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MEMORANDUM

TO: Christopher Harlow, Executive Director, Board of Pharmacy

FROM: Emily Caudill, Regulations Compiler

RE: Proposed Amendment or New Regulation – 201 KAR 002:370 and 201 KAR 002:470.

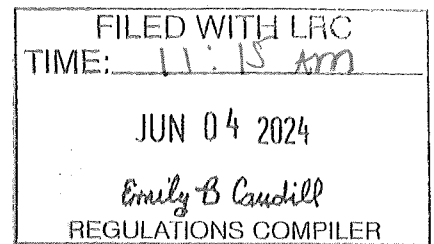
DATE: June 4, 2024

A copy of the administrative regulations listed above are enclosed for your files. These regulations are **tentatively** scheduled for review by the Administrative Regulation Review Subcommittee at its **SEPTEMBER 2024** 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 or a one-month extension request for these regulations are due **by noon on September 13, 2024**. Please reference KRS 13A.270 and 13A.280 for other requirements relating to the public hearing and public comment period and Statements of Consideration.

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

Enclosures



1 BOARD AND COMMISSIONS

2 Kentucky Board of Pharmacy

3 (New Administrative Regulation)

4 201 KAR 2:470. Change of Ownership

5 RELATES TO: KRS 315.035, 315.036(1), 315.340(6), 315.350(4), 315.405(5),
6 315.4104(1)

7 STATUTORY AUTHORITY: 315.191(1)

8 NECESSITY, FUNCTION, AND CONFORMITY: 315.191(1) authorizes the board to
9 promulgate administrative regulations to regulate pharmacists, pharmacies, wholesalers
10 and manufacturers. KRS 315.035 discusses changes of ownership of a pharmacy and
11 requires notice to be provided no fewer than five days before the transaction occurs and
12 authorizes a buyer to operate under a seller's permit pending the application. Due to the
13 nature of business structures, it is not clear when a change of ownership of a regulated
14 entity is considered to occur, and therefore this regulation provides clarity for making
15 those determinations.

16 Section 1. Change of entity ownership requiring a new license or permit means:

17 (1) Partnership. In the case of a partnership, the removal, addition, or substitution of a
18 partner.

- 1 (2) Unincorporated sole proprietorship. In the case of an unincorporated sole
2 proprietorship, the transfer of title and property to another party.
- 3 (3) Corporation. In the case of a corporation, the merger of the licensed corporation into
4 another corporation or the consolidation of two or more corporations, resulting in the
5 creation of a new corporation.
- 6 (a) Transfer of corporate stock or the merger of another corporation into the licensed
7 corporation does not constitute change of entity ownership; however, notification
8 pursuant to section 2 of this regulation shall be provided within thirty days of the
9 transaction occurring.
- 10 (4) Limited liability company (LLC). In the case of an LLC, the merger of the licensed
11 LLC into another LLC or the consolidation of two or more LLCs, resulting in the creation
12 of a new LLC.
- 13 (a) Transfer of company stock or the merger of another LLC into the licensed LLC does
14 not constitute change of ownership; however, notification pursuant to section 2 of this
15 regulation shall be provided within thirty days of the transaction occurring.
- 16 Section 2. Procedure.
- 17 1. Written notice of the following shall be provided to the Board no more than thirty
18 calendar days after the transaction occurs:
- 19 (a) A transfer of stock of greater than 10% in a non-publicly traded corporation which is
20 the direct owner of an entity;
- 21 (b) A transfer of membership interest in a limited liability company which is the direct
22 owner of a entity; and
- 23 (c) A change of corporate officer.

1 2. Written notification shall include providing a copy of the purchase agreement in the
2 case of a stock or membership interest transfer. Purchase amounts and proprietary
3 information may be redacted.

4 Section 3. Responsibility.

5 1. A permit or license which has been served with a complaint and notice of hearing
6 pursuant to KRS 13B for a pending disciplinary proceeding with the Board of Pharmacy
7 may not change ownership until the issuance of a final order by the Board or upon the
8 agreement of all parties to the terms of a settlement.

