**IN THE DISTRICT COURT OF OKLAHOMA COUNTY**
**STATE OF OKLAHOMA**

| | |
|---|---|
| (1) OKLAHOMA COALITION FOR REPRODUCTIVE JUSTICE, on behalf of itself and its members; and<br>(2) NOVA HEALTH SYSTEMS, D/B/A REPRODUCTIVE SERVICES, on behalf of itself, its staff, and its patients,<br><br>Plaintiffs,<br>v.<br><br>(3) TERRY L. CLINE, in his official capacity as Oklahoma Commissioner of Health; and,<br>(4) LYLE KELSEY, in his official capacity as Executive Director of the Oklahoma State Board of Medical Licensure and Supervision,<br><br>Defendants. | Case No. _____<br><br>Judge _____ |

**VERIFIED PETITION**

Plaintiffs Oklahoma Coalition for Reproductive Justice 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

1. This is a civil rights action challenging Oklahoma House Bill 2684 ("H.B. 2684" or "the Act"), under the Constitution of the State of Oklahoma. 2014 Okla. Sess. Laws Serv. Ch. 121 (West). H.B. 2684 is scheduled to take effect November 1, 2014. The Act is attached hereto as Exhibit A.

2. The Act is an unconstitutional intrusion on women's reproductive rights that will harm women's health and well-being.

3. This lawsuit seeks to safeguard Oklahoma women's reproductive autonomy by preserving their ability to safely and effectively terminate an early pregnancy using medications alone, rather than undergoing surgery. This procedure is known as a "medication abortion." The medications most commonly used for medication abortion in the United States are mifepristone and misoprostol, which are taken in tandem according to a specific regimen.

4. The U.S. Food and Drug Administration ("FDA") approved mifepristone in 2000 (under its commercial name Mifeprex) as an effective method of terminating an early pregnancy.

5. However, medical research and physicians' clinical experiences do not stop after a medication is approved. Instead, as with other medications, the way that physicians prescribe abortion medications has continued to evolve based on new medical research and clinicians' own experiences, making medication abortion increasingly safer, more effective, able to be used later in pregnancy, more accessible, and with fewer side effects.

6. Using an FDA-approved drug in a different dosage or method of administration, or for a different purpose than that for which the manufacturer sought FDA approval, is known as "off-label" use.

7. When off-label use reflects clear, significant, generally-accepted developments in medical research, it is commonly referred to as "evidence-based" medicine. Evidence-based medicine is the gold standard of patient care.

8. The American Medical Association ("AMA") and the American College of

Obstetricians and Gynecologists ("ACOG") recognize that evidenced-based regimens for medication abortion are superior to the regimen that appears in the FDA-approved final printed labeling for mifepristone (hereinafter, the "Mifeprex regimen").

9. In 2012, the Oklahoma Supreme Court affirmed a district court decision striking down as unconstitutional a 2011 law very similar to the one challenged in this litigation. The State appealed the decision all the way to the United States Supreme Court, which initially accepted the case for review, but eventually declined review and let stand the Oklahoma Supreme Court's decision. *See Okla. Coal. for Reprod. Justice v. Cline*, No. CV-2011-1722 (Okla. Cnty. Dist. Ct. May 11, 2012), *aff'd*, 2012 OK 102, 292 P.3d 27 (affirming the district court's ruling in a memorandum opinion), *cert. granted*, 133 S. Ct. 2887 (2013), *certifying questions*, 2013 OK 93, 313 P.3d 253 (answering certified questions), *cert. dismissed as improvidently granted*, 134 S. Ct. 550 (2013), all attached hereto as Exhibits B–F.

10. H.B. 2684, like the statute restricting medication abortion that preceded it, requires physicians to ignore decades of medical research, the opinion of leading medical organizations, and their own clinical experience, and instead administer medication abortion according to the outdated and inferior Mifeprex regimen.

11. As a result, the Act will prevent some of Reproductive Services' patients from obtaining a medication abortion altogether. For others, the Act's arbitrary and burdensome restrictions will prevent them from receiving medical treatment according to current scientific evidence and advances in medicine.

12. For these reasons, the Act violates the constitutional rights of Oklahoma women to choose to terminate a pregnancy, to bodily integrity, and to equal protection under the Oklahoma Constitution.

13. In addition, the Act violates the Oklahoma Constitution's prohibition against special laws and its equal protection guarantee, and constitutes an improper delegation of legislative authority.

14. Preliminary and permanent injunctive relief is necessary to protect the constitutional rights of Plaintiffs, their patients, and their members, and the health and safety of Oklahoma women.

