CV-11-1722
Owens

IN THE DISTRICT COURT OF OKLAHOMA COUNTY
STATE OF OKLAHOMA

(1) OKLAHOMA COALITION FOR REPRODUCTIVE JUSTICE, on behalf of itself and its members; and (2) NOVA HEALTH SYSTEMS, D/B/A REPRODUCTIVE SERVICES, on behalf of itself, its staff, and its patients, Plaintiffs, v. (3) TERRY L. CLINE, in his official capacity as Oklahoma Commissioner of Health; and, (4) LYLE KELSEY, in his official capacity as Executive Director of the Oklahoma State Board of Medical Licensure and Supervision; and, (5) CATHERINE C. TAYLOR, in her official capacity as the President of the Oklahoma State Board of Osteopathic Examiners, Defendants.	Case No. CV-2011-1722 Judge _____ FILED IN THE DISTRICT COURT OKLAHOMA COUNTY, OKLA. OCT - 5 2011 PATRICIA PRESLEY, COURT CLERK by _____ DEPUTY

PETITION

1. Plaintiffs Oklahoma Coalition for Reproductive Justice ("OCRJ") and Nova Health Systems d/b/a Reproductive Services ("Reproductive Services"), by and through their undersigned attorneys, bring this Petition against the above-named Defendants, their employees, agents, and successors in office, and in support thereof allege the following:

I. PRELIMINARY STATEMENT

2. This is a civil rights action challenging Oklahoma House Bill 1970 ("H.B. 1970" or "the Act"), under the Constitution of the State of Oklahoma. 2011 Okla. Sess. Laws 1276. H.B. 1970 is scheduled to take effect November 1, 2011. The Act is attached hereto as

Exhibit A.

3. The Act seeks to elevate politicians' ideological objections to abortion over women's health and well-being. It imposes severe restrictions on the use of FDA-approved medications for the purpose of ending a pregnancy. Those restrictions are contrary to all available medical evidence and serve no legitimate governmental interest.

4. By imposing these burdensome and arbitrary restrictions on care provided for pregnancy terminations, the Act prevents doctors from providing, and women from receiving, medical treatment according to sound medical judgment, current scientific evidence, and advances in medicine as they are able to do in all other areas of medical practice. The Act, therefore, violates the rights of Plaintiffs, and those whose interests Plaintiffs represent, to equal protection of the laws, privacy, bodily integrity, and freedom of speech, secured by the Oklahoma Constitution. It also violates Oklahoma's constitutional prohibitions against special laws and delegation of legislative authority.

5. In addition to the irreparable injury caused by violation of these constitutionally-protected rights, the Act will irreparably injure the health and well-being of women who seek to end their pregnancies by non-surgical means. Because of the Act, those women will be deprived of the safest and most effective methods of doing so.

II. JURISDICTION AND VENUE

6. Jurisdiction is conferred on this Court by OKLA. CONST. art. VII, § 7(a).

7. Plaintiffs' claims for declaratory and injunctive relief are authorized by OKLA. STAT. tit. 12, §§ 1651 and 1381 and by the general equitable powers of this Court.

8. Venue is appropriate under OKLA. STAT. tit. 12, § 133 because several Defendants have official residences in Oklahoma County.

III. THE CHALLENGED STATUTE

9. Until April 20, 2010, when OKLA. STAT. tit. 63, § 1-729a became effective, Oklahoma law did not distinguish between medication abortion and surgical abortion. Under that law, which is currently in effect, several conditions are imposed on physicians' use of a particular medication used for terminating a pregnancy. That medication was approved by the U.S. Food and Drug Administration for marketing under the name Mifeprex and is also known as mifepristone (its generic name) and RU-486 (the name of its French counterpart).

10. On May 11, 2011, Governor Mary Fallin signed into law Oklahoma House Bill 1970. H.B. 1970 amends OKLA. STAT. tit. 63, § 1-729a.

11. The Act expands the scope of OKLA. STAT. tit. 63, § 1-729a to apply to not only mifepristone, but also any "abortion-inducing drug." The Act defines the term "abortion-inducing drug" as:

> 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. 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.

H.B. 1970 § 1(A)(1).

12. In addition, the Act imposes several new restrictions on physicians' ability to provide abortion-inducing drugs (including mifepristone) to patients.

