BOARDS AND COMMISSIONS

Board of Pharmacy

(Amendment)

201 KAR 2:105. Requirements for wholesalers, medical gas wholesalers, wholesale distributors, and virtual wholesale distributors.

RELATES TO: KRS 315.010, 315.121, 315.350, 315.400, 315.402, 315.404, 315.406, 315.408, 315.410, 315.412

STATUTORY AUTHORITY: KRS 315.010, 315.191(1)(a), 315.350, 315.402, 315.406

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations to regulate and control all matters set forth in KRS Chapter 315. KRS 315.350, 315.402 and 315.406 require the board to promulgate administrative regulations to regulate wholesalers, medical gas wholesalers, wholesale distributors, and virtual wholesale distributors of prescription drugs and drug-related devices. This administrative regulation establishes the requirements for the regulation of wholesalers, medical gas wholesalers, wholesale distributors, and virtual wholesale distributors.

Section 1. Definitions.

(1) "Component" means any raw material, ingredient, or article intended for use in the manufacture of a drug and drug-related device.

(2) "Distribution" or "distribute" is defined by KRS 315.400(5).

(3) "Drug sample" means a unit of a prescription drug that is not intended to be sold and is intended to promote the sale of the drug.

(4) "Illegitimate Product" is defined by KRS 315.400(11).

(5) "Medical gas wholesaler" is defined by KRS 315.400(13).

(6) "Product" means a prescription drug in a finished dosage form for administration to a patient without substantial further manufacturing, such as capsules, tablets, and lyophilized products before reconstitution.

(7) "Suspect product" means a component, prescription drug, or drug-related device for which there is reason to believe that such component, prescription drug, or drug-related device:

(a) Is potentially counterfeit, diverted, or stolen;

(b) Is potentially intentionally adulterated such that the component, prescription drug, or drug-related device would result in serious adverse health consequences or death to humans or animals;

(c) Is potentially the subject of a fraudulent transaction; or

(d) Appears otherwise unfit for distribution such that the component, prescription drug, or drug-related device would result in serious adverse health consequences or death to humans or animals.

(8) "Wholesale distribution" is defined by KRS 315.400(20).

(9) "Wholesale distributor" is defined by KRS 315.400(21).

(10) "Wholesaler" is defined by KRS 315.010(28), and includes medical gas wholesalers, wholesale distributors, and virtual wholesale distributors.

(11) "Virtual wholesale distributor" has the same meaning given in KRS 315.400(21).

Section 2. Requirements.

(1) A wholesaler engaged in wholesale distribution in the Commonwealth shall apply for a license from the Board of Pharmacy in accordance with KRS 315.350, 315.402, 315.406, and this administrative regulation.

(2) A surety bond is required of not less than $25,000, or other equivalent means of security acceptable to the Board of Pharmacy or a third party recognized by the Board of

Pharmacy such as insurance, an irrevocable letter of credit, or funds deposited in a trust account or financial institution. This shall be used to secure payment of any administrative penalties imposed by the Board of Pharmacy and any fees or costs incurred by the Board of Pharmacy regarding that licensee if those penalties, fees, or costs are authorized under state law, and the licensee fails to pay thirty (30) days after the penalty, fee, or costs becomes final. A separate surety bond or other equivalent means of security is not required for each company's separate locations or for affiliated companies or groups~~[orgroups]~~ if separate locations or affiliated companies or groups~~[orgroups]~~ are required to apply for or renew their wholesaler license with the Board of Pharmacy. The Board of Pharmacy may make a claim against the bond or other equivalent means of security until one (1) year after the wholesaler's license closes, lapses or expires, or until sixty (60) days after any administrative or legal proceeding before or on behalf of the Board of Pharmacy that involves the wholesaler is concluded, including any appeal, whichever occurs later. The Board of Pharmacy may waive the bond requirement, if the wholesaler:

(a) Has previously obtained a comparable surety bond or other equivalent means of security for the purpose of licensure in another state, where the wholesaler possesses a valid license in good standing;

(b) Is a publicly held company;

(c) Is a medical gas wholesaler; or

(d) Has a license for the sole purpose of distribution within a health care entity under common ownership.

(3) A separate license shall be required for each wholesaler's facility that engages in wholesale distribution within the Commonwealth regardless of whether joint ownership or control exists.

