

1 Boards and Commissions

2 Board of Pharmacy

3 (Amendment)

4 201 KAR 2:105. Requirements for wholesalers, medical gas wholesalers, wholesale distributors,  
5 and virtual wholesale distributors.

6 RELATES TO: KRS 315.010, 315.121, 315.350, 315.400, 315.402, 315.404, 315.406, 315.408,  
7 315.410, 315.412

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

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

16 Section 1. Definitions.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

23 Section 2. Requirements.

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

4 (2) A surety bond is required of not less than \$25,000, or other equivalent means of security  
5 acceptable to the Board of Pharmacy or a third party recognized by the Board of Pharmacy such  
6 as insurance, an irrevocable letter of credit, or funds deposited in a trust account or financial  
7 institution. This shall be used to secure payment of any administrative penalties imposed by the  
8 Board of Pharmacy and any fees or costs incurred by the Board of Pharmacy regarding that  
9 licensee if those penalties, fees, or costs are authorized under state law, and the licensee fails  
10 to pay thirty (30) days after the penalty, fee, or costs becomes final. A separate surety bond or  
11 other equivalent means of security is not required for each company's separate locations or for  
12 affiliated companies or groups if separate locations or affiliated companies or groups are required  
13 to apply for or renew their wholesaler license with the Board of Pharmacy. The Board of  
14 Pharmacy may make a claim against the bond or other equivalent means of security until one  
15 (1) year after the wholesaler's license closes, lapses or expires, or until sixty (60) days after any  
16 administrative or legal proceeding before or on behalf of the Board of Pharmacy that involves  
17 the wholesaler is concluded, including any appeal, whichever occurs later. The Board of  
18 Pharmacy may waive the bond requirement, if the wholesaler:

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

22 (b) Is a publicly held company;

23 (c) Is a medical gas wholesaler; or

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

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

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

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

9 (a) Adequate operational, maintenance, and storage conditions to ensure proper lighting,  
10 ventilation, temperature and humidity control, sanitation, space, and security as per label  
11 requirements or official United States Pharmacopoeia (USP) compendium requirements, USP  
12 Chapter 659, Packaging and Storage Requirements. Appropriate manual, electromechanical or  
13 electronic temperature and humidity recording equipment, devices, or logs shall be utilized to  
14 document proper storage of prescription drugs and drug-related devices;

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

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

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

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

1 (7) Wholesalers shall establish a system to:

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

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

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

7 Section 3. Qualifications for License.

8 (1) The Board of Pharmacy shall consider, at a minimum, the following factors in reviewing the  
9 qualifications of persons who engage in wholesale distribution of prescription drugs and drug-  
10 related devices within the Commonwealth:

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

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

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

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

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

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

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

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

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

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

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

10 (4) A license issued pursuant to this administrative regulation failing to comply with the provisions  
11 of KRS 315.350, 315.400, 315.402, 315.404, 315.406596, 315.408, 315.410, 315.412, or this  
12 administrative regulation may result in action under KRS 315.121.

#### 13 Section 4. Application, Fees, Renewals.

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

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

17 (3) An application shall include:

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

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

20 (c) Addresses, telephone numbers, and the names of contract persons for all facilities used by  
21 the licensee for the storage, handling, and distribution of prescription drugs and drug-related  
22 devices;

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

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

- 1 1. If a person, the name and Social Security number of the person;
- 2 2. If a partnership, the name and Social Security number of each partner, and the name of the
- 3 partnership;
- 4 3. If a corporation, the name, Social Security number and title of each corporate officer and
- 5 director, the corporate names, and the name of the state of incorporation; and
- 6 4. If a sole proprietorship, the full name and Social Security number of the sole proprietor and
- 7 the name of the business entity;
- 8 (f) A list of all licenses and permits issued to the applicant by any other state that authorizes the
- 9 applicant to purchase or possess prescription drugs and drug-related devices; and
- 10 (g) Proof of surety bond or equivalent.

11 (4) All licenses shall:

- 12 (a) Expire on September 30 following date of issuance; and
- 13 (b) Be renewable annually thereafter upon submission of the Renewal Application to Operate as
- 14 a Wholesaler accompanied by the renewal fee set forth in 201 KAR 2:050 and shall be
- 15 nontransferable.

