CABINET FOR HEALTH AND FAMILY SERVICES
Office of Inspector General
Division of Health Care
(Amended After Comments)

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.
(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) above, 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~~[to be eligible for certification]~~.

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; 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.

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

Section 8. Notice of Adverse Action.

(1) Except as set out in KRS 216B.208(1)(e)~~[1.]~~, 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 ~~**[in fifteen (15) days]**~~ 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 the date the agency receives 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**~~**[July]**~~ 2022 edition;

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

(c) Form OIG 20-365C, "Physician Dispensing Agreement Form", **November**~~**[July]**~~ 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.

ADAM MATHER, Inspector General
ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: November 9, 2022
FILED WITH LRC: November 14, 2022 at 2:15 p.m.
CONTACT PERSON: Krista Quarles, Policy Specialist, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-6746; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person:Kara Daniel; Stephanie Brammer-Barnes, Krista Quarles

(1) Provide a brief summary of:

(a) What this administrative regulation does:

This new administrative regulation establishes requirements for the Kentucky Abortion-Inducing Drug Certification Program and registration requirements for physicians to provide abortion-inducing drugs.

(b) The necessity of this administrative regulation:

This new administrative regulation is necessary to comply with KRS 216B.202 – 216B.210, 311.7731, 311.7733, 311.7734 (HB 3).

(c) How this administrative regulation conforms to the content of the authorizing statutes:

This new administrative regulation conforms to the content of KRS 216B.202 – 216B.210, 311.7731, 311.7733, 311.7734 (HB 3) by establishing requirements for the Kentucky Abortion-Inducing Drug Certification Program and registration requirements for physicians to provide abortion-inducing drugs.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:

This new administrative regulation assists in the effective administration of the statutes by establishing requirements for the Kentucky Abortion-Inducing Drug Certification Program and registration requirements for physicians to provide abortion-inducing drugs as required by HB 3 enacted by the 2022 General Assembly.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation:

In response to public comments, this amended after comments regulation added clarifying language to Section 7(3) to align with the requirements of KRS 216B.208(1)(a) for the cabinet to immediately report certain violations to local law enforcement in addition to other applicable agencies, updated the language of Section 8(2) to align with the requirement of KRS 216B.208(1)(e)4. for permanent revocation of certification if the offender fails to demonstrate compliance within ninety (90) calendar days rather than fifteen (15) days, and added clarifying language to Form OIG 20-365C to align with KRS 216B.206. In response to the agency comment, the cabinet modified the language of Section 3(2)(b) to require pharmacies to submit evidence of certification by the U.S. Food and Drug Administration (FDA) within 180 days after implementation of the FDA's anticipated certification program and evidence of certification by the drug manufacturer within 180 days after implementation of the manufacturer's certification program if compliance with KRS 216B.204(3) becomes possible. The cabinet also made conforming changes in Section F of Form OIG 20-365B. In response to public comments, the amended after comments regulation deletes the requirement from the OIG 20-365A for physicians to identify the counties in which services are provided because information regarding the physical address is already captured. In addition, the requirement for evidence of hospital admitting privileges was deleted in favor of requiring an attestation of hospital admitting privileges as

well as a list of hospitals that have granted admitting privileges if the physician does not produce a copy of a current associated physician agreement.

(b) The necessity of the amendment to this administrative regulation:
In response to public comments, this amended after comments regulation is necessary to add clarifying language to Section 3(1)(b), Section 7(3)(b), Section 8(2), Section 10, and Form OIG 20-365A, Form OIG 20-365B, and Form OIG 20-365C.

(c) How the amendment conforms to the content of the authorizing statutes:
This amended after comments regulation conforms to the content of KRS 216B.202 – 216B.210, 311.7731, 311.7733, 311.7734 (HB 3) by establishing requirements for the Kentucky Abortion-Inducing Drug Certification Program and registration requirements for physicians to provide abortion-inducing drugs.

(d) How the amendment will assist in the effective administration of the statutes:
This is amended after comments regulation assists in the effective administration of the statutes by establishing requirements for the Kentucky Abortion-Inducing Drug Certification Program and registration requirements for physicians to provide abortion-inducing drugs as required by HB 3 enacted by the 2022 General Assembly.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:
This new administrative regulation affects manufacturers, distributors, pharmacies, and abortion facilities that will transport, supply, sell, or dispense abortion-inducing drugs, and physicians who will provide abortion-inducing drugs. It is not known how many entities and physicians will apply for certification or registration.

