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Primary Sponsor: Sen. S. Huffman

Amy L. Archer, Research Analyst

Audra Tidball, Attorney

SUMMARY

Prohibition on provision of abortion-inducing drugs

- Prohibits a person from knowingly providing an abortion-inducing drug to another, unless the person is certified under the bill's Abortion-Inducing Drug Certification Program, meets other requirements to be considered a "qualified physician," and provides the drug in accordance with the bill's requirements.
- Prohibits a public school, institution of higher education, or any other type of educational program on public grounds from providing any abortion-inducing drugs.

Qualified physician requirements

- Requires a qualified physician, no later than 24 hours prior to providing an abortion-inducing drug, to take certain action, including examining the patient in person and verifying that the patient receiving the abortion-inducing drug is pregnant.
- Adds the following to the informed consent requirements under continuing law that must be satisfied before an abortion may be performed or induced with an abortion-inducing drug:
  - The pregnant woman has been provided with the (1) notification form and (2) acknowledgment of risks and consent form.
  - The physician has met all of the bill's requirements governing the provision of abortion-inducing drugs.
- Prohibits a qualified physician from providing an abortion-inducing drug if certain conditions apply to the patient, including, for example, the patient is not pregnant or the gestational age of the unborn child of the pregnancy is more than 70 days or ten weeks.

- Requires a qualified physician or physician's agent, after an abortion-inducing drug is provided to a patient, to do the following:
  - Schedule an in-person follow-up appointment to confirm the completion of the abortion and to assess bleeding.
  - Make all reasonable efforts to ensure that the patient returns for the follow-up appointment.
  - If applicable, provide or refer the patient for emergency surgical intervention in cases of medical complications and assure patient access to medical facilities equipped for necessary treatments.
- Repeals the prohibition on a physician personally furnishing or providing an abortion-inducing drug to a pregnant woman unless the physician is physically present where and when the initial dose of the drug is consumed.

Penalties

- Creates the criminal offense of unlawful provision of an abortion-inducing drug, generally a fourth degree felony, if an offender violates, or fails to comply with, the bill's requirements governing the provision of abortion-inducing drugs.
- Provides, in addition to remedies available under existing law, that a violation of, or failure to comply with, the requirements governing the provision of abortion-inducing drugs may also be the basis of a (1) civil action and (2) disciplinary action by a professional licensing board.

Required forms and reports

- Requires the qualified physician providing an abortion-inducing drug to give the patient (1) a notification form and (2) an acknowledgment of risks and consent form.
- Requires the qualified physician to sign a declaration prior to providing a patient with an abortion-inducing drug.
- Requires, in addition to reports required under continuing law, a facility that provides abortion-inducing drugs to complete, and the qualified physician who provides the abortion-inducing drug to sign, an individual report for each abortion by an abortion-inducing drug.
- Requires any other health care professional who diagnoses or treats a patient for an abortion complication or adverse event related to the abortion-inducing drug to complete and sign an individual report.
- Requires the above-mentioned reports to be submitted to the Department of Health, generally on a monthly basis.

Department of Health comprehensive statistical report

- Requires the Department of Health to annually prepare, and submit to the General Assembly, a comprehensive statistical report compiling the data gathered from select reports on the provision of abortion-inducing drugs.
- Requires the Department to summarize the aggregate data and submit the information to the federal Centers for Disease Control and Prevention to be included in the annual Vital Statistics Report.

Abortion-Inducing Drug Certification Program and Reporting System

- Requires the State Board of Pharmacy to establish an Abortion-Inducing Drug Certification Program to oversee and regulate the provision of abortion-inducing drugs in Ohio.
- As part of that program, requires physicians, manufacturers, and distributors to be certified by the Pharmacy Board to personally furnish or provide abortion-inducing drugs in Ohio.
- Establishes civil liability, criminal penalties, and regulatory fines and sanctions against physicians, manufacturers, and distributors that violate the bill's certification and reporting requirements.
- Requires the Pharmacy Board to establish a system for reporting complications and adverse events from the use of abortion-inducing drugs and requires physicians to report to that system.

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DETAILED ANALYSIS

Overview

The bill expands the regulation of the provision of medications used to induce abortion. Under the bill, no person, except a qualified physician who meets the bill's requirements, including being certified by the State Board of Pharmacy under the Abortion-Inducing Drug Certification Program that is to be established under the bill, can knowingly provide (meaning give, sell, prescribe, dispense, administer, or transfer possession of) an abortion-inducing drug (a medicine, drug, or other substance, including off-label use of drugs known to have abortion-inducing effects such as RU-486 (mifepristone), misoprostol, and methotrexate, intended to induce an abortion). Additionally, the bill establishes required procedures, restrictions, civil actions, a criminal offense, and professional sanctions; forms and reports regarding the provision of abortion-inducing drugs; and a system for reporting abortion complications (the Abortion-Inducing Drug Complication Reporting System).

