
ABORTION-INDUCING DRUGS SAFETY ACT (RESPONSE TO WEBCAM ABORTIONS)

Model Legislation & Policy Guide
For the 2016 Legislative Year



*Accumulating Victories, Building Momentum,
Advancing a Culture of Life in America*

INTRODUCTION

The incidence of chemical abortions,¹ such as those using the Mifeprex regimen (also known as the “RU-486 regimen”), is on the rise. Abortion-inducing drugs are also being dispensed in greater amounts, from non-specialized clinics, and in a manner not approved by the U.S. Food and Drug Administration (FDA). It is imperative that states enact legislation protecting women from the abortion industry’s flagrant misuse of abortion-inducing drugs.

In a 2014 report, the pro-abortion Guttmacher Institute estimated that chemical abortions account for 23 percent of all abortions—an increase from 2008, when chemical abortions accounted for 17 percent of all abortions.²

This increase does not come as a surprise. AUL has long warned of a “chemical abortion revolution” – a marked increase in and emphasis on drug-induced abortions – because chemical abortions are easier and more profitable for abortion providers. By handing out abortion drugs to a woman and sending her on her way (often without an opportunity to seeing a physician), abortion providers are able to “serve” more women in a day.

Guttmacher’s report confirms that the promised “chemical abortion revolution” is here. Not only is the incidence of chemical abortion on the rise, but 46 percent of chemical abortions occur at non-specialized clinics. Lack of regulation has allowed chemical abortion to become a veritable “pot of gold” for Planned Parenthood and other abortion providers. Abortion providers often misuse the drugs in order to boost their profit margins.

For example, the Food and Drug Administration (FDA) approved the Mifeprex regimen to be used only in the first 49 days following a woman’s last menstrual period (LMP), at a clinic or medical facility, under the supervision of a physician, and in the following manner:

- Day One, Mifeprex Administration: Three 200 mg tablets of Mifeprex are taken in a single oral dose;
- Day Three, Misoprostol Administration: Two 200 mcg tablets of misoprostol are taken orally;

¹ “Chemical abortion” involves the ingestion of drugs in order to terminate pregnancy. It is contrasted with surgical abortion procedures (such as dilation & curettage), where the abortion provider physically removes the unborn child.

² Guttmacher Institute, *Abortion Incidence and Service Availability in the United States*, 2011 (Mar. 2014), available at <http://www.guttmacher.org/pubs/journals/psrh.46e0414.pdf> (last visited July 10, 2015).

- Day 14, Post-Treatment Examination: The patient must return to confirm that a complete termination has occurred. If not, surgical termination is recommended to manage medical abortion treatment failures.³

However, abortion providers including Planned Parenthood readily admit⁴ that they provide the Mifeprex regimen to women up to 63 days LMP and provide women with just a single oral dose of mifepristone, followed by a single dose of misoprostol which they direct women to administer vaginally or buccally instead of orally. Abortion providers even direct women to take the drugs at home and in the absence of physician oversight. No follow-up care is ensured.

This blatant misuse does not demonstrate a concern for women or their health and safety. Instead, abortion providers misuse the Mifeprex regimen because it is more convenient and more profitable for them. By providing the Mifeprex regime to women through 63 days LMP and sending them home to ingest misoprostol (the second drug) alone, abortion providers can “serve” and charge more women for abortions, increasing their profits exponentially.

The fact that Big Abortion’s agenda is dominated by financial priorities rather than concern for women’s health has been recently confirmed in Iowa, where abortion providers began using “webcam” or “telemed” services to provide the Mifeprex regimen (*i.e.*, a “webcam” or “telemed” abortion). Rather than meet with the woman personally, abortion provider Susan Haskell and Planned Parenthood of the Heartland began consulting with patients over Skype or other teleconferencing systems. Under this scheme, Haskell briefly addresses abortion patients from a teleconferencing hook-up originating from her office in Des Moines. After explaining the chemical abortion process, a button is pushed and an electronic drawer opens that contains the drugs. There is no examination, no physician-patient relationship, and no patient follow-up with a physician. However, it allows Haskell the opportunity to provide abortions to more women without ever having to meet with the women in person.⁵

Yet abortion providers misleadingly label this misuse as “evidence-based.” However, what the “evidence” actually demonstrates is that even the FDA-approved protocol carries significant risks and administering the drugs outside the FDA protocol places women at even greater risk. The drug manufacturer admits that “[n]early all of the women who receive Mifeprex and

³ See Mifeprex Final Printed Labeling (FPL), available at http://www.accessdata.fda.gov/drugsatfda_docs/label/2005/020687s013lbl.pdf (last visited July 10, 2015) (hereinafter “Mifeprex FPL”); FDA, *Mifeprex (mifepristone) Information* (July 19, 2011), available at <http://www.fda.gov/drugs/drugsafety/postmarketdrugssafetyinformationforpatientsandproviders/ucm111323.htm> (last visited July 10, 2015).

