
The Abortion-Inducing Drug Risk Protocol

Model Legislation & Policy Guide



*Advancing the Human Right to Life
in Culture, Law, and Policy*

Introduction

Chemical abortion is a serious procedure with inherent safety risks, but despite that fact there is a reckless, all-out push for its expansion without proper safeguards. From and after the United States Food and Drug Administration's (FDA) approval of the chemical abortion drug RU-486 in September 2000, the abortion industry has blatantly ignored the sanctioned protocol for the use and distribution of this dangerous drug, often providing chemical abortion in a manner that directly conflicted with the standard of practice prescribed by the FDA. Then in December 2021, the FDA made permanent a total removal of the in-person dispensing requirement and permitted, for the first time, the abortion drug regimen (mifepristone and misoprostol) to be mailed to a woman's home for a DIY abortion, or dispensed through certified pharmacies rather than directly from certified providers.

The abortion industry used this loosening of the rules as pretext for "advance prescribing," or selling pills to a woman who is not pregnant so she can keep them for later use or give them to someone else. In October 2022, the FDA pushed back against this dangerous practice, calling it an "unauthorized use", and raising concerns about the lack of screening or oversight which places women at even higher risk of complications.

Further, RU-486 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 which may cause bleeding, severe pain, and even death. The drug manufacturer even admits that "[n]early all of the women who receive [RU-486] will report adverse reactions, and many can be expected to report more than one such reaction."¹ These adverse reactions include, but are not limited to, abdominal pain, cramping, vomiting, headache, fatigue, uterine hemorrhage, viral infections, and pelvic inflammatory disease.²

In fact, in July 2011, the FDA reported 2,207 adverse events after women used RU-486. Among those were 14 deaths, 612 hospitalizations, 339 blood transfusions, and 256 infections (including 48 "severe infections").³ Of the reported deaths, eight were from severe bacterial infections. All eight women administered misoprostol (the second drug in the

¹ See Mifeprex (RU-486) Final Printed Labeling (FPL), http://www.accessdata.fda.gov/drugsatfda_docs/label/2005/020687s013lbl.pdf (last visited August 31, 2017); FDA, Mifeprex (mifepristone) Information (July 19, 2011), <http://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm111323.htm> (last visited August 31, 2017).

² *Id.* at 12 (Table 3).

³ FDA, *Mifepristone U.S. Postmarketing Adverse Events Summary Through 04/30/11* (July 2011), <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM263353.pdf> (last visited August 31, 2017).

chemical abortion regimen) in an off-label, unapproved manner—alarmingly now the same regimen used in the current FDA protocol.⁴

Such an 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 such abortions are easier for abortion providers and more profitable. By dispensing abortion drugs to a woman by mail or at a clinic without a physical exam (often without an opportunity to see a physician), abortion providers are able to dispense (and charge) the drugs to more women in a day. The abortion industry has increasingly relied on drug-induced abortions. Surveys document that drug-induced abortions account for an increasing percentage of abortions performed in the United States each year. In a 2014 report, the pro-abortion Guttmacher Institute estimated that drug-induced abortions accounted for 23 percent of all abortions that year—an increase from 2008, when they accounted for 17 percent of all abortions.⁵ Given that many abortion providers quickly announced an expansion of their abortion drug businesses in response to the FDA’s lowered standard of care, the annual percentage of drug-induced abortions will only continue to increase. In fact, data from Guttmacher Institute shows that in 2020, 53 percent of all abortions performed were chemical abortions.⁶

In response to *Dobbs*, the Biden administration has gone on the attack against states that seek to utilize their authority to limit abortion. In an August 2022 report, the U.S. Department of Health and Human Services (HHS) laid out an action plan utilizing the full force and multiple agencies of the federal government to push abortion, especially abortion-inducing drugs, onto the states, threatening the loss of federal funds and other leverage. This plan includes guidance to roughly 60,000 U.S. retail pharmacies, asserting the authority of the FDA, indefensible threats to emergency rooms, threatening to invoke civil rights laws against health care providers who oppose abortion based on moral, ethical, or religious grounds, and much more. However, most of the items in the HHS report are ‘paper tigers’ that states should push back against, as Texas and Idaho have already done in federal courts.

Additionally, in July 2022, the Biden Administration’s Department of Education published a proposed rule that would redefine “discrimination on the basis of sex” in Title IX to include “termination of pregnancy.” This would mean that any school receiving federal funding could be forced to make chemical abortion drugs available to its students or else forfeit those

⁴ *Id.*

⁵ Guttmacher Institute, *Abortion Incidence and Service Availability in the United States*, 2011 (Mar. 2014), <http://www.guttmacher.org/pubs/journals/psrh.46e0414.pdf> (last visited August 31, 2017).

