

216B.204 Duties of cabinet -- Eligibility for certification.

- (1) The cabinet, shall, at a minimum:
 - (a) Require completion of the certification process for pharmacies, manufacturers, distributors, and abortion facilities;
 - (b) Notify certified pharmacies, manufacturers, distributors, and abortion facilities which physicians are registered as nonsurgical abortion providers with the cabinet;
 - (c) Prohibit intentionally, knowingly, or recklessly shipping abortion-inducing drugs to physicians who become unregistered;
 - (d) Audit newly certified pharmacies, manufacturers, and distributors within ninety (90) calendar days after certification and annually thereafter, to ensure that all processes and procedures are in place and functioning to support the requirements of the Abortion-Inducing Drug Certification Program;
 - (e) Suspend immediately a pharmacist's, manufacturer's, or distributor's certification if found to be noncompliant until full compliance is demonstrated;
 - (f) Enforce compliance and develop a compliance reporting system;
 - (g) Prohibit pharmacies from intentionally, knowingly, or recklessly dispensing or distributing abortion-inducing drugs directly to a patient in the Commonwealth; and
 - (h) Require manufacturers and distributors of abortion-inducing drugs to intentionally and knowingly distribute only to certified pharmacies and in-person dispensing clinics, medical offices, and hospitals that are in compliance with the United States Federal Drug Administration's outlined Mifepristone Risk Evaluation and Mitigation Strategy in effect on April 14, 2022.
- (2) To be eligible for certification, pharmacies, manufacturers, and distributors of abortion-inducing drugs shall:
 - (a) Have either obtained a Kentucky license as a distributor, or a Kentucky permit as a pharmacy or manufacturer;
 - (b) Only distribute to or fulfill prescriptions requested by qualified physicians who are registered as nonsurgical abortion providers with the cabinet;
 - (c) Abide by all applicable standards of the National Association of Boards of Pharmacy;
 - (d) For online sales or orders, hold a current pharmacy or pharma domain and abide by all required standards by the National Association of Boards of Pharmacy to maintain the domain;
 - (e) Follow all other applicable state or federal laws related to the dispensation, distribution, or delivery of legend drugs, including abortion-inducing drugs; and
 - (f) Follow all acceptable processes and procedures to maintain a dispensation, distribution, or delivery system that is secure, confidential, and follows all processes and procedures, including those for storage, handling, shipping, tracking packages, serial numbers, National Drug

Codes, lot numbers, expiration dates, proof of delivery, and controlled returns of abortion-inducing drugs.

- (3) To be eligible for certification, pharmacies shall:
- (a) Be certified by the United States Food and Drug Administration to dispense abortion-inducing drugs;
 - (b) Submit proof of certification by the abortion-inducing drug manufacturer for the distribution of abortion-inducing drugs; and
 - (c) Only fulfill prescriptions that are accompanied by the required patient consent form.

Effective: April 14, 2022

History: Created 2022 Ky. Acts ch. 210, sec. 16, effective April 14, 2022.