CHITHEM

June 4, 2024

Christopher Harlow, Pharm.D.
Executive Director
Board of Pharmacy

PUBLIC HEARING AND PUBLIC COMMENT PERIOD:

A public hearing on this administrative regulation shall be held on August 28, 2024, at 10:00 a.m. Eastern Time via zoom teleconference. 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 August 31, 2024. 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: Christopher Harlow, 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 Christopher.harlow@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

201 KAR 2:470. Change of Ownership.

Contact person: Christopher Harlow, Phone 502-564-7910, email christopher.harlow@ky.gov

(1) Provide a brief summary of:

(a) What this administrative regulation does: This regulation provides rules around changes of ownership when a facility regulated by the Board of Pharmacy changes owners.

(b) The necessity of this administrative regulation: To codify the process the board already utilizes to ensure regulated parties know when a change of ownership application is needed and when simple notice is needed.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This regulation establishes rules for the governance of when a change of ownership of a pharmacy requires a new application. KRS 315.191(1)(a) authorizes the Board of Pharmacy to make rules to govern any matter related to pharmacies.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: 315.191(1) authorizes the board to promulgate administrative regulations to regulate pharmacists, pharmacies, wholesalers and manufacturers. KRS 315.035 discusses changes of ownership of a pharmacy and requires notice to be provided no fewer than five days before the transaction occurs and authorizes a buyer to operate under a seller's permit pending the application. Due to the nature of business structures, it is not clear when a change of ownership of a regulated entity is considered to occur, and therefore this regulation provides clarity for making those determinations.

(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: n/a

(b) The necessity of the amendment to this administrative regulation: n/a

(c) How the amendment conforms to the content of the authorizing statutes: n/a

(d) How the amendment will assist in the effective administration of the statutes: n/a

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: Pharmacies, wholesalers, manufacturers, third party logistics providers and outsourcing facilities are affected by this regulation.

(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: The Board is not changing the process we currently utilize, we are simply placing it in rule so that it's

easier for regulated parties to find it and know what to do should an ownership change arise.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): nothing.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): The entities will have greater clarity about what is required to provide the board if they are going through an ownership change.

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

(a) Initially: There is no cost.

(b) On a continuing basis: There is no cost.

(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 fee increase will be needed.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: No fees are established directly or indirectly by this regulation.

(9) TIERING: Is tiering applied? (Explain why tiering was or was not used) Tiering is not applied because the regulation is applicable to all pharmacists and pharmacies equally.

FISCAL IMPACT STATEMENT

Regulation No. 201 KAR 2:470. Change of Ownership.

Contact Person: Christopher Harlow, Phone 502-564-7910; Email:

Christopher.harlow@ky.gov

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

(2) Identify the promulgating agency and any other affected state units, parts, or divisions:
The Kentucky Board of Pharmacy

(a) Estimate the following for the first year:

Expenditures: none.

Revenues: none.

Cost Savings: none.

(b) How will expenditures, revenues, or cost savings differ in subsequent years? There will be no expenditures or cost savings.

(3) Identify affected local entities (for example: cities, counties, fire departments, school districts): None, only the Kentucky Board of Pharmacy is impacted.

(a) Estimate the following for the first year:

Expenditures: none.

Revenues: none.

Cost Savings: none.

(b) How will expenditures, revenues, or cost savings differ in subsequent years? This regulation does not create any expenditures, revenues or cost savings.

(4) Identify additional regulated entities not listed in questions (2) or (3): none.

(a) Estimate the following for the first year:

Expenditures: none.

Revenues: none.

Cost Savings: none.

(b) How will expenditures, revenues, or cost savings differ in subsequent years? This regulation does not create any expenditures, revenues or cost savings.

(5) Provide a narrative to explain the:

(a) Fiscal impact of this administrative regulation: There is no fiscal impact from this regulation.

(b) Methodology and resources used to determine the fiscal impact: There are no fees or costs associated with this regulation.

(6) Explain:

(a) Whether this administrative regulation will have an overall negative or adverse major economic impact to the entities identified in questions (2) - (4). (\$500,000 or more, in aggregate). This administrative regulation will not have an overall negative or adverse major economic impact to the entities identified.

(b) The methodology and resources used to reach this conclusion: There are no costs, expenditures or revenues from this regulation.