Current law, repealed under the bill, prohibits a person, other than a physician who meets federal law governing RU-486 (mifepristone), from knowingly giving, selling, dispensing, administering, personally furnishing, and otherwise providing mifepristone to another person for the purpose of inducing an abortion or enabling the other person to induce an abortion in any person. The bill also repeals the current law prohibition on a physician personally furnishing or providing an abortion-inducing drug to a pregnant woman unless the physician is physically present where and when the initial dose of the drug is consumed.

Prohibition on provision of abortion-inducing drugs

By person other than a qualified physician

The bill prohibits a person from knowingly providing an abortion-inducing drug to another for the purpose of inducing an abortion in any person or enabling the other person to induce an abortion in any person, unless the person who provides the abortion-inducing drug is a qualified physician (see definition below) and the physician provides the abortion-inducing drug to the other person for the purpose of inducing an abortion in accordance with the bill's requirements.

Under the bill, a person who provides an abortion-inducing drug to another in accordance with the criteria described above cannot be prosecuted based on a violation of those criteria unless either of the following apply:

- The person knows that the person is not a qualified physician; or
- The person did not provide the abortion-inducing drug in accordance with the bill's provisions.[1]

Under current law, no person can knowingly give, sell, dispense, administer, or otherwise provide RU-486 (mifepristone) to another for the purpose of inducing an abortion in any person or enabling the other person to induce an abortion in any person, unless the person who gives, sells, dispenses, administers, or otherwise provides the mifepristone (1) is a physician, (2) has satisfied all the criteria established by federal law that a physician must satisfy to provide mifepristone for inducing abortions, and (3) provides the mifepristone to the other person for the purpose of inducing an abortion in accordance with all provisions of federal law that govern the use of mifepristone for inducing abortions.

By public school, institution of higher education, or other

The bill also expressly prohibits a public school, institution of higher education, or any other type of educational program on public grounds from providing any abortion-inducing drugs.[2]

Definitions

The bill defines the following terms:

- "Abortion" is the purposeful termination of a human pregnancy by any person, including the pregnant woman herself, with an intention other than to produce a live birth or to remove a dead fetus or embryo.
- "Abortion-inducing drug" is a medicine, drug, or other substance, including the off-label use of drugs known to have abortion-inducing effects such as RU-486 (mifepristone), misoprostol, and methotrexate, intended to induce an abortion. "Abortion-inducing drug" excludes any medicine, drug, or other substance that may be known to induce an abortion but that are provided to a pregnant woman for other medical purposes.
- "Gestational age" is the age of an unborn child as calculated from the first day of the last menstrual period of a pregnant woman.
- "Physician" is a person who is licensed to practice medicine and surgery or osteopathic medicine and surgery by the State Medical Board or a person who otherwise is

[1] R.C. 2919.291, with conforming changes in R.C. 109.572 and 2953.25.

[2] R.C. 3301.83(B).

authorized to practice medicine and surgery or osteopathic medicine and surgery in Ohio.

- "Provide" is any act of giving, selling, prescribing, dispensing, administering, or transferring possession of an abortion-inducing drug.
- "Qualified physician" is a physician who is certified under the Abortion-Inducing Drug Certification Program established under the bill (see "**Abortion-Inducing Drug Certification Program**," below) and who has the ability to do all of the following:
  - Identify and document a viable intrauterine pregnancy;
  - Assess the gestational age of a pregnancy and inform patients of gestational age-specific risks of abortion-inducing drugs;
  - Diagnose an ectopic pregnancy;
  - Determine blood type and administer RH0-(D)-immune globulin for women who are RH negative;
  - Assess for signs of domestic abuse, reproductive control, human trafficking, and signs of coerced abortion;
  - Provide surgical intervention;
  - Be credentialed and competent to handle complication management, including emergency transfer;
  - Supervise and bear legal liability for any agent, employee, or contractor who is participating in any part of an abortion procedure, including evaluation and care prior to the procedure.
- "Unborn child" is an individual organism of the species *Homo sapiens* from fertilization until live birth.[3]

Qualified physician requirements

Procedures prior to providing abortion-inducing drug

The bill requires, in addition to the informed consent requirements described below, a qualified physician, no later than 24 hours prior to providing an abortion-inducing drug, to do all of the following:

- Examine the patient in person and independently verify that the patient receiving the abortion-inducing drug is pregnant;
- Determine the patient's blood type and, if the patient has an RH negative blood type, administer RH0-(D)-immune globulin to the patient prior to providing the abortion-inducing drug;

[3] R.C. 2919.29(A), (B), (F), and (I) to (M) and 3301.83(A).

