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LEGISLATIVE RESEARCH COMMISSION

State Capitol 700 Capital Avenue Frankfort KY 40601

502-564-8100

Capitol Fax 502-564-2922

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MEMORANDUM

TO: Larry Hadley, Executive Director, Kentucky Board of Pharmacy  
FROM: Emily Caudill, Regulations Compiler  
RE: Acknowledgement of Proposed Administrative Regulation & Emergency – 201 KAR 002:106 & E.  
DATE: December 14, 2021

A copy of the ordinary and emergency administrative regulation listed above is enclosed for your files. Pursuant to KRS 13A.190, the emergency administrative regulation became effective upon filing with our office on **December 14, 2021** and, unless an extension on the accompanying ordinary is requested, will expire either in 270 days on **September 10, 2022**, or when replaced by its corresponding ordinary regulation, whichever occurs first. Please note - Expiration dates may be impacted by KRS Chapter 39A, as amended by Senate Bill 1 during the 2021 Regular Session, and by KRS Chapters 13A and 214, as amended by Senate Bill 2 during the 2021 Regular Session.

Please reference KRS 13A.270 and 13A.280, as amended by Senate Bill 2, 2021 Regular Session, for other requirements relating to the public hearing and public comment period and Statements of Consideration.

**Emergency regulation**

The emergency regulation is tentatively scheduled for review by the Administrative Regulation Review Subcommittee at its **February 2022** meeting. We will notify you of the date and time of this meeting once it has been scheduled. Pursuant to KRS 13A.280, **if** comments are received during the public comment period, a Statement of Consideration for this emergency regulation is due **by noon on February 15, 2022**.

**Ordinary regulation**

The ordinary regulation is tentatively scheduled for review by the Administrative Regulation Review Subcommittee at its **March 2022** meeting. We will notify you of the date and time of this meeting once it has been scheduled. Pursuant to KRS 13A.280, **if** comments are received during the public comment period, a Statement of Consideration for this ordinary regulation or a one-month extension request is due **by noon on March 15, 2022**.

If you have questions, please contact us at RegsCompiler@LRC.ky.gov or (502) 564-8100.

Enclosures

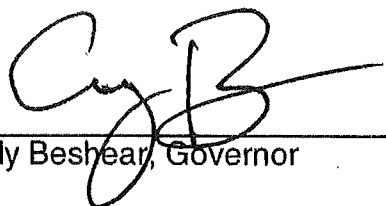
FILED WITH LRC TIME: 12:49 PM
DEC 14 2021
Emily B. Cusick REGULATIONS COMPILER

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.



Andy Beshear, Governor



Larry Hadley, Executive Director

1   BOARDS AND COMMISSIONS

2   Kentucky Board of Pharmacy

3   (Emergency Amendment)

4   201 KAR 002:106E. Licensed or Permitted Facility Closures.

5   RELATES TO: KRS 315.035, 315.0351, 315.036, 315.121, 315.340, 315.342, 315.350,  
6   315.402, 315.4102

7   STATUTORY AUTHORITY: KRS 315.191(1)(a)

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

12   Section 1. Definitions.

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

14   (a) Acute illness or incapacitation;

15   (b) Death;

16   (c) Fire, flood, or other natural disaster;

17   (d) Bankruptcy proceedings; or

18   (e) Court, government, or Board of Pharmacy action.

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

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

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

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

8 Section 2. Procedures for Closure Applicable to All Licensees and Permit Holders. (1)  
9 Permanent voluntary closure.

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

- 14 1. Date of business termination; 2. Name, address, and DEA number of registrant to  
15 whom the prescription drugs and drug related devices including controlled substances  
16 are to be transferred; and  
17 3. Name, address, and DEA number of registrant to whom the records including inven-  
18 tories, acquisition records, purchase records, and disposition records are to be trans-  
19 ferred.

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

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

- 3 1. U.S. Official Order Forms, DEA-222 Schedule II;
- 4 2. Schedules III, IV, and V Invoices; and
- 5 3. Controlled substances inventory.

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

- 8 1. Inventories;
- 9 2. Acquisition records;
- 10 3. Purchase records; and
- 11 4. Disposition records.

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

14 (f) Upon termination, a licensee or permit holder shall: 1. Remove all signs pertinent to  
15 pharmacy or drugs from the building and premises; and

16 2. Return the voided permits, the DEA registration, and unused Schedule II Order  
17 Forms to their respective office of issue.