⁴ Planned Parenthood has admitted this misuse in court records in litigation in Arizona and Ohio. Other abortion providers have admitted this misuse in court records in litigation in Oklahoma.

⁵ The Iowa Board of Medicine issued regulations requiring the physical examination of a patient by the physician, but the regulations are currently in litigation.

misoprostol will report adverse reactions, and many can be expected to report more than one such reaction.”⁶ These adverse reactions include, but are not limited to, abdominal pain, cramping, vomiting, headache, fatigue, uterine hemorrhage, viral infections, and pelvic inflammatory disease.⁷

In fact, in July of 2011, the FDA reported 2,207 adverse events in the U.S. after women used the Mifeprex regimen. Among those were 14 deaths, 612 hospitalizations, 339 blood transfusions, and 256 infections (including 48 “severe infections”).⁸ Of the reported deaths, eight were from severe bacterial infection. All eight women administered misoprostol either vaginally or buccally (*i.e.*, in an off-label, unapproved manner).⁹

Further, the Mifeprex regimen is particularly dangerous because its side effects are confusingly similar to the symptoms of an ectopic pregnancy. Failing to properly diagnose an ectopic pregnancy can lead to a rupture of the fallopian tube, causing bleeding, severe pain, and even death.

By failing to follow the FDA protocol, abortion providers are clearly placing women’s health and lives at significant risk.

In order to protect women against the risks and misuse of the Mifeprex regimen, AUL has drafted the *Abortion-Inducing Drugs Safety Act*. Importantly, this model language includes a requirement that a physician actually examine a woman before providing the Mifeprex regimen, effectively precluding the use of so-called “webcam” or “telemed” abortions. For more information and drafting assistance, please contact AUL’s Legislative Coordinator at (202) 289-1478 or Legislation@AUL.org.

DENISE M. BURKE, ESQ.
Vice President of Legal Affairs
Americans United for Life

⁶ See Mifeprex FPL, *supra* (emphasis added).

⁷ *Id.* at 12 (Table 3).

⁸ FDA, *Mifepristone U.S. Postmarketing Adverse Events Summary Through 04/30/11* (July 2011), available at <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM263353.pdf> (last visited July 10, 2015).

⁹ *Id.*

ABORTION-INDUCING DRUGS SAFETY ACT

[Drafter’s Note: *AUL has drafted detailed talking points to assist those interested in introducing this model language in preparing for and countering arguments typically raised by abortion advocates. Those talking points are available upon request by contacting AUL’s Legislative Coordinator at (202) 289-1478 or Legislation@AUL.org.]*

HOUSE/SENATE BILL No. _____
By Representatives/Senators _____

Section 1. Title.

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

Section 2. Legislative Findings and Purposes.

[Drafter’s Note: *Challenges to Mifeprex regulations have demonstrated the necessity of including certain facts related to the Mifeprex regimen in order to make clear the State’s intent in enacting this model language. It is imperative to include the following findings, as well as the definitions, in the model language and/or as part of the legislative record.]*

- (a) The [Legislature] of the State of [Insert name of State] finds that:
- (1) The Food and Drug Administration (FDA) approved the drug mifepristone (brand name “Mifeprex”), a first-generation [*selective*] progesterone receptor modulator ([S]PRM), as an abortion-inducing drug with a specific gestation, dosage, and administration protocol.
 - (2) The FDA approved mifepristone (brand name “Mifeprex”) under the rubric of 21 C.F.R. § 314.520, also referred to as “Subpart H,” which is the only FDA approval process that allows for post-marketing restrictions. Specifically, the Code of Federal Regulations (CFR) provides for accelerated approval of certain drugs that are shown to be effective but “can be safely used only if distribution or use is restricted.”
 - (3) The FDA does not treat Subpart H drugs in the same manner as drugs which undergo the typical approval process.
 - (4) As approved by the FDA and as outlined in the Mifeprex final printed labeling (FPL), an abortion by mifepristone consists of three (3) two-hundred (200) mg tablets of mifepristone taken orally, followed by two (2) two-hundred (200) mcg

tablets of misoprostol taken orally, through forty-nine (49) days LMP (a gestational measurement using the first day of the woman's "last menstrual period" as a marker). The patient is to return for a follow-up visit in order to confirm that a complete termination of pregnancy has occurred. This FDA-approved protocol is referred to as the "Mifeprex regimen."

