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LEGISLATIVE RESEARCH COMMISSION

State Capitol 700 Capital Avenue Frankfort KY 40601

502-564-8100

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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 002:015, 201 KAR 002:030, 201 KAR 002:050, and 201 KAR 002:465.

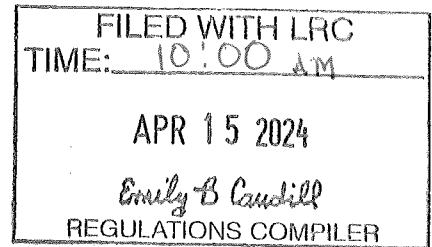
DATE: April 15, 2024

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 **JULY 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 is due **by noon on JULY 15, 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 GENERAL GOVERNMENT CABINET

2 Kentucky Board of Pharmacy

3 (New Administrative Regulation)

4 201 KAR 2:465. Non-Resident Pharmacy Applications and Waivers.

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) authorizes the

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

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

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

11 administrative regulation establishes the requirements to obtain a non-resident

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. Waiver.

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

20 (2) An isolated transaction is defined as a transaction in which dispensing is limited to
21 an established patient of the dispensing pharmacy no more than three times per
22 calendar year.

23 Section 4. Applications.

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

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

6 (b) a letter from the regulatory or licensing agency of the state in which the pharmacy is
7 located that certifies the pharmacy is in good standing.

8 (2) Each applicant must disclose the following:

9 (a) names and license numbers of all pharmacists and pharmacist-managers

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

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

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

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

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

22 (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 entity 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) A person who engages in the practice of the profession of pharmacy for a Kentucky
9 resident shall hold an active Kentucky pharmacist license except under Section 3 of this
10 regulation.

11 Section 5. A nonresident pharmacy permit applicant shall submit:

12 (1) An initial or renewal application for a nonresident pharmacy permit on either the:

13 (a) Application for Non-Resident Pharmacy Permit; or

14 (b) Application for Non-Resident Pharmacy Permit Renewal; and

15 (2) As appropriate, the:

16 (a) Initial application fee established by 201 KAR 2:050, section 1(8); or

17 (b) Renewal fee established by 201 KAR 2:050, section 1(9).

18 Section 6. Incorporation by Reference.

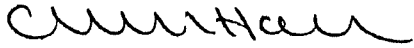
19 (1) The following material is incorporated by reference:

20 (a) Application for Non-Resident Pharmacy Permit, 04/2024; and

21 (b) Application for Non-Resident Pharmacy Permit Renewal, 04/2024.

22 (2) This material may be inspected, copied, or obtained, subject to applicable copyright
23 law, at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125

- 1 Holmes Street, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m.
- 2 This material is also available on the board's Web site at
- 3 [https://pharmacy.ky.gov/Businesses/Pages/Non-Resident-Pharmacy-Permit-](https://pharmacy.ky.gov/Businesses/Pages/Non-Resident-Pharmacy-Permit-Information.aspx)
- 4 [Information.aspx](https://pharmacy.ky.gov/Businesses/Pages/Non-Resident-Pharmacy-Permit-Information.aspx)



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

April 15, 2024

Date

PUBLIC HEARING AND PUBLIC COMMENT PERIOD:

A public hearing on this administrative regulation shall be held on June 25, 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 June 30, 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 2:465. Non-Resident Pharmacy Applications and Waivers
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: KRS 315.191(1)(a), (d) authorizes the board to promulgate administrative regulations and issue and renew permits for all pharmacies and require all persons who engage in the practice of the profession of pharmacy for a Kentucky resident to hold an active Kentucky pharmacist license. This administrative regulation establishes the requirements to obtain a non-resident pharmacy permit to engage in the practice of pharmacy in the Commonwealth.

