STATE OF OKLAHOMA

2nd Session of the 54th Legislature (2014)

HOUSE BILL 2684 By: Grau

AS INTRODUCED

An Act relating to public health and safety; amending 63 O.S. 2011, Section 1-729a, which relates to the sale or distribution of RU-486; making legislative findings; modifying, adding and deleting certain definitions; updating statutory references; providing specifications for certain regimen; and providing an effective date.

BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:

SECTION 1. AMENDATORY 63 O.S. 2011, Section 1-729a, is amended to read as follows:

Section 1-729a. A. The Legislature finds that:

1. The U.S. Food and Drug Administration (FDA) approved the drug mifepristone (brand name "Mifeprex"), a first-generation [selective] progesterone receptor modulator ([S]PRM), as an abortion-inducing drug with a specific gestation, dosage, and administration protocol;

2. The FDA approved mifepristone (brand name Mifeprex) under the rubric of 21 C.F.R. Section 314.520, also referred to as

"Subpart H", which is the only FDA approval process that allows for postmarketing restrictions. Specifically, the Code of Federal Regulations (CFR) provides for accelerated approval of certain drugs that are shown to be effective but "can be safely used only if distribution or use is restricted";

3. The FDA does not treat Subpart H drugs in the same manner as drugs which undergo the typical approval process;

4. As approved by the FDA, and as outlined in the Mifeprex final printed labeling (FPL), an abortion by mifepristone consists of three two-hundred-milligram tablets of mifepristone taken orally, followed by two two-hundred-microgram tablets of misoprostol taken orally, through forty-nine (49) days LMP (a gestational measurement using the first day of the woman's "last menstrual period" as a marker). The patient is to return for a follow-up visit in order to confirm that the abortion has been completed. This FDA-approved protocol is referred to as the "Mifeprex regimen" or the "RU-486 regimen";

5. The aforementioned procedure requires three office visits by the patient, and the dosages may only be administered in a clinic, medical office, or hospital and under supervision of a physician;

6. The Mifeprex final printed labeling (FPL) outlines the FDA-approved dosage and administration of both drugs in the Mifeprex regimen, namely mifepristone and misoprostol;

7. When the FDA approved the Mifeprex regimen under Subpart H, it did so with certain restrictions. For example, the distribution and use of the Mifeprex regimen must be under the supervision of a physician who has the ability to assess the duration of pregnancy, diagnose ectopic pregnancies, and provide surgical intervention (or has made plans to provide surgical intervention through other qualified physicians);

8. One of the restrictions imposed by the FDA as part of its Subpart H approval is a written agreement that must be signed by both the physician and patient. In that agreement, the woman attests to the following, among other statements:

a. "I believe I am no more than 49 days (7 weeks) pregnant",

b. "I understand that I will take misoprostol in my provider's office two days after I take Mifeprex (Day 3)", and

c. "I will do the following: return to my provider's office in two days (Day 3) to check if my pregnancy has ended. My provider will give me misoprostol if I am still pregnant";

9. The FDA concluded that available medical data did not support the safety of home use of misoprostol, and it specifically rejected information in the Mifeprex final printed labeling (FPL) on self-administering misoprostol at home;

10. The use of abortion-inducing drugs presents significant medical risks to women, including but not limited to abdominal pain, cramping, vomiting, headache, fatigue, uterine hemorrhage, viral infections, and pelvic inflammatory disease;

11. Abortion-inducing drugs are associated with an increased risk of complications relative to surgical abortion. The risk of complications increases with advancing gestational age, and, in the instance of the Mifeprex regimen, with failure to complete the two-step dosage process;

12. In July 2011, the FDA reported 2,207 adverse events in the U.S. after women used abortion-inducing drugs. Among those were 14 deaths, 612 hospitalizations, 339 blood transfusions, and 256 infections (including 48 "severe infections");