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

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

(a) Adequate operational, 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, USP Chapter 659, Packaging and Storage Requirements. Appropriate manual, electromechanical or electronic temperature and humidity recording equipment, devices, or logs shall be utilized to document proper storage of prescription drugs and drug-related devices;

(b) Separation and quarantine of deteriorated, damaged, outdated, misbranded, adulterated or otherwise recalled prescription drugs and drug-related devices until they are destroyed or returned;

(c) Providing accurate and precise records of all prescription drugs and drug-related devices sold, purchased, traded, delivered, handled, stored, or received and any other information pertinent to the distribution or disposition; and

(d) Providing proof of registration with the U.S. Drug Enforcement Administration (DEA) and shall comply with all DEA regulations, if applicable.

(6) Wholesale distributors and virtual wholesale distributors shall comply with all requirements outlined in the Drug Supply Chain Security Act (DSCSA), 21 U.S.C. 360eee-360eee-4.

(7) Wholesalers shall establish a system to:

(a) Quarantine and investigate suspect product to determine if it is illegitimate; and

(b) Notify U.S. Food and Drug Administration (FDA), if applicable, the Board of Pharmacy and recipient(s) of illegitimate product, if illegitimate product is found.

(8) A virtual wholesale distributer shall be exempt from the following, subsection 2(5)(a) and (b) of this Section, and Section 5(1)(a) and (b), and (2)(a) and (b) of this administrative regulation.

Section 3. Qualifications for License.

(1) The 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 and drug-related devices within the Commonwealth:

(a) Any convictions of the applicant under any federal, state, or local laws relating to drugs, including drug samples and controlled substances;

(b) Any felony convictions of the applicant under federal, state, or local laws;

(c) The applicant's past experience in the distribution of prescription drugs and drug-related devices, including drug samples and controlled substances;

(d) The furnishing by the applicant of false or fraudulent material in any application made in connection with the distribution of prescription drugs and drug-related devices;

(e) Suspension or revocation by federal, state, or local government of any license or permit currently or previously held by the applicant for distribution of any prescription drugs and drug-related devices, including drug samples and controlled substances;

(f) Compliance with the requirements under any previously granted license or permit, if any; and

(g) Compliance with requirements to maintain or make available to the Board of Pharmacy or to federal, state, or local law enforcement officials those records required under this administrative regulation.

(2) The 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.

(3) 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, state, and local 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 the application.

(4) A license issued pursuant to this administrative regulation failing to comply with the provisions of KRS 315.350, 315.400, 315.402, 315.404, 315.406, 315.408, 315.410, 315.412, or this administrative regulation may result in action under KRS 315.121.

Section 4. Application, Fees, Renewals.

(1) An application for a license shall be submitted to the Board of Pharmacy on the Application for a License to Operate as a Wholesaler.

(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 names 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 and drug-related devices;

(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;

(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 and drug-related devices; and

(g) Proof of surety bond or equivalent.

(4) All licenses shall:

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

(b) Be renewable annually thereafter upon submission of the Renewal Application to Operate as a Wholesaler accompanied by the renewal fee set forth in 201 KAR 2:050 and shall be nontransferable.

Section 5. Standards.

(1) Facilities.

(a) All facilities in which prescription drugs and drug-related devices are held for wholesale distribution, stored, 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) All facilities shall meet all applicable federal, state, and local standards. The facility shall quarantine prescription drugs and drug-related devices that are outdated, damaged, deteriorated, misbranded, recalled, 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.

(d) A facility shall be located apart and separate from a pharmacy permitted by the Board of Pharmacy, with the exception of a medical gas wholesaler.

(2) Security.

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

(b) A wholesaler 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 prescription drugs and drug-related devices 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 and drug-related devices.

(3) Recordkeeping requirements for companies handling prescription drugs and drug-related devices exempt from the DSCSA.

(a) Inventories and other records regarding the receipt and distribution or disposition of prescription drugs and drug-related devices shall be maintained and readily available for inspection or photocopying by the Board of Pharmacy and authorized law enforcement officials for a period of six (6) years). These records shall include:

1. The proprietary and established name of the prescription drug and related device, if applicable;

2. The dosage, if applicable;

3. The size of the container, if applicable;

4. The number of containers;

5. The lot number or control number of the prescription drug and related device, if applicable;

6. The business name and address of all parties involved in each receipt and distribution or disposition of the prescription drug and related device, starting with the manufacturer; and

7. The date of each receipt and distribution or disposition of the prescription drug and related device.

(b) Records described in this section that are kept at the inspection site or that can be readily retrievable within forty-eight (48) hours 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 the Board of Pharmacy or an authorized official of a federal, state, or local law enforcement agency.

