

**SUBJECT:** Regulating use of abortion-inducing drugs; creating an offense

**COMMITTEE:** Public Health — favorable, without amendment

**VOTE:** 6 ayes — Klick, Allison, Jetton, Oliverson, Price, Smith  
2 nays — Coleman, Zwiener  
3 absent — Guerra, Campos, Collier

**SENATE VOTE:** On final passage, August 11 — 19-10 (Alvarado, Blanco, Eckhardt, Gutierrez, Hinojosa, Johnson, Powell, West, Whitmire, Zaffirini)

**WITNESSES:** No public hearing.

**BACKGROUND:** Health and Safety Code sec. 171.061(5) defines "medical abortion" as the administration or use of an abortion-inducing drug to induce an abortion.

Sec. 171.061(2) defines "abortion-inducing drug" as a drug, a medicine, or any other substance, including a regimen of at least two drugs, prescribed, dispensed, or administered with the intent of terminating a clinically diagnosable pregnancy of a woman and with knowledge that the termination will, with reasonable likelihood, cause the death of the woman's unborn child. The term includes 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 the Mifeprex regimen. The term does not include a drug, medicine, or other substance that may be known to cause an abortion but is prescribed, dispensed, or administered for other medical reasons.

Under sec. 171.061(6), "Mifeprex regimen," "RU-486 regimen," or "RU-486" means the abortion-inducing drug regimen approved by the U.S. Food and Drug Administration (FDA) that consists of administering mifepristone and misoprostol.

The Mifeprex regimen currently is authorized by the FDA to end a pregnancy through 70 days gestation. It also is under the FDA's risk evaluation and mitigation strategy (REMS), which is a drug safety program that the FDA can require for certain medications with serious safety concerns to help ensure a medication's benefits outweigh its risks. Under REMS, the Mifeprex regimen must be dispensed in-person. However, in April this year during the COVID-19 public health emergency, the FDA announced its intentions to exercise enforcement discretion on the dispensing of Mifeprex or its approved generic version through the mail, either by or under a certified prescriber's supervision, or through a mail-order pharmacy under a certified prescriber's supervision.

Under Texas Health and Safety Code sec. 171.063, only a physician may knowingly give, sell, dispense, administer, provide, or prescribe an abortion-inducing drug to a pregnant woman to induce an abortion or enable another person to induce an abortion in the pregnant woman with an abortion-inducing drug that is authorized by the FDA as outlined in the drug's final printed label.

Before the physician gives, sells, dispenses, administers, provides, or prescribes an abortion-inducing drug, the physician must:

- examine the pregnant woman; and
- document in the woman's medical record the gestational age and intrauterine location of the pregnancy.

Under sec. 171.063(b), a physician may provide, prescribe, or administer the abortion-inducing drug in the dosage amount defined by the American Congress of Obstetricians and Gynecologists (ACOG) Practice Bulletin as those clinical management guidelines existed on January 1, 2013.

Sec. 171.006(a) defines "abortion complication" as any harmful event or adverse outcome that is diagnosed or treated by a health care practitioner or at a health care facility with respect to a patient on whom an abortion is performed. The term includes several conditions, such as cervical laceration, hemorrhage, infection, death of the patient, incomplete

abortion, or an infant born alive after the abortion, among other specified conditions.

Sec. 171.006(c) requires a physician to electronically submit a report to the Health and Human Services Commission on each abortion complication diagnosed or treated by that physician by the end of the third business day after the date on which the complication was diagnosed or treated. Under sec. 245.011, a physician who performs an abortion at an abortion facility must submit a monthly report to the Department of State Health Services on each abortion performed.

**DIGEST:**

SB 4 would prohibit a manufacturer, supplier, physician, or any other person from providing to a patient any abortion-inducing drug by courier, delivery, or mail service. The bill would repeal certain references to definitions under current law for the final printed label and abortion-inducing drug regimen approved by the U.S. Food and Drug Administration (FDA). A physician would have to ensure the physician did not provide an abortion-inducing drug for a woman whose pregnancy was more than 49 days (seven weeks) of gestational age.

The bill would expand the types of conditions that qualified as reportable abortion complications. It would create a state-jail felony for violation of the bill's provisions and repeal a reference to the American Congress of Obstetricians and Gynecologists' guidelines in current law.

The current definition of "abortion-inducing drug" would be expanded to include misoprostol (Cytotec) and methotrexate. The bill also would add to the existing definition of "medical abortion" the following terms: medication abortion, chemical abortion, drug-induced abortion, RU-486, and Mifeprex regimen.

**Physician requirements.** The bill would expand the list of actions a physician was required to take before providing an abortion-inducing drug to include:

- ensuring the physician did not provide an abortion-inducing drug

for a pregnant woman whose pregnancy was more than 49 days (seven weeks) of gestational age;

- examining the pregnant woman in person;
- independently verifying that a pregnancy existed;
- documenting in the woman's medical record the gestational age and intrauterine location of the pregnancy to determine whether an ectopic pregnancy existed;
- determining the pregnant woman's blood type; and
- documenting whether the pregnant woman received treatment for Rh negativity.

For a woman who was Rh negative, the physician would have to offer to administer Rh immunoglobulin at the time the abortion-inducing drug was administered or used or the abortion was performed or induced to prevent Rh incompatibility, complications, or miscarriage in future pregnancies.

**Consent.** The bill would prohibit a person from providing an abortion-inducing drug to a pregnant woman without satisfying the applicable informed consent requirements under current law.