- (5) The aforementioned treatment requires three (3) office visits by the patient, and the dosages may only be administered, under the supervision of a physician, in a clinic, medical office, or hospital.
- (6) The Mifeprex FPL outlines the FDA-approved dosage and administration of both drugs in the Mifeprex regimen, namely mifepristone and misoprostol.
- (7) When the FDA approved the Mifeprex regimen under Subpart H, it did so with certain restrictions. For example, the distribution and use of the Mifeprex regimen must be under the supervision of a physician who has the ability to assess the duration of pregnancy, diagnose ectopic pregnancies, and provide surgical intervention (or has made plans to provide surgical intervention through another qualified physician).
- (8) One of the restrictions imposed by the FDA as part of its Subpart H approval is a written agreement that must be signed by both the physician and patient. In that agreement, the woman, along with the physician, attests to the following, among other statements:
 - a. "I believe I am no more than 49 days (7 weeks) pregnant";
 - b. "I understand that I will take misoprostol in my provider's office two days after I take Mifeprex (Day 3)"; and
 - c. "I will do the following... return to my provider's office in 2 days (Day 3) to check if my pregnancy has ended. My provider will give me misoprostol if I am still pregnant."
- (9) The FDA concluded that available medical data did not support the safety of home use of misoprostol, and it specifically rejected information in the Mifeprex FPL on self-administering misoprostol at home.

- (10) Court testimony by Planned Parenthood and other abortion providers demonstrates that providers routinely fail to follow the FDA-approved protocol for the Mifeprex regimen, as it is outlined in the Mifeprex FPL. *See, e.g., Planned Parenthood Cincinnati Region v. Taft*, 459 F. Supp. 2d 626 (S.D. Oh. 2006).
 - (11) Specifically, Planned Parenthood and other abortion providers are administering a single oral dose of two-hundred (200) mg of mifepristone, followed by a single vaginal or buccal dose of eight-tenths (.8) mg misoprostol, through sixty-three (63) days LMP, without medical supervision and without follow-up care. *See, e.g., Planned Parenthood Cincinnati Region*, 459 F. Supp. 2d at 630n.7.
 - (12) The use of mifepristone presents significant medical risks to women including, but not limited to, abdominal pain, cramping, vomiting, headache, fatigue, uterine hemorrhage, viral infections, and pelvic inflammatory disease.
 - (13) Abortion-inducing drugs are associated with an increased risk of complications relative to surgical abortion. The risk of complications increases with advancing gestational age, and, in the instance of the Mifeprex regimen, with failure to complete the two-step dosage process.
 - (14) In July 2011, the FDA reported 2,207 adverse events in the U.S. after women used the Mifeprex regimen for the termination of pregnancy. Among those were 14 deaths, 612 hospitalizations, 339 blood transfusions, and 256 infections (including 48 “severe infections”).
 - (15) “Off-label” or so-called “evidence-based” use of the Mifeprex regimen may be deadly. To date, 14 women have reportedly died after administration of the Mifeprex regimen, with eight deaths attributed to severe bacterial infection. All eight of those women administered the regimen in an “off-label” or “evidence-based” manner advocated by abortion providers. The FDA has not been able to determine whether off-label use led to the eight deaths.
 - (16) Medical evidence demonstrates that women who use abortion-inducing drugs incur more complications than those who have surgical abortions.
- (b) Based on the findings in subsection (a), it is the purpose of this Act to:
- (1) Protect women from the dangerous and potentially deadly off-label use of abortion-inducing drugs such as, but not limited to the Mifeprex regimen; and

- (2) Ensure that physicians abide by the protocol approved by the FDA for these abortion-inducing drugs, as outlined in the drug labels.

Section 3. Definitions.

