

201 KAR 2:205. Pharmacist-in-charge.

RELATES TO: KRS 315.020, 315.0351, 315.191, 315.300, 315.335

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

NECESSITY, FUNCTION, AND CONFORMITY: KRS 315.191(1) authorizes the board to promulgate administrative regulations pursuant to KRS Chapter 13A necessary to regulate and control all matters relating to pharmacists, pharmacist interns, pharmacy technicians, pharmacies, wholesale distributors, and manufacturers. KRS 315.020(1) and 315.0351(7) require applicants for pharmacy permits to place a pharmacist in charge as a prerequisite to compounding and dispensing privileges granted by the Kentucky Board of Pharmacy. This administrative regulation establishes the requirements relating to a pharmacist-in-charge.

Section 1. Definition. "Pharmacist-in-charge" means a pharmacist licensed in the Commonwealth of Kentucky, or in the appropriate jurisdiction of an out-of-state pharmacy holding a Kentucky Board of Pharmacy permit, who accepts responsibility for the operation of a pharmacy in conformance with all laws and administrative regulations pertinent to the practice of pharmacy and the distribution of prescription drugs and who is personally in full and actual charge of the pharmacy.

Section 2. Duties and Responsibilities.

- (1) The pharmacist-in-charge shall be so designated in the application for a permit to operate a pharmacy and in each application for renewal of that permit thereafter.
- (2) A pharmacist shall not serve as a pharmacist-in-charge:
 - (a) For more than one (1) pharmacy at a time, except upon written approval from the Kentucky Board of Pharmacy; and
 - (b) Unless he or she is physically present in that pharmacy for a minimum of ten (10) hours per week or the amount of time appropriate to provide supervision and control.
- (3) The pharmacist-in-charge shall be responsible for:
 - (a) Quality assurance programs for pharmacy services designed to objectively and systematically monitor care, pursue opportunities for improvement, resolve identified problems as may exist, and detect and prevent drug diversion;
 - (b) The procurement, storage, security, and disposition of drugs and the provision of pharmacy services;
 - (c) Assuring that all pharmacists and interns employed by the pharmacy are currently licensed;
 - (d) Providing notification in writing to the Board of Pharmacy within fourteen (14) calendar days of any change in the:
 1. Employment of the pharmacist-in-charge;
 2. Employment of staff pharmacists; or
 3. Schedule of hours for the pharmacy;
 - (e) Making or filing of any reports required by state or federal laws and regulations;
 - (f) Responding to the Kentucky Board of Pharmacy regarding identified violations or deficiencies; and
 - (g) Filing of any report of a theft or loss to:
 1. The U. S. Department of Justice Drug Enforcement Agency as required by 21 C.F.R. 1301.76(b);
 2. The Department of the Kentucky State Police as required by KRS 315.335; and
 3. The board by providing a copy to the board of each report submitted.

Section 3. Incorporation by Reference.

- (1) The following material is incorporated by reference:
 - (a) "Application for Permit to Operate a Pharmacy in Kentucky", Form 1, 07/2012;

(b) "Application for Non-Resident Pharmacy Permit", Form 1, 07/2012;

(c) "Application for Resident Pharmacy Renewal", Form 2, 07/2012; and

(d) "Application for Non-Resident Pharmacy Permit Renewal", Form 2, 07/2012.

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(19 Ky.R. 1018; Am. 1340; eff. 11-30-92; 27 Ky.R. 194; 738; eff. 9-11-2000; 39 Ky.R. 508; eff. 2-1-2013.)