

201 KAR 2:106. Pharmacy, manufacturer, or distributor closures.

RELATES TO: KRS 315.035, 315.036

STATUTORY AUTHORITY: KRS 315.036, 315.191(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) 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.

Section 1. Definitions. As used in this administrative regulation:

(1) "Permanent closure" means a licensee:

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

(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.

(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.

Section 2. Procedures for Closure. (1) Permanent 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.

(c) A licensee shall inform the Board of Pharmacy, Drug Enforcement Administration, and the Cabinet for Human Resources by written notice fifteen (15) days prior to the anticipated closing and include the following information:

1. Date of business termination; and

2. Name, address, and DEA number of registrant to whom the prescription or controlled drugs are to be transferred.

(d) In the absence of directives to the contrary from the Drug Enforcement Administration, the Board of Pharmacy, or the Cabinet for Human Resources, the transfer shall be effected on the assigned date.

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

1. U.S. Official Order Forms, DEA-222 Schedule II; and

2. Schedules III, IV, and V Invoices) for a period of at least two (2) years.

(f) Upon termination, a licensee shall:

1. Remove all signs pertinent to pharmacy or drugs from the building and premises; and
2. Return the voided permits, the 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.

(3) Involuntary closure.

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

1. Notify the board in writing; and
2. Guarantee the safety and control of the licensed premises in a manner that will allow continued storage of controlled substances 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 shall effect arrangements for the lawful sale or other disposition of drugs and substances requiring board licensure.

(c) The board may assume control and responsibility of substances it deems necessary for disposition, if after the expiration of the sixty (60) day period following the effective date of involuntary closure:

1. A sale or other disposition has not been effected; or
2. An agreement between the board, and the licensee or person authorized to act on behalf of the licensee, has not been reached.

Section 3. Duties and Responsibilities of Licensee. A licensee or person authorized to act on his behalf shall:

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

(2) Be financially liable to the board for expenses incurred by the board in its implementation of the provisions of this administrative regulation. (16 Ky.R. 1718; Am. 2123; eff. 4-12-90; 23 Ky.R.

3866; 24 Ky.R. 61; eff. 6-18-97.)