Kansas Administrative Regulations

State Board of Pharmacy

Article 14.—Wholesale Distributors

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(3) have a quarantine area for storage of prescription-only drugs and devices that are outdated, damaged, deteriorated, misbranded, adulterated, or deemed unfit for distribution;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 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 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 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 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;

(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.

(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 Jan. 3, 2020.)