

BOARDS AND COMMISSIONS

Board of Pharmacy

(New Administrative Regulation)

201 KAR 2:460. Out-of-state pharmacy permits.

RELATES TO: KRS 315.191(1)(a), (d), KRS 315.0351, 201 KAR 2:050

STATUTORY AUTHORITY: KRS 315.191(1)(a), (d)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a), (d) authorize the board to promulgate administrative regulations and issue and renew permits for all pharmacies and require all persons who engages in the practice of the profession of pharmacy for a Kentucky resident hold an active Kentucky pharmacist license. This administrative regulation establishes the requirements to obtain an out of state pharmacy permit to engage in the practice of pharmacy in the Commonwealth.

Section 1. Inspection Requirements.

- (1) Each pharmacy shall provide to the board and also maintain, in readily retrievable form, the record of a satisfactory inspection conducted within the previous twenty-four (24) month period by the licensing entity of the state where the pharmacy is located.
- (2) If no such inspection record is readily available, the record of the satisfactory inspection conducted at the expense of the pharmacy within the previous twenty-four (24) months by a third party recognized by the board to inspect may be accepted.
- (3) If no such inspection has been performed within the previous twenty-four (24) months, the board shall conduct or contract with a third party recognized by the board to inspect the pharmacy, for which all costs shall be borne by the applicant.

Section 2. Pharmacist-in-Charge.

- (1) The pharmacist-in-charge shall directly and timely respond to any lawful request for information from the board or law enforcement authorities.
- (2) The pharmacist-in-charge shall be responsible for receiving and maintaining publications distributed by the board.
- (3) The pharmacist-in-charge shall be responsible for answering the toll-free telephone service six days a week and a minimum of forty hours per week. The toll-free telephone number shall be present on the label of each prescription dispensed by the pharmacy to a Kentucky resident. If the pharmacist-in-charge is unavailable, a staff pharmacist with access to patient records may answer the call but the staff pharmacist shall notify the pharmacist-in-charge of the call and provide the pharmacist-in-charge with a callback number for the patient. If the staff pharmacist is unable to resolve the patient's question, the pharmacist-in-charge shall return the call of the patient within forty-eight (48) hours.

Section 3. Exemptions.

- (1) The board may grant an exemption from the permitting requirements of this section to any nonresident pharmacy which limits its dispensing activity to isolated transactions.
- (2) An isolated transaction is defined as a transaction in which:
 - (a) Dispensing is limited to an established patient of the dispensing pharmacy no more than three (3) times per calendar year; and
 - (b) On a regular basis.

Section 4. Applications.

- (1) A prerequisite for receiving a permit as an out-of-state pharmacy is that the facility must be in good standing in the state where it is located and submit evidence consisting of the following:
 - (a) A copy of a valid license, permit or registration issued by the regulatory or licensing agency of the state in which the pharmacy is located; and

- (b) A letter from the regulatory or licensing agency of the state in which the pharmacy is located that certifies the pharmacy is compliant with the pharmacy laws of that state.
- (2) Each applicant must disclose the following:
- (a) Names and license numbers of all pharmacists and pharmacist-managers dispensing prescription legend drugs to an ultimate user in Kentucky, the names and, if available, the license or registration numbers of all supportive personnel employed by the out-of-state pharmacy who assist pharmacists in such dispensing;
 - (b) Names, locations, titles, social security number and date of birth of all principal corporate officers or members, if incorporated; and
 - (c) If the pharmacy is owned by a partnership or sole proprietorship, the name, location, title, social security number, and date of birth of any partner or owner of the pharmacy.
 - (d) A report containing this information shall be made on an annual basis and within thirty (30) days of each change for any principal office, pharmacist manager, corporate officer, partner, or owner of the pharmacy.
- (3) Each non-resident pharmacy shall develop and provide the board with a policy and procedure manual that sets forth:
- (a) Normal delivery protocols and times;
 - (b) The procedure to be followed if the patient's medication is not available at the out-of-state pharmacy, or if delivery will be delayed beyond normal delivery time;
 - (c) The procedure to be followed upon receipt of a prescription for an acute illness, which shall include a procedure for delivery of the medication to the patient from the out-of-state pharmacy at the earliest possible time, or an alternative that assures the patient the opportunity to obtain medication at the earliest possible time;
 - (d) The procedure to be followed when the out-of-state pharmacy is advised that the patient's medication has not been received within the normal delivery time and that the patient is out of medication and requires interim dosage until mail prescription drugs become available; and
 - (e) The procedure for shipping products pursuant to FDA approved and manufacturer guidelines.
- (4) An applicant for an out-of-state pharmacy permit must designate a resident agent in Kentucky for service of process. Any such out-of-state pharmacy that does not so designate a resident agent shall be deemed to have appointed the Secretary of State of the State of Kentucky to be its true and lawful attorney upon whom process may be served. All legal process in any action or proceeding against such pharmacy arising from shipping, mailing or delivering prescription drugs in Kentucky shall be served on the resident agent. In addition, a copy of such service of process shall be mailed to the out-of-state pharmacy by certified mail, return receipt requested, at the address of the out-of-state pharmacy as designated on the registration form filed with the board. Any out-of-state pharmacy which does not register in this state, shall be deemed to have consented to service of process on the Secretary of State as sufficient service.
- (5) Any person who ships, mails, or delivers prescription drugs to Kentucky residents from more than one (1) out-of-state pharmacy shall register each pharmacy separately.
- (6) An out-of-state pharmacy shall report to the disciplinary action taken by another state or jurisdiction against the pharmacy or pharmacy staff within thirty (30) days of final case resolution.
- (7) An applicant shall submit photographs of the exterior of the pharmacy building and working areas.
- (8) An out-of-state pharmacy that has not completed the application process and is not permitted by the board may not advertise its services to residents of Kentucky.
- (9) A person who engages in the practice of the profession of pharmacy for a Kentucky resident shall hold an active Kentucky pharmacist license except under Section 3 of this

administrative regulation.

(10) All pharmacy staff shall be provided a copy of this administrative regulation.

CHRISTOPHER HARLOW, Pharm.D., Executive Director

APPROVED BY AGENCY: September 14, 2022

FILED WITH LRC: September 14, 2022 at 3:15 p.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall be held on November 30, 2022, at 9:00 a.m. Eastern Time via zoom teleconference and at the Kentucky Transportation Cabinet Auditorium, 200 Mero Street, Frankfort, Kentucky 40601. 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 November 30, 2022. 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.