As used in this Act only:

(a) “**Abortion**” means the act of using or prescribing any instrument, medicine, drug, or any other substance, device, or means with the intent to terminate the clinically diagnosable pregnancy of a woman, with knowledge that the termination by those means will with reasonable likelihood cause the death of the unborn child. Such use, prescription, or means is not an abortion if done with the intent to:

- (1) Save the life or preserve the health of the unborn child;
- (2) Remove a dead unborn child caused by spontaneous abortion;
- (3) Remove an ectopic pregnancy; or
- (4) Treat a maternal disease or illness for which the prescribed drug is indicated.

(b) “**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 will 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 (*e.g.*, chemotherapeutic agents, diagnostic drugs, etc.).

Use of such drugs to induce abortion is also known as “**medical [, and] drug-induced [, and/or chemical] abortion.**”

(c) “**Department**” means the Department of [*Insert appropriate title*] of the State of [*Insert name of State*].

(d) “**Final printed labeling (FPL)**” means the FDA-approved informational document for an abortion-inducing drug which outlines the protocol authorized by the FDA and agreed upon by the drug company applying for FDA authorization of that drug.

(e) “**LMP**” or “**gestational age**” means the time that has elapsed since the first day of the woman’s last menstrual period.

- (f) **“Mifeprex regimen”** means the abortion-inducing drug regimen that involves administration of mifepristone (brand name “Mifeprex”) and misoprostol. It is the only abortion-inducing drug regimen approved by the FDA. It is also known as the **“RU-486 regimen”** or simply **“RU-486.”**
- (g) **“Mifepristone”** means the first drug used in the Mifeprex regimen.
- (h) **“Misoprostol”** means the second drug used in the Mifeprex regimen.
- (i) **“Physician”** means any person licensed to practice medicine in this State. The term includes medical doctors and doctors of osteopathy.
- (j) **“Pregnant”** or **“pregnancy”** means that female reproductive condition of having an unborn child in the mother’s [*woman’s*] uterus.
- (k) **“Unborn child”** means the offspring of human beings from conception until birth.

Section 4. Unlawful Distribution of Abortion-Inducing Drug.

- (a) It shall be unlawful to knowingly give, sell, dispense, administer, or otherwise provide or prescribe any abortion-inducing drug to a pregnant woman for the purpose of inducing an abortion in that pregnant woman or enabling another person to induce an abortion in a pregnant woman, unless the person who gives, sells, dispenses, administers, or otherwise provides or prescribes the abortion-inducing drug is a physician and the provision or prescription of the abortion-inducing drug satisfies the protocol authorized by the FDA, as outlined in the final printed labeling (FPL) for the drug or drug regimen. In the case of the Mifeprex regimen, the Mifeprex label includes the FDA-approved dosage and administration instructions for both mifepristone (Mifeprex) and misoprostol.
- (b) Because the failure and complication rates from [*medical, drug-induced, or chemical*] abortion increase with advancing gestational age; because the physical symptoms of [*medical, drug-induced, or chemical*] abortion can be identical to the symptoms of ectopic pregnancy; and, because abortion-inducing drugs do not treat ectopic pregnancies but rather are contraindicated in ectopic pregnancies, the physician giving, selling, dispensing, administering, or otherwise providing or prescribing the abortion-inducing drug must 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 the abortion-inducing drug.
- (c) Every pregnant woman to whom a physician gives, sells, dispenses, administers, or otherwise provides or prescribes any abortion-inducing drug shall be provided with a copy of the drug’s label.

(d) The physician giving, selling, dispensing, administering, or otherwise providing or prescribing the abortion-inducing drug must have a signed contract with a physician who agrees to handle complications and be able to produce that signed contract on demand by the patient or by the Department. The physician who contracts to handle emergencies must have active admitting privileges and gynecological/surgical privileges at a hospital designated to handle any emergencies associated with the use or ingestion of the abortion-inducing drug. Every pregnant woman to whom a physician gives, sells, dispenses, administers, or otherwise provides or prescribes any abortion-inducing drug shall receive the name and phone number of the contracted physician and the hospital at which that physician maintains admitting privileges can handle any emergencies.

(e) The physician giving, selling, dispensing, administering, or otherwise providing or prescribing any abortion-inducing drug, or an agent of said physician, must schedule a follow-up visit for the woman at approximately fourteen (14) days after administration of the abortion-inducing drug to confirm that the pregnancy is completely terminated and to assess the degree of bleeding. Said physician or agent of physician shall make all reasonable efforts to ensure that the woman returns for the scheduled appointment. 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 woman's medical record.

Section 5. Reporting.