## II. JURISDICTION AND VENUE

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

16. 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.

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

## III. PARTIES

18. 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 need to terminate a pregnancy in Oklahoma in the future.

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

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

21. 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.

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

23. 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(A), (B)(1); OKLA. ADMIN. CODE § 310:600-7-3. He is sued in his official capacity.

24. 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, *amended by* 2014 Okla. Sess. Law Serv. Ch. 176 (H.B. 2791) (effective Nov. 1, 2014); OKLA. STAT. tit. 59, § 509. He is sued in his official capacity.

## IV. FACTUAL BACKGROUND AND LEGISLATIVE HISTORY

### A. Safety of Medication Abortion

25. Women seek abortions for a variety of medical, familial, economic, and personal reasons. Approximately one in three women in the United States will have an abortion in their lifetimes.

26. Most women having abortions (over 60%) already have at least one child, and most (66%) also plan to have children in the future—many when they are older, financially able to

provide for them, and/or in a supportive relationship with a partner so their children will have two parents.

27. Since 2000, when Mifeprex first received FDA approval, over two million women have used medication abortion to safely and effectively terminate a pregnancy in the United States.

28. Currently, and for over a decade, Oklahoma women in the first nine weeks of pregnancy, as measured from the woman's last menstrual period ("LMP") have had the option of choosing between surgical abortion and medication abortion. Both are extremely safe and effective procedures.

29. Surgical abortions are typically performed in an outpatient setting. Surgical abortion procedures are done through insertion of instruments through the vagina and into the uterus. The procedure is short in duration, typically lasting about five to ten minutes for an uncomplicated first trimester abortion. Medication abortions typically involve the use of mifepristone, which is taken by the patient at her health care facility, in conjunction with misoprostol, which is usually taken by the patient at home.

30. Over half of Plaintiff Reproductive Services' patients choose to have a medication abortion. These women choose to have a medication abortion for a variety reasons.

31. Many prefer medication abortion because it feels more natural, like a miscarriage, and/or because they can complete a medication abortion in the privacy of their homes rather than in a medical clinic, with a support person present, and at a time of their choosing.

32. Other women choose medication abortion because they fear any procedure with surgical instruments, or because they do not wish to undergo mild or moderate sedation, which may be administered in conjunction with a surgical abortion. Victims of rape or

women who have experienced sexual abuse or molestation may choose medication abortion to feel more in control of the experience and to avoid the trauma of having instruments placed in their vagina.

33. For some, medication abortion offers important clinical advantages over surgical abortion. In particular, some women have medical conditions that make medication abortion a safer option, with a lower risk of both complications and failure than a surgical abortion. These conditions, including obesity, uterine anomalies (i.e. bicornuate or double uterus, or an extremely flexed uterus), large uterine fibroids, and cervical stenosis (tightly closed uterus), make it difficult to access the pregnancy inside the uterus as part of a surgical abortion.

34. The risk of complications associated with medication abortion are comparable to the risk associated with surgical abortion. Major complications from medication abortion are extremely rare, and far rarer than those associated with pregnancy and childbirth.

**B. Safety of Evidence-Based Medication Abortion Regimens**

35. Virtually all medication abortions performed in the United States, including those performed at Reproductive Services, use an off-label, evidence-based regimen involving a lower dose of mifepristone, a different route of administration for the misoprostol, and self-administration of misoprostol by the patient rather than a physician, as compared to the Mifeprex regimen. *See Cline*, 2013 OK 93, ¶ 21, 313 P.3d at 260-61.

36. Indeed, once mifepristone was approved in 2000, the overwhelming majority of abortion providers in the United States began following evidence-based regimens in light of newer research showing that the lower dose of mifepristone (200 milligrams instead of 600) combined with a different dose and route of self-administered misoprostol was equally safe and effective, able to be used by women through at least 63 days LMP, and more convenient for patients.

37. Evidence-based medication abortion regimens have been endorsed by leading medical organizations, including ACOG and the World Health Organization, as "safer and more effective than the now-outdated [Mifeprex] regimen." *Cline*, 2013 OK 93, ¶ 21, 313 P.3d at 261. ACOG's 2014 Practice Bulletin, Medical Management of First-Trimester Abortion, recognizes evidence-based regimens as medically superior to the Mifeprex regimen.

