**BOARDS AND COMMISSIONS**

**Board of Pharmacy**

**(Amended After Comments)**

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

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

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

NECESSITY, FUNCTION, AND CONFORMITY: 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.

Section 1. Inspection Requirements.

(1) Each pharmacy shall provide to the board and also maintain, in readily retrievable form, the record of a satisfactory inspection conducted within the previous twenty-four (24) month period by the licensing entity of the state where the pharmacy is located.

(2) If no such inspection record is readily available, the record of the satisfactory inspection conducted at the expense of the pharmacy within the previous twenty-four (24) months by a third-party recognized by the board to inspect may be accepted.

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

Section 2. Pharmacist-in-Charge.

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

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

(3) The pharmacist-in-charge shall be responsible for answering the toll-free telephone service six (6) days a week and a minimum of forty (40) hours per week. The toll-free telephone number shall be present on the label of each prescription dispensed by the pharmacy to a Kentucky resident. If the pharmacist-in-charge is unavailable, a staff pharmacist with access to patient records may answer the call but the staff pharmacist shall notify the pharmacist-in-charge of the call and provide the pharmacist-in-charge with a callback number for the patient. If the staff pharmacist is unable to resolve the patient's question, the pharmacist-in-charge shall return the call of the patient within forty-eight (48) hours.

Section 3. Waiver.

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

(2) An isolated transaction is defined as a transaction in which dispensing is limited to an established patient of the dispensing pharmacy no more than three (3) times per calendar year.

Section 4. Applications.

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

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

(b) A letter from the regulatory or licensing agency of the state in which the pharmacy is located that certifies the pharmacy is in good standing. **If the licensing agency does not provide a letter, primary source verification may be utilized.**

(2) Each applicant must disclose the following:

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

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

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

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

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

(a) Normal delivery protocols and times;

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

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

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

~~**[(e)] [The procedure for shipping products pursuant to FDA approved and manufacturer guidelines]**~~.

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

(5) Any entity who ships, mails, or delivers prescription drugs to Kentucky residents from more than one (1) out-of-state pharmacy shall register each pharmacy separately.

(6) An out-of-state pharmacy shall report to the disciplinary action taken by another state or jurisdiction against the pharmacy or pharmacy staff within thirty days of final case resolution.

(7) An applicant shall submit photographs of the exterior of the pharmacy building and working areas.

(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.

*CHRISTOPHER HARLOW, Executive Director*

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# REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

**Contact Person:Christopher Harlow**

**(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:**

**(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 the administrative body 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?**

All resident and non-resident pharmacies are treated uniformly regarding licensure in the Commonwealth.

# FISCAL IMPACT STATEMENT

**(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.