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MEMORANDUM

TO: Christopher Harlow, Executive Director, Kentucky Board of Pharmacy

FROM: Emily Caudill, Regulations Compiler

RE: Proposed Amendment or New Regulation – 201 KAR 002:030, 201 KAR 002:360, and 201 KAR 002:460.

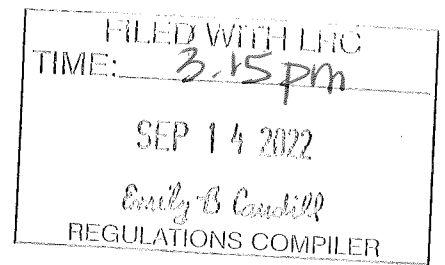
DATE: September 14, 2022

A copy of each administrative regulation listed above is enclosed for your files. These regulations are tentatively scheduled for review by the Administrative Regulation Review Subcommittee at its **DECEMBER 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 or a one-month extension request for these regulations is due **by noon on December 15, 2022**. 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 GENERAL GOVERNMENT CABINET

2 Kentucky Board of Pharmacy

3 (New Administrative Regulation)

4 201 KAR 2:460. Out of State Pharmacy Permits.

5 RELATES TO: KRS 315.191(1)(a), (d), KRS 315.0351, 201 KAR 2:050

6 STATUTORY AUTHORITY: KRS 315.191(1)(a), (d)

7 NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a), (d) authorize the

8 board to promulgate administrative regulations and issue and renew permits for all

9 pharmacies and require all persons who engages in the practice of the profession of

10 pharmacy for a Kentucky resident hold an active Kentucky pharmacist license. This

11 administrative regulation establishes the requirements to obtain an out of state

12 pharmacy permit to engage in the practice of pharmacy in the Commonwealth.

13 Section 1. Inspection Requirements.

14 (1) Each pharmacy shall provide to the Board and also maintain, in readily retrievable

15 form, the record of a satisfactory inspection conducted within the previous twenty-four

16 (24) month period by the licensing entity of the state where the pharmacy is located.

17 (2) If no such inspection record is readily available, the record of the satisfactory

18 inspection conducted at the expense of the pharmacy within the previous twenty-four

19 (24) months by a third party recognized by the Board to inspect may be accepted.

1 (3) If no such inspection has been performed within the previous twenty-four (24)
2 months, the Board shall conduct or contract with a third party recognized by the Board
3 to inspect the pharmacy, for which all costs shall be borne by the applicant.

4 Section 2. Pharmacist-in-Charge.

5 (1) The pharmacist-in-charge shall directly and timely respond to any lawful request for
6 information from the Board or law enforcement authorities.

7 (2) The pharmacist-in-charge shall be responsible for receiving and maintaining
8 publications distributed by the Board.

9 (3) The pharmacist-in-charge shall be responsible for answering the toll-free telephone
10 service six days a week and a minimum of forty hours per week. The toll-free telephone
11 number shall be present on the label of each prescription dispensed by the pharmacy to
12 a Kentucky resident. If the pharmacist-in-charge is unavailable, a staff pharmacist with
13 access to patient records may answer the call but the staff pharmacist shall notify the
14 pharmacist-in-charge of the call and provide the pharmacist-in-charge with a callback
15 number for the patient. If the staff pharmacist is unable to resolve the patient's question,
16 the pharmacist-in-charge shall return the call of the patient within forty-eight hours.

17 Section 3. Exemptions.

18 (1) The Board may grant an exemption from the permitting requirements of this section
19 to any nonresident pharmacy which limits its dispensing activity to isolated transactions.

20 (2) An isolated transaction is defined as a transaction in which:

21 (a) dispensing is limited to an established patient of the dispensing pharmacy no more
22 than three times per calendar year; and

23 (b) on a regular basis.

1 Section 4. Applications.

2 (1) A prerequisite for receiving a permit as an out-of-state pharmacy is that the facility
3 must be in good standing in the state where it is located and submit evidence consisting
4 of the following:

5 (a) a copy of a valid license, permit or registration issued by the regulatory or licensing
6 agency of the state in which the pharmacy is located; and

7 (b) a letter from the regulatory or licensing agency of the state in which the pharmacy is
8 located that certifies the pharmacy is compliant with the pharmacy laws of that state.

