

BOARDS AND COMMISSIONS

Board of Pharmacy

(Amended at ARRS Committee)

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), 315.404(4)(f)(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: *KRS 315.191(1) authorizes the board to promulgate administrative regulations to control all matters set forth in KRS Chapter 315 relating to pharmacies and pharmacists. KRS 315.191(1)(f) authorizes the board to promulgate administrative regulations for the retrieval of prescription drugs. KRS 315.404(4) authorizes pharmacies to accept returns of prescription drugs. This administrative regulation establishes procedures for pharmacists accepting returned prescription drugs and prohibits pharmacists from accepting returned prescription drugs for sale or reuse except for in specific circumstances ~~[To prevent the dispensing of drugs that have been adulterated, contaminated or misbranded].~~*

Section 1. *A ~~pharmacy, pharmacist, or agent thereof shall not accept a prescription drug~~ for reuse or resale ~~of a prescription drug~~. This administrative regulation shall not apply to ~~sealed or unopened~~ sealed/unopened prescription drugs in the original standard unit ~~dose, unit~~ of ~~dispensing.~~ use or tamper resistant drug packaging.*

Section 2. Drug Integrity ~~Shall **Must**~~ Be Verified Before Accepting Return.

(1) ~~A **No**~~ pharmacist shall **not** accept the return of a prescription drug unless:

(a) The drug is in a sealed container by which it ~~may **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 *Pharmacopeia* ~~*Pharmacopocia*~~ 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) of this section 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 *Health and Family Services* ~~*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.

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