

BILL ANALYSIS

Senate Research Center
87R14125 SCL-F

C.S.S.B. 394
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State Affairs
3/15/2021
Committee Report (Substituted)

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

Current Texas law does little to regulate drugs used in drug-induced abortions. These drugs are in the special United States Food and Drug Administration's special program Risk Evaluation Mitigation Strategies due to their potential harmful impact. If this classification were to change, Texas would not be able to maintain these safety standards until the legislature convenes.

S.B. 394 creates a state standard for the use of these drugs, which closely matches those set forth by the current FDA. Also, by creating a state standard, the state will have a mechanism to track the health and safety impacts of these drugs with data reported to state agencies.

(Original Author's/Sponsor's Statement of Intent)

C.S.S.B. 394 amends current law relating to abortion complication reporting and the regulation of drug-induced abortion procedures, providers, and facilities and creates a criminal offense.

RULEMAKING AUTHORITY

This bill does not expressly grant any additional rulemaking authority to a state officer, institution, or agency.

SECTION BY SECTION ANALYSIS

SECTION 1. Provides that the legislature finds that:

- (1) Texas has an interest to protect the health and welfare of every woman considering a drug-induced abortion.
- (2) the use of Mifeprex or mifepristone presents significant medical complications including, but not limited to, uterine hemorrhage, viral infections, abdominal pain, cramping, vomiting, headache, fatigue, and pelvic inflammatory disease; and
- (3) the risk of failure rate and complications increases with advancing gestational age.

SECTION 2. Amends Sections 171.006(a) and (b), Health and Safety Code, as added by Chapter 4 (H.B. 13), Acts of the 85th Legislature, 1st Called Session, 2017, as follows:

(a) Redefines "abortion complication" and defines "adverse event" to mean any harmful event or adverse outcome with respect to a patient related to an abortion that is performed or induced on the patient and that is diagnosed or treated by a health care practitioner or at a health facility and includes:

- (1) shock;
- (2) uterine perforation;
- (3) cervical laceration;

- (4) hemorrhage;
- (5) aspiration or allergic reaction;
- (6) infection;
- (7) sepsis;
- (8) death of the patient;
- (9) incomplete abortion;
- (10) damage to the uterus;
- (11) an infant born alive after the abortion;
- (12) blood clots resulting in pulmonary embolism or deep vein thrombosis;
- (13) failure to actually terminate the pregnancy;
- (14) pelvic inflammatory disease;
- (15) endometriosis;
- (16) missed ectopic pregnancy;
- (17) cardiac arrest;
- (18) respiratory arrest;
- (19) renal failure;
- (20) metabolic disorder;
- (21) embolism;
- (22) coma;
- (23) placenta previa in subsequent pregnancies;
- (24) preterm delivery in subsequent pregnancies;
- (25) fluid accumulation in the abdomen;
- (26) hemolytic reaction resulting from the administration of ABO-incompatible blood or blood products;
- (27) adverse reactions to anesthesia or other drugs; or
- (28) any other adverse event as defined by the United States Food and Drug Administration's criteria provided by the MedWatch Reporting System.

(b) Provides that the reporting requirements of Section 171.006 (Abortion Complication Reporting Requirements; Civil Penalty) apply only to:

- (1) a physician who performs or induces, rather than performs, at an abortion facility an abortion that results in an abortion complication

diagnosed or treated by that physician, or diagnoses or treats an abortion complication that is the result of an abortion performed or induced by another physician, rather than diagnoses or treats at an abortion facility an abortion complication that is the result of an abortion performed by another physician at the facility; or

(2) a health care facility that is a hospital, abortion facility, freestanding emergency medical care facility, or health care facility that provides emergency medical care, as defined by Section 773.003 (Definitions).

SECTION 3. Amends Section 171.061, Health and Safety Code, by amending Subdivisions (2) and (5) and adding Subdivisions (2-a) and (8-a), as follows:

(2) Redefines "abortion-inducing drug" to include off-label use of drugs, medicines, or other substances known to have abortion-inducing properties that are prescribed, dispensed, or administered with the intent of causing an abortion, including misoprostol (Cytotec) and methotrexate.

(2-a) Defines "adverse event" or "abortion complication" as meaning any harmful event or adverse outcome with respect to a patient related to an abortion, including the abortion complications listed in Section 171.006, Health and Safety Code, as added by Chapter 4 (H.B. 13), Acts of the 85th Legislature, 1st Called Session, 2017.

(5) Redefines "medical abortion" to mean the administration or use of an abortion-inducing drug to induce an abortion, and provides that it may also be referred to as a "medicated abortion," a "chemical abortion," a "drug-induced abortion," "RU-486," or the "Mifiprex regimen."

(8-a) Defines "provide" to mean, when used regarding abortion-inducing drugs, any act of giving, selling, dispensing, administering, transferring possession, or otherwise providing or prescribing an abortion-inducing drug.

