BOARDS AND COMMISSIONS

Board of Pharmacy

(Amendment)

201 KAR 2:390. Requirements for third-party logistics providers.

RELATES TO: KRS 315.0351, 315.121, 315.191(1)(a), 315.400, 315.4102, 315.4104, 315.4106, 315.4108, 315.4110[~~, 21 U.S.C. 360eee-360eee-4~~]

STATUTORY AUTHORITY: KRS 315.191(1)(a), 315.4102, 315.4104, 315.4106, 315.4108, 315.4110

NECESSITY, FUNCTION AND CONFORMITY: KRS 315.191(1)(a), 315.4102, 315.4104, 315.4106, 315.4108, and 315.4110 authorizes the board to promulgate administrative regulations to regulate third-party logistics providers. This administrative regulation establishes requirements for the regulation of third-party logistics providers

Section 1. Definitions.

(1) "Board" means the Board of Pharmacy.

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

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

(4) "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.

(5) "Illegitimate product" is defined by KRS 315.400(11).

(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 a reason to believe that the component, prescription drug, or drug-related device:

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

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

(8) "Third-party logistics provider" is defined by KRS 315.400(18).

Section 2. Requirements. (1) A third-party logistics provider providing services in the Commonwealth, including distributing into the Commonwealth, shall apply for a license from the Board in accordance with KRS 315.4102 and this administrative regulation.

(2) A separate license shall be required for each third-party logistics provider's facility that provides services in the Commonwealth, including distributing into 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 if 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 operation, 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, as incorporated by reference in 201 KAR 2:105. Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs shall be utilized to document proper storage of components, prescription drugs, or drug-related devices;

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

(c) If applicable, provide proof of registration with the U.S. Food and Drug Administration (FDA) and U.S. Drug Enforcement Administration (DEA) and shall comply with all federal laws, state and local laws, and regulations.

(5) A third-party logistics provider shall comply with all requirements as outlined in the Drug Supply Chain Security Act (DSCSA), 21 U.S.C 360eee-360eee-4, and other applicable federal laws.

(6) A third-party logistics provider shall establish a system to quarantine or destroy suspect or illegitimate product if directed to do so by the manufacturer, repackager, wholesale distributor, dispenser, or authorized government agency.

(7) A third-party logistics provider shall have readily retrievable within forty-eight (48) hours, upon written request of the board or its agents, and maintain for board inspection, a list of all manufacturers, wholesale distributors, repackagers, and dispensers for whom the third-party logistics provider provides services;

(8) A third-party logistics provider shall have readily retrievable within forty-eight (48) hours, upon written request of the board or its agents, and maintain for Board inspection, a list of each partner, limited liability company member, corporate officer or director, and facility manager, including a description of the duties and qualifications of each; and

(9) A third-party logistics provider shall have readily retrievable within forty-eight (48) hours, upon written request of the board or its agents, and maintain for board inspection, records with capability to trace the receipt and outbound distribution or disposition of components, prescription drugs, or drug-related devices and records of inventory.

Section 3. Qualifications for Licensure. (1) The Board shall consider, at a minimum, the following factors in determining the eligibility for initial licensure and renewal of third-party logistics providers:

(a) Minimum considerations in KRS 315.4106(1);

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

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

(d) Compliance with the requirements under any previously granted license or permit, if any.

(2) The Board may deny a license to an applicant if it finds 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:

(a) That the applicant is in compliance with all applicable federal, state, and local laws and regulations relating to prescription drugs and drug-related devices; and

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

(4) A license issued pursuant to this administrative regulation failing to comply with the provisions of KRS 315.400, 315.4102, 315.4104, 315.4106, 315.4108, 315.4110, or this administrative regulation may result in discipline, suspension, or revocation under KRS 315.121.

Section 4. Application, Fees, Renewals.

