HOUSE DOCKET, NO. 1451 FILED ON: 2/8/2021

HOUSE . . . . . No. 3961

The Commonwealth of Massachusetts

PRESENTED BY:

Peter J. Durant

To the Honorable Senate and House of Representatives of the Commonwealth of Massachusetts in General Court assembled:

The undersigned legislators and/or citizens respectfully petition for the adoption of the accompanying bill:

An Act regulating the use of abortion-inducing drugs.

PETITION OF:

NAME:	DISTRICT/ADDRESS:	DATE ADDED:
Peter J. Durant	*6th Worcester*	*2/8/2021*
Joseph D. McKenna	*18th Worcester*	*3/10/2021*

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HOUSE . . . . . No. 3961

By Mr. Durant of Spencer, a petition (accompanied by bill, House, No. 3961) of Peter J. Durant and Joseph D. McKenna relative to regulating the use of abortion-inducing drugs. The Judiciary.

The Commonwealth of Massachusetts

In the One Hundred and Ninety-Second General Court
(2021-2022)

An Act regulating the use of abortion-inducing drugs.

Be it enacted by the Senate and House of Representatives in General Court assembled, and by the authority of the same, as follows:

SECTION 1. Chapter 112 of the General Laws is hereby amended by adding the following 8 sections:-

Section 290. As used in sections 290 through 298, inclusive, the following words shall, unless the context clearly requires otherwise, have the following meanings:-

"Abortion", the act of using or prescribing any instrument, medicine, drug or any other substance, device or means with the intent to terminate the clinically diagnosable pregnancy of a woman, with knowledge that the termination by those means will with reasonable likelihood cause the death of the unborn child. Such use, prescription or means is not an abortion if done with the intent to:

(i) save the life or preserve the health of the unborn child;

(ii) remove a dead unborn child caused by spontaneous abortion;

(iii) remove an ectopic pregnancy; or

(iv) treat a maternal disease or illness for which the prescribed drug is indicated.

"Abortion-inducing drug", a medicine, drug or any other substance prescribed or dispensed with the intent of terminating the clinically diagnosable pregnancy of a woman, with knowledge that the termination will with reasonable likelihood cause the death of the unborn child. This includes the off-label use of drugs known to have abortion-inducing properties, which are prescribed specifically with the intent of causing an abortion, such as mifepristone, also known as Mifeprex, misoprostol, also known as Cytotec, and methotrexate; provided, however, that this shall not include drugs that may be known to cause an abortion, but which are prescribed for other medical indications including, but not limited to chemotherapeutic agents and diagnostic drugs.

The use of such drugs to induce abortion shall also be known as a medical, medication, RU-486, chemical, Mifeprex regimen, or drug-induced abortion.

"Adverse event", any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related, pursuant to 21 CFR 312.32. An adverse event shall not include an adverse event or suspected adverse reaction that, had it occurred in a more severe form, might have caused death.

"Associated physician", a person licensed to practice medicine pursuant to this chapter, including medical doctors and doctors of osteopathy, that has entered into an associated physician agreement.

"Department", the department of public health.

"Hospital", an institution providing medical and surgical treatment and nursing care for sick or injured people or institutions.

"LMP" or "gestational age", the time that has elapsed since the first day of the woman's last menstrual period.

"Physician", any person licensed to practice medicine pursuant to this chapter, including medical doctors and doctors of osteopathy.

"Pregnant" or "pregnancy", that female reproductive condition of having an unborn child in the woman's uterus.

"Provide", any act of giving, selling, dispensing, administering, transferring possession to or otherwise providing or prescribing an abortion-inducing drug.

"Qualified physician", a physician who has the ability to:

(i) identify and document a viable intrauterine pregnancy;

(ii) assess the gestational age of pregnancy and inform the patient of gestational age-specific risks;

(iii) diagnose ectopic pregnancy;

(iv) determine blood type and administer RhoGAM if a woman is Rh negative;

(v) assess for signs of domestic abuse, reproductive control, human trafficking and other signals of coerced abortion;

(vi) provide surgical intervention or has entered into a contract with another qualified physician to provide surgical intervention; and

(vii) supervise and bear legal responsibility for any agent, employee, or contractor who is participating in any part of procedure, including but not limited to, pre-procedure evaluation and care.

