

902 KAR 55:065. Return of prescription drugs prohibited, exceptions.

RELATES TO: KRS 217.005-217.215, 217.992

STATUTORY AUTHORITY: KRS 194.050, 211.090, 217.125

NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.125 authorizes the Cabinet for Human Resources to administer the provisions of KRS 217.005 to 217.215 and 217.992. The purpose of this administrative regulation is to prevent the dispensing of prescription drugs that may be adulterated or misbranded.

Section 1. Return of Prescription Drugs Prohibited; Exceptions. (1) No pharmacist, practitioner, or agent thereof shall accept the return of a prescription drug for reuse or resale unless:

(a) The drug is in a sealed container by which it can be readily determined by a pharmacist employed by the dispensing pharmacy or by the dispensing practitioner 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 or to the dispensing practitioner 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 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 distributed 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 or practitioner to accept the return of a prescription drug. (15 Ky.R. 1618; Am. 1853; eff. 3-15-89; 20 Ky.R. 2226; eff. 3-14-94.)