BOARDS AND COMMISSIONS

Board of Pharmacy

(Amendment)

201 KAR 2:190. Return of prescription drugs~~[prohibited.]~~

RELATES TO: KRS Chapters 217 and 315

STATUTORY AUTHORITY: KRS 217.055, 217.215,~~[315.010(5),]~~ 315.191(1), (5)

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: To prevent the dispensing of drugs that have been adulterated, contaminated or misbranded.

Section 1. No pharmacy, pharmacist, or agent thereof shall accept for reuse or resale a prescription drug. This administrative regulation shall not apply to sealed/unopened prescription drugs in the original standard unit~~[dose, unit]~~ of dispensing.~~[use or tamper resistant drug packaging.]~~

Section 2. Drug Integrity Must Be Verified Before Accepting Return.

(1) No pharmacist shall accept the return of a prescription drug unless:

(a) The drug is in a sealed container by which it can be readily determined by a pharmacist employed by the dispensing pharmacy that entry or attempted entry by any means has not been made;

(b) The drug container meets the standards of the United States Pharmacopoeia for storage conditions including temperature, light sensitivity, moisture, chemical and physical stability;

(c) The drug labeling and packaging has not been altered or defaced and the identity of the drug, its potency, lot number and expiration date are legible;

(d) The drug does not require refrigeration; and

(e) The drug is returned to a pharmacist employed by the dispensing pharmacy within fourteen (14) days.

(2) Subsection (1)(d) and (e) shall be waived if all other conditions are met and if:

(a) The drug was dispensed for a patient in a health care facility licensed by the Cabinet for Human Resources;

(b) The drug has not come into the physical possession of the person for whom it was prescribed;

(c) The drug has been under the continuous control of personnel in the health care facility who are trained and knowledgeable in the storage and administration of drugs;

(d) The drug has been properly stored in an area which is regularly inspected by a pharmacist; and

(e) The drug is not expired.

(3) Drugs dispensed within an acute care facility shall be exempt from the provisions of subsection 1(a), (d), and (e) of this section.

(4) Nothing in this administrative regulation shall be construed to require a pharmacist to accept the return of a prescription drug.

Section 3. Violation of any provision of this administrative regulation constitutes unethical or unprofessional conduct in accordance with KRS 315.121.

CHRISTOPHER HARLOW, Pharm D, Executive Director

APPROVED BY AGENCY: December 4, 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; Drugs and Medicines; Public Health

(1) Provide a brief summary of:

(a) What this administrative regulation does:

This administrative regulation prohibits pharmacies, pharmacists, or their agents from accepting previously dispensed prescription drugs for reuse or resale except when the drugs are in sealed, unopened, unit-dose, unit-of-use, or tamper-resistant packaging.

(b) The necessity of this administrative regulation:

This regulation is necessary to establish clear prohibitions on accepting returned prescription drugs, except under tightly controlled conditions, thereby safeguarding drug integrity, preventing diversion, and ensuring that only medications of verified quality enter the pharmaceutical supply chain.

(c) How this administrative regulation conforms to the content of the authorizing statutes:

KRS 315.191(1) empowers the Board to promulgate administrative regulations to regulate and control all matters relating to the practice of pharmacy including establishing standards for dispensing, handling and safeguarding prescription medications. By prohibiting the acceptance of returned drugs except under safe, controlled conditions, 201 KAR 2:190 directly implements the Board's statutory mandate to protect drug integrity and public safety.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:

This regulation supports effective statutory administration by establishing definitive standards for when dispensed drugs may or may not be accepted back into the pharmacy, thereby allowing the Board to uniformly enforce safeguards that protect drug integrity, prevent diversion, and uphold the statutory mandate to ensure public health and safety.

(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:

(b) The necessity of the amendment to this administrative regulation:

This amendment is necessary because it clarifies the conditions under which a pharmacist may accept a returned prescription drug including tamper-evident packaging, proper storage, labeling integrity, and time limits, thereby ensuring that only medications meeting verified safety standards may be considered for reuse.

(c) How the amendment conforms to the content of the authorizing statutes:

The amendment is consistent with the Board's authority under KRS 315.191(1), which authorizes the promulgation of regulations governing the practice of pharmacy and the safeguarding of prescription drugs. By establishing clear standards for the acceptance, storage conditions, and verification of returned medications, the amendment fulfills the statutory mandate to ensure safe pharmacy operations and prevent adulterated or compromised drugs from re-entering the supply chain.

(d) How the amendment will assist in the effective administration of the statutes:
The amendment assists in the effective administration of the statutes by creating clear, objective criteria for when prescription drugs may be accepted for return, enabling consistent enforcement and ensuring pharmacists comply with statutory requirements related to drug integrity and patient safety.

(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 board anticipates no one will be affected by the administrative regulation amendment as the same protections are already enacted by other provisions of Kentucky law.

(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 significant changes.

(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.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (4):
Compliance will give pharmacists definitive, legally supported guidance for dispensing noncontrolled refills during declared emergencies, enabling uninterrupted patient access to essential medications while ensuring adherence to statutory requirements and promoting public health. (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:

The Controlled Substances Act; KRS 217, KRS 315.191(1) empowers the Board to promulgate administrative regulations to regulate and control all matters relating to the practice of pharmacy including establishing standards for dispensing, handling and safeguarding prescription medications. By prohibiting the acceptance of returned drugs except under safe, controlled conditions, 201 KAR 2:190 directly implements the Board's statutory mandate to protect drug integrity and public safety.

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

No.

(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.