

### **194A.458 Required administrative regulations.**

The Cabinet for Health and Family Services shall promulgate administrative regulations to establish:

- (1) The requirements for health facilities and pharmacies to accept and dispense donated legend drugs or supplies needed to administer legend drugs under KRS 194A.452 and 194A.454, including all of the following:
  - (a) Eligibility criteria for health facilities;
  - (b) Standards and procedures for accepting, safely storing, and dispensing donated legend drugs or supplies needed to administer legend drugs;
  - (c) Standards and procedures for inspecting donated legend drugs or supplies needed to administer legend drugs to determine if these are in their original, unopened, sealed, and tamper-evident unit dose packaging or, if packaged in single-unit doses, the single-unit dose packaging is unopened; and
  - (d) Standards and procedures for inspecting donated legend drugs or supplies needed to administer legend drugs to determine that these are not adulterated or misbranded;
- (2) Eligibility criteria for individuals to receive donated legend drugs or supplies needed to administer legend drugs dispensed under KRS 194A.452 and 194A.454;
- (3) Standards for prioritizing the dispensation to individuals who are uninsured or indigent, or to others if an uninsured or indigent individual is unavailable;
- (4) A means by which an individual who is eligible to receive a donated legend drug or supplies needed to administer a legend drug may indicate that eligibility;
- (5) Necessary forms for administration of the legend drug repository program;
- (6) The maximum handling fee that a health facility may charge for accepting, distributing, or dispensing donated legend drugs or supplies needed to administer legend drugs;
- (7) A list of legend drugs and supplies needed to administer legend drugs that the legend drug repository program may accept for dispensing; and
- (8) A list of legend drugs and supplies needed to administer legend drugs that the legend drug repository program shall not accept for dispensing, including the reason why the legend drug or supply is ineligible for donation.

**Effective:** June 20, 2005

**History:** Created 2005 Ky. Acts ch. 136, sec. 5, effective June 20, 2005.

**Legislative Research Commission Note** (6/20/2005). 2005 Ky. Acts chs. 11, 85, 95, 97, 98, 99, 123, and 181 instruct the Reviser of Statutes to correct statutory references to agencies and officers whose names have been changed in 2005 legislation confirming the reorganization of the executive branch. Such a correction has been made in this section.