CABINET FOR HEALTH AND FAMILY SERVICES
Office of Inspector General
Division of Health Care
(New Administrative Regulation)
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) 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:


(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:

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) Report the violation to the Kentucky Board of Medical Licensure 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 revoked in fifteen (15) days if OIG determines that a certified entity has intentionally,
knowingly, or recklessly violated KRS 216B.200 to 216B.210.

(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", July 2022 edition;

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

(c) Form OIG 20-365C, "Physician Dispensing Agreement Form", 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:
902 KAR 20:365

REVIEWED:

7/14/2022

Adam Mather, Inspector General
Office of Inspector General

APPROVED:

7/15/2022

Eric C. Friedlander, Secretary
Cabinet for Health and Family Services
PUBLIC HEARING AND PUBLIC COMMENT PERIOD:

A public hearing on this administrative regulation shall, if requested, be held on September 26, 2022, at 9:00 a.m. using the CHFS Office of Legislative and Regulatory Affairs Zoom meeting room. The Zoom invitation will be emailed to each requestor the week prior to the scheduled hearing. Individuals interested in attending this hearing shall notify this agency in writing by September 19, 2022, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation until September 30, 2022. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. In the event of an emergency, the public hearing will be held using the CHFS Office of Legislative and Regulatory Affairs Zoom meeting room. The Zoom invitation will be emailed to each requestor in advance of the scheduled hearing. Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

CONTACT PERSON: Krista Quarles, Policy Specialist, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, KY 40621; Phone: 502-564-6746; Fax: 502-564-7091; CHFSregs@ky.gov.
REGULATORY IMPACT ANALYSIS
AND TIERING STATEMENT

Administrative Regulation: 902 KAR 20:365
Agency Contact: Kara Daniel; Stephanie Brammer-Barnes
Phone Number: (502) 564 – 2888
Email: karal.daniel@ky.gov; sbrammerbarnes@ky.gov

Contact Person: Krista Quarles
Phone Number: (502) 564-6746
Email: CHFSregs@ky.gov

(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: This is a new administrative regulation.
(b) The necessity of the amendment to this administrative regulation: This is a new administrative regulation.
(c) How the amendment conforms to the content of the authorizing statutes: This is a new administrative regulation.
(d) How the amendment will assist in the effective administration of the statutes: This is a new administrative regulation.

(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 website, 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 established any fees or directly or indirectly increased any fees: This administrative regulation establishes an
initial and annual fee of $155 for registered or certified entities.

(9) TIERING: Is tiering applied? (Explain why or why not) Tiering is not applicable as compliance with this administrative regulation applies equally to all entities regulated by it.
FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

Administrative Regulation: 902 KAR 20:365
Agency Contact: Kara Daniel; Stephanie Brammer-Barnes
Phone Number: (502) 564 – 2888
Email: karal.daniel@ky.gov; srammerbarnes@ky.gov

Contact Person: Krista Quarles
Phone Number: (502) 564-6746
Email: CHFSregs@ky.gov

(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.

(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.
COMMONWEALTH OF KENTUCKY
CABINET FOR HEALTH AND FAMILY SERVICES
OFFICE OF INSPECTOR GENERAL


SUMMARY OF MATERIAL INCORPORATED BY REFERENCE

Form OIG 20:365A, "Application for Registration to Provide Abortion-Inducing Drugs", July 2022 edition, is the 3-page application form that qualified physicians are required to submit to the Office of Inspector General prior to obtaining registration to provide abortion-inducing drugs and annually thereafter as part of the renewal process.

Form OIG 20:365B, "Application for Participation in the Abortion-Inducing Drug Certification Program", July 2022 edition, is the 4-page application form that manufacturers, distributors, pharmacies, and abortion facilities are required to submit to the Office of Inspector General prior to obtaining certification to transport, supply, sell, or dispense abortion-inducing drugs.

Form OIG 20:365C, "Physician Dispensing Agreement Form", July 2022 edition, is the 1-page form that qualified physicians are required to submit to the Office of Inspector General along with their application to register to provide abortion-inducing drugs.

A total of eight (8) pages are incorporated by reference.