



Andy Beshear  
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## KENTUCKY BOARD OF PHARMACY

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083, Capital Annex  
702 Capitol Avenue  
Frankfort, Kentucky 40601

December 2, 2024

Dear Co-Chairs,

After consideration of the issues raised by 201 KAR 2:465 and the attorney general's opinion referencing such, the Board of Pharmacy proposes the attached agency amendment to this ordinary administrative regulation.

Sincerely,

Christopher Harlow, Executive Director  
Kentucky Board of Pharmacy

Final, 11-25-2024 – Amended After Comments Version

AGENCY AMENDMENT

BOARDS AND COMMISSIONS

Board of Pharmacy

201 KAR 2:465. Non-resident pharmacy applications and waivers.

**NOTE TO COMPILER:** Please make the changes as directed in the Staff Suggested Amendment for this administrative regulation first and then make these changes as directed in this agency amendment.

**NECESSITY, FUNCTION, AND CONFORMITY**

After “permits for all pharmacies”, delete the following:  
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

**Section 4(7)**

After “working areas.”, insert the following:

Section 5. A nonresident pharmacy permit applicant shall submit:

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

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

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

(2) As appropriate, the:

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

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

Section 6. Incorporation by Reference.

(1) The following material is incorporated by reference:

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

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

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m. This material is also available on the board’s Web site at <https://pharmacy.ky.gov/Businesses/Pages/Non-Resident-Pharmacy-Permit-Information.aspx>.

**Section 4(8)**

Delete the following:

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

**REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT**

At the time the agency files this agency amendment, the agency shall file one (1) clean updated copy of its RIA that:

- Includes updated answers to Questions (1)(a) and (b), (4), and 4(a)-(c) for consistency and to delete references to the additional fees for non-resident pharmacists and the licensure of non-resident pharmacists that have been removed from the regulation.

#### **FISCAL IMPACT STATEMENT**

At the time the agency files this agency amendment, the agency shall file one (1) clean updated copy of its Fiscal Impact Statement that:

- Includes an updated answers to Questions (2)(a), (4)(a), (5)(a) and (b) to delete references to the additional fees for non-resident pharmacists and the licensure of non-resident pharmacists that have been removed from the regulation.

## 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. 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 new administrative regulation provides further clarity on statutory requirements for non-resident pharmacies.

(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.

(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: Non-resident pharmacies will need to familiarize themselves with this regulation. Most non-resident

pharmacies already comply with the provisions that are in this regulation, as they are congruent with other states.

(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 pharmacies the cost of permitting which is already required per KRS 315.0351 and 201 KAR 2:050.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): The non-resident pharmacies 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.  
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: n/a

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.

(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: n/a

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: This regulation does not have an impact on existing fees.

(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.