CABINET FOR HEALTH AND FAMILY SERVICES
Office of Inspector General
Division of Health Care
(Amended at ARRS Committee)

902 KAR 20:365. Kentucky abortion-inducing drug certification program and registration of qualified physicians.

RELATES TO: KRS 216B.015, 216B.105, 216B.200 - 216B.210, 311.720(1), 311.7731, 311.7733, 311.7734

STATUTORY AUTHORITY: KRS 216B.202(1), 216B.206

NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.202(1) requires the cabinet to promulgate administrative regulations in accordance with KRS Chapter 13A to establish a certification program to oversee and regulate the distribution and dispensing of abortion-inducing drugs. KRS 216B.206 requires the cabinet to establish requirements for physicians who prescribe abortion-inducing drugs. KRS 311.7733 requires a physician to be registered with the cabinet before providing abortion-inducing drugs. This administrative regulation establishes requirements for physicians, manufacturers, distributors, and abortion facilities that prescribe, transport, supply, dispense, or sell abortion-inducing drugs.

Section 1. Definitions.

(1) "Abortion" is defined by KRS 311.720(1).
(2) "Abortion facility" is defined by KRS 216B.015(1).
(3) "Abortion-inducing drug" is defined by KRS 311.7731(2).
(4) "Cabinet" is defined by KRS 311.7731(5).
(5) "Distributor" is defined by KRS 311.7731(9).
(6) "Hospital" is defined by KRS 311.720(7).
(7) "Manufacturer" is defined by KRS 311.7731(9).
(8) "Physician" is defined by KRS 311.720(12).
(9) "Provide" is defined by KRS 311.7731(13).
(10) "Qualified physician" is defined by KRS 311.7731(14).

Section 2. Physician registration.

(1) In accordance with KRS 311.7733, only a qualified physician registered with the cabinet may provide abortion-inducing drugs to a pregnant person.
(2) To be eligible for registration, a qualified physician shall:
  (a) Demonstrate compliance with KRS 216B.206(1)(a), (c), (m), and (n); and
  (b) Certify compliance with KRS 216B.206(1)(b), (d) - (l), (o), and (p).

Section 3. Certification of manufacturers, distributors, pharmacies, and abortion facilities.

(1) In accordance with KRS 216B.202 and 216B.204, the following entities shall be certified by the cabinet:
  (a) A manufacturer or distributor that transports, supplies, or sells abortion-inducing drugs;
  (b) A pharmacy that dispenses abortion-inducing drugs; or
  (c) A licensed abortion facility.
(2)
  (a) To be eligible for certification, a manufacturer, distributor, or pharmacy shall:
    1. Demonstrate compliance with KRS 216B.204(2)(a) and (d); and
    2. Certify compliance with KRS 216B.204(2)(b), (c), (d), (e), and (f).
  (b) In addition to complying with paragraph (a) of this subsection, a pharmacy shall also comply with KRS 216B.204(3) if the U.S. Food and Drug Administration (FDA) and drug manufacturers implement certification programs for pharmacies to dispense

abortion-inducing drugs and compliance with KRS 216B.204(3) becomes possible. A pharmacy shall submit evidence of certification by the FDA within 180 days after creation and implementation of the FDA certification program and shall submit evidence of certification by the drug manufacturer within 180 days after creation and implementation of the manufacturer's certification program.

Section 4. Application and fees.

(1) A qualified physician applicant for registration to provide abortion-inducing drugs shall submit to the Office of Inspector General:

(a) A completed Application for Registration to Provide Abortion-Inducing Drugs;

(b) A completed Physician Dispensing Agreement Form; and

(c) An accompanying fee in the amount of $155, made payable to the Kentucky State Treasurer and sent to the Cabinet for Health and Family Services, Office of Inspector General, Division of Health Care, 275 East Main Street 5E-A, Frankfort, Kentucky 40621.

(2) A manufacturer, distributor, pharmacy, or abortion facility applicant for certification to transport, supply, sell, or dispense abortion-inducing drugs shall submit to the Office of Inspector General:

(a) A completed Application for Participation in the Abortion-Inducing Drug Certification Program; and

(b) An accompanying fee in the amount of $155, made payable to the Kentucky State Treasurer and sent to the Cabinet for Health and Family Services, Office of Inspector General, Division of Health Care, 275 East Main Street 5E-A, Frankfort, Kentucky 40621.