⁶ Guttmacher Institute, *Medication Abortion Now Accounts for More Than Half of All US Abortions* (Feb. 2022), <https://www.guttmacher.org/article/2022/02/medication-abortion-now-accounts-more-half-all-us-abortions> (last visited Dec. 15, 2022).

federal funds. The Department of Education would thereby circumvent any life-protecting laws the states in which these schools operate may have. If this report and proposed rule are any indication of the passion that the Biden administration has for pushing abortion, states should take note and immediately pass the health and safety protections contained in this model bill.

It is clear the States can no longer rely on the FDA to regulate chemical abortions. Thus, lawmakers must incorporate safeguards into state law to protect women from this dangerous overreach. The Supreme Court made it clear in *Dobbs* that states may regulate, or even prohibit, abortion throughout pregnancy, *regardless of the method*, for many legitimate reasons including respecting human life, ensuring women and girls receive appropriate medical care, and preventing the degradation of the medical profession.

Even states that have enforceable gestational protections throughout pregnancy—meaning there are virtually no legal abortions happening—need to collect public health data from emergency rooms and have strong enforcement provisions to seek justice against lawbreakers. In states with exceptions for rape and incest, women still deserve information, options, and safeguards when they seek abortion under the exception. Abortion is never the best, or only, option.

It is imperative that states enact legislation protecting women from the abortion industry's systematic misuse of RU-486 and other abortion-inducing drugs. It is vital that states ensure that women are fully informed about the inherent health risks of drug-induced abortions, are given accurate information about their unborn child's development, are aware of alternatives to abortion, and are told of the potential to reverse drug-induced abortions. States must enact specific reporting requirements for drug-induced abortions and their complications to facilitate more extensive medical research into and study of these risky drugs.

In order to better protect women against the risks and misuse of abortion-inducing drugs, Americans United for Life collaborated with other pro-Life groups to offer model state legislation to codify longstanding health and safety protections, with a special focus on preventing the use of mail-order abortion. This coalition includes Susan B. Anthony Pro-Life America, Christian Medical & Dental Associations, Family Policy Alliance, Heartbeat International, Students for Life Action, Abortion Pill Reversal, and Lozier Institute. The *Abortion-Inducing Drug Risk Protocol* offers a regulatory framework to certify and track the dispensing of abortion-inducing drugs in the state, including tracking medical complications like sepsis and emergency surgery.

This model will provide strong and much-needed oversight over the negligent and profit-seeking abortion drug industry in your state. For more information or drafting assistance, please contact AUL at Legislation@aul.org.

THE ABORTION-INDUCING DRUG RISK PROTOCOL

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

Section 1. Title. The [State Name] Abortion-Inducing Drug Risk Protocol

[Drafter's Note: We encourage states to incorporate existing findings, definitions, and provisions that mirror this bill when they are relevant and comprehensive to address today's threats. The post-Dobbs landscape provides an opportunity to evaluate and modernize laws.]

Section 2. Legislative Findings and Purposes.

(a) The [Legislature] of the State of [Insert name of State] finds that:

- (1) In September 2000, the Food and Drug Administration (FDA) approved the distribution and use of mifepristone (brand name Mifeprex), originally referred to as "RU-486", an abortion-inducing drug, under the authority 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."
- (2) The FDA does not treat Subpart H drugs in the same manner as drugs which undergo the typical approval process, giving them heightened scrutiny after approval.
- (3) In September 2000, the FDA prescribed a specific gestation (49 days LMP), dosage, and administration protocol for Mifeprex/mifepristone.
- (4) The approved FDA protocol for Mifeprex/mifepristone was modified in March 2016 and December 2021 yet maintains that certain distribution restrictions are still necessary because of the drug's potential for serious complications.
- (5) As approved by the FDA, the 2016 administration protocol consists of Mifeprex/mifepristone (one 200 mg tablet in a single oral dose), followed by misoprostol (four 200 mcg tablets) taken 24 to 48 hours later buccally (in the cheek pouch), through seventy (70) days LMP. The patient is to return for a follow-up visit to confirm that a complete abortion has occurred (7 to 14 days after administration of the abortion-inducing drug).