38. Under the evidence-based regimen used by Plaintiff Reproductive Services, medication abortion patients take 200 milligrams (mg) of mifepristone at the provider's office, and approximately six to twenty-four hours later, take 800 micrograms (µg) of misoprostol at home (or another location of their choosing) by inserting the tablets vaginally or buccally (allowing the tablets to dissolve between the gum and cheek). The physicians at Reproductive Services have chosen this regimen based upon the medical literature, including recommendations from ACOG, and their own experience providing medication abortions.

39. Evidence-based regimen offers a number of other advantages as compared to the Mifeprex regimen.

40. *First*, they are effective for longer in pregnancy, allowing medication abortions to be performed up to 10 weeks (70 days) LMP, which in turn allows many more women to avail themselves of that method. Those additional weeks are significant because many women do not realize they are pregnant until close to 7 weeks (49 days) LMP, the cutoff under the Mifeprex regimen.

41. *Second*, self-administration of misoprostol eliminates an unnecessary trip to the health facility, allowing the woman greater control over the timing of the procedure. In addition, it ensures that patients will experience the bleeding and cramping that follow in a

location of their choosing, rather than in a car, at rest stop, or some other equally inappropriate and potentially dangerous location.

42. *Third*, evidence-based regimens have been shown to have a higher rate of effectiveness and require fewer surgical interventions to complete the procedure, as compared to the Mifeprex regimen.

43. *Fourth*, the lower mifepristone dosage reduces the cost of the procedure significantly.

**C. The FDA's Approval of Mifeprex for Marketing Purposes in 2000**

44. The FDA is an agency within the U.S. Department of Health and Human Services. Drug manufacturers wishing to market a new prescription drug in the United States must obtain FDA approval to do so.

45. A drug manufacturer submits to the FDA a new drug application with information about the drug's test results, 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 drug outweigh its known risks, it is approved for marketing in the United States.

46. The drug manufacturer's proposed label for the drug is called the Final Printed Label ("FPL"). The FPL contains information about a drug's indications, warnings, precautions, side effects, dosage, and method of administration.

47. The FDA's regulatory authority with respect to drugs is limited to approving new drug applications for marketing purposes; the FDA does not regulate the practice of medicine. Neither a drug's FPL nor any FDA regulations "limit the manner in which a physician may use an approved drug;" thus, physicians are free to prescribe approved drugs "for uses or in treatment regimens or patient populations that are not included in approved labeling." *Cline*, 2013 OK 93, ¶ 20, 313 P.3d at 260 (citing FDA Drug Bulletin 12:4-5,

1982).

48. In 2000, the FDA approved Mifeprex (generically known as "mifepristone" or "RU-486") for marketing purposes as an effective alternative to surgical abortion in early pregnancy. As part of that approval process, the manufacturer of Mifeprex proposed, and the FDA approved, an FPL that reflected the regimen used in the clinical trials for Mifeprex, which were completed prior to 1996 and involved fewer than 3000 women.

49. Under the protocol used in the Mifeprex clinical trials, the patient first takes 600 milligrams (mg) of mifepristone orally at her physician's office. Mifepristone works by blocking the hormone progesterone, which is necessary to maintain a pregnancy. The patient then returns to the health center 48 hours later to take 400 micrograms (μg) of misoprostol orally. Misoprostol, sometimes known by its brand name Cytotec, causes the uterus to contract and expel its contents. Approximately 14 days later, the patient returns for a follow-up visit to ensure that a complete abortion has occurred.

50. The Mifeprex clinical trials found this regimen to be safe and effective through 49 days LMP. Thus, the Mifeprex FPL reflects this regimen and this gestational age limit.

51. In approving mifepristone, the FDA did not authorize or prohibit the use of any particular regimen for administering the drug. The FDA has never required that prescribers of mifepristone follow any particular regimen and has never imposed a gestational age limit on its use. *Cline*, 2013 OK 93, ¶ 21 n.17, 313 P.3d at 261 n.17.

52. "[M]edical research and advances do not stop upon a particular drug's approval by the FDA." *Cline*, 2013 OK 93, ¶ 21, 313 P.3d at 260. Indeed, "[r]esearchers continue to perform clinical trials, doctors continue to gain experience, and widespread use of a particular treatment allows the medical community to collect data about side effects,

alternative doses, and potential new uses for treatments." *Id*. Moreover, an FDA-approved FPL does not, and is not required to, provide information about any safe and effective uses of a medication outside of the regimen for which it originally received FDA approval. Thus, a drug's FPL can often be out of date or not based on the most current scientific evidence.

