifications. This list shall be made available for inspection by the board.

(i) Compliance with federal, state, and local law.

(1) Each registrant that deals in controlled substances shall register with the DEA.

(2) Each registrant shall permit the board's authorized personnel to enter and inspect the registrant's premises and delivery vehicles and to audit the records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

(3) Each registrant shall operate in accordance with the requirements of 21 U.S.C. 360eee, or any implementing regulation. (Authorized by K.S.A. 65-1630; implementing K.S.A. 65-1634 and K.S.A. 65-1655a; effective P-_____.)

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68-14-7b. Outsourcing facilities; minimum requirements for operation and maintenance of records. Each registrant who is the owner of an outsourcing facility shall meet the following minimum requirements for operation and the maintenance of records:

(a) Facilities. Each outsourcing facility shall meet the following requirements:

- (1) Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
- (2) have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
- (3) have a quarantine area for storage of prescription-only drugs and devices that are outdated, damaged, deteriorated, misbranded, adulterated, or deemed unfit for distribution;
- (4) have a quarantine area designated for holding products waiting for testing data before being released for distribution;
- (5) be maintained in a clean and orderly condition;
- (6) be free from infestation by insects, rodents, birds, or vermin of any kind;
- (7) be a commercial location and not a personal dwelling or residence; and
- (8) have sufficient storage space to maintain records of all shipments pertaining to outsourcing for at least five years.

(b) Security.

(1) Each facility used for outsourcing shall be secure from unauthorized entry.

(A) Access from outside the premises shall be kept to a minimum and be well controlled.

(B) The outside perimeter of the premises shall be well lighted.

(C) Entry into areas where prescription-only drugs and devices are held shall be limited to

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authorized personnel.

(2) Each facility shall be equipped with an alarm system to detect entry after hours.

(3) Each facility shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(c) Storage. All prescription-only drugs and devices shall be stored at appropriate temperatures and under appropriate conditions in accordance with manufacturer's recommendations to preserve the stability of these drugs and devices.

(1) If no storage requirements are established for a prescription-only drug or device, the drug or device may be held at room temperature, as defined in an official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(2) Appropriate manual, electromechanical, or electronic temperature and humidity-recording equipment, devices, logs, or a combination of these means shall be utilized to document proper storage of prescription-only drugs and devices at least once during each 24-hour period.

(3) The recordkeeping requirements in subsection (f) shall be followed for all stored prescription-only drugs and devices.

(d) Examination of materials.

(1) Upon receipt, each outside shipping container shall be visually examined to identify and to prevent the acceptance of prescription-only drugs or devices that are contaminated or otherwise unfit for distribution. This examination shall be adequate to reveal container damage

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that would suggest possible contamination or other damage to the contents.

(2) Each outgoing shipment shall be carefully inspected to identify the prescription-only drugs or devices and to ensure that there is no delivery of prescription-only drugs or devices that have been damaged in storage or held under improper conditions.

(3) The recordkeeping requirements in subsection (f) shall be followed for all incoming and outgoing prescription-only drugs and devices.

(e) Returned, damaged, and outdated prescription-only drugs and devices.

(1) Prescription-only drugs or devices that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription-only drugs and devices until they are destroyed.

(2) Each prescription-only drug or device whose immediate or sealed outer or sealed secondary container has been opened or used shall be identified as such and shall be quarantined and physically separated from other prescription-only drugs until the drug or device is either destroyed or returned to the supplier.

(3) If the conditions under which a prescription-only drug or device has been returned cast doubt on the drug's or device's safety, identity, strength, quality, or purity, then the drug or device shall be destroyed, unless examination, testing, or other investigations prove that the drug or device meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether or not the conditions under which a drug or device has been returned cast doubt on the drug's or device's safety, identity, strength, quality, or purity, the registrant shall consider, among other factors, the conditions under which the drug or device has been held, stored, or shipped before or during its return and the condition of the drug or device and its

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container, carton, or labeling, as a result of storage or shipping.

(4) The recordkeeping requirements in subsection (f) shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription-only drugs and devices.

(f) Recordkeeping.