13. "Off-label" or so-called "evidence-based" use of abortion-inducing drugs may be deadly. To date, 14 women have reportedly died after administering abortion-inducing drugs, with eight deaths attributed to severe bacterial infection. All eight of those women administered the drugs in an "off-label" or "evidence-based" manner advocated by many abortion providers. The FDA has received no reports of women dying from bacterial infection following administration according to the FDA-approved protocol for the Mifeprex regimen. The FDA has not been able to conclude one way or another whether off-label use led to the eight deaths;

14. Medical evidence demonstrates that women who utilize abortion-inducing drugs incur more complications than those who have surgical abortions;

15. Based on the foregoing findings, it is the purpose of this act to:

a. protect women from the dangerous and potentially deadly off-label use of abortion-inducing drugs, and

b. ensure that physicians abide by the protocol approved by the FDA for the administration of abortion-inducing drugs, as outlined in the drugs' final printed labeling (FPL); and

16. In response to the Oklahoma Supreme Court's decision in *Cline v. Oklahoma Coalition for Reproductive Justice* (No. 111,939), in which the Oklahoma Supreme Court determined, in contravention of this Legislature's intent, that this act prohibits all uses of misoprostol for chemical abortion and prohibits the use of methotrexate in treating ectopic pregnancies, it is also the purpose of this act to legislatively overrule the decision of the Oklahoma Supreme Court and ensure that should such questions be presented before that Court in the future it will reach the proper result that this act does not ban use of misoprostol in chemical abortion (and allows it as part of the FDA-approved Mifeprex regimen) nor prevent the off-label use of drugs for the treatment of ectopic pregnancy.

B. As used in this section:

1. "Abortion-inducing drug" means a medicine, drug, or any other substance prescribed or dispensed with the intent of ~~terminating the clinically diagnosable pregnancy of a woman, with knowledge that the termination shall with reasonable likelihood cause the death of the unborn child~~ inducing an abortion. This includes off-label use of drugs known to have abortion-inducing properties, which are prescribed specifically with the intent of causing an abortion, such as misoprostol (Cytotec), and methotrexate. This definition does not apply to drugs that may be known to cause an abortion, but which are prescribed for other medical indications, such as chemotherapeutic agents or diagnostic drugs, or for treatment of an ectopic pregnancy;

2. "Abortion" means the use or prescription of any instrument, medicine, drug, or any other substance or device intentionally to terminate the pregnancy of a female known to be pregnant with an intention other than to increase the probability of a live birth, to preserve the life or health of the child after live birth, to remove an ectopic pregnancy, or to remove a dead unborn child who died as the result of a spontaneous miscarriage, accidental trauma, or a criminal assault on the pregnant female or her unborn child;

3. "Drug label" or "drug's label" means the pamphlet accompanying an abortion-inducing drug which outlines the protocol ~~tested and~~ authorized by the U.S. Food and Drug Administration (FDA) and agreed upon by the drug company applying for FDA authorization

of that drug. Also known as "final ~~printing~~ printed labeling ~~instructions~~ (FPL)" or referred to as the "FDA-approved label", it is the FDA-approved document which delineates how a drug is to be used according to the FDA approval;

~~3. "Federal law" means any law, rule, or regulation of the United States or any drug approval letter of the U.S. Food and Drug Administration that governs or regulates the use of RU-486 (mifepristone) or any abortion-inducing drug for the purpose of inducing abortions;~~

4. "Mifeprex regimen" means the abortion-inducing drug regimen that is described in the FDA-approved Mifeprex final printed labeling, and which involves administration of mifepristone (brand name "Mifeprex") and misoprostol. It is the only abortion-inducing drug regimen approved by the FDA, and it does not include any dosage or administration not explicitly approved in Mifeprex final printed labeling. It is also commonly referred to as the "RU-486 regimen" or simply "RU-486";

5. "Mifepristone" means the first drug used in the Mifeprex regimen;

6. "Misoprostol" means the second drug used in the Mifeprex regimen;

7. "Personal identifying information" means any information designed to identify a person and any information commonly used or

capable of being used alone or in conjunction with any other information to identify a person; and

~~5.~~ 8. "Physician" means a doctor of medicine or osteopathy legally authorized to practice medicine in the state.