53. It is standard medical practice for physicians to prescribe or dispense FDA-approved drugs in dosages and for indications that were not specifically approved or contemplated by the FDA, particularly when supported by adequate study. The FDA has repeatedly acknowledged that use of such evidence-based regimens, which vary from the drug's FPL, is common, and can be required by "[g]ood medical practice and the best interests of the patient." *Cline*, 2013 OK 93, ¶ 21, 313 P.3d at 261 (quoting U.S. Food and Drug Administration, *Regulatory Information: "Off-Label" and Investigational Use of Marketed Drugs, Biologics, and Medical Devices – Information Sheet*, available at http://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm).

### D. Oklahoma Laws Governing Abortion and Recent Restrictions on the Provision of Medication Abortion

54. The provision of abortion in Oklahoma is subject to extensive regulation by the State. Indeed, the Oklahoma Legislature has enacted over 20 restrictions that dictate when and under what conditions a woman may have an abortion.

55. For example, any facility performing first trimester abortions must be licensed as an abortion facility. OKLA. STAT. tit. 63, §§ 1-701, 1-705, 1-737; OKLA. ADMIN. CODE 310:600-3-1. Licensed abortion facilities are subject to extensive regulations addressing patient care, physician qualifications, staffing and personnel, emergency protocols, equipment and supplies, medications, laboratory testing, recordkeeping, signage, and physical plant

requirements. *See* OKLA. STAT. tit. 63, §§ 1-729.1, 1-731, 1-733, 1-737, 1-737.4, 1-744.2, 1-745.6; OKLA. ADMIN. CODE §§ 310:600 *et seq*.

56. All abortion facilities are required to undergo on-site inspections by the Department of Health, and to comply with mandatory reporting requirements regarding every abortion procedure performed at the facility. OKLA. STAT. tit. 63, §§ 1-738i, 1-738j, 1-738k, 1-738n; OKLA. ADMIN. CODE 310:600-7-1.

57. At least twenty-four (24) hours before a woman can receive an abortion, she must undergo a mandatory state-directed counseling session and receive specific information and warnings related to the procedure and her pregnancy. *See* OKLA. STAT. tit. 63, § 1-738.2.

58. Over the past several years, the Oklahoma Legislature has passed a number of restrictions on physicians' use of medications to terminate an early pregnancy.

59. In 2011, the Legislature enacted House Bill 1970 (hereinafter "H.B. 1970"), which required physicians providing or prescribing any abortion-inducing drug to do so according to the drug's FDA-approved label. *Cline*, 2013 OK 93, ¶ 16, 313 P.3d at 259.

60. Under H.B. 1970's plain language, the use of misoprostol as part of a medication abortion regimen and the use of methotrexate as a treatment for ectopic pregnancies were prohibited, since neither drug was labeled for use as an abortifacient. *Cline*, 2013 OK 93, ¶ 25, 313 P.3d at 262.

61. In October 2011, Plaintiffs OCRJ and Reproductive Services filed a lawsuit against the named Defendants in this case,[1] seeking an injunction against H.B. 1970's ban on off-label use of abortion-inducing medications.

[1] In the prior case, Plaintiffs also sued the President of the Osteopathy Board, in her official capacity.

62. Following extensive briefing and evidentiary development, the district court granted summary judgment to OCRJ and Reproductive Services and permanently enjoined H.B. 1970. *Cline*, No. CV-2011-1722, slip op. at 3. The district court determined that H.B. 1970 violated women's fundamental rights to terminate a pregnancy and to bodily integrity guaranteed by Art. II, § 7 of the Oklahoma Constitution. *Id*. at 2-3.

63. In so ruling, the court made a number of factual findings that are relevant to the constitutionality of the Act challenged here.

64. First, the court expressly rejected the State's unsubstantiated claims regarding the relative safety and efficacy of evidence-based regimens as compared to FDA-labeled regimens, finding that "[g]ood medical practice and the best interests of the patient often includes drug use that is not displayed in the FPL of that drug and requires physicians use legally available drugs according to their best knowledge and judgment." *Id*. at 2.

65. The district court further recognized that, since 2000, when mifepristone was first approved for marketing by the FDA, "a regimen different from that set forth in the FPL has been used in a great majority of cases of medication abortions in the United States [which has been] demonstrated by scientific research to be safer and more effective than the regimen provided in the RU-486 FPL." *Id.*

66. The district court concluded that H.B. 1970's "restriction of the use of the drug RU-486 or any other abortion inducing drug, medicine or other substance in the manner and to the regimen set forth in the medication FPL when used for abortion is so completely at odds with the standard that governs the practice of medicine that it can serve no purpose other than to prevent women from obtaining abortions and to punish and discriminate against those women who do." *Id.* at 2-3 (internal quotation and citation omitted).