13. Currently, under OKLA. STAT. tit. 63, § 1-729a, physicians have the option of providing Mifeprex to patients using a regimen based in current scientific research (an "evidence-based regimen"). OKLA. STAT. tit. 63, § 1-729a(C). The Act prohibits the use of

evidence-based regimens. Instead, it requires physicians to provide abortion-inducing drugs "according to the protocol tested and authorized by the U.S. Food and Drug Administration and as authorized in the drug label for the RU-486 (mifepristone) or any abortion-inducing drug." H.B. 1970 § 1(C).

14. The term "drug label" is defined as:

> 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 printed labeling instructions", it is the FDA document which delineates how a drug is to be used according to the FDA label.

H.B. 1970 § 1(A)(2).

15. Similarly, under OKLA. STAT. tit. 63, § 1-729a, physicians providing Mifeprex are required to explain to patients "whether the physician is using the drug in accordance with the U.S. Food and Drug Administration regimen or an evidence-based regimen, and, if using an evidence-based regimen, specifying that the regimen differs from the U.S. Food and Drug Administration regimen and providing detailed information on the evidence-based regimen being used." OKLA. STAT. tit. 63, § 1-729a(C). The Act modifies this explanation. It requires physicians who provide abortion-inducing drugs to tell their patients "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 abortion-inducing drug," and to 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 being used." H.B. 1970 §§ 1(D)(1),(2).

16. The Act creates a new section, which provides that:

> Because the failure and complications from medical abortion increase with

> increasing gestational age, because the physical symptoms of medical abortion 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, the physician ... providing or prescribing RU-486 (mifepristone) or any 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 ... providing or prescribing RU-486 (mifepristone) or any abortion-inducing drug.

H.B. 1970 §1(E).

17. Current law requires reasonable efforts on the part of a physician or her agent to ensure that a patient who receives Mifeprex returns for a follow-up appointment within 12 to 18 days. The Act expands the physician's obligations as follows:

> 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 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.

H.B. 1970 §1(F) (emphasis reflects changes made by the Act).

18. Finally, current law requires physicians who provide Mifeprex to make a written report to the drug manufacturer, Board of Medical Licensure and Supervision and/or Board of Osteopathic Examiners if the physician knows that a medication abortion patient experiences any of the following within a year of the medication abortion: "an incomplete abortion, severe bleeding, or an adverse reaction to the RU-486 (mifepristone) or is hospitalized, receives a transfusion, or experiences any other serious event." OKLA. STAT. tit. 63, § 1-729a(E). The Act expands this reporting obligation to any physician who provides an "abortion-inducing drug" and a patient who uses an "abortion-inducing drug." H.B. 1970 § 1(G)(1).

19. A physician who "knowing[ly] and reckless[ly]" fails to comply with the Act is subject to civil liability for "actual and punitive" damages. OKLA. STAT. tit. 63, § 729a(F). In addition, failure to comply with H.B. 1970 exposes a physician to disciplinary sanctions by the relevant licensing board, and exposes the licensed health care facility at which the physician performs the medication abortion to disciplinary action against its license. *See* OKLA. STAT. tit. 63 § 1-706(B)(1); OKLA. STAT. tit. 59 §§ 503, 509, 637; OKLA. ADMIN. CODE § 310:600-7-3.

IV. PARTIES

20. Plaintiff Oklahoma Coalition for Reproductive Justice ("OCRJ") is a non-profit organization dedicated to promoting reproductive justice in Oklahoma through education and advocacy. OCRJ is dedicated to ensuring that reproductive health care is available to all women in Oklahoma and OCRJ's membership includes women of reproductive age who may want to obtain abortions and/ or who may experience ectopic pregnancies in Oklahoma in the future.

21. OCRJ's members pay taxes to the State of Oklahoma.

22. OCRJ brings claims on behalf of itself and its members.

23. Plaintiff Reproductive Services, a part of NOVA Health Systems, a non-profit charitable corporation, is a medical clinic in Tulsa, Oklahoma that has been in operation since 1974. Reproductive Services provides a range of reproductive health care services to women in Oklahoma, including surgical and medication abortions, contraception counseling and services, pregnancy testing, options counseling, adoption counseling, and referrals for other medical and social services, including referrals to an on-site licensed adoption agency. It is a member of the National Abortion Federation ("NAF") and is licensed as an abortion

facility by the Oklahoma State Department of Health.