"Unborn child", an individual organism of the species homo sapiens, beginning at fertilization, until the point of being born-alive as defined in section 1 USC §8.

Section 291. (a) Prior to providing an abortion-inducing drug, a licensed physician shall:

(i) independently verify that a pregnancy exists;

(ii) determine the woman's blood type and, if she is Rh negative, be able to and offer to administer RhoGAM at the time of the abortion;

(iii) document in the woman's medical chart the gestational age and intrauterine location of the pregnancy and whether she received treatment for Rh negativity as diagnosed by the most accurate standard of medical care.

(b) Any qualified physician providing an abortion-inducing drug shall: (i) have a signed contract with an associated physician, to be known as an associated physician agreement, who is credentialed to handle complications and (ii) be able to produce that signed contract upon request of the pregnant woman or by the department. Any pregnant woman to whom a qualified physician provides any abortion-inducing drug shall be given the name and phone number of the associated physician.

(c) The qualified physician providing any abortion-inducing drug, or an agent of the qualified physician, shall schedule a follow-up visit for the woman at approximately 7 to 14 days after administration of the abortion-inducing drug to confirm that the pregnancy is completely terminated and to assess the degree of bleeding. The qualified physician shall make all reasonable efforts to ensure that the woman returns for the scheduled appointment. A brief description of the efforts made to comply with this subsection, including the date, time and identification by name of the person making such efforts, shall be included in the woman's medical record.

Section 292. Abortion-inducing drugs shall only be provided by a qualified physician in person following procedures laid out in this chapter. It shall be unlawful for any manufacturer, supplier, physician, qualified physician or any other person to provide any abortion-inducing drug via courier, delivery or mail service.

Section 293. Notwithstanding any general or special law to the contrary, abortion-inducing drugs shall not be provided in any school facility or on state grounds including, but not limited to, elementary, secondary and institutions of higher education.

Section 294. (a) No abortion-inducing drug shall be provided without the informed consent, as described in this section, of the pregnant woman to whom the abortion-inducing drug is provided.

(b) Informed consent to a chemical abortion must be obtained at least 24 hours before the abortion-inducing drug is provided to the pregnant woman; provided, however, that informed consent may be obtained less than 24 hours before the abortion-inducing drug is provided to the pregnant woman if, in the physician's reasonable medical judgment, compliance with this

subsection would pose a greater risk of: (1) the death of the pregnant woman; or (2) the substantial and irreversible physical impairment of a major bodily function, not including psychological or emotional conditions, of the pregnant woman.

(c) The department shall create a form be used by a qualified physician to obtain the consent required pursuant to subsection (b) prior to providing an abortion-inducing drug.

(d) A consent form is not valid and consent is not sufficient, unless:

(1) the patient initials each entry, list, description or declaration required to be on the consent form, as detailed in clauses (1) through (6), inclusive, of subsection (e);

(2) the patient signs the consent statement described in clause (6) of subsection (e); and

(3) The qualified physician signs the qualified physician declaration described in clause (7) of subsection (e).

(e) The consent form shall include, but shall not be limited to, the following statements:

(1) the probable gestational age of the unborn child as determined by both patient history and by ultrasound results used to confirm the gestational age;

(2) a detailed description of the steps to complete the chemical abortion;

(3) a detailed list of the risks related to the specific abortion-inducing drug or drugs to be used including, but not limited to hemorrhage; failure to remove all tissue of the unborn child which may require an additional procedure; sepsis; sterility and possible continuation of pregnancy;

(4) information about Rh incompatibility, including that if the pregnant woman has an Rh negative blood type, the pregnant woman should receive an injection of Rh immunoglobulin, also known as RhoGAM, at the time of the abortion to prevent Rh incompatibility in future pregnancies, which can lead to complications and miscarriage;

(5) that the risks of complications from a chemical abortion may include incomplete abortion which may increase with advancing gestational age;

(6) that it may be possible to reverse the effects of the chemical abortion should the pregnant woman change her mind, but that time is of the essence;

(7) that information on and assistance with reversing the effects of abortion-inducing drugs are available in the state-prepared materials; and

(8) a consent statement which must be signed by the patient. The consent statement shall include, but shall not be limited to the following declarations, which must be individually initialed by the patient:

(i) that the patient understands that the abortion-inducing drug regimen or procedure is intended to end her pregnancy and will result in the death of her unborn child;

(ii) that the patient is not being forced to have an abortion, that she has the choice not to have the abortion and that she may withdraw her consent to the abortion-inducing drug regimen or procedure;

(iii) that the patient understands that the chemical abortion regimen or procedure to be used has specific risks and may result in specific complications;

(iv) that the patient has been given the opportunity to ask questions about her pregnancy, the development of her unborn child, alternatives to abortion, the abortion-inducing drug or drugs to be used and the risks and complications inherent to the abortion-inducing drug or drugs to be used;

(v) that she was specifically given information on the potential ability of qualified medical professionals to reverse the effects of an abortion obtained through the use of abortion-inducing drugs, including information directing women to obtain further information at http://www.abortionpillreversal.com/ and by contacting (877) 558-0333 for assistance in locating a medical professional that can aide in the reversal of an abortion;

(vi) that she has been provided access to state-prepared, printed materials on informed consent for abortion and the state-prepared and maintained website on informed consent for abortion and, if applicable, that she has been given the name and phone number of the associated physician who has agreed to provide medical care and treatment in the event of complications associated with the abortion-inducing drug regimen or procedure;

(vii) that the qualified physician will schedule an in-person follow-up visit for the patient at approximately 7 to 14 days after providing the abortion-inducing drug or drugs to confirm that the pregnancy is completely terminated and to assess the degree of bleeding and other complications pursuant to subsection (c) of section 291;

(viii) that the patient has received or been given sufficient information to give her informed consent to the abortion-inducing drug regimen or procedure; and

(ix) that the patient has a private right of action to sue the qualified physician if she feels that she has been coerced or misled prior to obtaining an abortion, and how to access state resources regarding her legal right to obtain relief.

(9) A qualified physician declaration, which shall be signed by the qualified physician, affirming that the qualified physician has explained the abortion-inducing drug or drugs to be used, has provided all of the information required pursuant to clauses (1) through (6), inclusive, of subsection (e) and has answered all of the pregnant woman's questions.

Section 295. (a) The department shall cause to be published on informed consent forms pursuant to subsection (c) of section 294 and on a website maintained by the department on informed consent for abortion required under the following statement:

"Information on the potential ability of qualified medical professionals to reverse the effects of an abortion obtained through the use of abortion-inducing drugs, including information directing women to obtain further information at http://www.abortionpillreversal.com/ and by contacting (877) 558-0333 for assistance in locating a medical professional that can aide in the reversal of an abortion."

(b) On an annual basis, the department shall review and update, if necessary, the statement required in subsection (a).

(c) As part of the informed consent counseling required pursuant to section 294, the qualified physician shall inform the pregnant woman about abortion pill reversal and provide her with the state-prepared materials and website link as proscribed by subsection (a).

Section 296. (a) For the purpose of promoting maternal health and adding to the sum of medical and public health knowledge through the compilation of relevant data, each hospital or other licensed facility which provides abortion-inducing drugs pursuant to this chapter shall prepare and deliver within 15 days after the end of each month to the department a monthly report which details each drug-induced abortion performed at the hospital or other licensed facility. The report shall be signed by each qualified physician who gave, sold, dispensed, administered or otherwise provided the abortion-inducing drug.

(b) Each report shall include, at minimum, the following information:

(1) Identification of the qualified physician or physicians who provided the abortion-inducing drug;

(2) Whether the chemical abortion was completed at the hospital or licensed facility in which the abortion-inducing drug was provided or at an alternative location;

(3) The referring physician, agency or service, if any;

(4) The pregnant woman’s county, state and country of residence;

(5) The pregnant woman's age and race;

(6) The number of previous pregnancies, number of live births and number of previous abortions of the pregnant woman;

(7) The probable gestational age of the unborn child as determined by both patient history and by ultrasound results used to confirm the gestational age. The report shall include the date of the ultrasound and gestational age determined on that date;

(8) The abortion-inducing drug or drugs used, the date each was provided to the pregnant woman and the reason for the abortion, if known;

(9) Preexisting medical condition or conditions of the pregnant woman which may complicate her pregnancy, if any;

(10) Whether the woman returned for a follow-up examination to determine completion of the abortion procedure and to assess bleeding and the date and results of any such follow-up examination, and what reasonable efforts were made by the qualified physician to encourage that she return for a follow-up examination if she did not;

(11) Whether the woman suffered any complications, what specific complications arose and any follow-up treatment needed;

(12) The amount billed to cover the treatment for specific complications, including whether the treatment was billed to Medicaid, private insurance, private pay or other method. This shall include charges for any physician, hospital, emergency room, prescription or other drugs, laboratory tests and any other costs for treatment rendered.

(c) Reports required under this subsection shall not contain:

(1) The name of the pregnant woman;

(2) Common identifiers such as her social security number or motor vehicle operator’s license number; or

(3) Other information or identifiers that would make it possible to identify, in any manner or under any circumstances, a woman who has obtained or seeks to obtain a chemical abortion.

(d) If a qualified physician provides an abortion-inducing drug to a pregnant woman for the purpose of inducing an abortion pursuant to sections 291 or 292, and if the qualified physician knows that the woman who uses the abortion-inducing drug for the purpose of inducing an abortion experiences, during or after the use of the abortion-inducing drug, an adverse event, the qualified physician shall provide a written report of the adverse event within 3 days of the event to the Federal Drug Administration via the Medwatch Reporting System and to the department and to the board of registration in medicine.

(e) Any physician, qualified physician, associated physician or other healthcare provider who treats a woman, either contemporaneously to or at any time after the procedure, for an adverse event related to a chemical abortion shall make a report of the adverse event to the department on forms prescribed by it. The reports shall be: (i) completed by the hospital or other facility in which the adverse event treatment was provided; (ii) signed by the physician, qualified physician, or other healthcare provider who treated the adverse event; and (iii) transmitted to the department within 15 days after each reporting month.

Each report shall include, at minimum, the following information:

(1) What specific complications arose, what, if any, emergency transfer was required and any follow-up treatment needed;

(2) Identification of the qualified physician who provided the abortion-inducing drug or drugs;

(3) Whether the chemical abortion was completed at the hospital or licensed facility in which the abortion-inducing drug was provided or at an alternative location;

(4) The referring physician, agency or service, if any;

(5) The pregnant woman’s county, state and country of residence;

(6) The pregnant woman's age and race;

(7) The number of previous pregnancies, number of live births and number of previous abortions of the pregnant woman;

(8) The probable gestational age of the unborn child as determined by both patient history and by ultrasound results used to confirm the gestational age. The report will include the date of the ultrasound and gestational age determined on that date;

(9) The abortion-inducing drug or drugs used, the date each was provided to the pregnant woman and the reason for the abortion, if known;

(10) Preexisting medical condition or conditions of the pregnant woman which would complicate her pregnancy, if any;

(11) Whether the woman returned for a follow-up examination to determine completion of the abortion procedure and to assess bleeding and the date and results of any such follow-up examination and what reasonable efforts were made by the qualified physician to encourage that she return for a follow-up examination if she did not; and

(12) The amount billed to cover the treatment for specific complications, including whether the treatment was billed to Medicaid, private insurance, private pay or other method. This should include charges for any physician, hospital, emergency room, prescription or other drugs, laboratory tests and any other costs for treatment rendered.

(f) The department shall prepare a comprehensive annual statistical report based upon the data gathered from reports under this section. Annually, not later than January 30, the department shall file comprehensive annual statistical report with the clerks of the house of representatives and the senate. The comprehensive annual statistical report shall also be made available to the public by the department in a downloadable format.

(g) The department shall summarize aggregate data from the reports required pursuant to this section and submit the data to the Centers for Disease Control and Prevention for the purpose of inclusion in the annual vital statistics report.

(h) Reports filed pursuant to this section shall be deemed public records and shall be available to the public in accordance with applicable confidentiality and public records reporting laws. Original copies of all reports filed under this subsection shall be available to the board of registration in medicine, board of registration in pharmacy, state law enforcement offices and child protective services for use in the performance of their official duties.

(i) Absent a valid court order or judicial subpoena, neither the department, any other state department, agency or office nor any employees thereof shall compare data concerning abortions or abortion complications maintained in an electronic or other information system file with data in any other electronic or other information system, the comparison of which could result in identifying, in any manner or under any circumstances, a woman obtaining or seeking to obtain a drug-induced abortion.

(j) Statistical information that may reveal the identity of a woman obtaining or seeking to obtain a drug-induced abortion shall not be maintained by the department or any other state department, agency, office or any employee or contractor thereof.

(k) Original copies of all reports filed pursuant to this section shall be available to the department and the board of registration in medicine for use in the performance of its official duties.

(l) The department shall communicate the reporting requirements pursuant to this section to all medical professional organizations, licensed physicians, hospitals, emergency rooms, abortion facilities, department clinics, ambulatory surgical facilities and other healthcare facilities.

(i) Any physician, including emergency medical personnel, who treats a woman for complications or adverse event arising from an abortion, shall file a written report with the department pursuant to this section.

(ii) A physician filing a written report with the department after treating a woman for complications or otherwise in an emergency capacity shall make reasonable efforts to include all of the required information that may be obtained without violating the privacy of the woman.

Section 297. (a) Any person who intentionally, knowingly, or recklessly violates sections 290 through 296, inclusive, shall be punished by imprisonment in a jail or house of correction for not more than 1 year and by a fine of $5,000.

(b) Any person who intentionally, knowingly or recklessly violates sections 290 through 296, inclusive, by fraudulent use of an abortion-inducing drug, with or without the knowledge of the pregnant woman, shall be punished by imprisonment in the state prison for not more than 5 years and by a fine of $10,000.

(c) No criminal penalty shall be assessed against the pregnant woman upon whom the drug-induced abortion is attempted, induced or performed.

Section 298. (a) In addition to whatever remedies are available, failure to comply with the requirements of sections 290 through 296, inclusive, shall:

(1) provide a basis for a civil malpractice action for actual and punitive damages;

(2) provide a basis for a professional disciplinary action under section 60B of chapter 231; and

(3) provide a basis for recovery for the woman's survivors for the wrongful death of the woman.

(b) No civil liability may be assessed against the pregnant woman upon whom the drug-induced abortion is attempted, induced or performed.

(c) When requested, the court shall allow a woman to proceed using solely her initials or a pseudonym and may close any proceedings in the case and enter other protective orders to preserve the privacy of the woman upon whom the drug-induced abortion was attempted, induced or performed.

(d) If judgment is rendered in favor of the plaintiff, the court shall also render judgment for reasonable attorney's fees in favor of the plaintiff against the defendant.

(e) If judgment is rendered in favor of the defendant and the court finds that the plaintiff's suit was frivolous and brought in bad faith, the court may render judgment for reasonable attorney's fees in favor of the defendant against the plaintiff.

SECTION 2. (a) Nothing in this act shall be construed as creating or recognizing a right to abortion.

(b) It is not the intention of this act to make lawful an abortion that is otherwise unlawful.

(c) Nothing in this act repeals, replaces or otherwise invalidates existing federal laws or general or special laws, regulations or policies.

SECTION 3. The department shall create and distribute the forms required by this act within 60 days after the effective date of this act. No provision of this act requiring the reporting of information on forms published by the department shall be applicable until 10 days after the requisite forms are first created and distributed or until the effective date of this act, whichever is later.

SECTION 4. The general court, by joint resolution, may appoint 1 or more of its members, who sponsored or cosponsored this act in their official capacity, to intervene as a matter of right in any case in which the constitutionality of this act is challenged.

SECTION 5. Section 1 shall take effect on January 21, 2023.