67. The State appealed to the Oklahoma Supreme Court, which affirmed the judgment in a memorandum opinion, finding the challenged act unconstitutional under the standard set forth in *Planned Parenthood v. Casey*, 505 U.S. 833 (1992). *Cline*, 2012 OK 102, 292 P.3d 27.

68. The State petitioned the United States Supreme Court for a writ of certiorari. The United States Supreme Court granted certiorari and certified to the Oklahoma Supreme Court the following questions: "Whether H. B. No. 1970, Section 1, Chapter 216, O.S.L. 2011 prohibits: (1) the use of misoprostol to induce abortions, including the use of misoprostol in conjunction with mifepristone according to a protocol approved by the Food and Drug Administration; and (2) the use of methotrexate to treat ectopic pregnancies." *Cline*, 133 S. Ct. at 2887.

69. The Oklahoma Supreme Court answered both certified questions in the affirmative, finding that under the plain meaning of the statute, both misoprostol and methotrexate were "abortion-inducing drugs," and that their off label use was prohibited by H.B. 1970. *Cline*, 2013 OK 93, ¶¶ 10-19, 313 P.3d at 258-60.

70. In addition, the Oklahoma Supreme Court found that "FDA-approved labeling is 'not intended to limit or interfere with the practice of medicine nor to preclude physicians from using their best judgment in the interest of the patient.'" *Cline*, 2013 OK 93, ¶ 20, 313 P.3d at 260 (quoting *Weaver v. Reagan*, 886 F.2d 194, 198 (8th Cir. 1989)). The Court further found that "the FDA-approved label for mifepristone requires a dosage level no longer considered medically necessary." *Cline*, 2013 OK 93, ¶ 25, 313 P.3d at 262.

71. The Oklahoma Supreme Court also recognized that both "the American College of Obstetricians and Gynecologists and the World Health Organization have endorsed these

alternate regimens as safer and more effective than the now-outdated regimen provided for in mifepristone's FDA-approved label," and further, that "[g]ood medical practice and the best interests of the patient require that physicians use legally available drugs, biologics and devices according to the best knowledge and judgment." *Cline*, 2013 OK 93, ¶ 21, 313 P.3d at 261 (internal quotation marks and citations omitted).

72. Finally, the Oklahoma Supreme Court ratified the district court's conclusion that forcing doctors to adhere to the Mifeprex drug label regimen was "**completely at odds with the standard that governs the practice of medicine**" and therefore "serve[d] no purpose other than to prevent women from obtaining abortions and to punish and discriminate against those who do." *Cline*, 2013 OK 93, ¶ 27, 313 P.3d at 262 (emphasis in original).

73. Upon receiving the answers from the Oklahoma Supreme Court, the U.S. Supreme Court dismissed the writ of certiorari as improvidently granted, and let stand the Oklahoma Supreme Court's earlier decision striking down H.B. 1970 as unconstitutional. *Cline*, 134 S. Ct. 550 (2013).

**E. The Legislature Enacts H.B. 2684 in Response to the Oklahoma Courts**

74. Mere months after the Oklahoma Supreme Court issued its decision and the U.S. Supreme Court dismissed the State of Oklahoma's appeal, the Legislature passed H.B. 2684, once again seeking to impose medically unwarranted and burdensome requirements on the provision of medication abortion in Oklahoma.

75. The bill's sponsors, Representatives Grau and Treat, were also the co-sponsors of H.B. 1970.

76. Governor Mary Fallin signed the bill into law on April 22, 2014. The Act is scheduled to take effect on November 1, 2014.

77. Like its predecessor, H.B. 2684 restricts the use of medications for purposes of terminating a pregnancy. However, H.B. 2684 clarifies that the Act does not prohibit the off-label use of abortion-inducing drugs for the purpose of treating an ectopic pregnancy.

78. The Act defines "mifepristone" as "the first drug used in the Mifeprex regimen," and "misoprostol" as "the second drug used in the Mifeprex regimen." H.B. 2684 §§ 1(B)(5), (6). It further defines the term "Mifeprex regimen" as follows:

> "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" . . . .

H.B. 2684 § 1(B)(4).

79. The Act expressly bans the use of any off-label or evidence-based regimens:

> 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.

H.B. 2684 § 1(D) (alterations from H.B. 1970 noted with underlined and crossed-out text for additions and deletions, respectively).

