

BOARDS AND COMMISSIONS

Board of Pharmacy

(Amendment)

201 KAR 2:106. Licensed or permitted facility closures.

RELATES TO: KRS 315.035, 315.0351, 315.036, 315.121, 315.340, 315.342, 315.350, 315.402, 315.4102

STATUTORY AUTHORITY: KRS 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations relating to subject matters governed by KRS Chapter 315. This administrative regulation establishes requirements relating to closure of business by licensees and permit holders.

Section 1. Definitions.

(1) "Involuntary closure" means an interruption of formal business activity resulting from:

- (a) Acute illness or incapacitation;
- (b) Death;
- (c) Fire, flood, or other natural disaster;
- (d) Bankruptcy proceedings; or
- (e) Court, government, or Board of Pharmacy action.

(2) "Non-use" means a failure to engage in formal business activity within one (1) year of initial licensing or permitting, or renewal of license or permit.

(3) "Permanent voluntary closure" means a licensee or permit holder:

- (a) Ceases to do business and permanently closes; and
- (b) Does not file application for a license or permit for the same location.

(4) "Temporary closure" means a pharmacy whose hours of operation have deviated over a period of two (2) consecutive days, five (5) aggregate working days within a fourteen (14) day period or nine (9) aggregate working days within a thirty (30) day period from those of record at the Board of Pharmacy office for a reason other than a federal holiday, permanent voluntary closure or involuntary closure.

Section 2. Procedures for Closure Applicable to All Licensees and Permit Holders.

(1) Permanent voluntary closure.

(a) A licensee or permit holder shall inform the Board of Pharmacy, and if applicable, the Drug Enforcement Administration (DEA), and the Cabinet for Health and Family Services by written notice fifteen (15) days prior to the anticipated closure and include the following information:

1. Date of business termination;
2. Name, address, and DEA number of registrant to whom the prescription drugs and drug-related devices including controlled substances are to be transferred; and
3. Name, address, and DEA number of registrant to whom the records including inventories, acquisition records, purchase records, and disposition records are to be transferred.

(b) In the absence of directives to the contrary from the DEA, the Board of Pharmacy, or the Cabinet for Health and Family Services, the transfer shall be effected on the assigned date.

(c) The transferor and the transferee shall each maintain copies of the following records relating to transferred controlled substances for at least two (2) years following closure:

1. U.S. Official Order Forms, DEA-222 Schedule II;
2. Schedules III, IV, and V Invoices; and

3. Controlled substances inventory.

(d) The transferee shall maintain copies of the following records relating to prescription drugs and drug-related devices for at least two (2) years following closure:

1. Inventories;
2. Acquisition records;
3. Purchase records; and
4. Disposition records.

(e) The records in paragraph (d) of this subsection may be stored on a computer or by other electronic means and shall be readily retrievable.

(f) Upon termination, a licensee or permit holder shall:

1. Remove all signs pertinent to pharmacy or drugs from the building and premises; and
2. Return the voided permits, the DEA registration, and unused Schedule II Order Forms to their respective office of issue.

(2) Involuntary closure.

(a) Within five (5) days of involuntary closure, a licensee or permit holder, or person authorized to act on behalf of the licensee or permit holder, shall:

1. Notify the Board of Pharmacy in writing; and
2. Guarantee the security and control of the licensed or permitted premises in a manner that will allow continued storage of prescription drugs and drug-related devices, including controlled substances, and records, including patient records, if applicable, for sixty (60) days after the effective date of the involuntary closure.

(b) Within sixty (60) days after the effective date of the involuntary closure, a licensee or permit holder shall make arrangements for the lawful transfer or other disposition of prescription drugs and drug-related devices, including controlled substances, and records.

(c) The Board of Pharmacy may assume control and responsibility of prescription drugs and drug-related devices, including controlled substances, and records, including patient records, if applicable, it deems necessary for disposition, if after the expiration of the sixty (60) day period following the effective date of involuntary closure:

1. A lawful transfer or other disposition has not been made; or
2. An agreement between the Board of Pharmacy and the licensee or permit holder or person authorized to act on behalf of the licensee or permit holder, has not been reached.

(3) Permanent voluntary closure of licensees and permit holders with patient records.

(a) A licensee or permit holder shall conspicuously place a sign notifying the public thirty (30) days in advance of the:

1. Termination date of business; and
2. Name and address of the licensee or permit holder to which prescription files or other patient records will be transferred.

(b) Except when prevented by the exercise of another party's legal rights:

1. The sign shall remain in place for a period of thirty (30) days after the closure; and
2. All efforts shall be undertaken to assure a smooth transition of uninterrupted service to those affected by the closure.