(1) An applicant for initial licensure or renewal as a third-party logistics provider shall submit:

(a) A non-refundable initial licensure or renewal fee of $400[~~$200~~] by check or money order made payable to the Kentucky State Treasurer;

(b) A complete, sworn, and notarized Application to Operate as a Third-Party Logistics Provider or Application for Third-Party Logistics Provider License Renewal;

(c) Unless previously provided, documentation of licensure as a third-party logistics provider through proof of registration with either:

1. The FDA; or

2. The state in which the third-party logistics provider is located;

(d) Unless previously provided, copy of most current inspection report conducted by the FDA. If the most current inspection report is not available from the FDA, the applicant shall submit an inspection report by:

1. The National Association of Boards of Pharmacy (NABP); or

2. The resident state licensing or permitting authority's authorized agent;

(e) A confirmation statement from the previous owner if ownership changed;

(f) Legal proof of any name change, if applicable;

(g) An explanation if an applicant, officer, partner, or director has ever been convicted of a felony or had a professional license or permit disciplined under federal, state, or local law;

(h) Ownership information for each partner, director, or officer, including:

1. Name and title;

2. Email addresses;

3. Federal employer identification number;

4. Address;

5. Phone number;

6. Social security number; and

7. Date of birth;

(i) State of incorporation or organization if the owner is a corporation; and

(j) Upon request, a list of all manufacturers, repackagers, wholesale distributors, and dispensers for whom the third-party logistics provider provides services.

(2) An applicant applying for any ownership or address change shall submit a non-refundable fee of $150[~~$100~~].

(3) Each license shall expire on June 30 following date of issuance, unless earlier suspended or revoked. There shall be a delinquent renewal fee of $150[~~$200~~] for failure to renew by June 30 of each year.

Section 5. Standards. (1) Facilities.

(a) All facilities in which components, prescription drugs, or drug-related devices are held 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 laws and regulations;

(c) A third-party logistics provider shall quarantine components, prescription drugs, or drug-related devices that are outdated, damaged, deteriorated, misbranded, recalled, or adulterated;

(d) A facility shall not be located in a residence; and

(e) A facility shall be located apart and separate from any pharmacy permitted by the Board.

(2) Security.

(a) A third-party logistics provider shall be equipped with an alarm system to detect entry after hours.

(b) A third-party logistics provider shall assure that access from outside the provider's 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 components, prescription drugs, or drug-related devices are held to authorized personnel. These policies shall provide protection against tampering with computers or electronic records.

(d) A third-party logistics provider shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in providing these services.

(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 components, prescription drugs, or drug-related devices shall be maintained and readily retrievable within forty-eight (48) hours for inspection or photocopying by the Board and authorized officials of any federal, state or local law enforcement agencies for a period of six (6) years. These records shall include:

1. The business name and address of the third-party logistics provider's client and the address of the location from which the components[~~component~~], prescription drugs, or drug-related devices were received;

2. The business name and address to whom the components, prescription drugs, or drug-related devices were distributed or disposed of;

3. The identity and quantity of the components, prescription drugs, or drug-related devices received and distributed or disposed of; and

4. The dates of receipt and distribution or disposition of the components, prescription drugs, or drug-related devices.

(b) Records described in this section that are kept at the inspection site or that may 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 the Board or an authorized official of any federal, state or local law enforcement agency.

(c) Third-party logistics providers shall maintain an ongoing list of verified persons or businesses to whom they ship prescription drugs and drug-related devices.

(d) Third-party logistics providers may distribute components, prescription drugs, or drug-related devices only to the following, except as established in KRS 315.0351(2) and 315.404:

1. A currently permitted manufacturer:

2. A currently licensed wholesaler;

3. A currently licensed third party logistics provider;

4. A currently permitted pharmacy;

5. A currently licensed outsourcing facility;

6. A currently licensed practitioner;

7. A currently permitted repackager;

8. A currently licensed hospital, but only for use by or in that hospital;

9. A person in charge of a laboratory, but only for use in that laboratory for scientific and medical research purposes; or

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

(4) Written policies and procedures.

(a) A third-party logistics provider shall establish, maintain, and adhere to written policies and procedures for the receipt, security, storage, inventory, and distribution or disposition of components, prescription drugs, or drug-related devices.

(b) There shall be written policies and procedures for identifying, recording, and reporting significant losses or thefts to the Board, and, if applicable, the FDA and the DEA.

(c) There shall be written policies and procedures for protecting against, and handling 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 as to the handling of any outdated, returned, or damaged prescription drugs and drug-related devices. Any outdated, returned, or damaged components, prescription drugs, or drug-related devices shall be segregated.

(f) There shall be written policies and procedures by which the third-party logistics provider exercises control over the shipping and receiving of all components, prescription drugs, or drug-related devices within the operation.

(g) There shall be written policies and procedures for quarantining suspect product and illegitimate product if directed to do so by the respective manufacturer, repackager, wholesale distributor, dispenser, or authorized government agency.

(5) Handling recalls. A third-party logistics provider shall establish, maintain, and adhere to a written policy and procedure in accordance with business agreements as to the handling of recalls and withdrawals of components, prescription drugs, or drug-related devices.