24. From time to time, Reproductive Services physicians have diagnosed patients seeking abortions with ectopic pregnancy. A patients who is diagnosed with a ruptured ectopic pregnancy is sent to the emergency room. Reproductive Services sends patients with unruptured ectopic pregnancy to the nearby hospital that will offer medication to manage ectopic pregnancy as an alternative to surgical management, if the patient is an appropriate candidate.

25. Reproductive Services brings claims on behalf of itself, its staff, and its patients.

26. Defendant Terry L. Cline is the Oklahoma Commissioner of Health. He oversees the Oklahoma State Board of Health, which issues licenses to facilities at which abortions are performed and oversees compliance with the regulation of such facilities. OKLA. STAT. tit. 63, § 1-706(B)(1); OKLA. ADMIN. CODE § 310:600-7-3. He is sued in his official capacity.

27. Defendant Lyle Kelsey is the Executive Director of the Oklahoma State Board of Medical Licensure and Supervision (the "Medical Board"). The Medical Board, among other things, issues medical licenses and has the authority to take disciplinary action against licensees. OKLA. STAT. tit. 59, §§ 503, 509. He is sued in his official capacity.

28. Defendant Catherine C. Taylor is the President of the Oklahoma State Board of Osteopathic Examiners (the "Osteopathy Board"). The Osteopathy Board, among other things, issues medical licenses to physicians trained in schools of osteopathic medicine and has the authority to take disciplinary action against licensees. OKLA. STAT. tit. 59, § 637. She is sued in her official capacity.

VI. FACTUAL ALLEGATIONS

A. FDA Approval of Medications and Final Printed Labels

29. The Food and Drug Administration ("FDA") is an agency within the U.S. Department of Health and Human Services. Drug sponsors wishing to market a new prescription drug in the United States must obtain FDA approval to do so. A drug manufacturer submits to the FDA a new drug application with information about the drug's test results, information about the manufacturer's ability to manufacture the drug properly, and the manufacturer's proposed label for the drug. If the FDA determines that the benefits of the drugs outweigh its known risks, it is approved for marketing in the United States.

30. The FDA does not test protocols or conduct clinical trials of new drugs. It does not review reports of studies other than ones regarding uses for which the FDA's approval for the drug is sought.

31. The manufacturer's proposed label for the drug that is the subject of a new drug application is called the Final Printed Label ("FPL"). An FPL contains information about the drug, including dosage and administration directions for the safe and effective use of the drug according to the purpose for which the manufacturer seeks FDA approval. The sponsor of a new drug application is responsible for creating the FPL and submitting it to the FDA. The FDA does not create FPLs, and FPLs are not FDA documents.

32. An FPL does not, and is not required to, provide information about the safe and effective uses of a medication other than the regimen for which it was originally approved for marketing. Because there may not be a commercial reason for the drug's manufacturer to market a medication for all of the uses supported by scientific evidence, an FPL can often be out of date or not based on current scientific evidence.

33. Neither the FPL nor any FDA regulations make it unlawful to prescribe or dispense approved drugs in a dosage or according to a method of administration that differs from the FPL. Neither the FPL nor any FDA regulation makes it unlawful to prescribe or dispense approved drugs for a purpose that differs from the purpose for which the manufacturer sought FDA approval.

34. Using an approved drug in a different dosage, or according to a different method of administration, or for a different purpose from the dosage, method of administration or purpose than that set out in the drug's FPL is known as "off-label use." Off-label use of drugs is common throughout the United States and is sometimes required by good medical practice. It allows physicians to implement advances in medicine with respect to a medication although its manufacturer does not intend to market the drug for those uses. Even the FDA recognizes that advances in medicine often precede changes to labeling, an acknowledgement that an off-label use may constitute better health care.

B. Medication Abortion

35. Medication abortion involves the use of medications, rather than a surgical procedure, to terminate a uterine pregnancy. The option of medication abortion is an important advance in medical care for women. It has expanded access to abortion nationwide. In fact, approximately 20% of the women who obtain abortions in the United States obtain medication abortions.