80. As with H.B. 1970, "drug label" is defined as "the pamphlet accompanying an abortion-inducing drug that outlines the protocol authorized by the U.S. Food and Drug Administration (FDA) and agreed upon by the drug company applying for FDA authorization of that drug." H.B. 2684 § 1(B)(3).

81. As with H.B. 1970, physicians providing abortion-inducing drugs must tell their patients that the drugs are being used in accordance with the protocol authorized by the FDA and as outlined in the drug label, and provide a copy of the drug manufacturer's medication guide and drug label to patients. H.B. 2684 § 1(E).

82. In a manner virtually identical to H.B. 1970, the Act requires that any "abortion-inducing drug [] 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." H.B. 2684 § 1(G).

83. Like H.B. 1970, the Act subjects any physician who "knowing[ly] and reckless[ly]" fails to comply with the statute to civil liability for "actual and punitive" damages. *Compare* H.B. 1970 §§ 1(G), (H) *with* H.B. 2684 §§ 1(H), (I).

84. Likewise, failure to comply exposes a physician to disciplinary sanctions by the relevant licensing board, and exposes the licensed health care facility at which the physician practices to license suspension or revocation. H.B. 2684 § 1(H)(2); OKLA. STAT. tit. 63 § 1-706(B)(1); OKLA. STAT. tit. 59 § 503, *amended by* 2014 Okla. Sess. Law Serv. Ch. 176 (H.B. 2791) (West) (effective Nov. 1, 2014); OKLA. STAT. tit. 59 §§ 509, 509.1, 637; OKLA. ADMIN. CODE § 310:600-7-3.

### F. Aside from the Act's Prohibitions, Off-Label Use of Medications is Protected By Oklahoma Law.

85. Outside of the context of abortion, Oklahoma law "recognize[s] the importance of allowing physicians to prescribe medications based on science and their medical judgment rather than dogmatic adherence to FDA labeling." *Cline*, 2013 OK 93, ¶ 22, 313 P.3d at 261.

86. For example, physicians are required by law to administer drugs according to "good medical practice," not FDA labels, and unprofessional conduct for physicians is defined to

include:

> Prescribing, dispensing or administering of controlled substances or narcotic drugs *in excess of the amount considered good medical practice*, or prescribing, dispensing or administering controlled substances or narcotic drugs without medical need in accordance with published standards . . . .

OKLA. STAT. tit. 59, § 509(16) (emphasis added).

87. Oklahoma law also prohibits health insurers from denying coverage for drugs for cancer treatment because such off-label use has not been approved by the FDA. OKLA. STAT. tit. 63, § 1-2604.

88. The State also instructs the Medicaid Drug Utilization Review Board to create "a retrospective and prospective drug utilization review program for medical outpatient drugs to ensure that prescriptions are appropriate, medically necessary, and not likely to result in adverse medical outcomes." *Id*. § 5030.4(1).

89. The Board is instructed to focus on prescriptions that are medically appropriate and safe, giving deference to physician decision-making, rather than FDA-approved drug labeling.

**G. Enforcement of H.B. 2684 Will Harm Plaintiffs and their Patients.**

90. Reproductive Services currently provides approximately 150-250 abortions per month, on average. Over 50% of patients who obtain abortions at Reproductive Services choose a medication abortion.

91. The Act bars abortion providers from using any evidence-based regimens, which offer patients the safest and most effective option supported by medical evidence. Instead, the Act will force physicians, against their best medical judgment and the recommendations of leading medical organizations, including ACOG and the AMA, to adhere to an outdated, inferior regimen.

92. Following the FDA protocol will impose a host of burdens on Reproductive Services and on women seeking to terminate a pregnancy. As an initial matter, if the Act is permitted to take effect, Reproductive Services could be forced to stop providing medication abortions altogether, because the Act requires the clinic's physicians to follow a medication protocol that serves no valid, medical purpose and to practice medicine in a way that does not comport with the current standard of care. Reproductive Services' physicians do not want to endanger the health and safety of their patients by following the inferior Mifeprex regimen.

93. Even if Reproductive Services' physicians were able to continue providing medication abortions, the Act's restrictions will subject all patients who choose a medication abortion to an inferior and outdated regimen and impose significant and unnecessary discomfort, inconvenience, and expense.

94. Compliance with H.B. 2684 will be particularly burdensome for women who have important personal reasons for choosing a medication abortion, and dangerous for women who have physical conditions that make medication abortion a significantly safer option than surgical abortion.

95. The Act's restrictions disregard the most up-to-date medical evidence, which clearly demonstrates that medication abortions using an evidence-based regimen can be safely and effectively offered to patients up to 70 days LMP.