18 (2) Involuntary closure.

19 (a) Within five (5) days of involuntary closure, a licensee or permit holder, or person au-  
20 thorized to act on behalf of the licensee or permit holder, shall:

- 21 1. Notify the Board of Pharmacy in writing; and
- 22 2. Guarantee the security and control of the licensed or permitted premises in a manner  
23 that will allow continued storage of prescription drugs and drug-related devices, includ-

1 ing controlled substances, and records, including patient records, if applicable, for sixty  
2 (60) days after the effective date of the involuntary closure.

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

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

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

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

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

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

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

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

1 (c) The posting of the sign required by paragraph (a) of this subsection shall not be re-  
2 quired if:

3 1. An application for a pharmacy permit or outsourcing facility license for the same loca-  
4 tion is filed; or

5 2. During a sale of a pharmacy or outsourcing facility, prescription records are trans-  
6 ferred to another permitted pharmacy or licensed outsourcing facility that is within five  
7 (5) miles of the location of the pharmacy or outsourcing facility that is sold and owned  
8 by the purchasing entity.

9 (4) ~~Temporary Closure~~ Deviation of Hours for Non-Pharmacy Licensees and Permit  
10  Holders.

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

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

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

22 1. License or permit shall be closed; and

23 2. Procedures for involuntary closure shall be followed.

24 (5) Temporary Closure of a Pharmacy.

1 (a) A pharmacy permit holder that is temporarily closed shall immediately notify the  
2 Board of Pharmacy in writing of the temporary closure, reason for the closure, the antic-  
3 ipated date of reopening, and the plan to provide emergency patient assistance and ac-  
4 cess to medication throughout the period of closure.

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

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

11 1. Pharmacy shall be closed; and

12 2. Procedures for involuntary closure shall be followed.

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

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

22 (f) The pharmacy permit holder shall have a pharmacist onsite or remotely if a common  
23 database is utilized and readily available during the posted pharmacy hours for the pur-



1 pose of transferring prescription record(s) or reversing adjudicated claim(s) to a third  
2 party payer during the time of the temporary closure.

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

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

6 (1) The Board of Pharmacy shall close a license or permit due to non-use if: (a) The li-  
7 censee or permit holder fails to notify the Board of Pharmacy of initiation of formal busi-  
8 ness activity within the first year of issuance;

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

11 (c) Inspection reveals a failure to engage in formal business activity within one (1) year  
12 of renewal.

13 (2) A licensee or permit holder may request an extension from closure due to non-use.

14 The request shall:

15 (a) Be in writing;

16 (b) Include a legitimate reason for the lack of formal business activity; and

17 (c) Provide a date by which formal business activity will commence or resume.

18 (3) Upon closure of a license or permit due to non-use, the Board of Pharmacy shall fol-  
19 low procedures for involuntary closure to secure and dispose of any prescription drugs  
20 and drug related devices and records.

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

23 (1) Fully cooperate with the Board of Pharmacy to promote the efficient administration of  
24 action required by the provisions of this administrative regulation; and

1 (2) Be financially liable to the Board of Pharmacy for expenses incurred by the Board of  
2 Pharmacy in its implementation of the provisions of this administrative regulation.  
3 Section 5. Violation. Violations of any of these provisions shall be grounds for the disci-  
4 pline of the license or permit pursuant to KRS 315.121.



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LARRY A. HADLEY, R.Ph.  
Executive Director  
Kentucky Board of Pharmacy

December 14, 2021

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DATE

## 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](mailto:Larry.Hadley@ky.gov).

## REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

### **201 KAR 2:106E Licensed or permitted facility closures.**

Contact person: Larry Hadley

Contact Phone No.: 502-564-7910

Contact email: [larry.hadley@ky.gov](mailto:larry.hadley@ky.gov)

#### 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. This administrative regulation establishes the requirements relating to closure of business by licensees and permit holders.

##### (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 governments 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 identities 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? (Explain why tiering was or was not used)

Tiering is not applied because the regulation is applicable to all pharmacies equally.

## FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

### **Regulation No. 201 KAR 2:106E Licensed or permitted facility closures.**

Contact Person: Larry Hadley

Contact Phone No.: 502-564-7910

Contact email: [larry.hadley@ky.gov](mailto:larry.hadley@ky.gov)

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