

1 BOARDS AND COMMISSIONS

2 Board of Pharmacy

3 (Amendment)

4 201 KAR 2:205. Pharmacist-in-charge.

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

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

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

14 Section 1. Definition. "Pharmacist-in-charge" means a pharmacist licensed in the
15 Commonwealth of Kentucky, who accepts responsibility for the operation of a pharmacy in
16 conformance with all laws and administrative regulations pertinent to the practice of pharmacy
17 and the distribution of prescription drugs and who is personally in full and actual charge of the
18 pharmacy.

19 Section 2. Duties and Responsibilities.

20 (1) The pharmacist-in-charge shall be so designated in the Application for Permit to Operate a
21 Pharmacy in Kentucky and in the Application for Non-Resident Pharmacy Permit, and in each

1 Application for Resident Pharmacy Renewal and Application for Non-Resident Pharmacy Permit
2 Renewal submitted for the renewal of that permit thereafter.

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

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

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

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

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

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

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

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

17 1. Employment of the pharmacist-in-charge;

18 2. Employment of staff pharmacists; or

19 3. Schedule of hours for the pharmacy;

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

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

22 and

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

1 1. The U. S. Department of Justice Drug Enforcement Agency as required by 21 C.F.R.
2 1301.76(b);

3 2. The Department of the Kentucky State Police as required by KRS 315.335; and

4 3. The board by providing a copy to the board of each report submitted.

5 ~~[Section 3. Incorporation by Reference.~~

6 ~~(1) The following material is incorporated by reference:~~

7 ~~(a) "Application for Permit to Operate a Pharmacy in Kentucky" Form 1, 5/2020;~~

8 ~~(b) "Application for Non-Resident Pharmacy Permit", Form 3, 5/2020;~~

9 ~~(c) "Application for Resident Pharmacy Renewal", Form 2, 5/2020; and~~

10 ~~(d) "Application for Non-Resident Pharmacy Permit Renewal", Form 4, 5/2020.~~

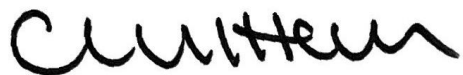
11 ~~(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at~~

12 ~~the Kentucky Board of Pharmacy, State Office Building Annex, Suite 300, 125 Holmes Street,~~

13 ~~Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 p.m. This material is also~~

14 ~~available on the board's Web site at~~

15 ~~<https://pharmacy.ky.gov/Businesses/Pages/Pharmacy.aspx>.]~~



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

June 7, 2023

Date

PUBLIC HEARING AND PUBLIC COMMENT PERIOD:

A public hearing on this administrative regulation shall be held on August 30, 2023, 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 August 31, 2023. 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 2:205. Pharmacist-in-charge.
Contact person: Christopher Harlow
Contact Phone No.: 502-564-7910
Contact email: Christopher.harlow@ky.gov

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 change is the removal of the applications incorporated by reference.

(b) The necessity of the amendment to this administrative regulation. Because the applications for pharmacies were incorporated by reference and those applications are more fitting attached to 201 KAR 2:050, they need to be deleted from this regulation.

(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 removal of 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 moving the pharmacy applications to a more relevant location for incorporation by reference.

3. List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: There will be no impact on any of these entities.

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: No changes to the substance of this regulation with this amendment.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): None.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): This amendment will remove the applications incorporated by reference 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.

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? (Explain why tiering was or was not used) Tiering is not applied because the regulation is applicable to all pharmacies that desire approval for a resident pharmacy permit or a non-resident pharmacy permit.

FISCAL NOTE

201 KAR 2:205 Pharmacist-in-Charge.

Contact Person: Christopher Harlow

Contact Phone No.: 502-564-7910

Contact 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 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. None.

(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 (+/-): 0

Expenditures (+/-): 0

Other Explanation: This regulation will not impact fees, revenues or expenditures.

(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? None.

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years? None.

(c) How much will it cost the regulated entities for the first year? In effect already. Permit fee is established by 201 KAR 2:050.

(d) How much will it cost the regulated entities for subsequent years? Renewal permit fee is set by 201 KAR 2:050.

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

Cost Savings (+/-):

Expenditures (+/-):
Other Explanation:

(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. [KRS13A.010(13)] There is no major economic impact from this amendment.