BILL ANALYSIS

Senate Research Center
83S10489 YDB-D

C.S.S.B. 18
By: Patrick
Health & Human Services
6/14/2013
Committee Report (Substituted)

AUTHOR'S / SPONSOR'S STATEMENT OF INTENT

Mifeprex (RU-486) was approved by the United States Food and Drug Administration (FDA) for use by pregnant women wishing to terminate a pregnancy for up to 49 days gestation only. The drug has no other approved indication for use during pregnancy. The RU-486 label instructs that tablets are intended for oral administration only, and should be administered only in a clinic, medical office, or hospital, and by or under the supervision of a physician able to assess the gestational age of an embryo and to diagnose ectopic pregnancies. Abortion-inducing drugs pose substantial risks to women, and these risks are magnified when the drugs are misused.

The purpose of C.S.S.B. 18 is to protect the health and welfare of women considering a drug-induced abortion. It ensures that physicians providing drug-induced abortions are only doing so in the way in which the FDA tested and approved the abortion-inducing drug.

C.S.S.B. 18 requires that Texas abortion providers meet the basic standards prescribed by the manufacturer of RU-486 and the FDA. This includes requiring that abortion-inducing drugs be provided only by a physician and that the physician examine the woman prior to administering the abortion-inducing drug. C.S.S.B. 18 requires that the drug label be provided to the patient.

In the event of an adverse reaction, C.S.S.B. 18 requires that the physician administering the abortion-inducing drug has signed a contract with a physician who will handle complications. Furthermore, the legislation requires that the woman receive the name and telephone number of the physician who will handle emergencies, and the hospital at which emergencies will be handled. The physician who contracts to handle emergencies must have active admitting privileges as well as gynecological and surgical privileges at the hospital. Finally, the physician must provide a written report of adverse events to the FDA MedWatch Reporting System.

C.S.S.B. 18 amends current law relating to distributing or prescribing abortion-inducing drugs, and provides penalties.

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. Amends Chapter 171, Health and Safety Code, by adding Subchapter C, as follows:

SUBCHAPTER C. ABORTION-INDUCING DRUGS

Sec. 171.051. DEFINITIONS. Defines "abortion-inducing drug," "final printed label" or "FPL," "gestational age," "medical abortion," "Mifeprex regimen," "RU-486 regimen" or "RU-486," "physician," "pregnant," and "unborn child" for this section.

Sec. 171.0511. APPLICABILITY TO MEDICAL ABORTION. Provides that this subchapter does not apply to an abortion done with the intent to save the life or preserve the health of an unborn child; remove a dead, unborn child whose death was caused by

spontaneous abortion; remove an ectopic pregnancy; or treat a maternal disease or illness for which a prescribed drug, medicine, or other substance is indicated.

Sec. 171.052. ENFORCEMENT BY TEXAS MEDICAL BOARD. Requires the Texas Medical Board (TMB), notwithstanding Section 171.005 (Department to Enforce), to enforce this subchapter.

Sec. 171.053. DISTRIBUTION OF ABORTION-INDUCING DRUG. (a) Prohibits a person 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) the person who gives, sells, dispenses, administers, provides, or prescribes the abortion-inducing drug is a physician;

(2) the physician administering the abortion-inducing drug administers the drug to the woman while both are present at an abortion facility licensed under Chapter 245 (Abortion Facilities); and

(3) the provision, prescription, or administration of the 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) Requires the physician, before the physician gives, sells, dispenses, administers, provides, or prescribes an abortion-inducing drug, to examine the pregnant woman and document, in the woman's medical record, the gestational age and intrauterine location of the pregnancy.

(c) Requires the physician who gives, sells, dispenses, administers, provides, or prescribes an abortion-inducing drug to provide the pregnant woman with:

(1) a copy of the final printed label of that abortion-inducing drug; and

(2) a telephone number by which the pregnant woman may reach the physician, or other health care personnel employed by the physician or by the facility at which the abortion was performed with access to the woman's relevant medical records, 24 hours a day to request assistance for any complications that arise from the administration or use of the drug or ask health-related questions regarding the administration or use of the drug.

(d) Requires the physician who gives, sells, dispenses, administers, provides, or prescribes the abortion-inducing drug, or the physician's agent, to schedule a follow-up visit for the woman to 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 pregnancy is completely terminated and assess the degree of bleeding.

(e) Requires the physician who gives, sells, dispenses, administers, provides, or prescribes the abortion-inducing drug, or the physician's agent, to make a reasonable effort to ensure that the woman returns for the scheduled follow-up visit under Subsection (d). Requires the physician or the physician's agent to document a brief description of any effort made to comply with this subsection, including the date, time, and name of the person making the effort, in the woman's medical record.

(f) Requires a physician, if the physician gives, sells, dispenses, administers, provides, or prescribes an abortion-inducing drug to a pregnant woman for the

purpose of inducing an abortion as authorized by this section and the physician knows that the woman experiences a serious adverse event, as defined by the MedWatch Reporting System, during or after the administration or use of the drug, to report the event to the United States Food and Drug Administration through the MedWatch Reporting System not later than the third day after the date the physician learns that the event occurred.

Sec. 171.054. ADMINISTRATIVE PENALTY. (a) Authorizes TMB to take disciplinary action under Chapter 164 (Disciplinary Actions and Procedures), Occupations Code, or assess an administrative penalty under Subchapter A (Administrative Penalties), Chapter 165 (Penalties), Occupations Code, against a person who violates Section 171.053.

(b) Prohibits a penalty from being assessed under this section against a pregnant woman who receives a medical abortion.

SECTION 2. Effective date: upon passage or on the 91st day after the last day of the legislative session.