~~B.~~ C. No person shall knowingly or recklessly give, sell, dispense, administer, prescribe, or otherwise provide ~~RU-486, also known as mifepristone, or any~~ an abortion-inducing drug ~~for the purpose of inducing an abortion in a pregnant female~~, including the Mifeprex regimen, unless the person who gives, sells, dispenses, administers, prescribes, or otherwise provides the ~~RU-486 (mifepristone) or any~~ abortion-inducing drug is a physician who:

1. Has the ability to assess the duration of the pregnancy accurately;

2. Has the ability to diagnose ectopic pregnancies;

3. Has the ability to provide surgical intervention in cases of incomplete abortion or severe bleeding, or has made and documented in the patient's medical record plans to provide such care through other qualified physicians; and

4. Is able to assure patient access to medical facilities equipped to provide blood transfusions and resuscitation, if necessary~~; and~~

~~5. Has read and understood the prescribing information for the use of RU-486 (mifepristone) or any abortion-inducing drug as~~

~~provided by the drug manufacturer in accordance with the requirements of the U.S. Food and Drug Administration~~.

~~C.~~ D. No physician who provides ~~RU-486 (mifepristone) or any~~ an abortion-inducing drug, including the Mifeprex regimen, shall knowingly or recklessly fail to provide or prescribe the ~~RU-486 (mifepristone) or any abortion-inducing~~ drug according to the protocol ~~tested and~~ authorized by the U.S. Food and Drug Administration and as ~~authorized~~ outlined in the ~~drug~~ FDA-approved label ~~for the RU-486 (mifepristone) or any abortion-inducing drug~~. In the specific case of the Mifeprex regimen, the Mifeprex label includes the FDA-approved dosage and administration instructions for both mifepristone (brand name Mifeprex) and misoprostol, and any provision accomplished according to that labeling is not prohibited.

~~D.~~ E. No physician who provides ~~RU-486 (mifepristone) or any~~ an abortion-inducing drug ~~for the purpose of inducing an abortion~~, including the Mifeprex regimen, shall knowingly or recklessly fail to:

1. Provide each patient with a copy of the drug manufacturer's medication guide and drug label for ~~RU-486 (mifepristone) or any abortion-inducing drug~~ the drug(s) being used; when the Mifeprex regimen is being utilized, this requirement is satisfied so long as the patient is provided the FDA-approved Mifeprex medication guide and final printed labeling;

2. Fully explain the procedure to the patient, including, but not limited to, explaining that the drug is being used in accordance with the protocol ~~tested and~~ authorized by the U.S. Food and Drug Administration and as outlined in the drug label for ~~RU-486 (mifepristone) or any~~ the abortion-inducing drug;

3. Provide the female with a copy of the drug manufacturer's patient agreement and obtain the patient's signature on the patient agreement;

4. Sign the patient agreement; and

5. Record the drug manufacturer's package serial number in the patient's medical record.

~~E.~~ F. Because the failure and complications rates from ~~medical abortion~~ abortion-inducing drugs increase with increasing gestational age, and because the physical symptoms of ~~medical abortion~~ an abortion induced by drugs can be identical to the symptoms of ectopic pregnancy, ~~and because RU-486 (mifepristone) or any abortion-inducing drug does not treat ectopic pregnancies but rather is contraindicated in ectopic pregnancies,~~ thereby increasing the risk of ruptured ectopic pregnancy, the physician giving, selling, dispensing, administering, or otherwise providing or prescribing ~~RU-486 (mifepristone) or any~~ the abortion-inducing drug shall first examine the woman and document, in the woman's medical chart, gestational age and intrauterine location of the pregnancy prior to giving, selling, dispensing, administering, or otherwise

providing or prescribing ~~RU-486 (mifepristone) or any~~ the abortion-inducing drug.

