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 $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 $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 $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 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", May 2020; and

(b) "Application for Third-Party Logistics Provider License Renewal", 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.

(44 Ky.R. 699, 1363, 1501; eff. 1-18-2018; 47 Ky.R. 2032; 48 Ky.R. 24; eff. 7-21-2021.)