201 KAR 2:105. Licensing and drug distribution requirements for wholesale distributors.

RELATES TO: KRS 315.010, 315.402, 315.406
STATUTORY AUTHORITY: KRS 315.010, 315.191(1), 315.402, 315.406
NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.402 and 315.406 authorizes the board to promulgate administrative regulations to regulate wholesale distributors of drugs. This administrative regulation establishes the requirements for the regulation of wholesale distributors.

Section 1. Definition. "Drug sample" means unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

Section 2. Requirements. (1) A wholesale distributor engaged in wholesale distribution in the Commonwealth shall apply for a license from the board in accordance with KRS 315.402, 315.406, and this administrative regulation.

(2) A separate license shall be required for each wholesale distributor's facility that distributes within the Commonwealth regardless of whether joint ownership or control exists.

(3) An agent or employee of a licensee shall not be required to obtain a license under this section when the agent or employee is acting in the usual course of business or employment.

(4) A license shall not be issued or renewed unless the applicant demonstrates or continues to demonstrate acceptable operational procedures, including:

(a) Adequate maintenance and storage conditions to ensure proper lighting, ventilation, temperature and humidity control, sanitation, space, and security as per label requirements or official United States Pharmacopoeia (USP) compendium requirements. Appropriate manual, electromechanical or electronic temperature and humidity recording equipment, devices, or logs shall be utilized to document proper storage of prescription drugs;

(b) Physical separation and quarantine of deteriorated, damaged, outdated, misbranded, adulterated or otherwise recalled merchandise until they are destroyed or returned;

(c) Providing accurate and precise records of all goods shipped or received including source or recipient, date, quantity, itemized description, and any other information pertinent to the transaction; and

(d) Providing proof of registration with the state controlled substance authority, and with the U.S. Drug Enforcement Administration and shall comply with all DEA regulations.

Section 3. Qualifications for License. (1) The minimum qualifications shall include:

(a) The Kentucky Board of Pharmacy shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in wholesale distribution of prescription drugs within the Commonwealth:

1. Any convictions of the applicant under any federal, state, or local laws relating to drug samples and wholesale or retail drug distribution of controlled substances;

2. Any felony convictions of the applicant under federal, state, or local laws;

3. The applicant's past experience in the wholesale distribution of prescription drugs, including controlled substances;

4. The furnishing by the applicant of false or fraudulent material in any application made in connection with wholesale distribution;

5. Suspension or revocation by federal, state, or local government of any license or permit currently or previously held by the applicant for wholesale distribution of any drugs, including controlled substances;

6. Compliance with the requirements under any previously granted license or permit, if any; and

7. Compliance with requirements to maintain or make available to the Kentucky Board of

Pharmacy or to federal, state, or local law enforcement officials those records required under this section.

(b) The Kentucky Board of Pharmacy shall have the right to deny a license to an applicant if it determines that the granting of that license would not be in the public interest based on health and safety considerations.

(2) A license shall not be issued pursuant to this administrative regulation unless the applicant has furnished proof satisfactory to the Board of Pharmacy:

(a) That the applicant is in compliance with all applicable federal and state laws and regulations relating to drugs; and

(b) That the applicant is equipped as to land, buildings, and security to properly carry on the business described in his application.

(3) A license issued pursuant to this administrative regulation may be suspended or revoked for failure to comply with the provisions of KRS 315.400, 315.402, 315.404, 315.406, 315.408, 315.410, 315.412, or this administrative regulation.

Section 4. Application, Fees, Renewals. (1) An application for a license shall be submitted to the Board of Pharmacy on "Application for a License to Operate as a Wholesale Distributor (KBP W 9:08)".

(2) An application shall be accompanied by the annual fee set forth in 201 KAR 2:050.

(3) An application shall include:

(a) The name, full business address, and telephone number of the licensee;

(b) All trade or business name used by the licensee;

(c) Addresses, telephone numbers, and the names of contract persons for all facilities used by the licensee for the storage, handling, and distribution of prescription drugs;

(d) The type of ownership or operation (i.e. partnership, corporation, or sole proprietorship);

(e) The name(s) of the owner and operator of the licensee, including;

1. If a person, the name and Social Security number of the person;

2. If a partnership, the name and Social Security number of each partner, and the name of the partnership;

3. If a corporation, the name, Social Security number and title of each corporate officer and director, the corporate names, and the name of the state of incorporation; and

4. If a sole proprietorship, the full name and Social Security number of the sole proprietor and the name of the business entity; and

(f) A list of all licenses and permits issued to the applicant by any other state that authorizes the applicant to purchase or possess prescription drugs.

(4) All licenses shall:

(a) Expire on September 30 following date of issuance; and

(b) Be renewable annually thereafter upon renewal application accompanied by the renewal fee set forth in 201 KAR 2:050 and shall be nontransferable.

Section 5. Standards. (1) Facilities.

