201 KAR 2:320. Permit requirements for manufacturers.

RELATES TO: KRS 315.020(2), 315.036, and 315.191(1)
STATUTORY AUTHORITY: KRS 315.020(2), 315.036, 315.191(1)
NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.036 and 315.191(1) authorizes the board to promulgate administrative regulations to regulate the manufacturers of drugs. KRS 315.036 authorizes the board to promulgate administrative regulations regarding manufacturer permits and the maintenance and reporting of accurate records of all drugs manufactured, received and sold. KRS 315.020(2) authorizes the Board to promulgate administrative regulations regarding the pharmacist-in-charge. This administrative regulation establishes the requirements for a manufacturer permit and for functioning as a manufacturer.

Section 1. Requirements. (1) A manufacturer shall apply for a permit from the board in accordance with KRS 315.036 and this administrative regulation.
(2) A separate permit shall be required for each facility within the Commonwealth regardless of whether joint ownership or control exists.
(3) An agent or employee of a permit holder shall not be required to obtain a permit under this section when the agent or employee is acting in the usual course of business or employment.
(4) A permit shall not be issued or renewed unless the applicant or its officers 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 current year 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(b) Physical separation and quarantine of deteriorated, damaged, outdated, misbranded, adulterated, or otherwise recalled merchandise until they are destroyed or returned;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;
(d) Providing proof of registration with the state controlled substance authority, and with the U.S. Drug Enforcement Administration and compliance with all DEA regulations.

Section 2. Qualifications for Permit. (1)(a) The Kentucky Board of Pharmacy shall consider, at a minimum, the following factors in reviewing the qualifications of persons who engage in manufacturer of prescription drugs within the Commonwealth:
1. Any convictions of the officers of the applicant under any federal, state, or local laws;
2. The applicant's past experience in the manufacture of prescription drugs, including controlled substances;
3. The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing;
4. Suspension or revocation by federal, state, or local government of any license or permit currently or previously held by the applicant or its officers for the manufacture of any drugs, including controlled substances;
5. Compliance with the requirements under any previously granted license or permit, if any; and
6. 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 permit to an applicant or its officers if it determines that the granting of that permit would not be in the public interest for any reason established in KRS 315.121.

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

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

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

(3) A permitted manufacturer may sell or distribute federal legend drugs only to the following:

(a) A currently permitted manufacturer;

(b) A currently licensed wholesale distributor;

(c) A currently permitted pharmacy;

(d) A currently licensed practitioner;

(e) A currently licensed hospital, but only for use by or in that hospital; or

(f) A person in charge of a laboratory, but only for use in that laboratory for scientific and medical research purposes.

(4) A permit holder may be disciplined for failure to comply with the provisions of KRS 315.036, pursuant to KRS 315.121, or this administrative regulation.

Section 3. Application, Fees; Renewals. (1) An application for a permit shall be submitted to the Board of Pharmacy on Application for a Permit to Operate as a Manufacturer (KBP M 5:09).

(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 applicant;

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

(c) Addresses, telephone numbers, and the names of the contact persons for the facility used by the permittee for the storage, handling, and manufacturing 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 permittee, 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 manufacture or possess prescription drugs.

(4) All permits shall:

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

(b) Be:

1. Renewable annually thereafter upon proper application accompanied by the renewal fee set forth in 201 KAR 2:050; and

2. Nontransferable.

Section 4. Standards. (1) Facilities.

(a) All buildings in which legend drugs are 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 manufacturer shall be equipped with an alarm system to detect entry after hours.

(b) A manufacturer 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 permit holder shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the manufacturer of prescription drugs.

(e) Lists of officers, directors, managers and other persons in charge of distribution, storage, and handling of prescription drugs, including a description of their duties and summary of their qualifications, shall be maintained for purpose of review.

(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 manufacturer shall establish, maintain, and adhere to written policies and procedures 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 ensure that the manufacturer 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 manufacturer's view, does not allow sufficient time for

repacking or resale shall be segregated from other stock and shall be prepared for return or otherwise destroyed, and this shall be documented.

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

(5) Returned, damaged, and outdated prescription drugs. A manufacturer's operation 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 to the supplier, 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 manufacturer 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 manufacturer shall adopt, maintain, and follow a 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 first expiration inventory is distributed first.

(c) A manufacturer 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 5. Pharmacist-in-charge. A manufacturer shall designate a pharmacist-in-charge of the facility who shall be responsible to the board for security and recordkeeping. The pharmacist-in-charge shall review the security and records by conducting an on-site inspection not less than quarterly.

Section 6. Violations. (1) A drug manufacturer 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 discipline of the permit pursuant to KRS 315.121.

Section 7. Incorporation by Reference. (1) "Application for a Permit to Operate as a Manufacturer", 6/09, 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 Administrative Building, Suite 302, 2624 Research Park Drive, Lexington, Kentucky 40511, Monday through Friday, 8 a.m. through 4:30 p.m. (36 Ky.R. 618; 778; eff. 10-21-2009.)