~~F. When RU-486 (mifepristone) or any~~ G. An abortion-inducing drug ~~is used for the purpose of inducing an abortion, the drug~~ must be administered in the same room and in the physical presence of the physician who prescribed, dispensed, or otherwise provided the drug to the patient. The physician inducing the abortion, or a person acting on behalf of the physician inducing the abortion, shall schedule the patient for a follow-up appointment and make all reasonable efforts to ensure that the patient returns twelve (12) to eighteen (18) days after the administration or use of ~~RU-486 (mifepristone) or any~~ the abortion-inducing drug for a follow-up visit so that the physician can confirm that the pregnancy has been terminated and assess the patient's medical condition. A brief description of the efforts made to comply with this subsection, including the date, time, and identification by name of the person making such efforts, shall be included in the patient's medical record.

~~G.~~ H. 1. If a physician provides ~~RU-486 (mifepristone) or any~~ an abortion-inducing drug ~~for the purpose of inducing an abortion and if the physician~~ and knows that the female who uses the ~~RU-486 (mifepristone) or any~~ abortion-inducing drug ~~for the purpose of inducing an abortion~~ experiences within one (1) year after the use of ~~RU-486 (mifepristone) or any~~ the abortion-inducing drug an

incomplete abortion, severe bleeding, or an adverse reaction to the ~~RU-486 (mifepristone) or any~~ abortion-inducing drug or is hospitalized, receives a transfusion, or experiences any other serious event, the physician shall, as soon as is practicable, but in no case more than sixty (60) days after the physician learns of the adverse reaction or serious event, provide a written report of the incomplete abortion, severe bleeding, adverse reaction, hospitalization, transfusion, or serious event to the drug manufacturer. If the physician is a doctor of medicine, the physician shall simultaneously provide a copy of the report to the State Board of Medical Licensure and Supervision. If the physician is a doctor of osteopathy, the physician shall simultaneously provide a copy of the report to the State Board of Osteopathic Examiners. The relevant Board shall compile and retain all reports it receives pursuant to this subsection. All reports the relevant Board receives under this subsection are public records open to inspection pursuant to the Oklahoma Open Records Act; however, absent an order by a court of competent jurisdiction, neither the drug manufacturer nor the relevant Board shall release the name or any other personal identifying information regarding a person who uses or provides ~~RU-486 (mifepristone) or any~~ the abortion-inducing drug for the purpose of inducing an abortion and who is the subject of a report the drug manufacturer or the relevant Board receives under this subsection.

2. No physician who provides ~~RU-486 (mifepristone) or any~~ an abortion-inducing drug to a pregnant female ~~for the purpose of inducing an abortion~~ shall knowingly or recklessly fail to file a report required under paragraph 1 of this subsection. Knowing or reckless failure to comply with this subsection shall subject the physician to sanctioning by the licensing board having administrative authority over such physician.

~~H.~~ I. Any female upon whom an abortion has been performed, the father of the unborn child who was the subject of the abortion if the father was married to the woman who received the abortion at the time the abortion was performed, or a maternal grandparent of the unborn child may maintain an action against the person who performed the abortion in knowing or reckless violation of this section for actual and punitive damages. Any female upon whom an abortion has been attempted in knowing or reckless violation of this section may maintain an action against the person who attempted to perform the abortion for actual and punitive damages.

~~I.~~ J. If a judgment is rendered in favor of the plaintiff in any action described in this section, the court shall also render judgment for a reasonable attorney fee in favor of the plaintiff against the defendant. If a 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 shall also render

judgment for a reasonable attorney fee in favor of the defendant against the plaintiff.

~~J.~~ K. No pregnant female who obtains or possesses ~~RU-486 (mifepristone) or any~~ an abortion-inducing drug ~~for the purpose of inducing an abortion~~ to terminate her own pregnancy shall be subject to any action brought under subsection H of this section.

~~K.~~ L. If some or all of the language in this section is ever temporarily or permanently restrained or enjoined by judicial order, then this section shall be enforced as though such restrained or enjoined provisions had not been adopted; provided, however, that whenever such temporary or permanent restraining order or injunction is stayed or dissolved, or otherwise ceases to have effect, such provisions shall have full force and effect.

SECTION 2. This act shall become effective November 1, 2014.

54-2-8754 AM 01/09/14