

201 KAR 2:230. Special limited pharmacy - central refill pharmacy.

RELATES TO: KRS 315.010(9), 315.020, 315.035, 315.191(1)(a)

STATUTORY AUTHORITY: KRS 315.020, 315.035, 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.020 requires that prescription drugs, medicines, and pharmaceuticals be dispensed or manufactured by a licensed pharmacist. KRS 315.035 requires that all pharmacies hold a permit issued by the board. This administrative regulation establishes, consistent with the requirements of KRS 315.191(1)(a), minimum requirements for the permitting of those pharmacies that package, label and distribute refill prescriptions to pharmacies in the Commonwealth.

Section 1. Definition. "Central refill pharmacy" means a pharmacy located in the Commonwealth that provides packaging, labeling and delivery of a refill prescription product to another pharmacy for the purpose of the refilling of a valid prescription.

Section 2. The central refill pharmacy shall:

(1) Either:

(a) Have a written contract with the pharmacy which has custody of the original prescription authorization for refill dispensing; or

(b) Be under common ownership with that pharmacy;

(2) Prepare the label for the refill prescription product which clearly identifies the name and address of the pharmacy preparing the product for refill dispensing and the name and address of the pharmacy that will receive the prepared product for dispensing to the patient;

(3) In addition to its obligation to maintain complete and accurate records of drug products received and otherwise disposed of, maintain complete and accurate records of the preparation of the refilled prescription product, including the name of the:

(a) Pharmacist who verified the accuracy of the refilled prescription product;

(b) Pharmacy preparing the refilled prescription product; and

(c) Pharmacy to which the prepared refill prescription product is delivered;

(4) Provide the originating pharmacy with written information that describes how a patient may contact the central refill pharmacy if the patient has any questions about the preparation of the prescription refill; and

(5) Be responsible for ensuring that the order has been properly prepared and verified by a pharmacist.

Section 3. The pharmacy to which a prepared prescription refill product is delivered shall:

(1) In addition to its obligation to maintain complete and accurate records of drug products received and otherwise disposed of, maintain complete and accurate records of the receipt and dispensing of the centrally refilled prescription product, including the name of the:

(a) Pharmacist who verified the accuracy of the refilled prescription product prior to its dispensing; and

(b) Pharmacy preparing the refilled prescription product;

(2) Be responsible for ensuring that the refill has been properly prepared, packaged and labeled;

(3) Provide the patient with written information that described how a patient may contact either:

(a) The central refill pharmacy if the patient has any questions about the preparation of the prescription refill; or

(b) The dispensing pharmacy if the patient has any questions about the use of the medication; and

(4) Be responsible for adherence to the requirements of 201 KAR 2:210. (26 Ky.R. 1735; 2238; eff. 6-12-2000; 35 Ky.R. 1851; eff. 3-11-2009.)