36. For some women, medication abortion offers advantages over surgical abortion. Medication abortion can be performed earlier in pregnancy than surgical abortion and is less invasive. Some women also consider it to be more private. It is often medically advantageous for women with certain conditions to have a medication rather than a surgical

abortion.

37. The vast majority of medication abortions in the United States are induced using a combination of mifepristone and misoprostol.

38. Mifepristone blocks the hormone progesterone, which is necessary to maintain a pregnancy. Mifepristone is sold in the United States by Danco Laboratories, LLC under the brand name Mifeprex and is also known as RU-486. It was the first medication approved by the U.S. Food and Drug Administration ("FDA") for marketing for first-trimester abortion, and it is the only medication to have received approval from the FDA for marketing for that purpose.

39. Misoprostol causes a woman's cervix to open and her uterus to contract and expel its contents. It is sold in the United States under the brand name Cytotec for the purpose of treating gastric ulcers. It has not been approved for marketing for medication abortion.

40. The FDA approved Mifeprex in September 2000. The FDA's approval was based on the agency's review of three medical trials demonstrating the safety and efficacy of mifepristone, which had been submitted to the FDA with the drug's new drug application in 1996. All three trials followed the same dosage and administration method: oral ingestion of 600 mg of mifepristone, followed two days later by oral ingestion of 400 mcg of misoprostol administered at a health care facility. The trials demonstrated that this regimen is safe and effective for terminating pregnancies through 49 days' gestation lmp.

41. The Mifeprex FPL contains information about the regimen used during the three clinical trials described in the Mifeprex new drug application. Under that regimen, on Day One at the health care facility, a patient whose pregnancy is less than or equal to 49 days' gestation lmp reads the Medication Guide, signs the Patient Agreement, and orally ingests

600 mg of mifepristone; on Day Three the patient returns to the health care facility and, unless the abortion had already occurred, orally ingests 400 mcg of misoprostol; and approximately fourteen days after ingesting mifepristone, the patient returns to the health care facility to confirm that her pregnancy has been terminated.

42. Researchers have developed new protocols for dosage and administration of mifepristone and misoprostol to induce an abortion in the years since the clinical trials described in the Mifeprex new drug application ("evidence-based regimens"). Several studies have been conducted using these alternative dosage and administration protocols. Among other things, studies of evidence-based regimens have found that 200 mg of mifepristone is effective, in combination with varying dosages and administration routes of misoprostol; that women can safely self-administer misoprostol at a location other than the health care facility; and that these protocols are effective through 63 days' gestation.

43. As a result of the medical evidence, leading health organizations, including the American College of Obstetricians and Gynecologists ("ACOG") and the World Health Organization ("WHO"), have recognized that evidence-based regimens for Mifeprex and misoprostol can be safer and more effective, with fewer side effects and at lower cost, than the regimen described in the Mifeprex FPL.

44. Medication abortion using an evidence-based regimen is extremely safe. Use of many FDA-approved drugs carries a significantly higher risk of complication and death than evidence-based use of Mifeprex and misoprostol.

C. Medical Management of Ectopic Pregnancies

45. An ectopic pregnancy occurs when a fertilized egg implants outside of a woman's uterus. Ninety-seven percent of ectopic pregnancies occur in a woman's fallopian tube

("tubal" ectopic pregnancies).

46. Ectopic pregnancies occur in about two percent of pregnancies.

47. Ectopic pregnancy is a threat to a woman's health and life.

48. Surgery to terminate the pregnancy is one method of treating a woman's ectopic pregnancy. For a woman with a tubal ectopic pregnancy, surgery can involve removing all or part of her fallopian tube in order to remove the pregnancy.

49. Surgical management of ectopic pregnancy carries risks to a woman's health. For some women, surgical management also carries risks to future fertility.

50. Because of the risks associated with surgical management of ectopic pregnancy, off-label use of methotrexate, a cancer-treating drug, is often the preferred method of treatment. An injection of methotrexate is a non-invasive way to terminate an ectopic pregnancy. ACOG has recommended the use of methotrexate for certain women with ectopic pregnancies.