- Inform the patient that she may see the remains of her unborn child in the process of completing the abortion;
- Ensure the patient has initialed, signed, and certified, as applicable, the informed consent form, notification form, and acknowledgment of risks and consent form (described below);
- Sign the qualified physician declaration (described below);
- Document the following, as diagnosed by the most accurate standard of medical care, in the patient's medical record:
  - The gestational age of the unborn child of the pregnancy;
  - The intrauterine location of the pregnancy;
  - Whether the patient has an RH negative blood type and received RH0-(D)-immune globulin for RH negative blood type.[4]

Informed consent requirements

Under continuing law, except when there is a medical emergency or medical necessity, an abortion can be performed or induced only if certain conditions are satisfied, such as, for example, a physician meeting with the pregnant woman at least 24 hours prior to the performance or inducement of the abortion to give her adequate opportunity to ask questions about the abortion. The bill adds the following conditions that must be satisfied in order that an abortion can be performed or induced with an abortion-inducing drug:

- The pregnant woman has been provided with the (1) notification form and (2) acknowledgment of risks and consent form, described below.
- The physician has met all of the bill's requirements governing the provision of abortion-inducing drugs.[5]

Restrictions on provision of abortion-inducing drug

The bill prohibits a qualified physician from providing an abortion-inducing drug if any of the following apply to the patient:

- Not pregnant;
- The gestational age of the unborn child of the pregnancy is more than 70 days or ten weeks;
- Has an RH negative blood type, unless the physician administers RH0-(D)-immune globulin to the patient prior to providing the abortion-inducing drug in accordance with the bill's requirements;

[4] R.C. 2919.292.

[5] R.C. 2317.56(B).

- Has risk factors associated with complications from abortion-inducing drugs, including any of the following:
  - Ectopic pregnancies;
  - Problems with adrenal glands near kidneys;
  - Receiving treatment with long-term corticosteroid therapy;
  - Previous allergic reactions to abortion-inducing drugs, including mifepristone, misoprostol, or similar drugs;
  - Has a bleeding disorder or problem or is taking an anticoagulant drug;
  - Has inherited porphyria;
  - Has an intrauterine device in place.[6]

Requirements following provision of an abortion-inducing drug

Under the bill, following the provision of an abortion-inducing drug by a qualified physician to a patient, all of the following apply:

- The physician or an agent of the physician must schedule an in-person follow-up appointment for the patient between seven to 14 days after the provision of the abortion-inducing drug to confirm the completion of the abortion and to assess bleeding.
- The physician or agent of the physician must make all reasonable efforts to ensure that the patient returns for the follow-up appointment. A brief description of the efforts made to comply with this requirement, including the date, time, and identification by name of the person making the efforts, must be recorded in the patient's medical record.
- If applicable, provide or refer the patient for emergency surgical intervention in cases of incomplete abortion, severe bleeding, or other medical complications and assure patient access to medical facilities equipped to provide blood transfusions, resuscitation, and other necessary treatments.[7]

[6] R.C. 2919.293.

[7] R.C. 2919.294. An LSC corrective amendment is required to specify that "the physician or agent of the physician" must provide or refer the patient for emergency surgical intervention.

Repeal of physical presence requirement for abortion-inducing drugs

The bill repeals the prohibition on a physician personally furnishing or providing an abortion-inducing drug to a pregnant woman unless the physician is physically present at the location where and when the initial dose of the drug is consumed.[8]

Penalties

Criminal penalties

Under the bill, whoever intentionally, knowingly, or recklessly violates, or fails to comply with, the bill's requirements governing the provision of abortion-inducing drugs is guilty of unlawful provision of an abortion-inducing drug, a fourth degree felony. However, the violation is a third degree felony if the offender previously has been convicted of or pleaded guilty to other abortion-related crimes, including, for example, partial birth feticide.[9]

The crime described above does not apply to the following:

- A pregnant woman who obtains or possesses an abortion-inducing drug for the purpose of inducing an abortion to terminate her own pregnancy;
- The legal transport of abortion-inducing drugs by any person or entity and the legal delivery of abortion-inducing drugs by any person to the recipient, except for any conduct unrelated to the abortion-inducing drug's transport and delivery to the recipient;
- The distribution, provision, or sale of an abortion-inducing drug by any legal manufacturer or distributor of abortion-inducing drugs, provided the manufacturer or distributor made a good faith effort to comply with any applicable requirements regarding the distribution, provision, or sale.[10]

Civil and disciplinary actions

Under the bill, in addition to any other remedy available under the law, an intentional, knowing, or reckless violation of, or failure to comply with, the requirements governing the provision of abortion-inducing drugs (described above) may also be the basis of the following:

- A civil action brought by a woman upon whom an abortion has been attempted, induced, or performed, or the parent or guardian of a minor upon whom an abortion has been attempted, induced, or performed, for actual and punitive damages and reasonable attorney's fees;

[8] R.C. 2919.124, repealed.

[9] An LSC technical amendment is required to correct a cross-reference error to "sections 2919.291 to 2919.294 of the Revised Code" from "these sections."

[10] R.C. 2919.2919.

- Disciplinary action by the State Medical Board (described below).

A civil action for the unlawful provision of an abortion-inducing drug must be commenced within one year after the performance or inducement of the abortion.