96. Thus, for patients who are more than 49 days LMP, the Act will prevent them from obtaining a medical abortion altogether, regardless of whether a medication abortion might be the best medical option for a particular patient.

97. In addition, requiring women to take misoprostol at the clinic forces them to undergo the expected side effects of the medication, which always include bleeding and cramping and

may also include, nausea, vomiting, diarrhea, and fever, either at the clinic or, more likely, during their journey home.

98. The additional trip required by the Act for women to receive the misoprostol at the health care facility will interfere with patients' ability to monitor their pain level, bleeding, body temperature, and possible signs of infection, and may also interfere with their ability to take medications that minimize unpleasant side effects.

99. For this reason, the vast majority of medication abortion providers, including Plaintiff Reproductive Services, follow an evidence-based regimen permitting patients to self-administer misoprostol at home or another safe place of their choosing.

100. Women who seek treatment at Reproductive Services come from across the state of Oklahoma. Approximately 30% of patients seeking an abortion at Reproductive Services in the first half of 2014 traveled more than 50 miles, or around one hour of driving time each way, to reach the clinic.

101. Compliance with the Act will mean that women who have medication abortions at Reproductive Services must visit the clinic a minimum of three times and in some cases four times to complete treatment.

102. Oklahoma law already requires women seeking an abortion to undergo a mandatory twenty-four-hour waiting period prior to the procedure. OKLA. STAT. tit. 63, § 1-738.2(B).

103. Some women who seek a medication abortion at Reproductive Services receive this mandatory counseling by telephone, which is permitted under the applicable law, but approximately half of all patients seeking a medication abortion arrive in person at the clinic seeking care, and must therefore return to the clinic twenty-four hours after their initial

visit to begin the medication regimen. The extra trip required under the Act will entail additional travel and time away from home, children, and work.

104. This additional travel will be particularly difficult for low-income women, women who live far from a major metropolitan area, women who have limited access to transportation, and women who are victims of abuse. For some, the extra trip requirement will be cost prohibitive.

105. Finally, the Act will impose an additional financial obstacle for women. Reproductive Services currently charges patients $550 for a medication abortion.

106. Each Mifeprex pill containing 200 milligrams of mifepristone costs approximately $80.

107. In order to comply with the Act, which forces patients to ingest three times as much medication as is necessary, the cost of a medication abortion would increase by a minimum of $160.

108. In addition to the adverse impact on its patients, compliance with the Act will impose logistical and financial burdens on Plaintiff Reproductive Services. The Act requires the physician to be present with the patient when she takes the second drug, misoprostol.

109. This requirement will likely necessitate opening the clinic on Saturdays to permit timely administration of the misoprostol, as well as compensating staff to assist patients on those dates. Additional costs may arise in order to ensure the presence of the same physician at both appointments where the medications are administered.

110. The vast majority of Reproductive Services' patients self-pay because they lack insurance coverage that will cover the cost of the procedure. A significant number of women who seek treatment at Reproductive Services require financial assistance to pay for

abortions. Approximately 20% of patients qualify for financial assistance from private organizations that help pay for a portion of the procedure cost; in order to qualify to receive such assistance, patients must demonstrate that their household income is at or below 100% of the Federal Poverty Guidelines.

111. As a result of the Act's requirements, far fewer women will be able to have a medication abortion, since most women who choose this option do so primarily because it can be done at home and affords them more privacy, which will no longer be the case. The additional travel, increased expense, and other burdens imposed by the Act will prevent some women from obtaining a medication abortion altogether, and delay others who must first make the necessary arrangements for payment, transportation, childcare, and time off work. Even for patients who are willing and able to make the necessary arrangements, unforeseen and uncontrollable circumstances, such as bad weather or road conditions, could impose additional delays.

112. Furthermore, because there is only a small window of time when medication abortions are performed, any delay could foreclose the option altogether for some women, including those for whom a medication abortion is medically-indicated or highly preferred for important personal reasons. Moreover, while legal abortion is an extremely safe procedure, delaying the procedure until later in pregnancy increases the risks of the procedure and the rate of complications.

## V. CLAIMS FOR RELIEF

**First Claim for Relief**
**(Substantive Due Process)**

113. The allegations of paragraphs 1 through 112 are incorporated as though fully set forth herein.

114. The Act violates women's fundamental rights to choose to terminate a pregnancy and to bodily integrity in violation of OKLA. CONST. art. II, § 7.

115. The Act violates women's fundamental rights to terminate a pregnancy and to bodily integrity in violation of OKLA. CONST. art. II, § 2.