(c) Wholesalers shall maintain an ongoing list of verified persons or businesses with whom they do business.

(d) A wholesaler may sell or distribute prescription drugs and drug-related devices only to the following, except as provided in KRS 315.0351(2) and 315.404:

1. A currently licensed wholesaler;
2. A currently licensed third party logistics provider;
3. A currently permitted pharmacy;
4. A currently licensed outsourcing facility;
5. A currently licensed practitioner;
6. A currently permitted repackager;
7. A currently licensed hospital, but only for use by or in that hospital pursuant to KRS 217.182(1);
8. A person in charge of a laboratory, but only for use in that laboratory for scientific and medical research purposes pursuant to KRS 217.182(1); or
9. Any other appropriately licensed or permitted facility in the jurisdiction in which it is located.

(e) A wholesaler may acquire prescription drugs and drug-related devices only from the following, except as provided in KRS 315.404:

1. A currently permitted manufacturer;
2. A currently permitted repackager;
3. A currently licensed wholesaler; or
4. A currently licensed third-party logistics provider.

(f) Wholesalers shall maintain a system for the mandatory reporting of any theft, suspected theft, diversion, or other significant loss of any prescription drug and related device to the Board of Pharmacy, and if applicable, the FDA and DEA.

(4) Written policies and procedures, requirements for companies handling prescription drugs and drug-related devices exempt from the DSCSA.

(a) A wholesaler shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, distribution, and disposition of prescription drugs and drug-related devices

(b) There shall be written policies and procedures for identifying, recording, and reporting losses or thefts.

(c) There shall be written policies and procedures to assure that the wholesaler 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.

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

(e) There shall be written policies and procedures to assure that any outdated stock or any stock with an expiration date that, in the wholesaler'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.

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

(g) There shall be written policies and procedures for investigating suspect product and reporting illegitimate product to the Board of Pharmacy and the FDA pursuant to the DSCSA, if applicable.

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

(6) Handling recalls. A wholesaler shall establish, maintain, and adhere to a written policy and procedure for handling recalls and withdrawals of prescription drugs and drug-related devices. The policy and procedure shall cover all recalls and withdrawals of drugs and drug-related devices due to:

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

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

(c) Replacement of existing.

(7) Procedures

(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 expiration date is taken into consideration when distributing inventory.

(c) A wholesaler shall be subject to the provisions of any applicable federal, state, or local laws or regulations that relate to prescription drug and related device salvaging or reprocessing.

Section 6. Violations.

(1) A wholesaler shall not distribute prescription drugs and drug-related devices directly to a consumer or a patient, except as provided in KRS 315.0351(2).

(2) A wholesaler shall not operate in a manner that endangers the public health.

(3) Violations of any of these provisions shall be grounds for action under KRS 315.121.

Section 7. Incorporation by Reference.

(1) The following material is incorporated by reference:

(a) "Application for a License to Operate as a Wholesaler", June 2023~~[May 2020]~~;

(b) "Renewal Application to Operate as a Wholesaler", June 2023~~[May 2020]~~; and

(c) "USP Chapter 659 Packaging and Storage Requirements", April 1, 2021~~[November 1, 2020]~~.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601-8024. Monday through Friday, 8 a.m. to 4:30 p.m. or on the Board's website at https://pharmacy.ky.gov/Businesses/Pages/Wholesale-Distributors.aspx.

CHRISTOPHER P. HARLOW, Executive Director

APPROVED BY AGENCY: June 7, 2023
FILED WITH LRC: June 7, 2023 at 1:45 p.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall be held on August 30, 2023, at 10:00 a.m. Eastern Time via zoom teleconference. Individuals interested in being heard at this hearing shall notify this agency in writing by five workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through August 31, 2023. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person.