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment:
In accordance with HB 3 and this administrative regulation, entities seeking certification and physicians seeking registration will be required to submit an initial and annual renewal application to the cabinet with accompanying documentation. They will have to comply with the extensive requirements in HB 3.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3):
This regulation establishes application and renewal fees of $155 per applicant. This amount is consistent with application fees paid by abortion facilities licensed under 902 KAR 20:360.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3):
Entities seeking certification and physicians seeking registration to provide abortion-inducing drugs must demonstrate compliance with this administrative regulation and HB 3.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially:

The Office of Inspector General (OIG) will seek to hire one (1) additional grade 15 position to implement and oversee HB 3's new registration and certification program and draft an annual report, plus one-half of one position to investigate complaints. The cost of the additional staff will be approximately $132,000. Additionally, changes to the cabinet's website will be necessary to build an electronic system to store and track information, display certified and qualified providers on the web site, and create a way to accept anonymous complaints, at an estimated cost of $25,000.

(b) On a continuing basis:

The continuing costs will be approximately $132,000 per year for one and one-half employees.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation:

State general funds and agency monies will be used to implement and enforce this administrative regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment:

This administrative regulation establishes an initial and annual registration fee of $155 for qualified physicians. This administrative regulation also establishes an initial and annual registration fee of $155 for manufacturers, distributors, pharmacies, and abortion facilities.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees:

This administrative regulation establishes an initial and annual fee of $155 for registered or certified entities.

(9) TIERING: Is tiering applied?

Tiering is not applicable as compliance with this administrative regulation applies equally to all entities regulated by it.

FISCAL NOTE

(1) What units, parts, or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation?

This administrative regulation impacts manufacturers, distributors, pharmacies, abortion facilities, and physicians and the Cabinet for Health and Family Services, Office of Inspector General.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation.

KRS 216B.202 – 216B.210, 311.7731, 311.7733, 311.7734.

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year?

This regulation establishes an initial and annual fee of $155 for registration or certification. KRS 216B.208 authorizes the cabinet to impose fines of $100,000 - $5 million for noncompliance. However, it is not known how many entities or physicians will apply for registration or certification, or be subject to a fine after registration or certification.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years?

This regulation establishes an initial and annual fee of $155 for registration or certification. KRS 216B.208 authorizes the cabinet to impose fines of $100,000 - $5 million for noncompliance. However, it is not known how many entities or physicians will apply for registration or certification, or be subject to a fine after registration or certification.

(c) How much will it cost to administer this program for the first year?

The Office of Inspector General (OIG) will seek to hire one (1) additional grade 15 position to implement and oversee HB 3's new registration and certification program and draft an annual report, plus one-half of one position to investigate complaints. The cost of the additional staff will be approximately $132,000. Additionally, changes to the cabinet's website will be necessary to build an electronic system to store and track information, display certified and qualified providers on the website, and create a way to accept anonymous complaints, at an estimated cost of $25,000.

(d) How much will it cost to administer this program for subsequent years?

The continuing costs will be approximately $132,000 per year.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation:

(4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.

No answer provided.

(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year?

This administrative regulation will not generate cost savings for regulated entities during the first year.

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years?

This administrative regulation will not generate cost savings for regulated entities during subsequent years.

(c) How much will it cost the regulated entities for the first year?

This administrative regulation will cost regulated entities a fee of $155 during the first year.

(d) How much will it cost the regulated entities for subsequent years?

This administrative regulation will cost regulated entities a fee of $155 during subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Cost Savings (+/-):

Expenditures (+/-):

Other Explanation:

(5) Explain whether this administrative regulation will have a major economic impact, as defined below.

"Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars ($500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. [KRS 13A.010(13)] It is not known how many entities and physicians will apply for registration or certification, and the costs to the applicants of the additional requirements are difficult to quantify. Therefore, the cabinet is unable to determine whether this administrative regulation will have a major economic impact on the regulated entities.