(1) Each registrant shall establish and maintain records of all transactions regarding the receipt and distribution or other disposition of prescription-only drugs and devices and any bulk active pharmaceutical ingredients used in compounding or manufacturing. These records shall include the following information:

(A) The source of the drugs and devices or the active pharmaceutical ingredients, including the name and principal address of the seller or transferor, the address of the location from which the drugs or devices were shipped, and the certificate of analysis if an active pharmaceutical ingredient was received;

(B) the identity and quantity of the drugs and devices or the active pharmaceutical ingredients received and either distributed or disposed of; and

(C) the date of receipt of the drugs and devices and the date of distribution or any other disposition of the drugs and devices.

(2) Records shall be made available for inspection and photocopying by an authorized representative of the board for five years following disposition of the prescription-only drugs or devices.

(3) The records described in this regulation that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be readily available for authorized inspection during the retention period. Records kept at a central location apart from

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the inspection site and not electronically retrievable shall be made available for inspection within two working days of a request by an authorized representative of the board.

(4) Each registrant shall post all current federal and state registrations in a conspicuous place.

(g) Written policies and procedures. Each registrant shall establish, maintain, and adhere to written policies and procedures concerning the receipt, security, storage, inventory, and distribution of prescription-only drugs and devices, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. In addition, each registrant shall establish, maintain, and adhere to the following written policies and procedures:

(1) A procedure by which the oldest approved stock of a prescription-only drug or device is distributed first. The procedure may permit deviation from this requirement, if the deviation is temporary and appropriate to meet the needs of the receiving facility;

(2) a procedure to be followed for handling recalls and withdrawals of prescription-only drugs and devices including written notification to the board within 24 hours. This procedure shall be adequate to deal with recalls and withdrawals due to any of the following:

(A) Any action initiated at the request of the food and drug administration or other federal, state, or local law enforcement or other government agency, including the board;

(B) any voluntary action by the registrant to remove defective or potentially defective drugs or devices from the market; or

(C) any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design;

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(3) a procedure to ensure that the registrant prepares for, protects against, and handles any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or national emergency;

(4) a procedure to ensure that all outdated prescription-only drugs or devices are segregated from other drugs or devices and destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription-only drug or device. This documentation shall be maintained for five years after disposition of the outdated prescription-only drug or device; and

(5) a procedure to ensure that prescription-only drugs and devices are sold only to registered entities with the authority to possess prescription-only drugs and devices in Kansas and to maintain documentation of this authority as part of the distribution record.

(h) Responsible persons. Each registrant shall establish and maintain a list of officers, directors, managers, pharmacists, pharmacy technicians, and other persons in charge of drug compounding, distribution, storage, and handling, including a description of their duties and a summary of their qualifications. This list shall be made available for inspection by the board.

(i) Compliance with federal, state, and local law.

(1) Each registrant that deals in controlled substances shall register with the DEA.

(2) Each registrant shall permit the board's authorized personnel to enter and inspect the registrant's premises and delivery vehicles and to audit the records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

(3) Each registrant shall operate in accordance with section 503B of the federal food, drug, and cosmetic act, 21 U.S.C. 353b.

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(4) Each drug manufactured, prepared, propagated, compounded, or processed by an outsourcing facility without a registration issued by the board shall be deemed misbranded.

(Authorized by K.S.A. 65-1630; implementing K.S.A. 65-1634 and K.S.A. 65-1655b; effective

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68-19-1. Minimum program requirements. Each pharmacy's continuous quality improvement program shall meet the following minimum requirements:

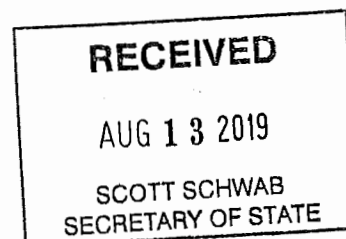
- (a) Meet at least once each quarter of each calendar year;
- (b) have the pharmacy's ~~pharmacist in charge~~ pharmacist-in-charge in attendance at each meeting; and
- (c) perform the following during each meeting:
 - (1) Review all incident reports generated for each reportable event associated with that pharmacy since the last quarterly meeting;
 - (2) for each incident report reviewed, establish the steps taken or to be taken to prevent a recurrence of the incident; and
 - (3) review each board newsletter published since the last quarterly meeting; and
 - (4) create a report of the meeting, including at least the following information:
 - (A) A list of the persons in attendance;
 - (B) a list of the incident reports and newsletters reviewed; and
 - (C) a description of the steps taken or to be taken to prevent recurrence of each incident reviewed. (Authorized by and implementing L. 2008, ch. 104, §16 K.S.A. 65-1695; effective April 10, 2009; amended P-_____.)

