KENTUCKY BOARD OF PHARMACY
125 Holmes Street, Ste 300
Frankfort KY 40601

Agenda for Regulation Committee

I. Call to Order

II. Minutes – May 20, 2019

III. Discussion:

A. 201 KAR 2:175, Emergency/72 hour prescription refills
B. 201 KAR 2:105, Licensing and drug distribution requirements for wholesale distributors.
C. 201 KAR 2:106, Pharmacy, manufacturer, or distributor closures.
D. 201 KAR 2:320, Permit requirements for manufacturers.
E. 201 KAR 2:280, Prescription dispensing for formulary compliance.
F. Repository regulation
G. Unused Permits

IV. Next meeting date

v. Adjournment

201 KAR 2:175. Emergency/seventy-two (72) hour prescription refills.

RELATES TO: KRS Chapters 217,315

STATUTORY AUTHORITY: KRS 217.215(3), 315.191

NECESSITY, FUNCTION, AND CONFORMITY: This administrative regulation sets out the conditions whereby a prescription may be refilled in an emergency situation and the prescriber is unavailable.

Section 1. If a pharmacist receives a request for a prescription refill with no refill authorized and the pharmacist is unable to readily obtain refill authorization from the prescriber, the pharmacist may dispense a one (1) time emergency refill of up to a seventy-two (72) hour supply of the medication when:

(1) The prescription refill is not for a controlled substance;

(2) The medication is essential to the maintenance of life or to the continuation of therapy in chronic conditions;

(3) In the pharmacist's professional judgment, the interruption of therapy might reasonably produce undesirable health consequences or may be detrimental to the patient's welfare and cause physical or mental discomfort;

(4) The pharmacist notes on the prescription record the date, the quantity dispensed, and his name or initials; and

(5) In all situations an emergency refill must be followed by authorization from the prescriber for continued therapy.

Section 2. Violation of any provision of this administrative regulation constitutes unethical or unprofessional conduct in accordance with KRS 315.121. (9 Ky.R. 1265; Am. 10 Ky.R. 5; eff. 6-1-83;16 Ky.R. 798; eff. 1-12-90.)

201 KAR 2:175. Emergency/seventy-two (72) hour prescription refills.

RELATES TO: KRS Chapters 217, 315

STATUTORY AUTHORITY: KRS 217.215(3), 315.191

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(2) The medication is essential to the maintenance of life or to the continuation of therapy in chronic conditions;

(3) In the pharmacist's professional judgment, the interruption of therapy might reasonably produce undesirable health consequences or may be detrimental to the patient's welfare and cause physical or mental discomfort;

(4) The pharmacist notes on the prescription record the date, the quantity dispensed, and his name or initials; and

(5) In all situations an emergency refill must be followed by authorization from the prescriber for continued therapy.

(6) A pharmacist may dispense greater than a seventy-two (72) hour supply of maintenance medication if:

a. The standard unit of dispensing for the drug exceeds a seventy two (72) hour supply;

b. The pharmacist dispenses a supply of the drug that is equal to the standard unit of dispensing for the drug; and

c. The drug is used for insulin therapy or the treatment of chronic respiratory diseases.

Section 2. Violation of any provision of this administrative regulation constitutes unethical or unprofessional conduct in accordance with KRS 315.121.

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 di- rector, 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 in- accuracies 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; Am. 11 Ky.R. 1616; eff. 6-4-85; 16 Ky.R.1597; eff. 4-12-90; 18 Ky.R. 2348; 2832; 2917; eff. 3-25-92; 19 Ky.R. 445; eff. 10-8-92; 28 Ky.R. 2406; 29 Ky.R. 98; eff. 7-15-2002; 35 Ky.R. 982; 1826; 1740; eff. 2-18-2009.)

201 KAR 2:106. Pharmacy, manufacturer, or distributor closures.

RELATES TO: KRS 315.035, 315.036

STATUTORY AUTHORITY: KRS 315.036, 315.191(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) requires the board to promulgate administrative regulations relating to subject matters governed by KRS Chapter 315. This administrative regulation establishes requirements relating to closure of business by licensees.

Section 1. Definitions. As used in this administrative regulation:

(1) "Permanent closure" means a licensee:

(a) Ceases to do business and permanently closes; and

(b) Does not file application for a pharmacy license for the same location;

(2) "Voluntary closure" means a closing or abandonment of premises resulting from:

(a) Chronic mental or physical deterioration; or

(b) A deviation from the business hours listed on the current permit application or amendments filed thereto; or

(c) Cessation of the practice of pharmacy at the licensed location for a reason other than permanent or involuntary closure.

(3) "Involuntary closure" means an interruption of formal business activity resulting from:

(a) Acute illness or incapacitation;

(b) Death;

(c) Fire, flood or other natural disaster;

(d) Bankruptcy proceedings; or

(e) Court, government, or Board of Pharmacy action.

Section 2. Procedures for Closure. (1) Permanent closure.

(a) A licensee shall conspicuously place a sign notifying the public thirty (30) days in advance of the:

1. Termination date of business; and

2. Name and address of the licensee to which prescription files or other pertinent records will be transferred.

(b) Except when prevented by the exercise of another party's legal rights:

1. The sign shall remain in place for a period of thirty (30) days after the closure; and

2. All efforts shall be undertaken to assure a smooth transition of uninterrupted service to those affected by the closure.

