

**STATEMENT OF EMERGENCY
201 KAR 002:106E**

Widespread pharmacy closures are occurring across the Commonwealth preventing patients from accessing essential medication. Due to staffing shortages, pharmacies are closing for partial days to full days without advance notice to the Board of Pharmacy, patients or prescribers. When these pharmacies are closed, they are frequently not available to answer phone calls to transfer a prescription to another pharmacy. The prescription is held hostage, forcing a pharmacist at another pharmacy to contact the prescriber to request a duplicate prescription. When this occurs insurance companies often reject the duplicate prescription because the initial prescription has already been billed even though it has not been dispensed. In these situations, despite a medication being available, many patients cannot afford to pay out-of-pocket and are forced to go without essential medication. The Board of Pharmacy has received numerous complaints from patients across the Commonwealth that cannot access their medications or are experiencing significant delays in accessing their medication due to pharmacy closures. 201 KAR 2:106 only limits closures to periods of five days or more and deems such a temporary closure. Without an emergency regulation, the Board of Pharmacy has no method of ensuring patients receive their medication in a timely manner. The Board of Pharmacy acknowledges this as an imminent threat to public health. An amendment to the ordinary administrative regulation, alone, is not a sufficient avenue to address the current emergency and ensure patients have timely access to their medication. This emergency administrative regulation will be replaced by an ordinary administrative regulation. The ordinary administrative regulation is identical to this emergency administrative regulation.

**BOARDS AND COMMISSIONS
Board of Pharmacy
(Emergency Amendment)**

201 KAR 002:106E. Licensed or permitted facility closures.

EFFECTIVE: December 14, 2021

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 [~~licensee or permit holder~~] whose hours of operation have deviated over a period of two (2) consecutive days, five (5) aggregate[~~consecutive~~] 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) ~~Temporary Closure~~ 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 ~~working~~ 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 ~~reason for the~~ 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.

LARRY A. HADLEY, R.Ph, Executive Director

APPROVED BY AGENCY: December 14, 2021

FILED WITH LRC: December 14, 2021 at 12:49 p.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall be held on January 26, 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 January 31, 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.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact person: Larry Hadley

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes the requirements relating to closure of business by licensees and permit holders.

(b) The necessity of this administrative regulation: KRS 315.191(1)(a) authorizes the Board of Pharmacy to promulgate administrative regulations with minimum requirements for the permitting of those entities that provide non-dispensing pharmacy services.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation establishes the requirements relating to closure of business by licensees and permit holders.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:

The proposed amendment to this regulation will ensure the mission of the board included in KRS 315.005 is maintained and that patients have timely access to their medications.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: This amendment modifies the definition of temporary closures and creates new requirements for pharmacy permit holders that are temporarily closing.

(b) The necessity of the amendment to this administrative regulation: The amendment ensures that patients have timely access to their medications and are placed on notice of the closure and given the opportunity to transfer their prescription elsewhere to be dispensed.

(c) How the amendment conforms to the content of the authorizing statutes: KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations pertaining to pharmacists and pharmacies

(d) How the amendment will assist in the effective administration of the statutes: The amendment will further promote, preserve, and protect public health through effective regulation by ensuring that patients have timely access to their medications.

(3) List the type and number of individuals, businesses, organizations, or state and local government affected by this administrative regulation: The board anticipates pharmacies will be affected by this amendment.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: Pharmacies will have to familiarize themselves with amended language and ensure they follow the amended requirements if temporarily closing. The board will help to educate pharmacists and pharmacies in these changes

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): There are no expected costs for the entities identified to comply with the amendment.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): This amendment will ensure that the patients of pharmacies are taken care of and their health needs are met.

(5) Provide an estimate of how much it will cost to implement this administrative regulation:

(a) Initially: No costs will be incurred.

(b) On a continuing basis: No costs will be incurred.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Board revenues from pre-existing fees provide the funding to enforce the regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding will be required because of this new regulation.

(8). State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation does not establish fees or directly or indirectly increase any fees.

(9). TIERING: Is tiering applied? Tiering is not applied because the regulation is applicable to all pharmacists, pharmacist interns, and pharmacy technicians who wish to administer vaccinations.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

(1) What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Kentucky Board of Pharmacy will be the only entity impacted by this administrative regulation.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 315.191(1)(a).

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This administrative regulation will not generate revenue for the Board in the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? This administrative regulation will not generate revenue for the Board in subsequent years.

(c) How much will it cost to administer this program for the first year? No costs are required to administer this program for the first year.

(d) How much will it cost to administer this program for subsequent years? No costs are required to administer this program for subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation. N/A

Revenues (+/-): 0

Expenditures (+/-): 0

Other Explanation: