

Stricken language would be deleted from and underlined language would be added to present law.

1 State of Arkansas  
2 90th General Assembly  
3 Regular Session, 2015  
4

*As Engrossed: H2/25/15*

# A Bill

HOUSE BILL 1394

5 By: Representatives C. Fite, Ballinger, Baltz, Bentley, Copeland, Cozart, Gates, M. Gray, Harris,  
6 Henderson, Lundstrum, D. Meeks, Payton, Petty, Rushing, B. Smith, Speaks, Sullivan, Vaught  
7 By: Senators Files, J. Hendren, Hester, Irvin, B. Johnson, Rapert

## For An Act To Be Entitled

10 AN ACT TO ESTABLISH THE ABORTION-INDUCING DRUGS  
11 SAFETY ACT; AND FOR OTHER PURPOSES.

### Subtitle

15 TO ESTABLISH THE ABORTION-INDUCING DRUGS  
16 SAFETY ACT.

19 BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF ARKANSAS:

21 SECTION 1. Arkansas Code Title 20, Chapter 16, is amended to add an  
22 additional subchapter to read as follows:

#### Subchapter 15 – Abortion-Inducing Drugs Safety Act

##### 20-16-1501. Title.

27 This Act may be known and cited as the “Abortion-Inducing Drugs Safety  
28 Act.”

##### 20-16-1502. Legislative findings and purpose.

###### (a) The General Assembly finds that:

32 (1) The United States Food and Drug Administration approved the  
33 drug mifepristone, a first-generation progesterone receptor modulator, as an  
34 abortion-inducing drug with a specific gestation, dosage, and administration  
35 protocol;

36 (2) The United States Food and Drug Administration approved



1 mifepristone under the rubric of 21 C.F.R. § 314.520, also referred to as  
2 “Subpart H,” which is the only Food and Drug Administration approval process  
3 that allows for postmarketing restrictions and provides for accelerated  
4 approval of certain drugs that are shown to be effective but "can be safely  
5 used only if distribution or use is restricted";

6 (3) The United States Food and Drug Administration does not  
7 treat Subpart H drugs in the same manner as drugs which undergo the typical  
8 approval process;

9 (4) As approved by the United States Food and Drug  
10 Administration and as outlined in the final printed labeling of mifepristone,  
11 an abortion by mifepristone consists of three (3) two-hundred (200) mg  
12 tablets of mifepristone taken orally, followed by two (2) two-hundred (200)  
13 mcg tablets of misoprostol taken orally, through forty-nine (49) days from  
14 the first day of the woman’s last menstrual period;

15 (5) The patient is to return for a follow-up visit in order to  
16 confirm that a complete termination of pregnancy has occurred;

17 (6) This United States Food and Drug Administration-approved  
18 protocol is referred to as the “Mifeprex regimen”;

19 (7) This treatment requires three (3) office visits by the  
20 patient, and the dosages may only be administered in a clinic, medical  
21 office, or hospital and under supervision of a physician;

22 (8) The final printed labeling of Mifeprex outlines the United  
23 States Food and Drug Administration-approved dosage and administration of  
24 both drugs in the Mifeprex regimen, namely mifepristone and misoprostol;

25 (9) When the United States Food and Drug Administration approved  
26 the Mifeprex regimen under Subpart H, it did so with certain restrictions  
27 such as the requirement that the distribution and use of the Mifeprex regimen  
28 must be under the supervision of a physician who has the ability to assess  
29 the duration of pregnancy, diagnose ectopic pregnancies, and provide surgical  
30 intervention or has made plans to provide surgical intervention through other  
31 qualified physicians;

32 (10) One (1) of the restrictions imposed by the United States  
33 Food and Drug Administration as part of its Subpart H approval is a written  
34 agreement that must be signed by both the physician and patient;

35 (11) In that agreement, the woman, along with the physician,  
36 attests to the following, among other statements:

1 (A) "I believe I am no more than 49 days (7 weeks)  
2 pregnant";

3 (B) "I understand that I will take misoprostol in my  
4 provider's office two days after I take Mifeprex (Day 3)"; and

5 (C) "I will do the following: return to my provider's  
6 office in 2 days (Day 3) to check if my pregnancy has ended. My provider  
7 will give me misoprostol if I am still pregnant";

8 (12) The United States Food and Drug Administration concluded  
9 that available medical data did not support the safety of home use of  
10 misoprostol, and it specifically rejected information in the Mifeprex final  
11 printed labeling on self-administering misoprostol at home;

12 (13) Court testimony in Planned Parenthood Cincinnati Region v.  
13 Taft, 459 F. Supp. 2d 626 (S.D. Oh. 2006), by Planned Parenthood and other  
14 abortion providers demonstrates that providers routinely fail to follow the  
15 United States Food and Drug Administration-approved protocol for the Mifeprex  
16 regimen, as it is outlined in the Mifeprex final printed labeling and that  
17 providers are administering a single oral dose of two-hundred (200) mg of  
18 mifepristone, followed by a single vaginal or buccal dose of eight-tenths  
19 (.8) mg misoprostol, through sixty-three (63) days of the woman's last  
20 menstrual period, without medical supervision and without follow-up care;

21 (14) The use of mifepristone presents significant medical risks  
22 to women, including without limitation abdominal pain, cramping, vomiting,  
23 headache, fatigue, uterine hemorrhage, viral infections, and pelvic  
24 inflammatory disease;

25 (15) Abortion-inducing drugs are associated with an increased  
26 risk of complications relative to surgical abortion and the risk of  
27 complications increases with advancing gestational age, and, in the instance  
28 of the Mifeprex regimen, with failure to complete the two-step dosage  
29 process;

30 (16)(A) In July 2011, the United States Food and Drug  
31 Administration reported two thousand two hundred and seven (2,207) adverse  
32 events in the United States of America after women used the Mifeprex regimen  
33 for the termination of pregnancy.

34 (B) Among those were fourteen (14) deaths, six hundred and  
35 twelve (612) hospitalizations, three hundred and thirty-nine (339) blood  
36 transfusions, and two hundred and fifty-six (256) infections, including

1 forty-eight (48) severe infections;

2 (17)(A) Off-label or so-called evidence-based use of the  
3 Mifeprex regimen may be deadly.

4 (B) To date, fourteen (14) women have reportedly died  
5 after administration of the Mifeprex regimen, with eight (8) deaths  
6 attributed to severe bacterial infection.

7 (C) All eight (8) of those women administered the regimen  
8 in an off-label or evidence-based manner advocated by abortion providers.

9 (D) The United States Food and Drug Administration has not  
10 been able to conclude whether off-label use led to the eight (8) deaths; and

11 (18) Medical evidence demonstrates that women who use abortion-  
12 inducing drugs incur more complications than those who have surgical  
13 abortions.

14 (b) Based on the findings in subsection (a), it is the purpose of this  
15 subchapter to:

16 (1) Protect women from the dangerous and potentially deadly off-  
17 label use of abortion-inducing drugs, such as, but not limited to the  
18 Mifeprex regimen; and

19 (2) Ensure that physicians abide by the protocol tested and  
20 approved by the United States Food and Drug Administration for such abortion-  
21 inducing drugs, as outlined in the drug labels.

22  
23 20-16-1503. Definitions.

24 As used in this subchapter:

25 (1)(A) "Abortion" means the act of using or prescribing any  
26 instrument, medicine, drug, or any other substance, device, or means with the  
27 intent to terminate the clinically diagnosable pregnancy of a woman, with  
28 knowledge that the termination by those means will with reasonable likelihood  
29 cause the death of the unborn child.

30 (B) An act under subdivision (1)(A) of this section is not  
31 an abortion if the act is performed with the intent to:

32 (i) Save the life or preserve the health of the  
33 unborn child;

34 (ii) Remove a dead unborn child caused by  
35 spontaneous abortion;

36 (iii) Remove an ectopic pregnancy; or

1 (iv) Treat a maternal disease or illness for which  
2 the prescribed drug is indicated;

3 (2)(A) "Abortion-inducing drug" means a medicine, drug, or any  
4 other substance prescribed or dispensed with the intent of terminating the  
5 clinically diagnosable pregnancy of a woman, with knowledge that the  
6 termination will with reasonable likelihood cause the death of the unborn  
7 child.

8 (B) "Abortion-inducing drugs" includes off-label use of  
9 drugs known to have abortion-inducing properties, which are prescribed  
10 specifically with the intent of causing an abortion, such as misoprostol,  
11 Cytotec, and methotrexate.

12 (C) This definition does not apply to drugs that may be  
13 known to cause an abortion, but which are prescribed for other medical  
14 indications such as chemotherapeutic agents or diagnostic drugs.

15 (D) Use of drugs to induce abortion is also known as a  
16 medical, drug-induced, or chemical abortion;

17 (3) "Adverse event" means an undesirable experience associated  
18 with the use of a medical product in a patient, including without limitation  
19 an event that causes:

20 (A) Death;

21 (B) Threat to life;

22 (C) Hospitalization;

23 (D) Disability or permanent damage;

24 (E) Congenital anomaly or birth defect, or both;

25 (F) Required intervention to prevent permanent impairment  
26 or damage;

27 (G) Other serious important medical events, including  
28 without limitation:

29 (i) Allergic bronchospasm requiring treatment in an  
30 emergency room;

31 (ii) Serious blood dyscrasias;

32 (iii) Seizures or convulsions that do not result in  
33 hospitalization; and

34 (iv) The development of drug dependence or drug  
35 abuse;

36 (4) "Final printed labeling" means the United States Food and

1 Drug Administration-approved informational document for an abortion-inducing  
2 drug which outlines the protocol authorized by the United States Food and  
3 Drug Administration and agreed upon by the drug company applying for United  
4 States Food and Drug Administration authorization of that drug;

5 (5) "Gestational age" means the time that has elapsed since the  
6 first day of the woman's last menstrual period;

7 (6) "Mifeprax regimen" means the abortion-inducing drug regimen  
8 that involves administration of mifepristone or the brand name "Mifeprax" and  
9 misoprostol which is the only abortion-inducing drug regimen approved by the  
10 United States Food and Drug Administration and is also known as the RU-486  
11 regimen or simply RU-486;

12 (7) "Mifepristone" means the first drug used in the Mifeprax  
13 regimen;

14 (8) "Misoprostol" means the second drug used in the Mifeprax  
15 regimen;

16 (9) "Physician" means any person licensed to practice medicine  
17 in this state including medical doctors and doctors of osteopathy; and

18 (10) "Unborn child" means the offspring of human beings from  
19 conception until birth.

20  
21 20-16-1504. Unlawful distribution of abortion-inducing drug.

22 (a)(1) It shall be unlawful to knowingly give, sell, dispense,  
23 administer, or otherwise provide or prescribe an abortion-inducing drug to a  
24 pregnant woman to induce an abortion or enabling another person to induce an  
25 abortion, unless the person who gives, sells, dispenses, administers, or  
26 otherwise provides or prescribes the abortion-inducing drug is a physician  
27 and the provision or prescription of the abortion-inducing drug satisfies the  
28 protocol authorized by the United States Food and Drug Administration, as  
29 outlined in the final printed labeling for the drug or drug regimen.

30 (2) In the case of the Mifeprax regimen, the final printed  
31 labeling for Mifeprax includes the United States Food and Drug  
32 Administration-approved dosage and administration instructions for both  
33 mifepristone and misoprostol.