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68-21-6. Reciprocal agreements with other states or government entities to share

information. (a) Reciprocal agreements with one or more states ~~in~~ of the following entities ~~within~~ the United States may be entered into by the board to share program information data if the ~~other state's~~ entity's prescription monitoring program is compatible with the program. ~~If the board elects to evaluate the prescription monitoring program of another state, priority shall be given to a state that is contiguous to Kansas.;~~

(1) A state, commonwealth, district, or territory;

(2) a military or veteran health system;

(3) an Indian health system or service; or

(4) a city, county, municipality, or township.

(b) In determining the compatibility of the ~~other state's~~ entity's prescription monitoring program, the following may be considered by the board:

(1) The safeguards for privacy of patient records and the ~~other state's~~ entity's success in protecting patient privacy;

(2) the persons authorized ~~in~~ by the ~~other state~~ entity to view the data collected by the program;

(3) the schedules of controlled substances monitored ~~in~~ by the ~~other state~~ entity;

(4) the data required by the ~~other state~~ entity to be submitted on each prescription; and

(5) the costs and benefits to the board of mutually sharing information data with the ~~other state~~ entity.

(c) ~~Each~~ Any reciprocal agreement ~~shall~~ may be reviewed annually by the board to determine its continued compatibility with the program. (Authorized by K.S.A. 2009-Supp. 65-

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K.A.R. 68-21-6

p. 2

1692; implementing K.S.A. 2009-Supp. 65-1685; effective October 15, 2010; amended P-_____
_____.)

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

Kansas Board of Pharmacy
Agency

Alexandra Blasi
Agency Contact

785-296-8419
Contact Phone Number

68-7-15, 68-19-1, and 68-2-10
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. 68-7-15 is being amended to allow packaging of drugs dispensed or supplied by the pharmacy or any other pharmacy engaged in a shared services agreement under K.A.R. 68-7-20, and to provide necessary limitations for prepackaging and repackaging of parenteral products.

K.A.R. 68-19-1 is being amended to require review of the Board's quarterly newsletter during the pharmacy's quarterly continuous quality improvement meetings.

K.A.R. 68-2-10 is being amended to require closed pharmacies to notify the Board and patients about the location and disposition of patient records, and creating requirements for pharmacies accepting records of closed pharmacies.

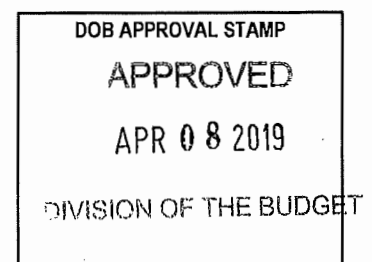
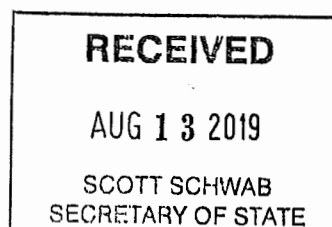
II. Statement by the agency if the rule(s) and regulation(s) is mandated by the federal government and a statement if approach chosen to address the policy issue is different from that utilized by agencies of contiguous states or the federal government. (If the approach is different, then include a statement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

Regulations are not mandated by the federal government. Amendments are consistent with other state requirements; language was specifically modeled from similar regulations in Arkansas.

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 Board anticipates no impact on 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;**

Any economic impact would stem only from K.A.R. 68-2-10 and would be specifically related to the closing pharmacy's new responsibility to notify patients of the closure and the disposition of patient records. Pharmacies are already required to maintain patient records for five years and, upon closure, are required to secure another pharmacy buyer or a permanent storage location for the files. The only new component is a notification to the patient about the disposition of the patient record. Notification may be made by mail or email, the economic effect of which may include the cost of paper, envelopes, and postage. This cost would be allocated to the closing pharmacy.

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

Pharmacies registered in Kansas

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

K.A.R. 68-7-15: Increased ability of pharmacies to capitalize on efficiencies and economies of scale in packaging and repackaging drugs for patients.