(a) If a physician provides an abortion-inducing drug to another for the purpose of inducing an abortion as authorized in Section 4 of this Act, and if the physician knows that the woman who uses the abortion-inducing drug for the purpose of inducing an abortion experiences (during or after the use) an adverse event, the physician shall provide a written report of the adverse event within three (3) days of the event to the FDA via the Medwatch Reporting System [*and to the State Medical Board*].

[(b) The State Medical Board shall compile and retain all reports it receives under this Section. All reports the Board receives are public records open to inspection under [Insert citation(s) to or appropriate reference(s) to applicable State code section(s) regarding public records]. In no case shall the State Medical Board release to any person or entity the name or any other personal identifying information regarding a person who uses an abortion-inducing drug for the purpose of inducing an abortion and who is the subject of a report the State Medical Board receives under this provision.]

(c) For the purposes of this Act, an "**adverse event**" shall be defined according to the FDA criteria given in the Medwatch Reporting System.

[Drafter's Note: *Inclusion of the reporting requirements is optional and may be removed without diminishing the effect of the regulation itself.*]

Section 6. Criminal Penalties.

(a) A person who intentionally, knowingly, or recklessly violates any provision of this Act is guilty of a *[Insert appropriate penalty/offense classification]*. In this Section, “**intentionally**” is defined by Section *[Insert section number or other appropriate reference]* of the *[state penal/criminal code]*.

(b) No criminal penalty may be assessed against the pregnant woman upon whom the drug-induced abortion is performed.

Section 7. Civil Remedies and Professional Sanctions.

(a) In addition to whatever remedies are available under the common or statutory law of this State, failure to comply with the requirements of this Act shall:

(1) Provide a basis for a civil malpractice action for actual and punitive damages.

(2) Provide a basis for a professional disciplinary action under *[Medical Malpractice Act]*.

(3) Provide a basis for recovery for the woman's survivors for the wrongful death of the woman under the *[Wrongful Death Act]*.

(b) No civil liability may be assessed against the pregnant woman upon whom the drug-induced abortion is performed.

(c) When requested, the court shall allow a woman to proceed using solely her initials or a pseudonym and may close any proceedings in the case and enter other protective orders to preserve the privacy of the woman upon whom the drug-induced abortion was performed.

(d) If judgment is rendered in favor of the plaintiff, the court shall also render judgment for reasonable attorney's fees in favor of the plaintiff against the defendant.

(e) If 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 reasonable attorney's fees in favor of the defendant against the plaintiff.

Section 8. Construction.

(a) Nothing in this Act shall be construed as creating or recognizing a right to abortion.

(b) It is not the intention of this Act to make lawful an abortion that is currently unlawful.

Section 9. Right of Intervention.

The [Legislature], by joint resolution, may appoint one or more of its members, who sponsored or cosponsored this Act in his or her official capacity, to intervene as a matter of right in any case in which the constitutionality of this law is challenged.