Further, the bill amends continuing law regarding a request for confidentiality by a woman bringing a civil action based on abortion to include a civil action for unlawful provision of an abortion-inducing drug. Under continuing law, in any civil action based on or related to any injury, death, or loss to a person or property suffered as a result of the unlawful provision of an abortion-inducing drug, the woman upon whom the abortion was performed, induced, or attempted may file a motion with the court requesting that her identity only be revealed to the defendant and the court, and that in all other respects the civil action be conducted in a manner that maintains her confidentiality.[11]

If the plaintiff's civil action is successful, the court must award reasonable attorney's fees. If the defendant prevails and the court finds that the plaintiff's action was frivolous and brought in bad faith, the court may award reasonable attorney's fees in favor of the defendant.[12]

Additionally, the bill provides that if the offender is a professionally licensed person, in addition to any other sanction imposed by law for the offense, the offender is subject to sanctioning as provided by law by the regulatory or licensing board or agency that has the administrative authority to suspend or revoke the offender's professional license, including the sanctioning provided by the State Medical Board for offenders who have a certificate to practice or certificate of registration issued by the State Medical Board and the Abortion-Inducing Drug Certification Program (described below).

Exceptions

The civil action and disciplinary action described above do not apply to either of the following individuals:

- A physician who performs or induces the abortion using an abortion-inducing drug if the physician believes that a medical emergency exists that prevents compliance with the bill's requirements;
- A pregnant woman on whom a drug-induced abortion is performed or induced or attempted to be performed or induced in violation of the bill's requirements governing the provision of abortion-inducing drugs.

A physician who performs or induces an abortion on a pregnant woman based on the above exception must make written notations in the pregnant woman's medical records of both of the following:

[11] R.C. 2919.2917(A), 2305.11, and 2307.46.

[12] R.C. 2919.2917(D).

- The physician's belief that a medical emergency necessitating the abortion existed;
- The medical condition of the pregnant woman that assertedly prevented compliance with the provision governing remedies.[13]

Required forms and reports

To be provided to patients

Notification form

The bill requires a qualified physician who provides abortion-inducing drugs to patients to provide, in addition to the informed consent form requirements (described above), a notification form to the patient. The patient must sign the form prior to the provision of an abortion-inducing drug.

The bill requires the Director of Health, no later than 60 days after the bill's effective date and in accordance with Administrative Procedure Act, to adopt rules necessary to carry out the bill's notification form requirements, including rules that prescribe a notification form informing the patient of the following:

- A detailed description of the steps to complete the abortion with the different abortion-inducing drugs;
- A detailed description of possible complications associated with the different abortion-inducing drugs, including hemorrhage, failure to remove all tissue of the unborn child which may require an additional procedure, sepsis, sterility, and possible continuation of the pregnancy, and notice that risk of associated complications increase with advancing gestational age;
- Information about RH incompatibility, including notice that a patient who has an RH negative blood factor must receive RH0-(D)-immune globulin prior to receiving the abortion-inducing drug to prevent RH incompatibility and possible complications in future pregnancies;
- The patient may see the remains of the unborn child in the process of completing the abortion.[14]

Acknowledgment of risks and consent form

The bill requires a qualified physician who provides abortion-inducing drugs to patients to provide an acknowledgment of risks and consent form to the patient. The patient must initial next to each statement on the form prior to the provision of an abortion-inducing drug.

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[13] R.C. 2919.2917(B) and (C). An LSC technical amendment is needed to correct the cross-reference error to "sections 2919.291 to 2919.294 of the Revised Code" from "division (A) of this section."

[14] R.C. 2919.296(A) and (B).

The bill requires the Director of Health, not later than 60 days after the bill's effective date and in accordance with Administrative Procedure Act, to adopt rules necessary to carry out this section, including rules that prescribe an acknowledgment of risks and consent form that includes the following statements:

- The patient understands that the abortion-inducing drug regimen or procedure is intended to end the pregnancy and will result in the death of the patient's unborn child.
- The patient is not being forced to have an abortion, the patient has the choice to not have the abortion, and the patient may withdraw consent to the abortion-inducing drug even after beginning the abortion-inducing drug regimen.
- The patient understands that the abortion-inducing drug to be used may result in risks or complications.
- The patient has been given the opportunity to ask questions about the patient's pregnancy, the development of the unborn child, alternatives to abortion, the abortion-inducing drug to be used, and any risks or complications related to the abortion-inducing drug.
- The patient has been provided the Department of Health's printed materials informing the patient about (1) family planning information and agencies and services to assist through pregnancy and after childbirth and (2) the probable anatomical and physiological characteristics of the zygote, blastocyte, embryo, or fetus during gestation.
- The qualified physician or the physician's agent will schedule an in-person follow-up appointment for the patient between seven and 14 days after providing the abortion-inducing drug to confirm the completion of the abortion and to assess the patient for bleeding and other complications.
- The patient has received or been given sufficient information to give her informed consent to the abortion-inducing regimen or procedure.
- A description of the civil or criminal actions that the patient has a right to pursue against the physician who provides the abortion-inducing drug to the patient if the physician violates or fails to meet conditions or requirements under the law related to the provision of an abortion;
- Information on how to access state resources regarding the patient's right to obtain relief.[15]

Enforcement of form provisions

The bill prohibits the enforcement of its provisions requiring a qualified physician who provides abortion-inducing drugs to patients to provide the notification form and the

[15] R.C. 2919.297(A) and (B).

acknowledgment of risks and consent form until ten days after the forms are completed and distributed by the Department of Health or the bill's effective date, whichever is later.[16]

To be completed by a qualified physician

Under the bill, a qualified physician who provides abortion-inducing drugs to patients must sign a qualified physician declaration prior to providing a patient with an abortion-inducing drug.

