

201 KAR 2:390. Third-party logistics provider.

RELATES TO: KRS 315.002, 315.005, 315.191(1)(a), 315.400(18), 315.4102, 315.4104, 315.4106, 315.4108, 315.4110

STATUTORY AUTHORITY: KRS 315.4102, 315.4104, 315.4106, 315.4108, 315.4110

NECESSITY, FUNCTION AND CONFORMITY: KRS 315.4102 requires a third-party logistics provider to be licensed and that the board establish the renewal fee by administrative regulation. KRS 315.4104 requires a board-approved application, licensure fee, and accompanying information. KRS 315.4106 establishes eligibility factors for licensure and renewal. KRS 315.4108 identifies persons disqualified as owners and designated representatives of third-party logistics providers. KRS 315.4110 establishes criteria for lawfully conducting business as a third-party logistics provider in the Commonwealth of Kentucky. This administrative regulation establishes requirements for third-party logistics providers to become licensed and operate.

Section 1. Application Requirements for Licensure Application and Renewal. (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 Facility;

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

1. The secretary of the U.S. Department of Health and Human Services, Food and Drug Administration; or

2. The state in which the provider ships;

(d) Unless previously provided, copy of current inspection report conducted by the United States Food and Drug Administration, if applicable. If a current inspection report is not available from the United States Food and Drug Administration, the applicant shall submit an inspection report by:

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

2. The board's authorized agent;

(e) A confirmation statement of 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, 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 ownership change fee of \$100 and a change of address 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 2. General Requirements. A third-party logistics provider shall:

(1) Immediately provide, upon written request of the board or its agents, and maintain for board inspection, a list of all manufacturers, wholesale distributors, and dispensers for whom the third-party logistics provider provides services;

(2) Immediately provide, upon written request of the board or its agents, and maintain for board inspection, a list of each partner, limited liability company member, and corporate officer or director, including a description of the duties and qualifications of each;

(3) Make available for board inspection, records of providing third-party logistics services involving prescription drugs, if such records are maintained; and

(4) Follow closure procedures established in 201 KAR 2:106, Section 2.

Section 3. Incorporation by Reference. (1) "Application to Operate as a Third-Party Logistics Facility", July 2017, is incorporated by reference.

(2) This form may be obtained, inspected, or copied, subject to applicable copyright law, at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601-8024, 8:00 a.m. to 4:30 p.m. Monday through Friday. (44 Ky.R. 699, 1363, 1501; eff. 1-18-2018.)