16 Section 5. Standards.

17 (1) Facilities.

- 18 (a) All facilities in which prescription drugs and drug-related devices are held for wholesale
- 19 distribution, stored, sold, offered for sale, exposed for sale, or kept for sale shall be of suitable
- 20 size, construction, and location to facilitate cleaning, maintenance, and proper operations.
- 21 (b) All facilities shall meet all applicable federal, state, and local standards. The facility shall
- 22 quarantine prescription drugs and drug-related devices that are outdated, damaged,
- 23 deteriorated, misbranded, recalled, or adulterated, or that are in immediate or sealed secondary
- 24 containers that have been opened.

- 1 (c) A facility shall not be located in a residence.
- 2 (d) A facility shall be located apart and separate from a pharmacy permitted by the Board of  
3 Pharmacy, with the exception of a medical gas wholesaler.
- 4 (2) Security.
- 5 (a) A wholesaler shall be equipped with an alarm system to detect entry after hours.
- 6 (b) A wholesaler shall ensure that access from outside their premises is well controlled and  
7 reduced to a minimum. This includes the installation of adequate lighting at the outside perimeter  
8 of the premises.
- 9 (c) Internal security policies shall be developed to provide reasonable protection against theft  
10 and diversion by limiting access to areas where prescription drugs and drug-related devices are  
11 held to authorized personnel. These policies shall provide protection against tampering with  
12 computers or electronic records.
- 13 (d) A licensee shall employ adequate personnel with the education and experience necessary  
14 to safely and lawfully engage in the wholesale distribution of prescription drugs and drug-related  
15 devices.
- 16 (3) Recordkeeping requirements for companies handling prescription drugs and drug-related  
17 devices exempt from the DSCSA.
- 18 (a) Inventories and other records regarding the receipt and distribution or disposition of  
19 prescription drugs and drug-related devices shall be maintained and readily available for  
20 inspection or photocopying by the Board of Pharmacy and authorized law enforcement officials  
21 for a period of six (6) years). These records shall include:
- 22 1. The proprietary and established name of the prescription drug and related device, if  
23 applicable;
- 24 2. The dosage, if applicable;



- 1 3. The size of the container, if applicable;
- 2 4. The number of containers;
- 3 5. The lot number or control number of the prescription drug and related device, if applicable;
- 4 6. The business name and address of all parties involved in each receipt and distribution or
- 5 disposition of the prescription drug and related device, starting with the manufacturer; and
- 6 7. The date of each receipt and distribution or disposition of the prescription drug and related
- 7 device.

8 (b) Records described in this section that are kept at the inspection site or that can be readily  
9 retrievable within forty-eight (48) hours by computer or other electronic means shall be readily  
10 available for authorized inspection during the retention period. Records kept at a central location  
11 apart from the inspection site and not electronically retrievable shall be made available for  
12 inspection within two (2) working days of a request by the Board of Pharmacy or an authorized  
13 official of a federal, state, or local law enforcement agency.

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

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

- 18 1. A currently licensed wholesaler;
- 19 2. A currently licensed third party logistics provider;
- 20 3. A currently permitted pharmacy;
- 21 4. A currently licensed outsourcing facility;
- 22 5. A currently licensed practitioner;
- 23 6. A currently permitted repackager;

1 7. A currently licensed hospital, but only for use by or in that hospital pursuant to KRS  
2 217.182(1);

3 8. A person in charge of a laboratory, but only for use in that laboratory for scientific and medical  
4 research purposes pursuant to KRS 217.182(1); or

5 9. Any other appropriately licensed or permitted facility in the jurisdiction in which it is located.

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

8 1. A currently permitted manufacturer;

9 2. A currently permitted repackager;

10 3. A currently licensed wholesaler; or

11 4. A currently licensed third-party logistics provider.

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

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

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

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

22 (c) There shall be written policies and procedures to assure that the wholesaler prepares for,  
23 protects against, and handles crisis situations that affect the security or operation of the facility.

1 These crises shall include fires, floods, or other natural disasters, and situations of local, state,  
2 or national emergency.

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

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

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

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

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

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

3 The policy and procedure shall cover all recalls and withdrawals of drugs and drug-related  
4 devices due to:

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

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

7 (c) Replacement of existing.