The Director of Health, no later than 60 days after the bill's effective date and in accordance with Administrative Procedure Act, must adopt rules necessary to carry out this section, including rules that prescribe a qualified physician declaration form that verifies the following:

- The physician has explained to the patient the abortion-inducing drugs to be used;
- The physician has provided to the patient the informed consent form, notification form, and acknowledgment of risks and consent form and all related information;
- The physician has answered all of the patient's questions.[17]

To be completed by a facility and signed by a qualified physician

Report for each abortion by abortion-inducing drug

The bill requires, in addition to (1) the physician's report on attempted or completed abortions and (2) physician and hospital abortion reports, both required under continuing law, a facility that provides abortion-inducing drugs to patients to complete, and the qualified physician who provides the abortion-inducing drug to sign, an individual report for each abortion performed or induced by an abortion-inducing drug. The report must be confidential and cannot contain the patient's name or any other identifying information.[18] The report must include all of the following, insofar as the patient makes the data available that is not within the physician's knowledge:

- The date of the ultrasound performed by the physician on the patient to determine the unborn child's gestational age and the gestational age determined on that date;
- The abortion-inducing drugs used and the date the abortion-inducing drugs were provided;
- The reason for the abortion;

[16] R.C. 2919.296(C) and 2919.297(C).

[17] R.C. 2919.298.

[18] An LSC corrective amendment is required to change "identifying information" to "personal identifying information."

- Whether the woman returned for the follow-up appointment required to be scheduled under the bill, the reasonable efforts made to encourage the patient's return for the follow-up appointment, and the results of the follow-up examination;
- Whether the patient experienced any abortion complications or adverse events and, if applicable, a description of the abortion complications or adverse events and the follow-up treatment required;
- If applicable, the amount the physician billed for the treatment for the abortion complication or adverse event, including all ICD-10 codes reported and any other treatment or procedure codes reported; charges for the physician, facility, prescription or other drug, and laboratory tests; and whether the treatment was billed to Medicaid, private insurance, the patient, or another person.[19]

Definitions

The bill defines the following terms:

- "Adverse event" is any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related.
- "Complication" or "abortion complication" means only the following physical or psychological conditions which, in the reasonable medical judgment of a licensed health care professional, arise as a primary or secondary result of an induced abortion: uterine perforation, cervical laceration, infection, bleeding, vaginal bleeding that qualifies as a grade two or higher adverse event according to the common terminology criteria for adverse events, pulmonary embolism, deep vein thrombosis, failure to actually terminate the pregnancy, incomplete abortion or retained tissue, pelvic inflammatory disease, endometritis, missed ectopic pregnancy, cardiac arrest, respiratory arrest, renal failure, shock, amniotic fluid embolism, coma, free fluid in the abdomen, allergic reactions to anesthesia and abortion-inducing drugs, psychological complications as diagnosed under the most recent edition of the diagnostic and statistical manual of mental disorders published by the American psychiatric association, and any related complication arising under the following ICD-10 codes, in effect as of the bill's effective date: O04.2, O04.5, O04.6, O04.7, O04.80, O04.81, O04.82, O04.84, O04.86, O04.87, O04.88, O07.0, O07.1, O07.2, O07.34, O07.38, and P04.88.
- "Facility" is any public or private hospital, clinic, center, medical school, medical training institution, health care business, physician's office, infirmary, dispensary, pharmacy, ambulatory surgical center, or other institution, location, or business wherein medical care or pharmaceuticals are provided.
- "Hospital" includes any person, corporation, association, board, or authority that is responsible for the operation of any hospital licensed or registered in the state,

[19] R.C. 2919.2910(A).

including, but not limited to, those that are owned or operated by the state, political subdivisions, any person, any corporation, or any combination of the state, political subdivisions, persons, and corporations. "Hospital" also includes any person, corporation, association, board, entity, or authority that is responsible for the operation of any clinic that employs a full-time staff of physicians practicing in more than one recognized medical specialty and rendering advice, diagnosis, care, and treatment to individuals. "Hospital" does not include any hospital operated by the United States government or any of its branches.

- "Personal identifying information" includes, but is not limited to, the following: the name, address, telephone number, driver's license, driver's license number, commercial driver's license, commercial driver's license number, state identification card, state identification card number, Social Security card, Social Security number, birth certificate, place of employment, employee identification number, mother's maiden name, demand deposit account number, savings account number, money market account number, mutual fund account number, other financial account number, personal identification number, password, or credit card number of a living or dead individual.[20]

Submission requirements

The bill requires the facility, no later than the 15th day of each month, to submit the report to the Department of Health in accordance with the forms, rules, and regulations adopted by the Department under the bill. However, if a qualified physician provides an abortion-inducing drug to a minor, or to a person under 21 years of age with a developmental disability or physical impairment, and the physician is required to file a report of child abuse or neglect in accordance with laws governing mandatory child abuse or neglect reporting regarding the minor or person, the facility must submit the report to the Department and the public children services agency no later than three days after the qualified physician provides the abortion-inducing drug, in accordance with the forms, rules, and regulations adopted by the Department under the bill.[21]

Enforcement of form provisions

Under the bill, the report and submission requirements described above cannot be enforced until ten days after the report forms are completed and distributed by the Department of Health or the bill's effective date, whichever is later.[22]

[20] R.C. 2919.29(C) to (E), (G), and (H). An LSC corrective amendment is required to change "identifying information" to "personal identifying information."