(c) A licensee shall inform the Board of Pharmacy, Drug Enforcement Administration, and the Cabinet for Human Resources by written notice fifteen (15) days prior to the anticipated closing and include the following information:

1. Date of business termination; and

2. Name, address, and DEA number of registrant to whom the prescription or controlled drugs are to be transferred.

(d) In the absence of directives to the contrary from the Drug Enforcement Administration, the Board of Pharmacy, or the Cabinet for Human Resources, the transfer shall be effected on the as- signed date.

(e) The transferor and the transferee shall each maintain copies of the following documents relating to transferred controlled substances for at least two (2) years:

1. U.S. Official Order Forms, DEA-222 Schedule II; and

2. Schedules Ill, IV, and V Invoices) for a period of at least two (2) years.

(f) Upon termination, a licensee shall:

1. Remove all signs pertinent to pharmacy or drugs from the building and premises; and

2. Return the voided permits, the Drug Enforcement Administration registration, and unused Schedule II Order Forms to their respective office of issue.

(g) The posting of the sign required by paragraph (a) of this subsection shall not be required if:

1. An application for a pharmacy license for the same location is filed; or

2. During a sale of a pharmacy, prescription records are transferred to another permitted pharmacy that is within five (5) miles of the location of the pharmacy that is sold and owned by the purchasing entity.

(2) Voluntary closure.

(a) A pharmacy or distributor licensed by the Kentucky Board of Pharmacy whose hours of operation have deviated over a period of five (5) consecutive working days from those of record at the Board of Pharmacy office shall immediately notify the board, verbally and in writing of the reason for the deviation and the anticipated period of continuance.

(b) Upon receipt of the notice, the Board of Pharmacy, with full cooperation of the licensee, shall make arrangements it deems necessary to provide adequate and continued security and control of all drugs, chemicals, poisons, and devices owned or controlled by the licensee.

(c) If normal operation cannot resume within sixty (60) days, or if satisfactory agreements cannot be reached between the Board of Pharmacy, the licensee, or his designated representative, the:

1. Permit shall be revoked; and

2. Board of Pharmacy shall notify the Cabinet for Human Resources to assume control

and responsibility of any drug, chemical, poison, or device deemed necessary in any manner deemed appropriate.

(d) If the Board of Pharmacy or the Cabinet for Human Resources or its agents liquidate or arrange for the liquidation of items specified in paragraphs (b) and (c) of this subsection, the board or the Cabinet for Human Resources may retain a portion of the proceeds realized from the liquidation equal to the expenses incurred.

(3) Involuntary closure.

(a) Within five (5) days of involuntary closure, a licensee, or person authorized to act on his be- half, shall:

1. Notify the board in writing; and

2. Guarantee the safety and control of the licensed premises in a manner that will allow continued storage of controlled substances consigned to the board permittees for sixty (60) days after the effective date of the involuntary closure.

(b) Within sixty (60) days after the effective date of the involuntary closure, a licensee shall effect arrangements for the lawful sale or other disposition of drugs and substances requiring board licensure.

(c) The board may assume control and responsibility of substances it deems necessary for disposition, if after the expiration of the sixty (60) day period following the effective date of involuntary closure:

1. A sale or other disposition has not been effected; or

2. An agreement between the board, and the licensee or person authorized to act on behalf of the licensee, has not been reached.

Section 3. Duties and Responsibilities of Licensee. A licensee or person authorized to act on

his behalf shall:

(1) Fully cooperate with the board to promote the efficient administration of action required by the provisions of this administrative regulation; and

(2) Be financially liable to the board for expenses incurred by the board in its implementation of the provisions of this administrative regulation. (16 Ky.R. 1718; Am. 2123; eff. 4-12-90; 23 Ky.R.3866; 24 Ky.R. 61; eff. 6-18-97.)

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 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 ininventories.

(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 pharma- cist-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; Am. 778; eff. 10-21-09.)

201 KAR 2:280. Prescription dispensing for formulary Compliance.

RELATES TO: KRS 217.814, 315.191
STATUTORY AUTHORITY: KRS 315.191(1)(a), (f)
NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations necessary to regulate and control all matters set forth in KRS Chapter 315 relating to pharmacists. KRS 315.191(1)(f) authorizes the board to promulgate administrative regulations to control the storage, retrieval, dispensing, refilling, and transfer of prescription drug orders within and between qualifying pharmacists and pharmacies. This administrative regulation establishes procedural and substantive requirements for dispensing an equivalent drug product pursuant to a practitioner declaration of formulary compliance approval.

Section 1. Dispensing. (1) A pharmacist may dispense a therapeutic equivalent drug product under the following conditions:

(a) The ordering practitioner has indicated "formulary compliance approval" on the prescription, in one of the following ways:

1. In the practitioner's own handwriting; or

2. By checking a "formulary compliance approval" box on a preprinted form;

(b) The pharmacist receives a formulary change as a consequence of the patient's third-party plan; and

(c) The product designated as "preferred" by the third-party formulary is in the same therapeutic class as the prescribed drug.

(2) The pharmacist, within twenty-four (24) hours of the formulary compliance substitution, shall notify the ordering practitioner, in an original writing or by facsimile:

(a) That the pharmacist engaged in formulary compliance; and

(b) The therapeutic equivalent drug product that was dispensed.

Section 2. The pharmacist may make adjustments in the quantity and directions to provide for an equivalent dose of the preferred formulary therapeutic alternative. (29 Ky.R. 2197; 2447; eff. 4-11-2003; Crt eff. 4-17-2019.)