51. For appropriate candidates with ectopic pregnancy, off-label use of methotrexate is considered standard management.

D. Impact of H.B. 1970

52. Reproductive Services provides approximately 200 abortions per month, on average. In 2010, about two-thirds of the patients who obtained first-trimester abortions at Reproductive Services chose medication abortions.

53. If the Act goes into effect, Reproductive Services will not be able to continue providing medication abortions because it is not possible to comply with the Act's requirements.

54. No protocols are tested or authorized by the FDA.

55. No part of a drug's label is an FDA document.

56. Even if the Act were construed to require medications to be used for pregnancy terminations in accordance with the regimens described in the FPL for that medication, it would not be possible to provide medication abortions in compliance with the Act because misoprostol is part of the regimen described in the Mifeprex FPL but misoprostol's FPL contains no information about its use in abortions. Similarly, methotrexate's FPL does not contain information about its use for management of ectopic pregnancy.

57. The physicians who provide medication abortions at Reproductive Services use the evidence-based regimen recommended by ACOG. Patients take 200 milligrams ("mg") of mifepristone buccally at the clinic, followed six to fourteen hours later by the vaginal self-administration of 800 micrograms ("mcg") of misoprostol at a location of their choosing. Reproductive Services' physicians have chosen this regimen based upon their own experience providing medication abortions and frequent discussions with other abortion providers within NOVA Health Systems about the best procedure for medication abortion.

58. Even if the Act were somehow interpreted to require medications to be used to induce abortions according to the Mifeprex FPL, it would still put unreasonable restrictions on physicians' ability to provide and women's ability to receive medication abortion.

59. For example, such an interpretation would bar abortion providers and their patients from using mifepristone and misoprostol according to the safest, most effective, and least expensive protocol supported by medical evidence.

60. In addition, such an interpretation would bar patients who are more than 49 days pregnant from obtaining a medical abortion, even though medical evidence shows that medication abortions using mifepristone and misoprostol can be safely and effectively

offered to patients who are up to 63 days pregnant.

61. If the Act goes into effect, women with unruptured tubal ectopic pregnancies will not have the option of treatment with methotrexate. Instead, they will be forced to have surgery on their fallopian tubes, with all its attendant risks.

VIII. CLAIMS FOR RELIEF

First Claim for Relief
(Equal Protection)

62. The allegations of paragraphs 1 through 61 are incorporated as though fully set forth herein.

63. The Act denies equal protection of the laws to women seeking medication abortions, women with ectopic pregnancies, and physicians who treat those women, in violation of OKLA. CONST. art. II, § 7.

Second Claim for Relief
(Improper Delegation)

64. The allegations of paragraphs 1 through 63 are incorporated as though fully set forth herein.

65. By requiring physicians who provide medication abortions to adhere to protocols "tested and authorized" by the FDA, the Act impermissibly delegates legislative authority to a federal agency in violation of OKLA. CONST. arts. IV and V.

Third Claim for Relief
(Vagueness)

66. The allegations of paragraphs 1 through 65 are incorporated as though fully set forth herein.

67. The Act is vague in violation of OKLA. CONST. art. II, § 7 because it fails to afford a person of ordinary intelligence a reasonable opportunity to know what is prohibited by its

terms. Among other things, the Act establishes requirements for the provision of medication abortions and the treatment of women with ectopic pregnancies that are impossible to satisfy.

Fourth Claim for Relief
(Substantive Due Process)

68. The allegations of paragraphs 1 through 67 are incorporated as though fully set forth herein.

69. The Act violates women's fundamental rights to privacy and bodily integrity in violation of OKLA. CONST. art. II, § 7.

70. The Act imposes arbitrary and irrational requirements on physicians in violation of OKLA. CONST. art. II, § 7.

Fifth Claim for Relief
(Special Law)

71. The allegations of paragraphs 1 through 70 are incorporated as though fully set forth herein.

72. The Act creates a special law where a general law could be made applicable in violation of OKLA. CONST. art. V, § 59 by, among other things, singling out for special treatment women seeking medication abortions, women with ectopic pregnancies, and physicians who treat those women.

73. The Act creates a special law regulating the practice or jurisdiction of the courts in violation of OKLA. CONST. art. V, § 46 by affording a private right of action to a special class of litigants.