[21] R.C. 2919.2910(B).

[22] R.C. 2919.2910(D).

Director and Department of Health requirements

The bill requires the Director of Health, no later than 60 days after the bill's effective date and in accordance with Administrative Procedure Act, to adopt rules as necessary to carry out the report and submission requirements described above.

Under the bill, the Department must communicate the reporting requirements described above and in the rules adopted under the bill to all professional health care organizations, licensed physicians, and facilities operating in Ohio.[23]

To be completed by other health care professional

Individual report

Under the bill, any health care professional, other than the qualified physician who provided the patient with an abortion-inducing drug, who diagnoses or treats a patient at any time for an abortion complication or adverse event related to the abortion-inducing drug must complete and sign an individual report. The report is confidential and cannot contain the patient's name or other identifying information.[24] The report must include all of the following, insofar as the patient makes the data available to the physician that is not within the physician's knowledge:

- A description of the abortion complication or adverse event, what, if any, emergency transfer was required, and any treatment required, including whether additional drugs were provided to complete the abortion;
- The date the patient presented for treatment related to an abortion complication or adverse event;
- Identification of the qualified physician who provided the abortion-inducing drug to the patient;
- The date or dates, as applicable, on which the patient took the abortion-inducing drugs;
- Whether the abortion was completed at the facility where the abortion-inducing drug was provided or at another location;
- Whether the patient obtained the abortion-inducing drug from a mail-order pharmacy or website and, as applicable, the pharmacy's or website's name, the website address, and telemedicine provider;
- If applicable, the referring physician, agency, or service;
- Whether the abortion complication or adverse event was previously managed by the abortion provider;

[23] R.C. 2919.2910(C) and (E).

[24] An LSC corrective amendment is required to change "identifying information" to "personal identifying information."

- The patient's county and state or, if not a resident of the United States, the country of residence;
- The patient's age;
- The patient's race;
- The patient's number of previous pregnancies, live births, and abortions;
- The abortion-inducing drugs used and the date the drugs were provided to the patient;
- The patient's reason for the abortion;
- Any preexisting medical condition of the patient, which may complicate the pregnancy;
- Whether the patient returned for the follow-up appointment with the qualified physician who provided the abortion-inducing drug to the patient and what known efforts were made by the physician or physician's agent to encourage the patient's return for the follow-up appointment;
- The amount the physician billed for the treatment of the abortion complication or adverse event, including all ICD-10 codes reported, charges for the physician, facility, prescription or other drug, and laboratory tests, and whether the treatment was billed to Medicaid, private insurance, out-of-pocket payment, or other method.[25]

Submission requirement

Under the bill, the health care professional must, not later than the 15th day of each month, submit the report to the Department of Health in accordance with the forms, rules, and regulations adopted by the Department under the bill.[26]

Enforcement of form provisions

Under the bill, the report and submission requirements described above cannot be enforced until ten days after the report forms are completed and distributed by the Department of Health or the bill's effective date, whichever is later.[27]

Director and Department of Health requirements

The bill requires the Director of Health, no later than 60 days after the bill's effective date and in accordance with Administrative Procedure Act, to adopt rules as necessary to carry out the report and submission requirements described above.

Under the bill, the Department must communicate the reporting requirements described above and in the rules adopted under the bill to all health professional organizations,

[25] R.C. 2919.2911(A).

[26] R.C. 2919.2911(B).

[27] R.C. 2919.2911(D).

licensed physicians, hospitals, emergency rooms, ambulatory surgical facilities, and other health care facilities operating in Ohio.[28]

Department of Health comprehensive statistical report

The bill requires the Department of Health to annually prepare a comprehensive statistical report compiling the data gathered from the following:

- The reports completed by a facility, and signed by a qualified physician, that provides abortion-inducing drugs; and
- The reports completed by any other health care professional who diagnoses or treats a patient for an abortion complication or adverse event related to an abortion-inducing drug,

Under the bill, the Department must submit the comprehensive statistical report to the General Assembly no later than October 1 of each year, and the report must be made available to the public in a downloadable format.[29]

Additionally, the bill requires the Department to summarize the aggregate data gathered for the report and submit the information to the federal Centers for Disease Control and Prevention to be included in the annual Vital Statistics Report.[30]

Inspection and availability of reports received

The bill provides that all reports the Department receives, as described above, are public records open to inspection under Public Records Law. In no case can the Department release to any person the name or any other personal identifying information regarding the person who is the subject of a report received by the Department.

