BILL ANALYSIS

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S.B. 1790
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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 their pregnancy for up to 49 days gestation only. The drug has no other approval indication for use during pregnancy. The Mifeprex (RU-486) label instructs that the 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 S.B. 1790 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.

S.B. 1790 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. S.B. 1790 requires that the drug label be provided to the patient.

In the event of an adverse reaction, S.B. 1790 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 receives the name and telephone number of the physician who will handle emergencies, and the hospital at which emergencies will be handled. Also, 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.

As proposed, S.B. 1790 amends current law relating to distributing or prescribing abortion-inducing drugs and provides penalties.

[**Note:** While the statutory reference in this bill is to the Texas Department of Health (TDH), the following amendments affect the Department of State Health Services, as the successor agency to TDH.]

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 D, as follows:

SUBCHAPTER D. ABORTION-INDUCING DRUGS

Sec. 171.081. DEFINITIONS. Defines, in this subchapter, "abortion," "abortion-inducing drug," "drug label," "gestational age," "medical abortion," "physician," "pregnant," and "unborn child."

Sec. 171.082. DISTRIBUTION OF ABORTION-INDUCING DRUG. (a) Prohibits a person, unless the person is a physician and the provision or prescription of the abortion-inducing drug satisfies the protocol tested and authorized by the United States Food and Drug Administration (FDA) as outlined in the drug's drug label, 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 a pregnant woman.

(b) Requires the physician to examine the pregnant woman and document, in the woman's medical record, the gestational age and intrauterine location of the pregnancy before giving, selling, dispensing, administering, providing, or prescribing the abortion-inducing drug.

(c) Requires the physician to provide a copy of the abortion-inducing drug's drug label to the pregnant woman.

(d) Requires the physician to have a signed contract with another physician who agrees to treat emergencies arising from the drug, and produce the signed contract on demand by the pregnant woman or the Texas Department of Health (TDH).

(e) Requires the physician to provide the pregnant woman with the name and phone number of the physician who would treat an emergency arising from the drug, and the hospital at which an emergency arising from the drug would be treated.

(f) Requires a physician who contracts to treat an emergency arising from an abortion-inducing drug to have active admitting, gynecological, and surgical privileges at the hospital designated to treat the emergency.

(g) Requires the physician who gives, sells, dispenses, administers, provides, or prescribes an 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 of the abortion-inducing drug. Requires the physician, at the follow-up visit, to confirm that the pregnancy is completely terminated, and assess the degree of bleeding.

(h) Requires the physician or the physician's agent to make a reasonable effort to ensure that the woman returns for the scheduled appointment. Requires the physician or the physician's agent to include 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.

(i) Requires the physician, if a physician provides 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 a person who uses the drug experiences a serious adverse event, as defined by the MedWatch Reporting System, during or after using the drug, to report the event to the FDA through the MedWatch Reporting System within three days of the event.

Sec. 171.083. CRIMINAL PENALTY. (a) Provides that a person commits an offense if the person violates Section 171.082.

(b) Provides that an offense under this section is a Class A misdemeanor.

(c) Provides that each violation constitutes a separate offense.

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

Sec. 171.084. CIVIL PENALTY. (a) Provides that a person who knowingly violates Section 171.082 is liable for a civil penalty of not less than $100 or more than $500 for each violation if TDH determines that the violation threatens the health and safety of a woman.

(b) Provides that each violation constitutes a separate ground for recovery.

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

Sec. 171.085. ADMINISTRATIVE PENALTY. (a) Authorizes TDH to assess an administrative penalty against a person who violates Section 171.082.

(b) Prohibits the penalty from exceeding $1,000 for each violation.

(c) Provides that each violation constitutes a separate violation.

(d) Requires TDH, in determining the amount of an administrative penalty assessed under this section, to consider the seriousness of the violation, the history of previous violations, the amount necessary to deter future violations, efforts made to correct the violation, and any other matters that justice may require.

(e) Provides that all proceedings for the assessment of an administrative penalty under this section are subject to Chapter 2001 (Administrative Procedure), Government Code.

(f) 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 September 1, 2011.