SECTION 4. Amends Section 171.063, Health and Safety Code, by amending Subsections (a), (c), and (e) and adding Subsection (b-1), as follows:

(a) Prohibits a person from knowingly providing, rather than from knowingly giving, selling, dispensing, administering, providing, or prescribing, an abortion-inducing drug to a pregnant woman for the purpose of inducing an abortion in the pregnant woman or enabling another person to induce an abortion in the pregnant woman unless:

(1) makes conforming changes;

(2) the provision of the abortion-inducing drug satisfies the protocol authorized by Subchapter D (Abortion-Inducing Drugs), rather than except as otherwise provided by Subsection (b) (relating to providing that it is unlawful for any manufacturer, supplier, physician, or any other person to provide any abortion-inducing drug via courier, delivery, or mail service), the provision, prescription, or administration of an abortion-inducing drug satisfies the protocol tested and authorized by the United States Food and Drug Administration as outlined in the final printed label of the abortion-inducing drug.

(b-1) Prohibits a manufacturer, supplier, physician, or any other person from providing an abortion-inducing drug by courier, delivery, or mail service.

(c) Requires a physician, before the physician provides, rather than before the physician gives, sells, dispenses, administers, provides, or prescribes, an abortion-inducing drug, to:

(1) examine the pregnant woman in person;

- (2) independently verify that a pregnancy exists;
 - (3) document, in the woman's medical record, the gestational age and intrauterine location of the pregnancy to determine if an ectopic pregnancy exists;
 - (4) determine the woman's blood type, and for a woman who is Rh negative, offer to administer Rh immunoglobulin (RhoGAM) at the time the abortion is performed or induced to prevent Rh incompatibility, complications, or miscarriage in future pregnancies;
 - (5) document whether the pregnant woman received treatment for Rh negativity, as diagnosed by the most accurate standard of medical care; and
 - (6) ensure the physician does not provide an abortion-inducing drug for a pregnant woman whose pregnancy is more than 49 days of gestational age.
- (e) Requires a physician who provides the abortion-inducing drug, or the physician's agent, to schedule a follow-up visit for the woman to occur not later than the 14th day after the earliest date on which the abortion is performed or induced or the drug is administered or used, rather than occur not more than 14 days after the administration or use of the drug. Requires the physician, at the follow-up visit, to confirm that the woman's pregnancy is completely terminated, and assess any continued blood loss, rather than assess the degree of bleeding.

Makes conforming and nonsubstantive changes.

SECTION 5. Amends Subchapter D, Chapter 171, Health and Safety Code, by adding Sections 171.0631, 171.0632, 171.065, and 171.066, as follows:

Sec. 171.0631. **VOLUNTARY AND INFORMED CONSENT REQUIRED.** Prohibits a person from providing an abortion-inducing drug to a pregnant woman without satisfying the applicable informed consent requirements of Subchapter B (Informed Consent), Health and Safety Code.

Sec. 171.0632. **REPORTING REQUIREMENTS.** Requires a physician who provides an abortion-inducing drug to comply with the applicable physician reporting requirements in Section 245.011 (Physician Reporting Requirements; Criminal Penalty), Health and Safety Code.

Sec. 171.065. **CRIMINAL OFFENSE.** (a) Provides that a person who intentionally, knowingly, or recklessly violates Subchapter D commits an offense. Provides that an offense under this subsection is a state jail felony.

(b) Provides that a pregnant woman on whom a drug-induced pregnancy is attempted, induced, or performed in violation of Subchapter D is not criminally liable for the violation.

(c) Authorizes conduct constituting an offense under this section to also be the basis for an administration violation under Section 171.064 (Administrative Penalty).

Sec. 171.066. **ENFORCEMENT OF SUBCHAPTER.** Prohibits a state executive or administrative official from declining to enforce Subchapter D, or from adopting a construction of Subchapter D in a way that narrows its applicability, based on the official's own beliefs on the requirements of the state or federal constitution unless the official is enjoined by a state or federal court from enforcing Subchapter D.

SECTION 6. Repealer: Section 171.061(3) (relating to defining "final printed label" or "FPL"), Health and Safety Code.

Repealer: Section 171.061(6) (relating to defining "Mifeprex regimen," "RU-486 regimen," or "RU-486"), Health and Safety Code.

Repealer: Section 171.063(b) (relating to authorizing a person to provide, prescribe, or administer the abortion-inducing drug in the dosage amount prescribed by certain clinical management guidelines), Health and Safety Code.

SECTION 7. (a) Requires that nothing in this Act be construed as creating or recognizing a right to abortion.

(b) Provides that it is not the intention of this Act to make lawful an abortion that is otherwise unlawful.

(c) Provides that nothing in this Act repeals, replaces, or otherwise invalidates existing Texas laws, regulations, or policies.

SECTION 8. Severability clause.

SECTION 9. (a) Provides that, except as provided by Subsection (b) of this section, the changes in law made by this Act apply only to an abortion performed or induced on or after the effective date of this Act.

(b) Provides that Section 171.065, Health and Safety Code, as added by this Act, applies only to an abortion performed or induced on or after September 1, 2021.

SECTION 10. Effective date: upon passage or September 1, 2021.