Under the bill, original copies of all reports made must be available to the Department and the State Medical Board for use in the performance of the Department's or Board's official duties.[31]

Interpretation of provisions governing abortion-inducing drugs

The bill specifies that nothing in the bill's provisions governing the provision of abortion-inducing drugs and related requirements can be construed to do any of the following:

- Create or recognize a right to abortion;
- Make lawful an abortion that is otherwise unlawful;

[28] R.C. 2919.2911(C) and (E).

[29] R.C. 2919.2914.

[30] R.C. 2919.2915.

[31] R.C. 2919.2912.

- Repeal, replace, or otherwise invalidate existing federal or state laws, regulations, or policies.[32]

Abortion-Inducing Drug Certification Program

The bill requires the State Board of Pharmacy to establish an Abortion-Inducing Drug Certification Program to oversee and regulate the provision of abortion-inducing drugs in Ohio. It prohibits noncertified physicians, manufacturers, and distributors from personally furnishing or providing abortion-inducing drugs in Ohio, as discussed below.[33]

Certification required

Under the bill, both of the following must be certified:

1. A physician who wishes to personally furnish abortion-inducing drugs in Ohio;

2. A manufacturer or distributor, including a wholesale distributor or terminal distributor,[34] that wishes to provide abortion-inducing drugs in Ohio.

Certification process and eligibility

Applications for certification must be submitted to the Pharmacy Board with a certification fee of $100. Certification is valid for one year and may be renewed if the applicant submits a renewal application, pays a $100 renewal fee, and continues to meet all requirements for certification.[35]

To be eligible for certification, the following requirements must be met:

For a physician:[36]

--Have a license in good standing with the State Medical Board;

--Sign a dispensing agreement form, to be developed by the Pharmacy Board, agreeing to comply with state and federal abortion requirements, including those established by the bill;

--Submit to the Pharmacy Board a written protocol that the physician will follow regarding scheduling patients for follow-up appointments.

For a manufacturer or distributor:[37]

--Have a license in good standing with the Pharmacy Board;

[32] R.C. 2919.2921.

[33] R.C. 4729.71(B).

[34] R.C. 4729.71(A)(2).

[35] R.C. 4729.71(C)(3).

[36] R.C. 4729.71(C)(1).

[37] R.C. 4729.71(C)(2).

--Be accredited or certified by the Utilization Review Accreditation Commission or the National Association for Boards of Pharmacy, or a successor organization of either;

--If abortion-inducing drugs will be sold online, the website must be verified by the National Association of Boards of Pharmacy's "Pharmacy Verified Websites Program" or a successor program.

Physician requirements

In addition to complying with other state and federal abortion requirements, a physician who is certified to personally furnish abortion-inducing drugs must:[38]

1. Record in a patient's medical record the serial number of each package of each abortion-inducing drug given to a patient;

2. Report to the Pharmacy Board and to the federal Food and Drug Administration (FDA) any death associated with an abortion-inducing drug as soon as possible, but not later than 15 calendar days from the date the physician is notified of the death. The report must include the serial number of the abortion-inducing drug provided to the patient and must not disclose the identity of the patient.

3. Report complications and adverse events within three days to the Pharmacy Board, Medical Board, and FDA's MedWatch reporting program;

4. Annually report to the Pharmacy Board all of the following:

   a. The number of patients provided abortion-inducing drugs;

   b. Each patient's age, race, residence, county where the drug was personally furnished, and identification of each drug provided and the date provided;

   c. A list of all staff attending to patients, including license numbers or other evidence of qualifications;

   d. Identification of any cases with unresolved complications or adverse events.

Manufacturer and distributor requirements

In addition to complying with other state and federal abortion requirements, a manufacturer or distributor certified under the Abortion-Inducing Drug Certification Program must record in its records the serial number of each package of an abortion-inducing drug given to a certified physician.[39]

[38] R.C. 4729.71(D).

[39] R.C. 4729.71(E).

Violations

Certificate suspension and revocation

If the Pharmacy Board determines that a certified physician, manufacturer, or distributor has violated provisions of the Abortion-Inducing Drug Certification Program, the Board must suspend the certification until the violation has been resolved. The Board may take remedial action as part of resolving the violation, including imposing additional education or reporting requirements. If a violation is not resolved within 90 calendar days, the Board must permanently revoke the certification.[40]

Civil actions

Any person who is harmed by a violation of the Abortion-Inducing Drug Certification Program has a private cause of action against the offender for injury, death, or loss to person or property that relates to the violation. Attorney's fees may be recovered in such an action. A court, on request, must allow a woman to proceed using only her initials or a pseudonym and may close the proceedings or enter protective orders to preserve the woman's privacy.

If the violation is by a health care professional, a medical malpractice claim may be brought, and a plaintiff may recover actual and punitive damages. If a proximate result of the violation is death, a wrongful death action may be brought.