9 (2) Each applicant must disclose the following:

10 (a) names and license numbers of all pharmacists and pharmacist-managers
11 dispensing prescription legend drugs to an ultimate user in Kentucky, the names and, if
12 available, the license or registration numbers of all supportive personnel employed by
13 the out-of-state pharmacy who assist pharmacists in such dispensing;

14 (b) names, locations, titles, social security number and date of birth of all principal
15 corporate officers or members, if incorporated; and

16 (c) if the pharmacy is owned by a partnership or sole proprietorship, the name, location,
17 title, social security number, and date of birth of any partner or owner of the pharmacy.

18 (d) A report containing this information shall be made on an annual basis and within
19 thirty (30) days of each change for any principal office, pharmacist manager, corporate
20 officer, partner, or owner of the pharmacy.

21 (3) Each non-resident pharmacy shall develop and provide the Board with a policy and
22 procedure manual that sets forth:

23 (a) normal delivery protocols and times;

1 (b) the procedure to be followed if the patient's medication is not available at the out-of-
2 state pharmacy, or if delivery will be delayed beyond normal delivery time;

3 (c) the procedure to be followed upon receipt of a prescription for an acute illness, which
4 shall include a procedure for delivery of the medication to the patient from the out-of-
5 state pharmacy at the earliest possible time, or an alternative that assures the patient
6 the opportunity to obtain medication at the earliest possible time;

7 (d) the procedure to be followed when the out-of-state pharmacy is advised that the
8 patient's medication has not been received within the normal delivery time and that the
9 patient is out of medication and requires interim dosage until mail prescription drugs
10 become available; and

11 (e) the procedure for shipping products pursuant to FDA approved and manufacturer
12 guidelines.

13 (4) An applicant for an out-of-state pharmacy permit must designate a resident agent in
14 Kentucky for service of process. Any such out-of-state pharmacy that does not so
15 designate a resident agent shall be deemed to have appointed the Secretary of State of
16 the State of Kentucky to be its true and lawful attorney upon whom process may be
17 served. All legal process in any action or proceeding against such pharmacy arising
18 from shipping, mailing or delivering prescription drugs in Kentucky shall be served on
19 the resident agent. In addition, a copy of such service of process shall be mailed to the
20 out-of-state pharmacy by certified mail, return receipt requested, at the address of the
21 out-of-state pharmacy as designated on the registration form filed with the Board. Any
22 out-of-state pharmacy which does not register in this State, shall be deemed to have
23 consented to service of process on the Secretary of State as sufficient service.

- 1 (5) Any person who ships, mails, or delivers prescription drugs to Kentucky residents
2 from more than one out-of-state pharmacy shall register each pharmacy separately.
- 3 (6) An out-of-state pharmacy shall report to the disciplinary action taken by another
4 state or jurisdiction against the pharmacy or pharmacy staff within thirty days of final
5 case resolution.
- 6 (7) An applicant shall submit photographs of the exterior of the pharmacy building and
7 working areas.
- 8 (8) An out-of-state pharmacy that has not completed the application process and is not
9 permitted by the Board may not advertise its services to residents of Kentucky.
- 10 (9) A person who engages in the practice of the profession of pharmacy for a Kentucky
11 resident shall hold an active Kentucky pharmacist license except under Section 3 of this
12 regulation.
- 13 (10) All pharmacy staff shall be provided a copy of this regulation.

Christopher Harlow

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

September 14, 2022

Date

PUBLIC HEARING AND PUBLIC COMMENT PERIOD:

A public hearing on this administrative regulation shall be held on November 30, 2022, at 9:00 a.m. Eastern Time via zoom teleconference and at the Kentucky Transportation Cabinet Auditorium, 200 Mero Street, 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 November 30, 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: 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 2:460. Out of State Pharmacy Permits.

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 new administrative regulation clarifies the requirements to obtain an out of state pharmacy permit to engage in the practice of pharmacy in the Commonwealth. This new administrative regulation requires that a person who engages in the practice of the profession of pharmacy for a Kentucky resident shall hold an active Kentucky pharmacist license. This new administrative regulation also clarifies provisions in KRS 315.0351.

(b) The necessity of this administrative regulation: This new administrative regulation provides rules where KRS 315.0351 is silent or ambiguous. Furthermore, this new administrative regulation is necessary for the Kentucky Board of Pharmacy as it serves the Commonwealth to promote, preserve, and protect the health, safety, and welfare through effective regulation of the practice of pharmacy.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This new administrative regulation, authorized by KRS 315.191(1)(a), (d), establishes the requirements to obtain an out of state pharmacy permit to engage in the practice of pharmacy in the Commonwealth and requires a person who engages in the practice of the profession of pharmacy for a Kentucky resident to hold an active Kentucky pharmacist license. This new administrative regulation conforms to the authorizing statute because the authorizing statute gives the board authority to promulgate administrative regulations and issue and renew permits and licenses.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This new administrative regulation provides rules where KRS 315.0351 is silent or ambiguous. Furthermore, this new administrative regulation is necessary for the Kentucky Board of Pharmacy as it serves the Commonwealth to promote, preserve, and protect the health, safety, and welfare through effective regulation of the practice of pharmacy.