Eighth Claim for Relief
(Compelled Speech)

74. The allegations of paragraphs 1 through 73 are incorporated as though fully set forth herein.

75. By requiring that physicians tell their patients that they are administering drugs "in accordance with the protocol tested and authorized by the [FDA]" when there is no such protocol, the Act compels physicians to make, and women to hear, untruthful and misleading statements in violation of OKLA. CONST. art. II, § 22.

VIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court:

76. Issue a declaratory judgment that H.B. 1970 violates the Oklahoma Constitution and is void and of no effect; and

77. Issue permanent injunctive relief, without bond, restraining Defendants, their employees, agents, and successors in office from enforcing H.B. 1970; and

78. Grant such other and further relief as the Court may deem just and proper, including reasonable attorney's fees and costs.

Dated: October 5, 2011

Respectfully submitted,

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ATTORNEYS FOR PLAINTIFFS

Exhibit A

An Act

ENROLLED HOUSE
BILL NO. 1970

By: Grau, Trebilcock, Cockroft, Reynolds, Faught, Ownbey, Kern, Ritze, Cooksey, Roberts (Dustin) and Peterson of the House

and

Treat, Brecheen and Allen of the Senate

An Act relating to public health and safety; amending Section 1, Chapter 48, O.S.L. 2010 (63 O.S. Supp. 2010, Section 1-729a), which relates to RU-486 for the purpose of inducing abortions; adding definitions; requiring that physicians prescribe certain drugs according to certain protocol; modifying duties of certain physicians; requiring physician to examine woman and document gestational age prior to administering certain drugs; requiring follow-up appointment to be scheduled for certain patient; providing for severability; and providing an effective date.

SUBJECT: Abortion

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

SECTION 1. AMENDATORY Section 1, Chapter 48, O.S.L. 2010 (63 O.S. Supp. 2010, Section 1-729a), is amended to read as follows:

Section 1-729a. A. 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. 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;

2. "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 labeling instructions", it is the FDA 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;

~~2.~~ 4. "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

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

B. No person shall knowingly or recklessly give, sell, dispense, administer, prescribe, or otherwise provide RU-486, also known as mifepristone, or any abortion-inducing drug for the purpose of inducing an abortion in a pregnant female, 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;

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. No physician who provides RU-486 (mifepristone) or any abortion-inducing drug 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 in the drug label for the RU-486 (mifepristone) or any abortion-inducing drug.

D. No physician who provides RU-486 (mifepristone) or any abortion-inducing drug for the purpose of inducing an abortion 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 being used;

2. Fully explain the procedure to the patient, including, but not limited to, explaining ~~whether the physician is using~~ that the drug is being used in accordance with the protocol tested and authorized by the U.S. Food and Drug Administration ~~regimen or an evidence-based regimen, and, if using an evidence-based regimen, specifying that the regimen differs from the U.S. Food and Drug Administration regimen and providing detailed information on the evidence-based regimen being used~~ and as outlined in the drug label for RU-486 (mifepristone) or any 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.

~~D.~~ E. Because the failure and complications from medical abortion increase with increasing gestational age, because the physical symptoms of medical abortion 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, the physician giving, selling, dispensing, administering, or otherwise providing or prescribing RU-486 (mifepristone) or any 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 abortion-inducing drug.

F. When RU-486 (mifepristone) or any abortion-inducing drug is used for the purpose of inducing an abortion, the drug must be administered ~~by or~~ 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 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.

~~E.~~ G. 1. If a physician provides RU-486 (mifepristone) or any abortion-inducing drug for the purpose of inducing an abortion and if the physician 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 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 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 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.

~~F.~~ H. 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.

~~G.~~ I. 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.

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

K. 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, 2011.

Passed the House of Representatives the 4th day of May, 2011.

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Presiding Officer of the House of Representatives

Passed the Senate the 26th day of April, 2011.

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Presiding Officer of the Senate

OFFICE OF THE GOVERNOR

Received by the Governor this_____

day of _____, 20____,

at_____ o'clock _____M.

_____

By: _____

Approved by the Governor of the State of Oklahoma the_____day of

_____, 20____, at_____ o'clock _____M.

_____

Governor of the State of Oklahoma

OFFICE OF THE SECRETARY OF STATE

Received by the Secretary of State this_____

_____day of_____, 20____,

at_____ o'clock _____M.

_____

By: _____