**Reporting.** The term "adverse event" would be added to the existing statutory definition of "abortion complication" to include, among other specified conditions:

- blood clots resulting in pulmonary embolism or deep vein thrombosis;
- failure to actually terminate the pregnancy;
- pelvic inflammatory disease;
- missed ectopic pregnancy;
- cardiac or respiratory arrest;
- adverse reactions to anesthesia or other drugs; or
- any other adverse event as defined by the FDA's criteria provided by the MedWatch Reporting System.

A physician who induced an abortion or provided an abortion-inducing

drug would have to comply with specified reporting requirements under current law.

**Enforcement.** A state executive or administrative official could not decline to enforce the bill, or adopt a construction of the bill in a way that narrowed its applicability, based on the official's own beliefs on the state or federal constitution's requirements unless the official was enjoined by a state or federal court from enforcing the bill.

**Criminal offense.** For an abortion performed or induced on or after January 1, 2022, a person who intentionally, knowingly, or recklessly violated the bill's provisions would commit a state-jail felony offense (180 days to two years in a state jail and an optional fine of up to \$10,000), which also could be the basis for an administrative violation under current law. A pregnant woman on whom a drug-induced abortion was attempted, induced, or performed on or after that date in violation of the bill would not be criminally liable.

**Construction of bill's provisions.** Nothing in the bill could be construed as creating or recognizing a right to abortion, and nothing in the bill would repeal, replace, or otherwise invalidate existing Texas laws, regulations, and policies.

**Severability.** If any provision or any application of the bill's provisions to any person or circumstance were held to be invalid or unenforceable, it would have to be construed to give the provision the maximum effect permitted by law, unless such a holding was one of utter invalidity or unenforceability, in which case the provision would be severable from others and not affect the remainder or the application of the provisions to other circumstances or persons not similarly situated.

**Other provisions.** The bill would repeal references to definitions under current law for the final printed label and abortion-inducing drug regimen approved by the FDA as well as a reference to the American Congress of Obstetricians and Gynecologists' guidelines.

Except as otherwise provided, the bill would apply only to an abortion performed or induced on or after the bill's effective date.

The bill would take immediate effect if finally passed by a two-thirds record vote of the membership of each house. Otherwise, it would take effect 91 days after the last day of the legislative session.

**SUPPORTERS  
SAY:**

SB 4 would help protect women's lives and reduce the number of abortions in Texas by prohibiting any person from providing abortion-inducing drugs to a patient by mail or delivery service. It would decrease from 70 days (10 weeks) to 49 days (seven weeks) the permissible time frame in which abortion-inducing drugs could be administered.

The U.S. Food and Drug Administration (FDA) currently authorizes the Mifeprex regimen to be provided up to 70 days (10 weeks) of gestation. However, the failure rate and risk of complications with drug-induced abortions increases with advancing gestational age. Reducing the time frame in which abortion-inducing drugs could be administered by repealing references to the FDA and prohibiting abortion-inducing drugs from being provided beyond seven weeks could reduce health risks to women and help save more unborn children.

The bill would help protect women's lives by prohibiting any person from providing abortion-inducing drugs to a patient by mail or delivery service. This would preserve the doctor-patient relationship and ensure the administration of an abortion-inducing drug was supervised by a qualified physician. Abortion-inducing drugs pose serious risks to women and may cause complications requiring immediate medical attention, such as hemorrhaging, blood clots, and pelvic inflammatory disease.

It is necessary to codify in state law requirements for abortion-inducing drugs to be administered in person, in the event federal or telemedicine rules change. The FDA this year announced its intentions to exercise enforcement discretion on the dispensing of Mifeprex or its approved generic version through the mail. Even though the FDA has chosen to exercise discretionary enforcement on the in-person dispensing

requirement, Texas maintains an interest in protecting the health and welfare of every woman considering a drug-induced abortion.

Prohibiting abortion-inducing drugs from being dispensed to a patient through mail-order or delivery services also could decrease a woman's risk of receiving the drugs from an abusive partner or the risk for women who are victims of human trafficking of receiving those drugs from traffickers.

The state-jail felony offense would be an appropriate punishment for violators and would incentivize compliance.

CRITICS  
SAY:

SB 4 would reduce a woman's access to reproductive health care by decreasing from 70 days (10 weeks) to 49 days (seven weeks) of gestation the maximum time frame in which an abortion-inducing drug could be administered.

Under current law, the Mifeprex regimen may be provided up to 70 days (10 weeks) of gestation, as authorized by the U.S. Food and Drug Administration. Many women do not find out they are pregnant until after the six-week mark, leaving women little time to make a decision about whether to continue or terminate a pregnancy. By prohibiting drug-induced abortions from being performed beyond seven weeks of gestational age of a woman's pregnancy, the bill could lead some women to use more dangerous alternatives to end a pregnancy.

The bill is unnecessary because Texas state law already requires in-person visits with a physician for an abortion procedure and when dispensing an abortion-inducing drug. The FDA's decision to use discretionary enforcement for the in-person dispensation requirement for abortion-inducing drugs would only affect states that allow telemedicine abortions, which Texas does not. The bill would reaffirm what state law already requires.

The state-jail felony offense for violations would be too punitive and could further intimidate health care professionals involved in abortion care.

OTHER  
CRITICS  
SAY:

SB 4 should give enforcement authority to the Office of the Attorney General to ensure violations were addressed evenly across the state. It also should authorize private citizens to file a cause of action against someone who violates the bill's provisions.

NOTES:

The House companion bill, HB 6 by Klick, was referred to the House Public Health Committee on August 23.