BOARDS AND COMMISSIONS
Board of Pharmacy
(Amendment)

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

RELATES TO: KRS 315.020, 315.035, 315.0351, 315.191, 315.300, 315.335, 21 C.F.R. 1301.76(b)

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

CERTIFICATION STATEMENT: This is to certify that this administrative regulation complies with the requirements of 2025 RS HB 6, Section 8.

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(1)(g) 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, 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 Permit to Operate a Pharmacy in Kentucky and in the Application for Non-Resident Pharmacy Permit, and in each Application for Resident Pharmacy Renewal and Application for Non-Resident Pharmacy Permit Renewal, as incorporated by reference in 201 KAR 2:050, and submitted for the 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 Administration as required by 21 C.F.R. 1301.76(b);
2. The Department of the Kentucky State Police as required by KRS 315.335;
3. The board by providing a copy to the board of each report submitted; and
4. The Cabinet for Health and Family Services.

(h) Ensuring appropriate equipment is available and in working order to allow within the pharmacy area. Such as the following:

1. A prescription balance with sensitivity not less than that of a Class 3 balance;
2. Weights-metric or apothecary-complete set;
3. Graduates capable of accurately measuring from one (1) ml to 250 ml;
4. Mortars and pestles-glass, porcelain, or Wedgewood;
5. Spatulas-steel and nonmetallic;
6. A heating unit;
7. Suitable refrigeration unit for proper storage of drugs; and
8. Ointment slab or ointment papers.

CHRISTOPHER HARLOW, PharmD, Executive Director

APPROVED BY AGENCY: December 3, 2025

FILED WITH LRC: December 12, 2025 at 10:45 a.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall be held on February 27, 2026, at 9:00 a.m. EST via a 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 was received by that date, the hearing may be cancelled. 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 February 28, 2026. 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

Contact Person:Christopher Harlow

Subject Headings:Pharmacy; Workforce Development; Occupations and Professions

(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. This amendment makes the pharmacist-in-charge responsible for ensuring all necessary reference material and equipment is available to pharmacy employees.

(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. This regulation amendment dictates the responsibilities of a pharmacist-in-charge as it relates to pharmacy reference materials and equipment.

(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. The amendment clarifies the responsibility for ensuring that the proper reference material and equipment is made available to pharmacy employees.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:
Pharmacist-in-charge requirements are established by this regulation. This amendment is clarification of what has already been the practical reality for the pharmacist-in-charge.

(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 amendment clarifies that it is the responsibility of the pharmacist-in-charge to ensure that a pharmacy has proper reference material and equipment.

(b) The necessity of the amendment to this administrative regulation:
Previously the duty was contained within 201 KAR 2:090, but this amendment seeks to move that language to be included within the pharmacist-in-charge regulation, which will be more efficient and provide clarification on this responsibility. This also codifies the existing practice of holding the pharmacist-in-charge as the responsible party for ensuring the proper reference material and equipment are accessible by pharmacy employees.

(c) How the amendment conforms to the content of the authorizing statutes:
KRS 315.002 and 315.005 authorize the Board to regulate the practice of pharmacy. KRS 315.191 authorizes the Board to promulgate administrative regulations pertaining to pharmacists and pharmacies. KRS 315.0353(6) authorizes the Board of Pharmacy to promulgate administrative regulations regarding reference material and equipment suitable for pharmaceutical practice. KRS 315.191(1)(a) authorizes the

board to promulgate administrative regulations pertaining to pharmacists and pharmacies.

(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 providing the most accurate and up to date information. In addition, the removal of the responsibility and inclusion of that language in 201 KAR 2:205 provides clarification for the responsibility of maintaining reference materials and equipment.

(3) Does this administrative regulation or amendment implement legislation from the previous five years?No.

(4) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:
The requirements are not changing and therefore the Board anticipates that no individual, business, organization or state or local government will be affected by this regulation. This is not a new responsibility but rather a clarification of an existing responsibility for a pharmacist-in-charge.

(5) Provide an analysis of how the entities identified in question (4) 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 (4) will have to take to comply with this administrative regulation or amendment:
Pharmacies and pharmacists will have to familiarize themselves with new amended language in the regulation. However, there has been no changes or additional responsibilities added.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (4):
There are no expected costs for the identities to comply with the amendment because there are no changes to requirements being made at this time.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (4):
Pharmacists and the public can refer to the correct information for reference material and equipment needs. An acting pharmacist-in-charge will better understand the responsibility to ensure proper reference material and equipment is available for pharmacy employees. (6) Provide an estimate of how much it will cost to implement this administrative regulation:

(6) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially:
No costs will be incurred.

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

(7) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation or this amendment:
Board revenues from pre-existing fees provide the funding to enforce the regulation.

(8) 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 or funding will be required because of this new regulation.

(9) 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.

(10) TIERING: Is tiering applied?

Tiering is not applied because the regulation is applicable to all pharmacists and pharmacies.

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 315.035(6) 315.020, 315.035, 315.0351, 315.191(1)(a).

(2) State whether this administrative regulation is expressly authorized by an act of the General Assembly, and if so, identify the act:
KRS 315.035(6); KRS 315.035(6); KRS 315.020; 315.035, 315.0351

(3)(a) Identify the promulgating agency and any other affected state units, parts, or divisions:
The Kentucky Board of Pharmacy will be impacted by this administrative regulation.

(b) Estimate the following for each affected state unit, part, or division identified in (3)(a):

1. Expenditures:

For the first year:$0

For subsequent years:$0

2. Revenues:

For the first year:$0

For subsequent years:$0

3. Cost Savings:

For the first year:$0

For subsequent years:$0

(4)(a) Identify affected local entities (for example: cities, counties, fire departments, school districts):
Only the Kentucky Board of Pharmacy will be impacted by this administrative regulation.

(b) Estimate the following for each affected local entity identified in (4)(a):

1. Expenditures:

For the first year:$0

For subsequent years:$0

2. Revenues:

For the first year:$0

For subsequent years:$0

3. Cost Savings:

For the first year:$0

For subsequent years:$0

(5)(a) Identify any affected regulated entities not listed in (3)(a) or (4)(a):
None.

(b) Estimate the following for each regulated entity identified in (5)(a):

1. Expenditures:

For the first year:$0

For subsequent years:$0

2. Revenues:

For the first year:$0

For subsequent years:$0

3. Cost Savings:

For the first year:$0

For subsequent years:$0

(6) Provide a narrative to explain the following for each entity identified in (3)(a), (4)(a), and (5)(a)

(a) Fiscal impact of this administrative regulation:

The regulation does not cost anything for regulated parties to implement nor does it have a cost to the Board to oversee.

(b) Methodology and resources used to reach this conclusion:

None.

(7) Explain, as it relates to the entities identified in (3)(a), (4)(a), and (5)(a):

(a) Whether this administrative regulation will have a "major economic impact", as defined by KRS 13A.010(14):

No, this administrative regulation does not have an overall negative or adverse major economic impact to regulated entities, or those entities identified in questions (2)-(4).

(b) The methodology and resources used to reach this conclusion:

Analysis of the Board’s expenditures as well as an assessment regarding cost of compliance for regulated entities.