

**BOARDS AND COMMISSIONS**  
**Board of Pharmacy**  
**(Amendment)**

**201 KAR 2:205. Pharmacist-in-charge.**

RELATES TO: KRS 315.020, 315.0351, 315.191, 315.300, 315.335

STATUTORY AUTHORITY: KRS 315.020(1), 315.0351, 315.191(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1) authorizes the board to promulgate administrative regulations pursuant to KRS Chapter 13A necessary to regulate and control all matters relating to pharmacists, pharmacist interns, pharmacy technicians, pharmacies, wholesale distributors, and manufacturers. KRS 315.020(1) and 315.0351(7) require applicants for pharmacy permits to place a pharmacist in charge as a prerequisite to compounding and dispensing privileges granted by the Kentucky Board of Pharmacy. This administrative regulation establishes the requirements relating to a pharmacist-in-charge.

Section 1. Definition. "Pharmacist-in-charge" means a pharmacist licensed in the Commonwealth of Kentucky~~[, or in the appropriate jurisdiction of an out-of-state pharmacy holding a Kentucky Board of Pharmacy permit]~~, who accepts responsibility for the operation of a pharmacy in conformance with all laws and administrative regulations pertinent to the practice of pharmacy and the distribution of prescription drugs and who is personally in full and actual charge of the pharmacy.

Section 2. Duties and Responsibilities. (1) The pharmacist-in-charge shall be so designated in the application for a permit to operate a pharmacy and in each application for renewal of that permit thereafter.

(2) A pharmacist shall not serve as a pharmacist-in-charge:

(a) For more than one (1) pharmacy at a time, except upon written approval from the Kentucky Board of Pharmacy; and

(b) Unless he or she is physically present in that pharmacy for a minimum of ten (10) hours per week or the amount of time appropriate to provide supervision and control.

(3) The pharmacist-in-charge shall be responsible for:

(a) Quality assurance programs for pharmacy services designed to objectively and systematically monitor care, pursue opportunities for improvement, resolve identified problems as may exist, and detect and prevent drug diversion;

(b) The procurement, storage, security, and disposition of drugs and the provision of pharmacy services;

(c) Assuring that all pharmacists and interns employed by the pharmacy are currently licensed;

(d) Providing notification in writing to the Board of Pharmacy within fourteen (14) calendar days of any change in the:

1. Employment of the pharmacist-in-charge;

2. Employment of staff pharmacists; or

3. Schedule of hours for the pharmacy;

(e) Making or filing of any reports required by state or federal laws and regulations;

(f) Responding to the Kentucky Board of Pharmacy regarding identified violations or deficiencies; and

(g) Filing of any report of a theft or loss to:

1. The U. S. Department of Justice Drug Enforcement Agency as required by 21 C.F.R. 1301.76(b);
2. The Department of the Kentucky State Police as required by KRS 315.335; and
3. The board by providing a copy to the board of each report submitted.

Section 3. Incorporation by Reference. (1) The following material is incorporated by reference:

- (a) "Application for Permit to Operate a Pharmacy in Kentucky" Form 1, 5/2020[07/2012];
- (b) "Application for Non-Resident Pharmacy Permit", Form 3[4], 5/2020[07/2012];
- (c) "Application for Resident Pharmacy Renewal", Form 2, 5/2020[07/2012]; and
- (d) "Application for Non-Resident Pharmacy Permit Renewal", Form 4[2], 5/2020[07/2012].

(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.

LARRY A. HADLEY, R.PH., Executive Director

APPROVED BY AGENCY: March 9, 2021

FILED WITH LRC: March 9, 2021 at 3:03 p.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall be held on May 25, 2021 at 9:00 a.m. Eastern Time at the Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, State Office Building Annex, 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 May 31, 2021. 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: Larry Hadley, 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 [Larry.Hadley@ky.gov](mailto:Larry.Hadley@ky.gov).

## REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact person: Larry Hadley

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes the requirements for the pharmacist-in-charge at pharmacies permitted by the Kentucky Board of Pharmacy.

(b) The necessity of this administrative regulation: KRS 315.191(1)(a) authorizes the Board of Pharmacy to promulgate administrative regulations necessary to regulate and control all matters relating to pharmacists and pharmacies. KRS 315.020(1) and KRS 315.0351(7) require applicants for pharmacy permits to place a pharmacist in charge as a prerequisite to compounding and dispensing privileges granted by the Board of Pharmacy. This regulation dictates the responsibilities of a pharmacist-in-charge.

(c) How this administrative regulation conforms to the content of the authorizing statutes: This administrative regulation establishes the requirements for the pharmacist-in-charge at pharmacies permitted by the Kentucky Board of Pharmacy.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation is essential for dispensing and compounding pharmacies to function. Pharmacist-in-charge requirements are established by this regulation.

(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? The only changes are the updated referenced applications.

(b) The necessity of the amendment to this administrative regulation. To update the referenced applications.

(c) How the amendment conforms to the content of the authorizing statutes: KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations pertaining to pharmacists and pharmacies. The only amendment made is the update to the applications.

(d) How the amendment will assist in the effective administration of the statutes: The amendment will further promote, preserve, and protect public health through effective regulation of pharmacists and pharmacies by updating the referenced applications

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: The board anticipates pharmacies and pharmacists will be affected minimally by this regulation amendment.

(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: Pharmacies and pharmacists will have to use the updated applications for initial application and renewal.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): The cost would be to increase the annual permit fee by \$25.00, thus the fee will increase from \$100.00 to \$125.00. This fee increase was already approved with the amendment effective February 4, 2021 to 201 KAR 2:050.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): This amendment will update the referenced applications only.

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

(a) Initially: No costs will be incurred.

(b) On a continuing basis: No costs will be incurred.

(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 increase in fees is necessary in this regulation. An amendment to 201 KAR 2:050, effective February 4, 2021 increased the annual permit fee by \$25.00 for all four referenced applications.

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

(9) TIERING: Is tiering applied? Tiering is not applied because the regulation is applicable to all pharmacists and sponsors that desire approval for a resident pharmacy permit or a non-resident pharmacy permit.

### FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

(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 administrative regulation.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. 315.020, 315.035, 315.0351, 315.191(1)(a).

(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. The fee increase effected by the amendment to 201 KAR 2:050 that applies to applications referenced in this regulation will generate approximately \$50,000 in revenue for the Kentucky Board of Pharmacy.

(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? N/A

(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? N/A

(c) How much will it cost to administer this program for the first year? No costs are required to administer this program for the first year.

(d) How much will it cost to administer this program for subsequent years? No costs are required to administer this program for the first year.

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

Revenues (+/-): Approximately \$50,000

Expenditures (+/-): 0

Other Explanation: