SENATE BILL 2281
By Bell

HOUSE BILL 2416

By Moody

AN ACT to amend Tennessee Code Annotated, Title 4; Title 53; Title 56; Title 63; Title 68 and Title 71, relative to abortion.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF TENNESSEE:

SECTION 1. Tennessee Code Annotated, Section 63-6-241, is amended by deleting the section.

SECTION 2. Tennessee Code Annotated, Title 63, Chapter 6, is amended by adding the following as a new part:

63-6-1101. Short title.

This part is known and may be cited as the "Tennessee Abortion-Inducing Drug Risk Protocol Act."

63-6-1102. Part definitions.

As used in this part:

(1) "Abortion":

(A) Means the use or prescription of an instrument, medicine, drug, or other substance, or device, with the intent to terminate the clinically diagnosable pregnancy of a patient, with knowledge that the termination by those means will, with reasonable likelihood, cause the death of the unborn child; and

(B) Does not mean an act to terminate a pregnancy 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;

(2) "Abortion-inducing drug" or "chemical abortion":

(A) Means a medicine, drug, or other substance provided with the intent of terminating the clinically diagnosable pregnancy of a patient, with knowledge that the termination will, with reasonable likelihood, cause the death of the unborn child;

(B) Includes the off-label use of drugs known to have abortion-inducing properties that are prescribed specifically with the intent of causing an abortion, such as mifepristone, misoprostol, and methotrexate; and

(C) Does not include drugs that may be known to cause an abortion that are prescribed for other medical indications;

(3) "Adverse event" means an untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related;

(4) "Associated physician" means an individual licensed, and in good standing, to practice medicine in this state pursuant to chapter 6 or 9 of this title and who has entered into an associated physician agreement pursuant to § 63-6-1104(b);

(5) "Complication" means an adverse physical or psychological condition arising from the performance of an abortion, including, but not limited to, uterine perforation; cervical perforation; infection; heavy or uncontrolled bleeding;

hemorrhage; blood clots resulting in pulmonary embolism or deep vein thrombosis; failure to actually terminate the pregnancy; incomplete abortion; pelvic inflammatory disease; endometritis; missed ectopic pregnancy; cardiac arrest; respiratory arrest; renal failure; metabolic disorder; shock; embolism; coma; placenta previa in subsequent pregnancies; preterm delivery in subsequent pregnancies; free fluid in the abdomen; hemolytic reaction due to the administration of ABO-incompatible blood or blood products; adverse reactions to anesthesia and other drugs; subsequent development of breast cancer; death; psychological complications, such as depression, suicidal ideation, anxiety, and sleeping disorders; and other adverse events;

(6) "Department" means the department of health;

(7) "Facility" means a public or private hospital, clinic, center, medical school, medical training institution, healthcare business, physician's office, infirmary, dispensary, ambulatory surgical center, or other institution, location, or business where medical care or pharmaceuticals are provided to individuals;

(8) "Hospital" has the same meaning as defined by § 68-11-201;

(9) "Last menstrual period" means the time that has elapsed since the first day of the patient's last menstrual period;

(10) "Physician" means an individual licensed, and in good standing, to practice medicine in this state pursuant to chapter 6 or 9 of this title;

(11) "Pregnant" or "pregnancy" means the female reproductive condition of having an unborn child in the patient's uterus;

(12) "Provide" means an act of giving, selling, dispensing, administering, transferring possession to, or otherwise providing or prescribing, an abortion-inducing drug;

(13) "Qualified physician" means a physician who has the ability to:

(A) Identify and document a viable intrauterine pregnancy;

(B) Assess the gestational age of pregnancy and inform the patient of gestational age-specific risks;

(C) Diagnose ectopic pregnancy;

(D) Determine blood type and administer RhoGAM if a patient is Rh negative;

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

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

(G) Supervise and bear legal responsibility for an agent, employee, or contractor who is participating in any part of a procedure, including, but not limited to, preprocedure evaluation and care;

(14) "Reasonable medical judgment" means a medical judgment that would be made by a reasonably prudent physician knowledgeable about the patient's case and the treatment possibilities with respect to the medical conditions involved; and

(15) "Unborn child" means an individual organism of the species homo sapiens, beginning at fertilization, until the point of being born alive as defined in 1 U.S.C. § 8(b).

63-6-1103. In-person requirement.

(a) An abortion-inducing drug may be provided only by a qualified physician following the procedures set forth in this part.

(b) A manufacturer, supplier, pharmacy, physician, qualified physician, or other person shall not provide an abortion-inducing drug via courier, delivery, or mail service.

63-6-1104. Distribution of abortion-inducing drugs.

(a) Because the failure and complication rates from a chemical abortion increase with advancing gestational age and because the physical symptoms of chemical abortion can be identical to the symptoms of ectopic pregnancy and abortion-inducing drugs do not treat ectopic pregnancies and are contraindicated in ectopic pregnancies, a qualified physician providing an abortion-inducing drug shall examine the patient in-person and, prior to providing an abortion-inducing drug:

(1) Independently verify that a pregnancy exists;

(2) Determine the patient's blood type, and, if the patient is Rh negative, offer to administer RhoGAM at the time of the abortion;

(3) Inform the patient that the patient may see the remains of the unborn child in the process of completing the abortion; and

(4) Document, in the patient's medical chart, the gestational age and intrauterine location of the pregnancy, and whether the patient received treatment for Rh negativity, as diagnosed by the most accurate standard of medical care.

(b) A qualified physician providing an abortion-inducing drug must be credentialed and competent to handle complication management, including emergency transfer, or must have a signed agreement with an associated physician who is credentialed to handle complications and be able to produce the signed agreement on demand by the patient or the department. The qualified physician providing an abortion-inducing drug to a patient shall provide the patient with the name and phone number of the associated physician.

(c) A qualified physician providing an abortion-inducing drug, or an agent of the qualified physician, shall schedule a follow-up visit for the patient at approximately seven (7) to fourteen (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 patient returns for the scheduled appointment. A brief description of the efforts made to comply with this subsection (c), including the date, time, and identification by name of the individual making the efforts, must be included in the patient's medical record.

63-6-1105. Prohibition on providing abortion-inducing drugs at elementary, secondary, and postsecondary schools.

An individual or entity shall not provide an abortion-inducing drug in an elementary, secondary, or postsecondary school facility or on school grounds.

63-6-1106. Informed consent requirements for abortion-inducing drugs.

(a) A qualified physician shall not provide an abortion-inducing drug to a pregnant patient without the informed consent of the pregnant patient.

(b) Informed consent to a chemical abortion must be obtained at least forty-eight (48) hours before the abortion-inducing drug is provided to the pregnant patient, except, if, in the qualified physician's reasonable medical judgment, compliance with this subsection (b) poses a greater risk of the following:

(1) The death of the pregnant patient; or

(2) The substantial and irreversible physical impairment of a major bodily function, not including psychological or emotional conditions, of the pregnant patient.

(c) A qualified physician shall use a form created by the department to obtain the informed consent required by this section prior to providing an abortion-inducing drug.

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

(1) The patient initials each entry, list, description, or declaration required to be included in the consent form as detailed in subdivisions (e)(1)-(6);

(2) The patient signs the "consent statement" described in subdivision (e)(10); and

(3) The qualified physician signs the "qualified physician declaration" described in subdivision (e)(11).

(e) The consent form required by subsection (c) must include, but is not limited to, the following:

(1) The probable gestational age of the unborn child as determined by both patient history and ultrasound results used to confirm 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 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 patient has an Rh negative blood type, the patient should receive an injection of Rh immunoglobulin at the time of the abortion to prevent Rh incompatibility in future pregnancies, which can lead to complications and miscarriage in future pregnancies;

(5) A description of the risks of complications from a chemical abortion, which increase with advancing gestational age;

(6) Information about the possibility of reversing the effects of the chemical abortion if the pregnant patient changes the patient's mind and that time is of the essence;

(7) Information that the pregnant patient could see the remains of the unborn child in the process of completing the abortion;

(8) Information that initial studies suggest that children born after reversing the effects of an abortion-inducing drug have no greater risk of birth defects than the general population and that initial studies suggest that there is no increased risk of maternal mortality after reversing the effects of an abortion-inducing drug;

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

(10) An acknowledgment of risks and a consent statement to be signed by the patient. The consent statement must include, but is not limited to, the following declarations, which must be individually initialed by the patient that:

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

(B) The patient is not being forced to have an abortion, the patient has the choice not to have the abortion, and the patient may withdraw the patient's consent to the abortion-inducing drug regimen even after beginning the abortion-inducing drug regimen;

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

(D) 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 the risks and complications inherent to the abortion-inducing drug to be used;

(E) The patient was specifically told that "information on the potential ability of qualified medical professionals to reverse the effects of an abortion obtained through the use of abortion-inducing drugs is available at www.abortionpillreversal.com, or you can contact (877) 558-0333 for assistance in locating a medical professional who can aide in the reversal of an abortion";

(F) The patient has been provided access to state-prepared, printed materials on informed consent for abortion, if applicable;

(G) The patient 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;

(H) The qualified physician will schedule an in-person follow-up visit for the patient at approximately seven (7) to fourteen (14) days after providing the abortion-inducing drug to confirm that the pregnancy is completely terminated and to assess the degree of bleeding and other complications;

(I) The patient has received or has been given sufficient information to give the patient's informed consent to the abortion-inducing drug regimen or procedure; and

(J) The patient has a private right of action to sue the qualified physician under the laws of this state if the patient feels coerced or misled prior to obtaining an abortion, and how to access state resources regarding the patient's legal right to obtain relief; and

(11) A qualified physician declaration that must be signed by the qualified physician, stating that the qualified physician has explained the abortion-inducing drug to be used, has provided all of the information required in subdivisions (e)(1)-(10), and has answered all of the patient's questions.

63-6-1107. Information required in state-prepared materials.

(a) The department shall publish state-prepared, printed materials on informed consent for abortion and include 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 is available at www.abortionpillreversal.com, or you can contact (877) 558-0333 for assistance in locating a medical professional who can aide in the reversal of an abortion.".

(b) The department shall annually review and update, if necessary, the statement required under subsection (a).

(c) As part of the informed consent counseling services required in § 63-6-1106, the qualified physician shall inform the pregnant patient about abortion pill reversal and provide the patient with the state-prepared materials as described in subsection (a).

63-6-1108. Reporting on chemical abortions.

(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, a report of each chemical abortion performed must be made to the department on forms prescribed by the department. The reports must be completed by the hospital or other

facility in which the abortion-inducing drug was provided; signed by the qualified physician who provided the abortion-inducing drug; and transmitted to the department within fifteen (15) days after each reporting month. The department shall update forms as needed to reflect changes to diagnostic and reimbursement coding classifications.

(b) A report must include, at a minimum, the following information:

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

(2) Whether the chemical abortion was completed at the hospital or 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 patient's county, state, and country of residence;

(5) The patient's age and race;

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

(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, and the date of the ultrasound and gestational age determined on that date;

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

(9) Preexisting medical conditions of the patient that would complicate the patient's pregnancy, if any;

(10) Whether the patient returned for a follow-up examination to determine completion of the abortion procedure and to assess bleeding and the date and results of the follow-up examination, and what reasonable efforts were

made by the qualified physician to encourage that the patient return for a follow-up examination if the patient did not;

(11) Whether the patient suffered complications, and, if so, what specific complications arose and what follow-up treatment was needed; 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 another method, including charges for a physician, hospital, emergency room, prescription or other drugs, laboratory tests, and costs for treatment rendered.

(c) A report required under this section must not contain:

(1) The name of the patient;

(2) Common identifiers, such as a social security number or driver license number; or

(3) Other information or identifiers that would make it possible to identify a patient who has obtained or seeks to obtain a chemical abortion.

(d) A qualified physician who provides an abortion-inducing drug to a patient and who knows that the patient experiences, during or after the use of the abortion-inducing drug, an adverse event shall provide a written report of the adverse event within three (3) days of the event to the United States food and drug administration via the medwatch reporting system, to the department, and to the board of medical examiners.

(e) A physician, qualified physician, associated physician, or other healthcare provider who treats a patient, either contemporaneously to or at any time after a chemical abortion, for an adverse event or complication related to a chemical abortion shall make a report of the adverse event or complication to the department on forms prescribed by the department. The reports must be completed by the hospital or other

facility in which the adverse event or complication treatment was provided; signed by the physician, qualified physician, or other healthcare provider who diagnosed or treated the abortion complication or adverse event or complication; and transmitted to the department within fifteen (15) days after each reporting month. The report must include, at a minimum, the following information:

(1) The date the patient presented for treatment;

(2) The age and race of the patient;

(3) The patient's state and county of residence;

(4) The number of previous pregnancies, number of live births, and number of previous abortions of the patient;

(5) The date the abortion was performed and type of abortion;

(6) Identification of the physician who performed the abortion, the facility where the abortion was performed, and the referring physician, agency, or service, if any;

(7) The specific complication that led to the treatment, including the following physical or psychological conditions which, in the reasonable medical judgment of a licensed healthcare professional, arose as a primary or secondary result of an induced abortion: uterine perforation, cervical laceration, infection, bleeding, vaginal bleeding that qualifies as a Grade 2 or higher adverse event according to the Common Terminology Criteria for Adverse Events (CTCAE), pulmonary embolism, deep vein thrombosis, failure to actually terminate the pregnancy, incomplete abortion (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 that are listed in the current Diagnostic and Statistical Manual (DSM), and any related complication arising under the following ICD 10 codes: 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;

(8) Whether the patient obtained abortion-inducing drugs via mail order or an internet website, and, if so, information identifying the name of the source, URL address, or telemedicine provider; and

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

(f) The department shall prepare a comprehensive annual statistical report for the general assembly based on the data gathered from reports under this section. The aggregated data must 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 under this section and submit the data to the United States centers for disease control and prevention for the purpose of inclusion in the annual vital statistics report.

(h) Reports filed pursuant to this section are public records and must be available to the public in accordance with the confidentiality and public records reporting laws of this state. Original copies of all reports filed under this section must be available to the department, the board of medical examiners, the board of pharmacy, law enforcement officials, and child protective services personnel for use in the performance of their official duties.

(i) Absent a valid court order or judicial subpoena, the department, or another state department, agency, or office, or employee thereof shall not compare data

concerning chemical abortions or abortion complications maintained in an electronic or other information system file with data in another electronic or other information system, the comparison of which could result in identifying a patient obtaining or seeking to obtain a chemical abortion.

(j) The department, another state department, agency, or office, or an employee or contractor thereof, shall not maintain statistical information that may reveal the identity of a patient obtaining or seeking to obtain a chemical abortion.

(k) The department shall communicate the reporting requirements of this section to all medical professional organizations, physicians, and facilities operating in this state.

(l) A physician, including emergency medical personnel, who treats a patient for complications or an adverse event arising from an abortion, shall file a written report as required by this section with the department.

(m) A physician filing a written report with the department after treating a patient 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 patient.

63-6-1109. Creation and distribution of forms.

The department shall create and distribute the forms required by this part no later than October 1, 2022, and annually update the forms as needed thereafter.

63-6-1110. Criminal penalties.

(a) An individual who intentionally, knowingly, or recklessly violates this part is guilty of a Class E felony and, upon conviction, shall be fined an amount not to exceed fifty thousand dollars ($50,000), be imprisoned for a term not to exceed twenty (20) years, or both. As used in this subsection (a), "intentional," "knowing," and "reckless" have the same meanings as provided in § 39-11-302.

(b) A criminal penalty shall not be assessed against a patient upon whom a chemical abortion is attempted or performed.

63-6-1111. Civil remedies and professional sanctions.

(a) In addition to all other remedies available under the laws of this state, failure to comply with this part:

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

(2) Provides a basis for professional disciplinary action under this title or title 68 for the suspension or revocation of the license of a healthcare provider or facility;

(3) Provides a basis for recovery for the patient's survivors for the wrongful death of the patient under a wrongful death action; and

(4) Provides a basis for a cause of action for injunctive relief against an individual who has provided an abortion-inducing drug in violation of this part to prevent the enjoined defendant from providing further abortion-inducing drugs in violation of this part. The action may be maintained by:

(A) A patient to whom the abortion-inducing drug was provided;

(B) An individual who is the spouse, parent, or guardian of, or a current or former licensed healthcare provider of, a patient to whom the abortion-inducing drug was provided; or

(C) A prosecuting attorney with appropriate jurisdiction.

(b) Civil liability shall not be imposed against a patient on whom a chemical abortion is attempted or performed.

(c) When requested, the court shall allow a patient to proceed using solely the patient's initials or a pseudonym and may close any proceedings in the case and enter

other protective orders to preserve the privacy of the patient on whom the chemical abortion was attempted or performed.

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

63-6-1112. Construction.

This part does not:

(1) Create or recognize a right to abortion;

(2) Make lawful an abortion that is otherwise unlawful; or

(3) Repeal, replace, or otherwise invalidate existing federal laws, regulations, or policies.

63-6-1113. Right of intervention.

The attorney general and reporter may bring an action to enforce compliance with this part or intervene as a matter of right in a case in which the constitutionality of this part is challenged.

SECTION 3. The board of medical examiners and department of health are authorized to promulgate rules to effectuate the purposes of act. The rules must be promulgated in accordance with the Uniform Administrative Procedures Act, compiled in Tennessee Code Annotated, Title 4, Chapter 5.

SECTION 4. If a provision of this act or its application to a person or circumstance is held invalid, then the invalidity does not affect other provisions or applications of the act that can be given effect without the invalid provision or application, and to that end, the provisions of this act are severable.

SECTION 5. The headings in this act are for reference purposes only and do not constitute a part of the law enacted by this act. However, the Tennessee Code Commission is requested to include the headings in any compilation or publication containing this act.

SECTION 6. For rule promulgation purposes, this act takes effect upon becoming a law, the public welfare requiring it. For all other purposes, this act takes effect January 1, 2023, the public welfare requiring it.