K.A.R. 68-19-1: Increased pharmacist, intern, and technician awareness and education; higher level of engagement with the Board; public safety and patient welfare.

K.A.R. 68-2-10: Patient access to previous medication records and future access to care.

- E. Measures taken by the agency to minimize the cost and impact of the proposed rule(s) and regulation(s) on business and economic development within the State of Kansas, local government, and individuals;**

Utilization of existing Board forms, resources, and processes.

- 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.**

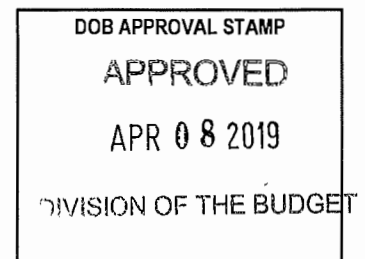
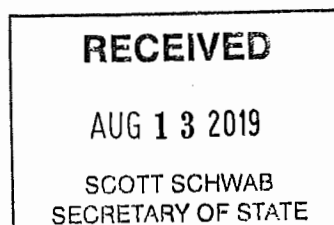
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An estimate, expressed as a total dollar figure, of the total implementation and compliance costs that are reasonably expected to be incurred by or passed along to business, local governments, or members of the public.

\$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.

n/a

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.

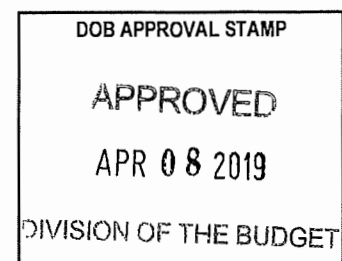
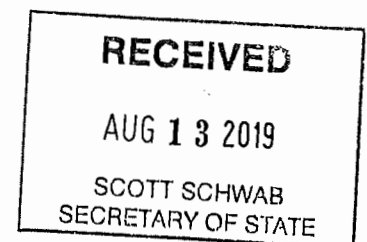
n/a

- 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).

After a recent abrupt pharmacy closure, the Board discussed changes to K.A.R. 68-2-10 in an open meeting. Requested changes to K.A.R. 68-7-15 were brought to the Board's attention during a public comment period by a large Kansas health system. The Board also discussed changes to K.A.R. 68-19-1 based on regular publication of the Board newsletter containing relevant policy and compliance articles which are evidently not being utilized or reviewed by Kansas pharmacists.

- 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).

n/a



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

Kansas Board of Pharmacy
Agency

Alexandra Blasi
Agency Contact

785-296-8419
Contact Phone Number

68-14-1, 68-14-2, 68-14-3, 68-14-4, 68-14-5, 68-14-7, 68-14-7a, 68-14-7b
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).

These regulations are proposed in response to 2017 HB 2055 to establish Kansas compliance with the Federal Drug Supply Chain Security Act (DSCSA), 21 U.S.C. 351 et seq. The law was amended at the federal level in 2014 to commence a 10-year process for updating requirements for those in the drug manufacturing and distribution chain, and to create an electronic, interoperable system to identify and trace prescription drugs from the manufacturer through distribution, to the ultimate consumer. These regulations align Board oversight of wholesale distributors, virtual wholesale distributors, third-party logistics providers, and outsourcing facilities with federal rules, including definitions, operational requirements, facilities, security, storage, and records. Kansas currently registers each of these facilities as a pharmacy, manufacturer, or distributor, but this is not how they are classified by the Federal Food and Drug Administration (FDA). Thus, new registration categories have been established and regulations are being adopted in response.

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)*

Regulations are not mandated by the federal government but are needed to allow facilities to be compliant on the state and national level and for consistency. Language is consistent with and was specifically modeled from similar regulations in 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;

Aligning state requirements with the federal rules and other states should enhance business activity related to the manufacture, distribution, and compounding of prescription drugs and devices by allowing these facilities to more readily transact business with Kansas. The regulations are also designed to maintain necessary public protection mechanisms within these facilities and ensure compliance with recognized pharmacy standards.

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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;**

Registration and renewal application fees have been set in a separate regulation. However, fees should have a null effect on revenue and expense because the Board is merely shifting registrants from one registration category to another. For the same reasons, there would not be any increased cost to the Board related to licensure or compliance. There could be an increase in the number of registered facilities in Kansas, which would result in an increase in revenue to the Board that is immeasurable.