(a) All buildings in which legend drugs are held for wholesale distribution, repackaged, stored, held, sold, offered for sale, exposed for sale, or kept for sale shall be of suitable size, construction, and location to facilitate cleaning, maintenance, and proper operations.

(b) Buildings shall meet all applicable federal, state, and local standards. The facility shall have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed secondary containers that have been opened.

(c) A facility shall not be located in a residence.

(2) Security.

(a) A wholesale distributor shall be equipped with an alarm system to detect entry after hours.

(b) A wholesale distributor shall ensure that access from outside their premises is well-controlled and reduced to a minimum. This includes the installation of adequate lighting at the outside perimeter of the premises.

(c) Internal security policies shall be developed to provide reasonable protection against theft and diversion by limiting access to areas where legend drugs are held to authorized personnel. These policies shall provide protection against tampering with computers or electronic records.

(d) A licensee shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the wholesale distribution of prescription drugs.

(3) Recordkeeping.

(a) Inventories and other records of transactions regarding the receipt and disposition of legend drugs shall be maintained and readily available for inspection or photocopying by authorized law enforcement officials for a period of two (2) years following disposition of the drugs. These records shall include:

1. The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

2. The identity and quantity of the drugs received and distributed or disposed of; and

3. The dates of receipt and distribution or other distribution of the drugs.

(b) Records described in this section 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 (2) working days of a request by an authorized official of a federal, state, or local law enforcement agency.

(4) Written policies and procedures.

(a) A Wholesaler Distributor distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts and to assure that the wholesale distributor prepares for, protects against, and handles crisis situations that affect the security or operation of the facility. These crises shall include fires, floods, or other natural disasters, and situations of local, state, or national emergency.

(b) There shall be written policies and procedures for managing and correcting all errors or inaccuracies in inventories.

(c) There shall be written policies and procedures to assure that any outdated stock or any stock with an expiration date that, in the wholesale distributor's view, does not allow sufficient time for repacking or resale shall be segregated from other stock and shall be prepared for return to the manufacturer or otherwise destroyed, and this shall be documented.

(d) There shall be written policies and procedures by which the wholesale distributor exercises control over the shipping and receiving of all stock within the operation.

(5) Returned, damaged, and outdated prescription drugs. A wholesale distributor shall maintain and follow a written procedure to assure the proper handling and disposal of returned goods if conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, then the drug shall be destroyed, or returned, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale distributor shall consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling, as a result of storage or shipping.

(6) Handling recalls. A wholesale distributor shall maintain and follow written policy for handling recalls and withdrawals of products. The policy shall cover all recalls and withdrawals of drug products due to:

(a) Any voluntary action on the part of the manufacturer;

(b) The direction of the Food and Drug Administration, or any other federal, state, or local government agency; and

(c) Replacement of existing merchandise with an improved product or new package design.

(7)(a) A visual examination of all materials received or shipped shall be made to guarantee product identity and to reasonably guard against acceptance or delivery of damaged, contaminated, tampered, or otherwise unfit stock.

(b) Procedures for distribution of approved stock shall provide for a rotation whereby the oldest inventory is distributed first.

(c) A wholesale distributor shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to prescription drug product salvaging or reprocessing.

Section 6. Pedigree. (1) Effective July 1, 2009 and in accordance with KRS 315.406, each person or entity engaged in the wholesale distribution of prescription drugs that leave or that have ever left the normal distribution channel shall, prior to the distribution of the prescription drug, provide a pedigree to the person receiving the prescription drug.

(2) The pedigree shall include the following information concerning the prescription drug:

(a) The proprietary and established name of the prescription drug;

(b) The dosage;

(c) The size of the container;

(d) The number of containers;

(e) The lot number of control number of the prescription drug;

(f) The business name and address of all parties to each prior transaction involving the drug, starting with the manufacturer; and

(g) The date of each previous transaction.

(3) Pedigree records shall be maintained and readily be available for inspections or photocopying by authorized law enforcement officials for a period of two (2) years.

Section 7. Violations. (1) A wholesale distributor shall not distribute legend drugs directly to a consumer or a patient or operate in a manner that endangers the public health.

(2) Violation of any of these provisions shall be grounds for the suspension or revocation of the license.

Section 8. Incorporation by Reference. (1) "Application for a License to Operate as a Wholesale Distributor" (KBP W 9:08) is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, Spindletop Administration Building Suite 302, 2624 Research Park Drive, Lexington, Kentucky 40511, Monday through Friday, 8 a.m. to 4:30 p.m. (9 Ky.R. 77; eff. 8-11-1982; 11 Ky.R. 1616; eff. 6-4-1985; 16 Ky.R. 1597; eff. 4-12-1990; 18 Ky.R. 2348; 2832; 2917; eff. 3-25-1992; 19 Ky.R. 445; eff. 10-8-1992; 28 Ky.R. 2406; 29 Ky.R. 98; eff. 7-15-2002; 35 Ky.R. 982; 1826; 1740; eff. 2-18-2009.)