**Second Claim for Relief**
**(Special Law)**

116. The allegations of paragraphs 1 through 115 are incorporated as though fully set forth herein.

117. 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, and physicians who treat those women.

118. 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.

**Third Claim for Relief**
**(Equal Protection)**

119. The allegations of paragraphs 1 through 118 are incorporated as though fully set forth herein.

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

**Fourth Claim for Relief**
**(Improper Delegation)**

121. The allegations of paragraphs 1 through 120 are incorporated as though fully set forth herein.

122. By requiring physicians who provide medication abortions to adhere to "the

protocol authorized" by the FDA, the Act impermissibly delegates legislative authority to a federal agency in violation of OKLA. CONST. arts. IV and V.

**Fifth Claim for Relief**
**(Declaratory Judgment – Unconstitutional and Void)**

123. The allegations of paragraphs 1 through 122 are incorporated as though fully set forth herein.

124. Because the Act violates the Oklahoma Constitution, and declaratory judgment would terminate the controversy giving rise to this proceeding, Plaintiffs request a declaration from this Court stating that the Act is unconstitutional and void. *See* OKLA. STAT. tit. 12, § 1651.

**Sixth Claim for Relief**
**(Temporary Injunction or Temporary Restraining Order)**

125. The allegations of paragraphs 1 through 124 are incorporated as though fully set forth herein.

126. Temporary injunctive relief is warranted because Plaintiffs, and those whose interests they represent, "will suffer [] irreparable injury" if the Act is allowed to take effect. *See id* § 1382.

**Seventh Claim for Relief**
**(Permanent Injunction)**

127. The allegations of paragraphs 1 through 126 are incorporated as though fully set forth herein.

128. Because the Act violates the Oklahoma Constitution, warranting a declaratory judgment stating that the Act is unconstitutional and void, Defendants should be permanently enjoined from enforcing the Act.

## VIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court:

129. Issue a declaratory judgment that H.B. 2684 violates the Oklahoma Constitution and is void and of no effect; and

130. Issue permanent injunctive relief, without bond, restraining Defendants, their employees, agents, and successors in office from enforcing H.B. 2684; and

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

Dated: _____, 2014

Respectfully submitted,

_____
J. Blake Patton, Oklahoma Bar No. 30673

WALDING & PATTON PLLC
400 N. Walker Avenue, Suite 195
Oklahoma City, OK 73102-1889
Phone: (405) 605-4440
Fax: N/A
Email: bpatton@waldingpatton.com

and

Martha M. Hardwick
Oklahoma Bar No. 3847
HARDWICK LAW OFFICE
P.O. Box 35975
Tulsa, OK 74153-0975
Phone: (918) 749-3313
Fax: (918) 742-1819
Email: mh@hardwicklawoffice.com

and

Autumn Katz*
New York Bar Registration No. 4394151
Zoe Levine*
New York Bar Registration No. 4813705
CENTER FOR REPRODUCTIVE RIGHTS
120 Wall Street, 14th Floor
New York, NY 10005-3904
Phone: (917) 637-3723
Fax: (917) 637-3666
Email: akatz@reprorights.org
zlevine@reprorights.org

**Out-of-State Attorney Applications Filed.*

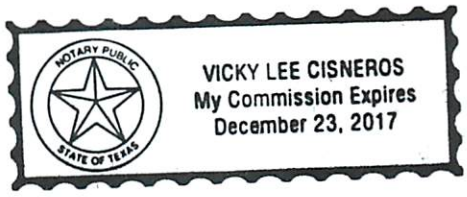
ATTORNEYS FOR PLAINTIFFS

## VERIFICATION

The undersigned represents Plaintiff Nova Health Systems d/b/a Reproductive Services. The undersigned has read the contents of the Verified Petition. The undersigned hereby verifies, under the penalty of perjury, that the contents of the Verified Petition are true and correct to the best of her present knowledge.

Marilyn Eldridge
President, Nova Health Systems d/b/a Reproductive Services

Sworn to before me this 29
day of September, 2014.




Vicky Lee Cisneros
NOTARY PUBLIC

## VERIFICATION

The undersigned represents Plaintiff Oklahoma Coalition for Reproductive Justice. The undersigned has read the contents of the Verified Petition. The undersigned hereby verifies, under the penalty of perjury, that the contents of the Verified Petition are true and correct to the best of her present knowledge.

Martha Skeeters

Martha Skeeters
President, Oklahoma Coalition for Reproductive Justice

Sworn to before me this 26
day of September, 2014.


NOTARY PUBLIC