If a judgment is rendered for the defendant and the court finds the plaintiff's suit was frivolous and brought in bad faith, the court may award reasonable attorney's fees to the defendant.[41]

Fines

If the Pharmacy Board finds a that a person who is not certified under the Abortion-Inducing Drug Certification Program personally furnishes or provides an abortion-inducing drug in Ohio,[42] the Board must immediately report the violation to law enforcement or another state agency for investigation and impose a fine of $5 million against a manufacturer or distributor or $250,000 against an individual.[43]

If the Board finds that any of the following have occurred,[44] the Board must impose a fine of at least $1 million against a manufacturer or distributor or at least $100,000 against a physician, as applicable:[45]

[40] R.C. 4729.71(F).

[41] R.C. 4729.71(H).

[42] R.C. 4729.71(B)(1).

[43] R.C. 4729.71(I)(1).

[44] R.C. 4729.71(B)(2) and (3).

[45] R.C. 4729.71(I)(2).

--A certified physician has obtained an abortion-inducing drug from a manufacturer or distributor that is not certified or not in good standing with the Certification Program;

--A certified manufacturer or distributor has provided an abortion-inducing drug to a physician who is not certified or not in good standing with the Certification Program;

--A certified manufacturer or distributor has provided an abortion-inducing drug to a patient through the mail.

Criminal penalties

The bill provides that a person who recklessly violates provisions related to the Abortion-Inducing Drug Certification Program is guilty of a fourth degree felony for the first offense, or a third degree felony if the offender has previously been convicted or pled guilty to the same or a similar violation. If the offender is a professionally licensed person, the offender is also subject to regulatory sanctioning.[46]

Professional disciplinary action

For physicians, the bill authorizes the Medical Board to take disciplinary action against the physician's license for a violation of the bill's provisions.[47]

Pregnant women exempt

The bill provides that a pregnant woman on whom a drug-induced abortion is attempted or performed in violation of the bill is not guilty of violating the bill's provisions or subject to civil liability.[48]

Pharmacy Board obligations

In addition to issuing certifications and resolving violations, the bill imposes the following requirements on the Pharmacy Board:

Website development

The Board must include on its website a list of names of physicians, manufacturers, and distributors certified under the Abortion-Inducing Drug Certification Program. It also must include a feature whereby persons may anonymously submit information about potential violations of the Abortion-Inducing Drug Certification Program or Abortion-Inducing Drug Complication Reporting System (discussed below).[49]

Review of reports of violations

The Board must review reports of violations submitted through its internet website and reach a disposition within 30 days. The Board must refer information as appropriate to other

[46] R.C. 4729.71(J).

[47] R.C. 4729.71(B)(56).

[48] R.C. 4729.71(K).

[49] R.C. 4729.71(G)(1)(a).

state agencies for investigation, such as to the Medical Board. Generally, the identity of the person who reported the information is confidential, except that the Pharmacy Board may share contact information with other state agencies as needed for investigation.[50]

Rules

The Pharmacy Board is required to adopt rules to implement the Abortion-Inducing Drug Certification Program and the Abortion-Inducing Drug Complication Reporting System (discussed below). The rules must be adopted in accordance with the Administrative Procedure Act (R.C. Chapter 119).[51]

Other obligations

The Pharmacy Board must notify certified manufacturers and distributors of physicians who are certified under the program. It also must audit for compliance certified physicians, manufacturers, and distributors. An initial audit must be conducted within 90 days of the certification being issued. Thereafter, audits must be conducted annually.[52]

Interpretation of provisions

The bill provides that its provisions regarding the Abortion-Inducing Drug Certification Program are not to be construed as creating or recognizing a right to abortion or affirming the lawfulness of an abortion that would otherwise be unlawful.[53]

Abortion-Inducing Drug Complication Reporting System

The bill requires the Pharmacy Board to establish a system for reporting complications and adverse events from the use of abortion-inducing drugs. The reporting system must track at least deaths, blood loss, blood transfusions, infections, administration of abortion-inducing drugs in ectopic pregnancies, and any complication or adverse event that requires hospitalization or additional medical care.[54]

Physicians certified under the Abortion-Inducing Drug Certification Program, as well as any other physician that treats a complication from an abortion-inducing drug, must report complications and adverse events to the Pharmacy Board. The Board may adopt rules requiring other individuals or entities to make reports to the reporting system.[55]

Violations related to the Abortion-Inducing Drug Complication Reporting System are subject to many of the same penalties as for violations of the Abortion-Inducing Drug Certification Program, discussed above, including:

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[50] R.C. 4729.71(G)(1)(b).

[51] R.C. 4729.71(M).

[52] R.C. 4729.71(G)(2) and (3).

[53] R.C. 4729.71(L).

[54] R.C. 4729.711(A).

[55] R.C. 4729.711(B).

--Suspension and revocation by the Pharmacy Board of a physician's certification under the program;[56]

--Civil liability, including actions for malpractice and wrongful death, as applicable;[57]

--Criminal penalties and regulatory sanctions;

--Disciplinary action by the Medical Board against a physician's license.[58]

HISTORY

Action	Date
Introduced	03-01-22

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[56] R.C. 4729.71(F).

[57] R.C. 4729.71(H).

[58] R.C. 4729.71(J) and 4731.22(B)(56).