(3) As a condition of annual renewal, the application required by subsections (1) and (2) of this section and a renewal fee in the amount of $155 shall be submitted to the cabinet at least thirty (30) days prior to the date of expiration of the registration or certification. Renewal fees shall be paid as set out in paragraph (2)(b) of this section.

Section 5. Operations.

(1) A manufacturer, distributor, physician, qualified physician, pharmacy, abortion facility, and any other person shall comply with KRS 311.7733(2) prohibiting the use of courier, delivery, or mail services.

(2) In accordance with KRS 216B.204(1)(c), no person or entity shall intentionally, knowingly, or recklessly ship abortion-inducing drugs to a physician unless the physician is registered with the cabinet pursuant to this administrative regulation and as shown on the Office of Inspector General's Web site: https://chfs.ky.gov/agencies/os/oig/dhc/Pages/default.aspx.

(3) In accordance with KRS 216B.204(1)(g), a pharmacy shall not intentionally, knowingly, or recklessly dispense or distribute abortion-inducing drugs directly to a patient in Kentucky.

(4) In accordance with KRS 216B.204(1)(h), manufacturers and distributors shall intentionally and knowingly distribute only to certified pharmacies and in-person dispensing clinics, medical offices, abortion facilities, and hospitals that are in compliance with the United States Federal Drug Administration's outlined Mifepristone Risk Evaluation and Mitigation Strategy in effect on July 14, 2022.

(5) A qualified physician registered with the cabinet shall maintain hospital admitting privileges or enter into a written associated physician agreement as required by KRS 311.7734(1)(b) and comply with all other provisions of KRS 216B.206(2) and 311.7734.

Section 6. Complaints. In accordance with KRS 216B.210, a complaint regarding potential violations of the Abortion-Inducing Drug Certification Program may be submitted on the

Office of Inspector General's Web site: https://chfs.ky.gov/agencies/os/oig/dhc/Pages/default.aspx.

Section 7. Denial, Suspension, Revocation, and Fines.

(1) The cabinet shall deny an application for registration or certification if:

(a) The applicant or existing agency knowingly misrepresents or submits false information on the application; or

(b) The applicant or existing agency fails to provide the information required by the application.

(2) The cabinet shall revoke or suspend certification and impose fines:

(a) In accordance with KRS 216B.208(1)(a) - (e); or

(b) If the cabinet determines that there has been substantial failure to comply with the provisions of this administrative regulation.

(3) If the cabinet determines that there has been substantial failure to comply with the provisions of this administrative regulation, the cabinet shall:

(a) Revoke or suspend registration of a physician and impose fines as set out in KRS 216B.208(1)(e)3.; and

(b) Immediately report the violation to the Kentucky Board of Medical Licensure and local law enforcement in accordance with KRS 216B.208(1).

Section 8. Notice of Adverse Action.

(1) Except as set out in KRS 216B.208(1)(e), OIG shall provide written notice of adverse action at least thirty (30) calendar days prior to the effective date of the denial or revocation.

(2) In accordance with KRS 216B.208(1)(e)1., the cabinet shall immediately notify a pharmacy, manufacturer, or distributor that its certification is suspended and will be permanently revoked if OIG determines that a certified entity has intentionally, knowingly, or recklessly violated KRS 216B.200 to 216B.210 and fails to demonstrate compliance within ninety (90) days.

(3) A notice of adverse action issued in accordance with subsection (1) or (2) of this section shall:

(a) Explain the reason for the denial or revocation, and monetary penalty if applicable;

(b) Advise the individual or entity that the right to request an appeal prior to the effective date of the denial or revocation, and monetary penalty if applicable; and

(c) Specify that the adverse action shall be stayed if an appeal is requested.

Section 9. Appeals. An individual or entity that submits a written request for appeal within thirty (30) calendar days of receiving a notice of adverse action, including revocation, shall be afforded a hearing in accordance with KRS 216B.105.

Section 10. Incorporation by Reference.

(1) The following material is incorporated by reference:

(a) Form OIG 20-365A, "Application for Registration to Provide Abortion-Inducing Drugs", November 2022 edition;

(b) Form OIG 20-365B, "Application for Participation in the Abortion-Inducing Drug Certification Program", November 2022 edition; and

(c) Form OIG 20-365C, "Physician Dispensing Agreement Form", November 2022 edition.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Office of Inspector General, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m. This material may also be viewed on the Office of Inspector General's Web site at: https://chfs.ky.gov/agencies/os/oig/dhc/Pages/ltcapplications.aspx.

(49 Ky.R. 504, 1310, 1433; eff. 1-12-2023.)

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