

1 **HOUSE OF REPRESENTATIVES - FLOOR VERSION**

2 STATE OF OKLAHOMA

3 2nd Session of the 54th Legislature (2014)

4 HOUSE BILL 2684

 By: Grau

7 AS INTRODUCED

8 An Act relating to public health and safety; amending
9 63 O.S. 2011, Section 1-729a, which relates to the
10 sale or distribution of RU-486; making legislative
11 findings; modifying, adding and deleting certain
 definitions; updating statutory references; providing
 specifications for certain regimen; and providing an
 effective date.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- 6 a. protect women from the dangerous and potentially
7 deadly off-label use of abortion-inducing drugs, and
8 b. ensure that physicians abide by the protocol approved
9 by the FDA for the administration of abortion-inducing
10 drugs, as outlined in the drugs' final printed
11 labeling (FPL); and

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

24 B. As used in this section:

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

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

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

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

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

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

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

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

22 7. "Personal identifying information" means any information
23 designed to identify a person and any information commonly used or
24

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

3 ~~5.~~ 8. "Physician" means a doctor of medicine or osteopathy
4 legally authorized to practice medicine in the state.

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

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

14 2. Has the ability to diagnose ectopic pregnancies;

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

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

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

24

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

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

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

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

24

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

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

9 4. Sign the patient agreement; and

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

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

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

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

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

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

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

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

18 ~~I.~~ J. If a judgment is rendered in favor of the plaintiff in
19 any action described in this section, the court shall also render
20 judgment for a reasonable attorney fee in favor of the plaintiff
21 against the defendant. If a judgment is rendered in favor of the
22 defendant and the court finds that the plaintiff's suit was
23 frivolous and brought in bad faith, the court shall also render
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1 judgment for a reasonable attorney fee in favor of the defendant
2 against the plaintiff.

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

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

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

15
16 COMMITTEE REPORT BY: COMMITTEE ON PUBLIC HEALTH, dated 02/18/2014 -
17 DO PASS.

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