

201 KAR 2:230. Special limited pharmacy permit – Central Fill.

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

STATUTORY AUTHORITY: KRS 315.020, 315.035, 315.0351, 315.191(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1)(a) authorizes the board to promulgate administrative regulations necessary to regulate and control all matters set forth in KRS Chapter 315 relating to pharmacists and pharmacies. KRS 315.020 requires that prescription drugs, medicines, and pharmaceuticals be dispensed or manufactured by a licensed pharmacist. KRS 315.035 and 315.0351 require 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 central fill prescriptions to pharmacies in the Commonwealth.

Section 1. Definition. "Central fill pharmacy" means a pharmacy that provides packaging, labeling, and delivery of a prescription product to another pharmacy for the purpose of the dispensing of a valid prescription.

Section 2. The central fill pharmacy shall:

(1) Either:

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

(b) Be under common ownership with that pharmacy;

(2) Prepare the label for the prescription product which clearly identifies the name and address of the pharmacy preparing the product for 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 prescription product, including the name of the:

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

(b) Pharmacy preparing the prescription product; and

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

(4) Provide the originating pharmacy with written information that describes how a patient may contact the central fill pharmacy if the patient has any questions about the preparation of the prescription; 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 centrally filled prescription 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 filled prescription product, including the name of the:

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

(b) Pharmacy preparing the prescription product;

(2) Be responsible for ensuring that the centrally filled prescription product 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 fill pharmacy if the patient has any questions about the preparation of the prescription; 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.

Section 4. Effective January 1, 2020, a pharmacist who provides a pharmacy service on a prescription dispensed in Kentucky shall be licensed in Kentucky. (26 Ky.R. 1735; 2238; eff. 6-12-2000; 35 Ky.R. 1851; eff. 3-11-2009; 46 Ky.R. 2292; 47 Ky.R. 41; eff. 7-29-2020.)