(b) The necessity of this administrative regulation: This administration ensures the Board of Pharmacy has jurisdiction over pharmacies and pharmacists that are mailing and dispensing prescriptions to Kentucky patients.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 315.191(1)(a) authorizes the board to promulgate regulations controlling all matters set forth in KRS 315. KRS 315.0351 lays out requirements for non-resident pharmacy licensure.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation will ensure that Kentucky patients are adequately protected per the mission of the Board of Pharmacy in KRS 315.005 and will provide clarity of requirements as listed in KRS 315.0351.

(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: This regulation will impact pharmacies located outside of the Commonwealth seeking a non-resident pharmacy permit with the board to ship medications to patients of the Commonwealth. In the past 5 years, the Kentucky Board of Pharmacy has issued an average of 88 non-resident pharmacy permits annually.

(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: This amendment will provide clarity to non-resident pharmacies regarding the telephone number and pharmacist in charge requirements. Moreover, this regulation will require non-resident pharmacists dispensing drugs to

Kentucky patients to be licensed by the board. This will ensure jurisdiction over those pharmacists.

(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 non-resident pharmacists dispensing drugs into the Commonwealth will have to become licensed via the path, as provided for in an amendment to 201 KAR 2:030 and a \$50 fee as provided in 201 KAR 2:050.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): It will cost non-resident pharmacists \$50 to become licensed in Kentucky plus the fee for the background check and NABP Verify.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): They will maintain licensure in Kentucky and provide services to Kentucky patients.

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

(a) Initially: It is built into the Board's operating costs and software.

(b) On a continuing basis: It is built into the Board's operating costs and software.

(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 source to enforce the regulation. This funding is used to estimate the biennial budget allocation request. The budget allocated to the board will be used to fund this administrative 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: There is no increase in fees or funding necessary to implement this administrative regulation.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This regulation does not establish fees.

(9) TIERING: Is tiering applied? (Explain why tiering was or was not used) All resident and non-resident pharmacies are treated uniformly regarding licensure in the Commonwealth.

FISCAL IMPACT STATEMENT

201 KAR 2:465. Non-Resident Pharmacy Applications and Waivers 201 KAR 2:460.
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)(d)

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

(a) Estimate the following for the first year:

Expenditures: \$146,922

Revenues: \$148,800

Cost Savings: N/A

(b) How will expenditures, revenues, or cost savings differ in subsequent years? This is not anticipated to differ in subsequent years.

(3) Identify affected local entities (for example: cities, counties, fire departments, school districts): Only the Board of Pharmacy is impacted.

(a) Estimate the following for the first year:

Expenditures: N/A

Revenues: N/A

Cost Savings: N/A

(b) How will expenditures, revenues, or cost savings differ in subsequent years? N/A

(4) Identify additional regulated entities not listed in questions (2) or (3): Non-resident pharmacy applicants and permit holders.

(a) Estimate the following for the first year:

Expenditures: \$148,800

Revenues: N/A

Cost Savings: N/A

(b) How will expenditures, revenues, or cost savings differ in subsequent years? This is not anticipated to differ in subsequent years.

(5) Provide a narrative to explain the:

(a) Fiscal impact of this administrative regulation: The estimate for the expenditure is based on the current data on the total number of non-resident pharmacists currently permitted by the board. Non-resident pharmacies account for approximately 3% of the total licenses, permit holders, and registrants of the board. Additional expenditure was estimated based on 0.5 FTE personnel costs. The revenue generated is based on the estimate for new non-resident pharmacy permit applications and renewals for the year.

(b) Methodology and resources used to determine the fiscal impact: Current and historical data was used to determine the fiscal impact.

(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 regulation will not have an overall negative or adverse major economic impact to the entities identified in questions (2) – (4).

(b) The methodology and resources used to reach this conclusion: The Board reviewed licensing data, current and historical to determine the fiscal impact.

SUMMARY OF MATERIAL INCORPORATED BY REFERENCE

The “Application for “Non-Resident Pharmacy Permit”, 04/2024 form is the 18-page form to be utilized by applicants for an initial non-resident pharmacy permit.

The “Application for “Non-Resident Pharmacy Permit –Renewal”, 04/2024 is the 14-page form to be utilized by applicants for annual non-resident pharmacy permit renewal.

