

1 BOARDS AND COMMISSIONS

2 Kentucky Board of Pharmacy

3 (Amendment)

4 201 KAR 002:106. 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 board
9 to promulgate administrative regulations relating to subject matters governed by KRS
10 Chapter 315. This administrative regulation establishes requirements relating to closure
11 of business by licensees and permit holders.

12

13 Section 1. Definitions.

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

15 (a) Acute illness or incapacitation;

16 (b) Death;

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

18 (d) Bankruptcy proceedings; or

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

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

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

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

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

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31 Section 2. Procedures for Closure Applicable to All Licensees and Permit Holders. (1)

32 Permanent voluntary closure.

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

37 1. Date of business termination;

38 2. Name, address, and DEA number of registrant to whom the prescription drugs and
39 drug related devices including controlled substances are to be transferred; and

40 3. Name, address, and DEA number of registrant to whom the records including
41 inventories, acquisition records, purchase records, and disposition records are to be
42 transferred.

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

4 (c) The transferor and the transferee shall each maintain copies of the following records
5 relating to transferred controlled substances for at least two (2) years following closure:
6 1. U.S. Official Order Forms, DEA-222 Schedule II;
7 2. Schedules III, IV, and V Invoices; and
8 3. Controlled substances inventory.

9 (d) The transferee shall maintain copies of the following records relating to prescription
10 drugs and drug-related devices for at least two (2) years following closure:
11 1. Inventories;
12 2. Acquisition records;
13 3. Purchase records; and
14 4. Disposition records.

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

17 (f) Upon termination, a licensee or permit holder shall: 1. Remove all signs pertinent to
18 pharmacy or drugs from the building and premises; and
19 2. Return the voided permits, the DEA registration, and unused Schedule II Order Forms
20 to their respective office of issue.

21 (2) Involuntary closure.

22 (a) Within five (5) days of involuntary closure, a licensee or permit holder, or person
23 authorized to act on behalf of the licensee or permit holder, shall:
24 1. Notify the Board of Pharmacy in writing; and
25 2. Guarantee the security and control of the licensed or permitted premises in a manner
26 that will allow continued storage of prescription drugs and drug-related devices, including
27 controlled substances, and records, including patient records, if applicable, for sixty (60)
28 days after the effective date of the involuntary closure.

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

33 (c) The Board of Pharmacy may assume control and responsibility of prescription drugs
34 and drug-related devices, including controlled substances, and records, including patient
35 records, if applicable, it deems necessary for disposition, if after the expiration of the sixty
36 (60) day period following the effective date of involuntary closure:
37 1. A lawful transfer or other disposition has not been made; or
38 2. An agreement between the Board of Pharmacy and the licensee or permit holder or
39 person authorized to act on behalf of the licensee or permit holder, has not been reached.

1 (3) Permanent voluntary closure of licensees and permit holders with patient records. (a)
2 A licensee or permit holder shall conspicuously place a sign notifying the public thirty (30)
3 days in advance of the:

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

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

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

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

- 13 1. An application for a pharmacy permit or outsourcing facility license for the same
14 location is filed; or
- 15 2. During a sale of a pharmacy or outsourcing facility, prescription records are transferred
16 to another permitted pharmacy or licensed outsourcing facility that is within five (5) miles
17 of the location of the pharmacy or outsourcing facility that is sold and owned by the
18 purchasing entity.

19 (4) Temporary Closure Deviation of Hours for Non-Pharmacy Licensees and Permit
20 Holders.

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

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

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

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

34 (5) Temporary Closure of a Pharmacy.

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

39 (b) The pharmacy permit holder shall notify the Board of Pharmacy in writing of the
40 arrangements necessary to provide adequate and continued security and control of all

1 prescription drugs and drug-related devices and records maintained by the licensee or
2 permit holder.

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

5 1. Pharmacy shall be closed; and

6 2. Procedures for involuntary closure shall be followed.

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

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

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

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

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

25 (1) The Board of Pharmacy shall close a license or permit due to non-use if: (a) The
26 licensee or permit holder fails to notify the Board of Pharmacy of initiation of formal
27 business activity within the first year of issuance;

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

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

32 (2) A licensee or permit holder may request an extension from closure due to non-use.
33 The request shall:

34 (a) Be in writing;

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

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

37 (3) Upon closure of a license or permit due to non-use, the Board of Pharmacy shall follow
38 procedures for involuntary closure to secure and dispose of any prescription drugs and
39 drug related devices and records.

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1 Section 4. Duties and Responsibilities of Licensee and Permit Holder. A licensee, permit
2 holder or person authorized to act on behalf of the licensee or permit holder shall:
3 (1) Fully cooperate with the Board of Pharmacy to promote the efficient administration of
4 action required by the provisions of this administrative regulation; and
5 (2) Be financially liable to the Board of Pharmacy for expenses incurred by the Board of
6 Pharmacy in its implementation of the provisions of this administrative regulation.
7
8 Section 5. Violation. Violations of any of these provisions shall be grounds for the
9 discipline of the license or permit pursuant to KRS 315.121.