34 (b) Because the failure and complication rates from medical abortion  
35 increase with advancing gestational age, because the physical symptoms of  
36 medical abortion can be identical to the symptoms of ectopic pregnancy, and

1 because abortion-inducing drugs do not treat ectopic pregnancies but rather  
2 are contraindicated in ectopic pregnancies, the physician giving, selling,  
3 dispensing, administering, or otherwise providing or prescribing the  
4 abortion-inducing drug shall first examine the woman and document in the  
5 woman's medical chart prior to giving, selling, dispensing, administering, or  
6 otherwise providing or prescribing the abortion-inducing drug the following  
7 information without limitation:

8 (1) Gestational age; and

9 (2) Intrauterine location of the pregnancy.

10 (c) Every pregnant woman to whom a physician gives, sells, dispenses,  
11 administers, or otherwise provides or prescribes any abortion-inducing drug  
12 shall be provided with a copy of the drug's label.

13 (d)(1) The physician who gives, sells, dispenses, administers, or  
14 otherwise provides or prescribes the abortion-inducing drug shall have a  
15 signed contract with a physician who agrees to handle complications and be  
16 able to produce that signed contract on demand by the patient or by the  
17 Department of Health.

18 (2) The physician who contracts to handle emergencies shall have  
19 active admitting privileges and gynecological/surgical privileges at a  
20 hospital designated to handle any emergencies associated with the use or  
21 ingestion of the abortion-inducing drug.

22 (3) Every pregnant woman to whom a physician gives, sells,  
23 dispenses, administers, or otherwise provides or prescribes any abortion-  
24 inducing drug shall receive the name and phone number of the contracted  
25 physician and the hospital at which that physician maintains admitting  
26 privileges and which can handle any emergencies.

27 (e)(1) The physician who gives, sells, dispenses, administers, or  
28 otherwise provides or prescribes any abortion-inducing drug, or an agent of  
29 the physician, shall schedule a follow-up visit for the woman for  
30 approximately fourteen (14) days after administration of the abortion-  
31 inducing drug to confirm that the pregnancy is completely terminated and to  
32 assess the degree of bleeding.

33 (2) The physician or agent of physician shall make all  
34 reasonable efforts to ensure that the woman returns for the scheduled  
35 appointment.

36 (3) A brief description of the efforts made to comply with this

1 subsection, including without limitation the date, time, and identification  
2 by name of the person making such efforts, shall be included in the woman's  
3 medical record.

4  
5 20-16-1505. Reporting.

6 (a) If a physician provides an abortion-inducing drug to another for  
7 the purpose of inducing an abortion as authorized in § 20-16-1504, and if the  
8 physician knows that the woman who uses the abortion-inducing drug for the  
9 purpose of inducing an abortion experiences an adverse event, the physician  
10 shall provide a written report of the adverse event within three (3) days of  
11 the event to the United States Food and Drug Administration via the Medwatch  
12 reporting system and to the Arkansas State Medical Board.

13 (b)(1) The board shall compile and retain all reports it receives  
14 under this section.

15 (2)(A) All reports received by the board are public records open  
16 to inspection under the Arkansas Freedom of Information Act, § 25-19-101 et  
17 seq.

18 (B) The board shall not release to any person or entity  
19 the name or any other personal identifying information regarding a person  
20 who:

21 (i) Uses an abortion-inducing drug to induce an  
22 abortion; and

23 (ii) Is the subject of a report received by the  
24 board under this section.

25  
26 20-16-1506. Criminal penalties.

27 (a) A person who intentionally, knowingly, or recklessly violates a  
28 provision of this subchapter is guilty of a Class A misdemeanor.

29 (b) A criminal penalty may not be assessed against the pregnant woman  
30 upon whom the drug-induced abortion is performed.

31  
32 20-16-1507. Civil remedies and professional sanctions.

33 (a) In addition to whatever remedies are available under the common or  
34 statutory law of this State, failure to comply with the requirements of this  
35 subchapter shall provide a basis for:

36 (1) A civil malpractice action for actual and punitive damages;