8 (7) Procedures

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

12 (b) Procedures for distribution of approved stock shall provide for a rotation whereby the  
13 expiration date is taken into consideration when distributing inventory.

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

16 Section 6. Violations.

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

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

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

21 Section 7. Incorporation by Reference.

22 (1) The following material is incorporated by reference:

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

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

1 (c) "USP Chapter 659 Packaging and Storage Requirements", April 1, 2021 [~~November 1, 2020~~].  
2 (2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at  
3 the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street,  
4 Frankfort, Kentucky 40601-8024. Monday through Friday, 8 a.m. to 4:30 p.m. or on the Board's  
5 website at <https://pharmacy.ky.gov/Businesses/Pages/Wholesale-Distributors.aspx>.



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Christopher Harlow, Pharm.D.  
Executive Director  
Board of Pharmacy

June 7, 2023

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Date

## PUBLIC HEARING AND PUBLIC 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](mailto:Christopher.harlow@ky.gov).

## REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

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

Contact person: Christopher Harlow

Contact Phone No.: 502-564-7910

Contact email: Christopher.harlow@ky.gov

(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: How the amendment will change this existing administrative regulation: This amendment only amends the application and fee listed there.

(a) 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.

(b) 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.

(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.

(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:

(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? Tiering is not applied because the regulation is applicable to all entities wishing to distribute pharmaceuticals in Kentucky.

## FISCAL NOTE

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

Contact Person: Christopher Harlow

Contact Phone No.: 502-564-7910

Contact email: Christopher.harlow@ky.gov

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. N/A

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.

### Summary of Material Incorporated by Reference

The “Application for License to Operate as a Wholesaler”, June 2023 form is an 12-page form to be utilized by applicants for an initial license.

The “Renewal Application to Operate as a Wholesaler”, June 2023 form is an 10-page form to be utilized by applicants for annual license renewal.

“USP Chapter 659”, April 1, 2021 is a 6-page document that sets the standards for packaging and storage of drugs.

### Summary of Changes to Material Incorporated by Reference

Both the “Application for License to Operate as a Wholesaler” and “Renewal Application to Operate as a Wholesaler” were amended to ask for the website address, how the entity is registered with the Kentucky Secretary of State, and to include changes to formatting, the exclusion of content that is no longer relevant and the inclusion of content that is relevant in assessing if a license should be issued or renewed.

Final, 9-27-2023

STAFF-SUGGESTED AMENDMENT

BOARDS AND COMMISSIONS  
Board of Pharmacy

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

Page 1

RELATES TO

Line 6

After "KRS", insert "217.182".

After "315.010,", insert "315.0351".

Line 7

After "315.412", insert ", 21 U.S.C. 360eee-eee-4".

Page 2

Section 1(7)

Line 9

After "to believe that", insert "the".

Delete "such".

Page 2

Section 1(7)(b)

Line 11

After "adulterated", insert "so".

Delete "such".

Lines 11-12

After "drug-related device", insert "may".

Delete "would".

Page 2

Section 1(7)(d)

Line 15

After "unfit for distribution", insert "so".

Delete "such".

Line 15-16

After "drug-related device", insert "may".

Delete "would".

Page 5

Section 2(7)(b)

Lines 3-4

After "Pharmacy and", insert "the recipient or recipients".

Delete "recipient(s)".

Page 5

Section 2(8)

Line 5

After "subsection", delete "2".

**Page 6**

**Section 3(2)**

**Line 1**

After "The Board of Pharmacy", insert "may".

Delete the following:

shall have the right to

**Page 6**

**Section 4(3)(c)**

**Line 20**

After "the names of", insert "contact".

Delete "contract".

**Page 6**

**Section 4(3)(e)**

**Line 24**

After "The", insert "name or names".

Delete "name(s)".

**Page 8**

**Section 5(2)(b)**

**Line 6**

After "from outside", insert "the wholesaler's".

Delete "their".

**Page 8**

**Section 5(3)(a)**

**Line 21**

After "(6) years", delete "(").

**Page 13**

**Section 7(2)**

**Lines 4-5**

After "the Board's", insert "Web site".

Delete "website".