

201 KAR 2:400. Outsourcing facility.

RELATES TO: KRS 315.002, 315.005, 315.010(16), 315.191(1)(a), 315.340, 315.342

STATUTORY AUTHORITY: KRS 315.010(16), 315.340, 315.342

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.340 establishes requirements for in-state outsourcing facilities doing business in Kentucky, requires the board to set fees, and requires the board to promulgate administrative regulations relating to in-state permit applicants for licensure and renewal. KRS 315.342 establishes requirements for out-of-state outsourcing facilities doing business in Kentucky, requires the board to set fees, and requires the board to promulgate administrative regulations relating to in-state permit applicants for licensure and renewal. This administrative regulation establishes further licensure, renewal, and general requirements for in-state and out-of-state outsourcing facilities.

Section 1. Application Requirements for Initial Licensure and Renewal.

- (1) An applicant for initial licensure or renewal as an outsourcing facility shall submit:
 - (a) A nonrefundable initial licensure or renewal fee of \$250 by check or money order made payable to the Kentucky State Treasurer;
 - (b) A complete, sworn, and notarized Application to Operate as an Outsourcer Facility;
 - (c) Unless previously provided, proof of registration as an outsourcing facility with the secretary of the U. S. Department of Health and Human Services, Food and Drug Administration;
 - (d)
 1. Unless previously provided, a copy of the current inspection report conducted by the United States Food and Drug Administration pursuant to KRS 315.340(2)(a)2. and (b)1. or KRS 315.342(2)(a)2. and (b)1., if applicable; or
 2. If a current inspection report is not available from the United States Food and Drug Administration, the applicant shall submit an inspection report by:
 - a. The National Association of Boards of Pharmacy (NABP); or
 - b. 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, owner, officer, or pharmacist-in-charge has ever been convicted of a felony or had a professional license or permit disciplined under federal, state, or local law; and
 - (h) Ownership information for each owner or officer, including:
 1. Name and title;
 2. Address;
 3. Phone number;
 4. Social security number; and
 5. Date of birth.
- (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) A license shall expire on June 30 following date of issuance, unless earlier suspended or revoked. There shall be a delinquent renewal fee of \$250 for failure to renew by June 30 of each year.

Section 2. Qualifications for License.

- (1) The board shall consider the following in determining whether to grant a license:
 - (a) A felony conviction related to:
 1. The practice of pharmacy;
 2. Drugs; or
 3. Federal or state medical assistance programs;

- (b) The furnishing of false or fraudulent information in any application;
 - (c) Suspension or revocation of a license or permit by federal, state, or local government;
 - (d) Compliance with a previously granted license or permit; and
 - (e) Failure to maintain and make readily available those records required to be maintained by an outsourcing facility.
- (2) The board shall have the right to deny a license to an applicant if, in considering the factors listed in subsection 1 of this Section, it determines that granting such a license would not be consistent with public health and safety.
- (3) If the board considers denying or resolves to deny an application based solely on an applicant's prior conviction of a crime, the board shall follow the notification and procedure requirements in KRS 335B.030(2).

Section 3. General Requirements. An outsourcing facility shall:

- (1) Permit, to the extent authorized by laws or rules, board agents to enter and inspect its premises and delivery vehicles, to audit its records and written operating procedures, and to confiscate prescription drugs and records; and
- (2) Follow closure procedures established in 201 KAR 2:106 Section 2.

Section 4. Incorporation by Reference.

- (1) "Application to Operate as an Outsourcer Facility", July 2017, is incorporated by reference.
 - (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.
- (44 Ky.R. 701, 1502; eff. 1-18-2018; Cert eff. 12-2-2024.)