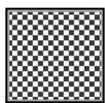
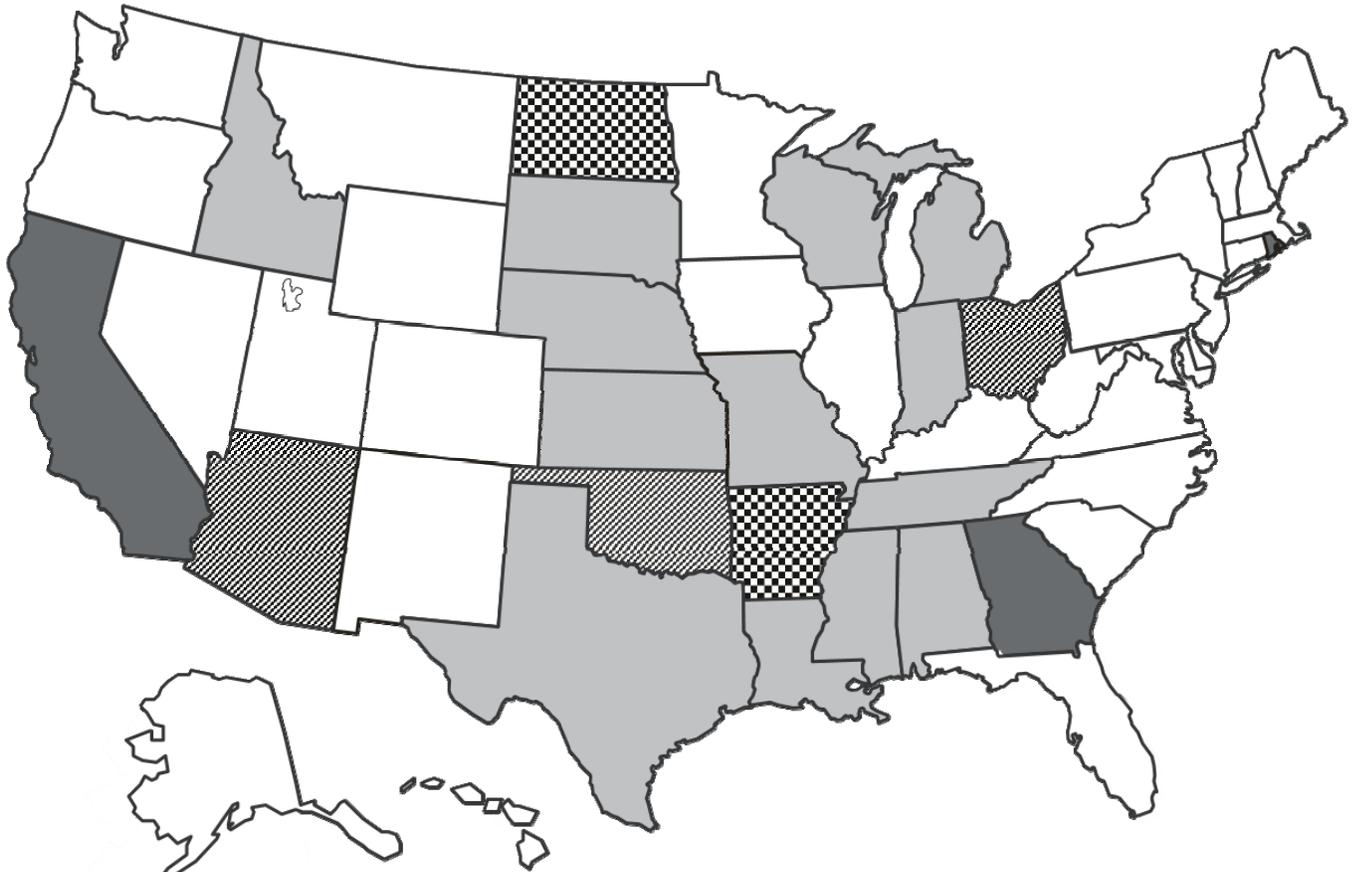
Section 10. Severability.

Any provision of this Act held to be invalid or unenforceable by its terms or as applied to any person or circumstance shall be construed so as to give it the maximum effect permitted by law, unless such holding shall be one of utter invalidity or unenforceability, in which event such provision shall be deemed severable herefrom and shall not affect the remainder hereof or the application of such provision to other persons not similarly situated or to other, dissimilar circumstances.

Section 11. Effective Date.

This Act takes effect on [Insert date].

STATE OF THE STATES: WHERE ARE WE NOW? ABORTION-INDUCING DRUGS REGULATIONS



Two states maintain comprehensive regulations of abortion-inducing drugs that limit administration to the protocol allowed by the FDA and effectively prohibit “webcam” or “telemed abortions”: AR and ND.



Three states maintain comprehensive regulations of abortion-inducing drugs that limit administration to the protocol allowed by the FDA and effectively prohibit “webcam” or “telemed abortions,” but are currently in litigation: AZ, OH (in effect during litigation), and OK.



Thirteen states maintain regulations that effectively prohibit “webcam” or “telemed abortions”: AL, ID, IN, KS, LA, MI, MS, MO, NE, SD, TN, TX, and WI.



Three states specifically impose minimal administrative regulations on the dispensing of abortion-inducing drugs: CA, GA, and RI.

More detailed information about the need and justification for laws regulating abortion-inducing drugs including RU-486 can be found in AUL's annual publication *Defending Life*.

Defending Life 2015 is available online at AUL.org.

For further information regarding this or other AUL policy guides, please contact:

AMERICANS UNITED FOR LIFE
655 15th Street NW, Suite 410
Washington DC 20005
202.289.1478 | Fax 202.289.1473 | Legislation@AUL.org

www.AUL.org

©2015 Americans United for Life

This policy guide may be copied and distributed freely as long as the content remains unchanged and Americans United for Life is referenced as the creator and owner of this content.