CONTACT PERSON: Christopher Harlow, Executive Director, Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, State Office Building Annex, Frankfort, Kentucky 40601, phone (502) 564-7910, fax (502) 696-3806, email Christopher.harlow@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person:Christopher Harlow

(1) Provide a brief summary of:

(a) What this administrative regulation does:
This administrative regulation establishes the requirements for the regulation of wholesalers, medical gas wholesalers, wholesale distributors and virtual wholesale distributors.

(b) The necessity of this administrative regulation:
KRS 315.191(1)(a) authorizes the Board of Pharmacy to promulgate administrative regulations with minimum requirements for the permitting of those entities that provide pharmacy services. This administrative regulation establishes the requirements for the regulation of wholesalers, medical gas wholesalers, wholesale distributors and virtual wholesale distributors.

(c) How this administrative regulation conforms to the content of the authorizing statutes:
This administrative regulation establishes the requirements for the regulation of wholesalers, medical gas wholesalers, wholesale distributors and virtual wholesale distributors.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:
Retitle this regulation and cleanup language to be consistent with Federal Regulations.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation:
No answer provided.

(b) The necessity of the amendment to this administrative regulation:
The criteria needed to be updated.(b) How the amendment conforms to the content of the authorizing statutes: KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations pertaining to pharmacists and pharmacies. The amendment ensures that the appropriate amount is listed in the applications.

(c) How the amendment conforms to the content of the authorizing statutes:
The amendment is only to the applications, and the amendment is required to align with proposed changes to 201 KAR 2:050. (d) How the amendment will assist in the effective administration of the statutes? The amendment is necessary to ensure that the regulation is aligned with the Board's fee regulation, 201 KAR 2:050.

(d) How the amendment will assist in the effective administration of the statutes:
The amendment will further promote, preserve, and protect public health through effective the correct fee amount being listed in the application.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:
The board anticipates pharmacies and pharmacists will be affected minimally by this regulation amendment. Wholesalers will be impacted.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment:

Pharmacies and pharmacists will have to familiarize themselves with amended language. The board will help to educate regulated entities about these changes.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3):

Due to the amendment to the fee amount in the form pursuant to 201 KAR 2:050, it will cost wholesalers an additional $25 per year in their licensing fee.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3):

This amendment will ensure robust regulation and quick administrative turn-around. (5) Provide an estimate of how much it will cost to implement this administrative Regulation:

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially:

There will be no costs incurred.

(b) On a continuing basis:

There will be no costs incurred.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation:

Board revenues from pre-existing fees provide the funding to enforce the regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment:

The fee for wholesale distributor permit will be increased by $25.00 in 201 KAR 2:050.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees:

This administrative regulation does not establish fees directly, but references in the forms a fee increase from 201 KAR 2:050.

(9) TIERING: Is tiering applied?

No. Tiering is not applied because the regulation is applicable to all entities wishing to distribute pharmaceuticals in Kentucky.

FISCAL NOTE

(1) What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation?

The Kentucky Board of Pharmacy will be the only entity impacted by this administrative regulation.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation.

KRS 315.191(1)(a).

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year?

It is estimated this administrative regulation will generate an annual increase in revenue in the amount of $106,800.00 for the Board in the first year. This regulation does not directly create a fee, but the application incorporated by reference does include a fee, as authorized in 201 KAR 2:050.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years?

It is estimated this administrative regulation will generate an annual increase in revenue in the amount of $106,800.00 for the Board in the first year. This regulation does not directly create a fee, but the application incorporated by reference does include a fee, as authorized in 201 KAR 2:050.

(c) How much will it cost to administer this program for the first year?

The administrative costs to administer this program include application processing, inspections, and general regulatory inquiries.

(d) How much will it cost to administer this program for subsequent years?

The administrative costs to administer this program include application processing, inspections, and general regulatory inquiries.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):proposed amendment will provide an annual $106,800 increase in revenue

Expenditures (+/-):-$106,800, cost of ensuring compliance of license holder.

Other Explanation:

n/a

(4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.

(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year?
None

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years?
None.

(c) How much will it cost the regulated entities for the first year?
$150 annually.

(d) How much will it cost the regulated entities for subsequent years?
$150 annually.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Cost Savings (+/-):0

Expenditures (+/-):-$150 annually

Other Explanation:
This is the cost of the annual permit.

(5) Explain whether this administrative regulation will have a major economic impact, as defined below.
"Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars ($500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. [KRS 13A.010(13)] This regulation does not have major economic impact.