

Final 11-23-2020

**SUGGESTED SUBSTITUTE**

**BOARDS AND COMMISSIONS  
Board of Pharmacy**

**201 KAR 2:106. Licensed or permitted facility closures [~~Pharmacy, manufacturer, or distributor 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 [~~315.036~~]; 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) **authorizes**~~[requires]~~ 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. ~~[As used in this administrative regulation:]~~

(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 [~~pharmacy license~~] or permit for the same location.**

**(4) "Temporary closure" means a licensee or permit holder whose hours of operation 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.**

~~[(2) "Voluntary closure" means a closing or abandonment of premises resulting from:~~

~~(a) Chronic mental or physical deterioration; or~~

~~(b) A deviation from the business hours listed on the current permit application or amendments filed thereto; or~~

~~(c) Cessation of the practice of pharmacy at the licensed location for a reason other than permanent or involuntary closure.]~~

~~[(2) [(3)] "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.~~

~~(3) "Temporary closure" means a licensee or permit holder whose hours of operation 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.~~

~~(4) "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.~~

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

(a) A licensee 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 to which prescription files or other pertinent 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.]~~

(a) ~~[(e)]~~ 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 ~~[Human Resources]~~ by written notice fifteen (15) days prior to the anticipated ~~[closing]~~ closure and include the following information:

- ~~1. Date of business termination; and~~
- ~~2. Name, address, and DEA number of registrant to whom the prescription drugs and drug-related devices including [or] controlled substances [drugs] 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.~~

~~[(d)]~~ In the absence of directives to the contrary from the DEA ~~[Drug Enforcement Administration]~~, the Board of Pharmacy, or the Cabinet for Health and Family Services ~~[Human Resources]~~, the transfer shall be effected on the assigned date.

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

- ~~1. U.S. Official Order Forms, DEA-222 Schedule II; and~~
- ~~2. Schedules III, IV, and V Invoices~~]]~~; and ~~[for a period of at least two (2) years]~~~~
- ~~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 ~~[subsection]~~ (d) of this subsection may be stored on a computer or by other electronic means and shall ~~[must]~~ 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 ~~[Drug Enforcement Administration]~~ registration, and unused Schedule II Order Forms to their respective office of issue.]~~

~~[(g)]~~ The posting of the sign required by paragraph (a) of this subsection shall not be required if:

- ~~1. An application for a pharmacy license for the same location is filed; or~~

~~2. During a sale of a pharmacy, prescription records are transferred to another permitted pharmacy that is within five (5) miles of the location of the pharmacy that is sold and owned by the purchasing entity. (2) Voluntary closure.~~

~~(a) A pharmacy or distributor licensed by the Kentucky Board of Pharmacy whose hours of operation have deviated over a period of five (5) consecutive working days from those of record at the Board of Pharmacy office shall immediately notify the board, verbally and in writing of the reason for the deviation and the anticipated period of continuance.~~

~~(b) Upon receipt of the notice, the Board of Pharmacy, with full cooperation of the licensee, shall make arrangements it deems necessary to provide adequate and continued security and control of all drugs, chemicals, poisons, and devices owned or controlled by the licensee.~~

~~(c) If normal operation cannot resume within sixty (60) days, or if satisfactory agreements cannot be reached between the Board of Pharmacy, the licensee, or his designated representative, the:~~

~~1. Permit shall be revoked; and~~

~~2. Board of Pharmacy shall notify the Cabinet for Human Resources to assume control and responsibility of any drug, chemical, poison, or device deemed necessary in any manner deemed appropriate.~~

~~(d) If the Board of Pharmacy or the Cabinet for Human Resources or its agents liquidate or arrange for the liquidation of items specified in paragraphs (b) and (c) of this subsection, the board or the Cabinet for Human Resources may retain a portion of the proceeds realized from the liquidation equal to the expenses incurred.]~~

~~(2)[(3)] Involuntary closure.~~

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

~~1. Notify the Board[board] of Pharmacy in writing; and~~

~~2. Guarantee the security [safety] 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, [consigned to the board permittees] 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 [effect] arrangements for the lawful transfer [sale] or other disposition of prescription drugs and drug-related devices, including controlled substances, and records [requiring board licensure].~~

~~(c) The Board[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 [sale] or other disposition has not been made [effected]; or~~

~~2. An agreement between the Board[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.

(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 shall immediately notify the Board of Pharmacy in writing of 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/would** be followed.

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/when**:

(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/engaged** 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/must**:

(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[3]. Duties and Responsibilities of Licensee and Permit Holder. A licensee, permit holder or person authorized to act on [his] behalf of the licensee or permit holder shall:

(1) Fully cooperate with the Board[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[board] of Pharmacy for expenses incurred by the Board[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.

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## REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT (RIA)

The agency needs to file one (1) clean copy of a corrected RIA at the time that it files this staff suggested substitute that:

- Is paginated as Page 11-13
- Corrects agency's response for Question 9. on tiering to clarify that tiering is not applied to different types of pharmacy closures.