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

Manufacturers, wholesale distributors, virtual wholesale distributors, third-party logistics providers, and outsourcing facilities of prescription drugs and devices.

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

These regulations benefit the aforementioned businesses that may be impacted by creating consistency with federal and state law, which will increase the level of compliance and the number of business transactions in Kansas related to the distribution of prescription drugs and devices. Furthermore, these regulations protect the public by ensuring these facilities meet recognized standards related to distribution of prescription drugs and devices, as well as outsourcing facilities which compound sterile preparations in bulk. Any costs are incidental and are related to routine operational costs of the Board.

- 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;**

Utilization of existing Board forms, resources, and processes. The Board also has planned a phased implementation to allow businesses with current registrations to shift categories without incurring additional expenses or application fees, and to minimize any impact on Board staff and resources.

- 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.**

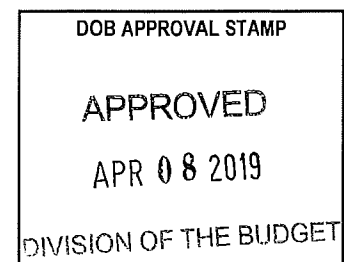
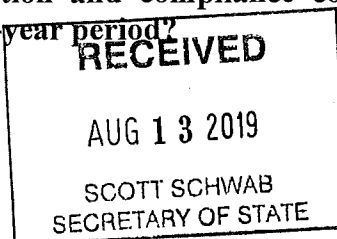
\$0 – costs to businesses may include time associated with completing necessary application forms and corresponding with the Board.

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.

n/a

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.**

n/a

- 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 has discussed implementation with other states and plans to solicit information from businesses with current registrations after adoption of regulations but prior to commencing the phased implementation process. In addition, the Board consulted with businesses at the time of the implementing legislation (2017 HB 2055).

- 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).**

n/a

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Proposed

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

Kansas Board of Pharmacy

Agency

Alexandra Blasi

Agency Contact

785-296-8419

Contact Phone Number

68-21-6

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. 68-21-6 is being amended to allow the Board to share K-TRACS data with other relevant government entities that have established prescription drug monitoring programs, including the Missouri St. Louis County initiative, military health system via the department of defense, Indian health systems, and veteran health system.

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)*

There are no federal mandates pertaining to these regulations. The Board currently shares data with 31 states and would like to expand this connectivity to share with federal health systems and Missouri which do not currently fit under the stated allowance for sharing with "state" programs. At the time the regulation was adopted, other data sharing was not conceived.

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 Board anticipates no impact on 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;

None. The Board has data sharing capabilities and will merely expand to these other entities. If there is any economic impact, it would be related to increased data sharing and increased program utilization which could positively benefit the health of patients.

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

These regulations are unlikely to affect businesses that employ prescribers and pharmacists (hospitals, clinics, pharmacies).

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

If there is any economic impact, it would be related to increased data sharing and increased program utilization which could positively benefit the health of patients and potentially decrease healthcare costs in the long run. Such impact is unknown to the Board and unquantifiable.

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

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.

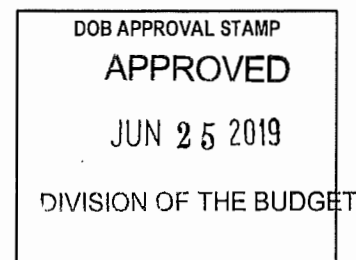
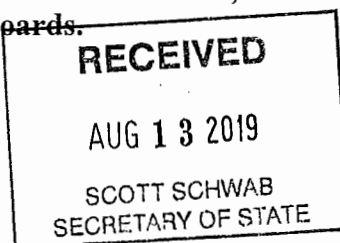
n/a

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.

n/a



- 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 discussed these regulatory changes in an open meeting of the Board of Pharmacy and consulted the PDMP Advisory Committee, which is composed of prescribers and pharmacists representing all relevant stakeholder organizations. Both groups agreed to move this regulation forward without opposition or objection. The Board also annually meets with other states regarding interstate data sharing and this model is consistent with successful models in other states.

- 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).**

n/a

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