(c) The posting of the sign required by paragraph (a) of this subsection shall not be required if:

1. An application for a pharmacy permit or outsourcing facility license for the same location is filed; or
2. During a sale of a pharmacy or outsourcing facility, prescription records are transferred to another permitted pharmacy or licensed outsourcing facility that is

within five (5) miles of the location of the pharmacy or outsourcing facility that is sold and owned by the purchasing entity.

(4) Deviation of Hours for Non-Pharmacy Licensees and Permit Holders.

(a) Licensees and permit holders whose hours of operations have deviated over a period of five (5) consecutive days from those of record at the Board of Pharmacy office for a reason other than permanent voluntary closure or involuntary closure shall immediately notify the Board of Pharmacy in writing of the deviation, reason for the deviation, and the anticipated period of continuance.

(b) The licensee or permit holder shall notify the Board of Pharmacy in writing of the arrangements necessary to provide adequate and continued security and control of all prescription drugs and drug-related devices and records maintained by the licensee or permit holder.

(c) If formal business activity cannot resume within sixty (60) days, or the security and control cannot be maintained, the:

1. License or permit shall be closed; and
2. Procedures for involuntary closure shall be followed.

(5) Temporary Closure of a Pharmacy.

(a) A pharmacy permit holder that is temporarily closed shall immediately notify the Board of Pharmacy in writing of the temporary closure, reason for the closure, the anticipated date of reopening, and the plan to provide emergency patient assistance and access to medication throughout the period of closure.

(b) The pharmacy permit holder shall notify the Board of Pharmacy in writing of the arrangements necessary to provide adequate and continued security and control of all prescription drugs and drug-related devices and records maintained by the licensee or permit holder.

(c) If formal business activity cannot resume within sixty (60) days, or the security and control cannot be maintained, the:

1. Pharmacy shall be closed; and
2. Procedures for involuntary closure shall be followed.

(d) At the time the pharmacy permit holder notifies the Board of Pharmacy of the temporary closure, the pharmacy shall place patient-facing signage on all pharmacy entrances and drive through windows providing up to date notification of the closure. The signage shall include notification of the closest, open pharmacy, regardless of ownership, that can assist patients immediately as well as anticipated date and time of reopening.

(e) The pharmacy permit holder shall update their phone message to include notice of the closure, and if the pharmacy has a Web site, the website shall also indicate the closure. The phone message and the website shall include a method to speak with an on-call pharmacist during regular operating hours on file with the Board of Pharmacy.

(f) The pharmacy permit holder shall have a pharmacist onsite or remotely if a common database is utilized and readily available during the posted pharmacy hours for the purpose of transferring prescription record(s) or reversing adjudicated claim(s) to a third party payer during the time of the temporary closure.

(g) The pharmacy permit holder shall make a reasonable effort to notify prescribers of the temporary closure and time and date of anticipated reopening.

Section 3. Closure of License or Permit Due to Non-use.

(1) The Board of Pharmacy shall close a license or permit due to non-use if:

(a) The licensee or permit holder fails to notify the Board of Pharmacy of initiation of formal business activity within the first year of issuance;

(b) Inspection reveals a failure to engage in formal business activity within the first year of issuance; or

- (c) Inspection reveals a failure to engage in formal business activity within one (1) year of renewal.
- (2) A licensee or permit holder may request an extension from closure due to non-use. The request shall:
 - (a) Be in writing;
 - (b) Include a legitimate reason for the lack of formal business activity; and
 - (c) Provide a date by which formal business activity will commence or resume.
- (3) Upon closure of a license or permit due to non-use, the Board of Pharmacy shall follow procedures for involuntary closure to secure and dispose of any prescription drugs and drug-related devices and records.

Section 4. Duties and Responsibilities of Licensee and Permit Holder. A licensee, permit holder or person authorized to act on behalf of the licensee or permit holder shall:

- (1) Fully cooperate with the Board of Pharmacy to promote the efficient administration of action required by the provisions of this administrative regulation; and
- (2) Be financially liable to the Board of Pharmacy for expenses incurred by the Board of Pharmacy in its implementation of the provisions of this administrative regulation.

Section 5. Violation. Violations of any of these provisions shall be grounds for the discipline of the license or permit pursuant to KRS 315.121.

(16 Ky.R. 1718; 2123; eff. 4-12-1990; 23 Ky.R. 3866; 24 Ky.R. 61; eff. 6-18-1997; 47 Ky.R. 123, 1364; eff. 2-4-2021; 48 Ky.R. 2116; eff. 6-2-2022.)

LARRY A. HADLEY, R.Ph, Executive Director

APPROVED BY AGENCY: December 14, 2021 at 12:49 p.m.

FILED WITH LRC: December 14, 2021

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall be held on February 23, 2022 at 9:00 a.m. Eastern Time via zoom teleconference with a physical location of the Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, State Office Building Annex, 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 February 28, 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: Larry Hadley, 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 Larry.Hadley@ky.gov.