(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 government affected by this administrative regulation: The board anticipates that out of state pharmacies and persons who are engaged in the practice of the profession of pharmacy for a Kentucky resident will be impacted by this new administrative 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: 1. Out of state pharmacies and persons who are engaged in the practice of the profession of pharmacy for a Kentucky resident will have to familiarize themselves with this new regulation. 2. This new administrative regulation establishes the requirements to obtain an out of state pharmacy permit. 3. This new administrative regulation requires that persons who are engaged in the practice of the profession of pharmacy for a Kentucky resident will have to obtain an active Kentucky pharmacist license. 4. The board will help educate identified entities of this new regulation.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): Out of state pharmacies will incur costs associated with obtaining and renewing an out of state pharmacy permit pursuant to 201 KAR 2:050. Persons who are engaged in the practice of the profession of pharmacy for a Kentucky patient will incur costs associated with obtaining and renewing a Kentucky pharmacist license pursuant to 201 KAR 2:050.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3). The ability to serve Kentucky patients.

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

- a. Initially: +20,000
- b. On a continuing basis: +20,000

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Board revenues from fees as prescribed by 201 KAR 2:050.

(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. However, out of state pharmacists that need to comply with this regulation will need to follow 201 KAR 2:030 and will pay the licensing and renewal fees as dictated in 201 KAR 2:050.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This new administrative regulation does not establish fees or directly or indirectly increase any fees. This administrative regulation does require out of state pharmacists practicing pharmacy for Kentucky patients to be licensed by the Board of Pharmacy. There is a fee for licensing pursuant to 201 KAR 2:050.

(9) TIERING: Is tiering applied? (Explain why tiering was or was not used)
Tiering is not applied because this new regulation is applicable to all out of state licensees and permit holders equally.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

201 KAR 2:460. Out of State Pharmacy Permits.

Contact Person: Christopher Harlow, Phone 502-564-7910, email Christopher.harlow@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 impacted by this new 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), (d) permits the board to promulgate administrative regulations pursuant to KRS Chapter 13A necessary to regulate and control all matters set forth in this chapter relating to pharmacists, pharmacist interns, pharmacy technicians, pharmacies, wholesale distributors, and manufacturers.

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 new administrative will generate revenue associated with permitting out of state pharmacies, but out of state pharmacies are already permitted by the Board pursuant to KRS 315.0351. This regulation does clarify that all persons engaged in the practice of the profession of pharmacy for a Kentucky resident must also be licensed. This could lead to generation of new revenue for individuals who have been practicing without a license in Kentucky.

(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 regulation specifically will not generate revenue, however the amendment to 201 KAR 2:030 creating a licensing mechanism for out of state pharmacists will generate revenue.

(c) How much will it cost to administer this program for the first year? Approximately \$20,000.

(d) How much will it cost to administer this program for subsequent years?
Approximately \$20,000.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain this fiscal impact of the administrative regulation.

Revenues (+/-): 0

Expenditures (+/-): -20,000

Other explanation: This administrative regulation on its own does not create revenue; however, 201 KAR 2:030 is the mechanism for out of state pharmacists to become licensed in the Commonwealth. That regulation does propose a fee of \$250 for out of state pharmacist licenses.

4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.

(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year? There is no cost savings for the first year.

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years? There is no cost savings for subsequent years.

(c) How much will it cost the regulated entities for the first year? The cost for permitting and licensing out of state facilities and pharmacists.

(d) How much will it cost the regulated entities for subsequent years? The cost for permitting and licensing and renewals for out of state facilities and pharmacists.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Cost Savings (+/-): 0

Expenditures (+/-): 0

Other Explanation: This regulation does not create new fees. However, this regulation does contain a rule requiring out of state facilities to be permitted and for non-resident pharmacists to be licensed. Non-resident permits are issued pursuant to KRS 315.0351 and a fee established in 201 KAR 2:050. Non resident pharmacist licenses are issued pursuant to 201 KAR 2:030 and fees as prescribed in 201 KAR 2:050.

5) Explain whether this administrative regulation will have a major economic impact, as defined below. "Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars (\$500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. [KRS 13A.010(13)]

- This administrative regulation does not have a major economic impact.