Section 6. Violations. (1) A third-party logistics provider shall not distribute components, prescription drugs, or drug-related devices directly to a consumer or a patient, except as established in KRS 315.0351(2).

(2) A third-party logistics provider 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 to Operate as a Third-Party Logistics Provider", June 2023[~~May 2020~~]; and

(b) "Application For Third-Party Logistics Provider License Renewal", June 2023[~~May 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, 8:00 a.m. to 4:30 p.m. This material is also available on the Board's Web site at https://pharmacy.ky.gov/Businesses/Pages/Third-Party-Logistics-Provider-License-Information.aspx.

June 7th, 2023

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

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. 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

201 KAR 2:390. Requirements for Third-party logistics providers.
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 acquiring and maintaining a license to be third-party logistics provider.
(b) The necessity of this administrative regulation: This administrative regulation establishes the requirements as authorized by KRS 315.4102-315.4110.
(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation establishes application requirements for initial application and renewal, qualifications for a license, and other general requirements as authorized by KRS 315.4102-4110.
(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: Third-party logistics providers are given greater direction on how to obtain a license and conduct business legally in the Commonwealth of Kentucky.

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: This amendment is limited to technical changes and a fee increase from $200 to $400.
(b) The necessity of the amendment to this administrative regulation: To ensure the Board is funded to provide proper regulatory oversight and guidance.
(c) How the amendment conforms to the content of the authorizing statutes: KRS 315.4102-315.4110 address statutory requirements for third-party logistics providers. KRS 315.191 authorizes the Board of Pharmacy to promulgate regulations to implement and interpret KRS 315.4102-315.4110.
(d) How the amendment will assist in the effective administration of the statutes: This amendment will ensure that the Board of Pharmacy is properly funded to support the administrative functions necessary to protect the public.

3. List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: The board of pharmacy, wholesalers and third-party logistics providers are impacted by this regulation.

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: The applicant will need to submit an application, pay a fee, and conduct business pursuant to the authorizing statutes and regulation.
(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): $400 annually.
(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Inspections and a license to operate as a third party logistics provider.

5. Provide an estimate of how much it will cost to implement this administrative Regulation:

(a) Initially: It costs approximately $400 per licensee to license, inspect, and enforce applicable laws and regulations that pertain to third-party logistics providers.

(b) On a continuing basis: The board will incur costs of approximately $400 per licensee annually on a continuing basis.

6. What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Enforcement of this regulation shall be accomplished through license fees. The Board of Pharmacy generates its own revenues without contribution from the General Fund.

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: A fee increase to $400 is required to implement this regulation.

8. State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation does establish fees.

9. TIERING: Is tiering applied? (Explain why tiering was or was not used) Tiering is not applied because the regulation is applied to all applicants equally.

FISCAL NOTE

201 KAR 2:390. Requirements for Third-party logistics providers.
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 315.4102-4110 and KRS 315.191(1)(a) authorize the board to promulgate administrative regulations to regulate and control third-party logistics providers.

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? The Board will receive $200 per license, and the license fee is utilized in licensing, inspecting and enforcing the board's regulations.
(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? This administrative regulation amendment will bring in $200 more per third-party logistics provider for the year.
(c) How much will it cost to administer this program for the first year? The costs to administer this licensing program are covered by the licensing fee of $400.
(d) How much will it cost to administer this program for subsequent years? Roughly $400 per applicant per year.

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

Revenues (+/-): +51,400

Expenditures (+/-): 0

Other Explanation:

(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. The cost will increase for regulated entities.

(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? $400 per third-party logistics provider.

(d) How much will it cost the regulated entities for subsequent years? $400 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 (+/-): $400
Other Explanation: This is the cost of the license.

(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 to Operate as a Third Party Logistics Provider", June 2023 form is the 12-page form to be utilized by applicants for an initial third party logistics provider license.

The "Application for Third Party Logistics Provider License Renewal", June 2023 form is the 9-page form to be utilized by applicants for annual non-resident pharmacy permit renewal.

Summary of Changes to Material Incorporated by Reference

The "Application to Operate as a Third Party Logistics Provider" and "Application for Third Party Logistics Provider License Renewal" 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 2:390. Requirements for third-party logistics providers.

Page 1
RELATES TO
Line 6

After “315.4110”, insert “, 21 U.S.C. 360eee-eee-4”.