Kansas Administrative Regulations

State Board of Pharmacy

Article 14.—Wholesale Distributors

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 the registrant and 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(3) have a quarantine area for storage of prescription-only drugs and devices that are outdated, damaged, deteriorated, misbranded, adulterated, counterfeit, or suspected of being counterfeit, or that are in immediate or sealed, secondary containers that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 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 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 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 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)(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 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 or 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 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) 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 representative of the board for five years following disposition of the prescription-only drugs or devices.

(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 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 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 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;

(4) a procedure to ensure that all outdated prescription-only drugs or devices 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 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 registrant shall establish and maintain 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 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. 353, 21 U.S.C. 360eee-1, 21 U.S.C. 360eee-2, and any implementing regulation.

(j) Salvaging and reprocessing. Each registrant shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to prescription-only drug or device salvaging or reprocessing.

(Authorized by K.S.A. 65-1630; implementing K.S.A. 65-1634 and K.S.A. 65-1655; effective June 15, 1992; amended July 23, 1999; amended Jan. 3, 2020.)