- (6) The 2016 FDA protocol also required that the distribution and use of Mifeprex/mifepristone be under the supervision of a qualified healthcare provider who can assess the duration of pregnancy, diagnose ectopic pregnancies, and provide surgical intervention (or has made plans to provide surgical intervention through another qualified physician).
- (7) On December 16, 2021, the FDA announced that it would no longer require an in-person medical examination and allow the drugs to be mailed to the patient, meaning that for the first time, pharmacies may fill prescriptions for abortion-inducing drugs if they are certified to do so by the manufacturers per FDA guidelines.
- (8) In October 2022, the FDA pushed back against “advanced prescribing,” or selling pills to a man or woman who is not pregnant, calling it an “unauthorized use” and raising concerns about the lack of screening or oversight which places women at even higher risk of complications.
- (9) The use of Mifeprex/mifepristone presents significant medical risks including, but not limited to, uterine hemorrhage, viral infections, abdominal pain, cramping, vomiting, headache, fatigue, and pelvic inflammatory disease.
- (10) A study of 423,000 abortions funded by state tax dollars through Medicaid programs found that chemical abortions were 53% more likely than surgical abortions to result in an abortion-related emergency room visit within 30 days of the abortion, and that the rate of chemical abortion-related ER visits increased over 500% from 2002-2015. The study also found that by 2015, more than 60% of chemical abortion-related ER visits were miscoded as miscarriages.
- (11) A follow-up study found that among women admitted to the hospital following an emergency room visit, women whose chemical abortions were miscoded were twice as likely to be admitted for surgery to complete the abortion and significantly more likely to require multiple hospitalizations.
- (12) If the woman is Rh negative and does not receive an injection of RH immunoglobulin at the time of the abortion, she may experience Rh incompatibility in future pregnancies, which can lead to complications and miscarriage. Therefore, it is critical for a qualified physician to determine blood type and administer Rh immunoglobulin if a woman is Rh negative.
- (13) The risk of complications increases with advancing gestational age and with the failure to either complete the two-step dosage process for the Mifeprex/mifepristone regimen or to receive abortion pill reversal care from a qualified healthcare professional.
- (14) Studies document that increased rates of complications (including incomplete abortion) occur even within the FDA-approved gestational limit.

- (15) As of March 2020, the FDA reported 4,480 adverse events after women used Mifeprex/mifepristone for abortions (Mifeprex/mifepristone --- outcome: abortion/abortion induced). Among these events were 1,183 hospitalizations, 339 blood transfusions, and 256 infections (including 48 “severe infections”).
- (16) The Adverse Event Reports (AER) systems relied upon by the FDA have limitations and typically detect only a small proportion of events that actually occur.
- (17) As of March 2020, 27 women have reportedly died after administration of Mifeprex/mifepristone, with six deaths attributed to severe bacterial infections. Eight of those women administered the Mifeprex/mifepristone regimen in an “off-label” or “evidence-based” manner then-advocated by abortion providers (only found four “off label use” deaths – not linked to the bacterial infection deaths). The FDA has not been able to determine whether this off-label use led to the deaths.
- (18) Medical evidence demonstrates that women who use abortion-inducing drugs risk four times more complications than those who undergo surgical abortions. At least 3-8% of chemical abortions fail to evacuate the pregnancy tissue and require surgical completion. One percent will fail to kill the fetus. If surgical completion is required after a failed chemical abortion, the risk of premature delivery in a subsequent pregnancy is more than three times higher. Failure rates increase as gestational age increases. The gestational age range of 63-70 days has been inadequately studied. The 2016 FDA gestational age extension was based on only one study worldwide of little more than three hundred women.
- (19) After enacting a new abortion complication reporting law in 2019, Arkansas found that of the forty-five complications reported in 2020, forty of them, or 88%, resulted from chemical abortions. In 2021, although chemical abortions decreased by 31% (to 38% of in-state abortions that year), they still represented 74% of total reported abortion complications.
- (20) One study reviewing abortion-related deaths found that the most common cause of death related to chemical abortion before 13 weeks’ gestation is infection. Beyond 13 weeks’ gestation, the most common causes of death are hemorrhage and infection.
- (21) Women traveling out of state for chemical abortions may experience complications that will be treated in their home state. In Missouri in 2019, due to women obtaining abortions in other states, far more chemical abortion-related complications were reported than the total number of chemical abortions occurring in Missouri.
- (22) A woman’s ability to provide informed consent depends on the extent to which the woman receives information sufficient to make an informed choice.
- (23) The decision to abort “is an important, and often a stressful one, and it is desirable and imperative that it be made with full knowledge of its nature and consequences.” *Planned Parenthood v. Danforth*, 428 U.S. 52, 67 (1976).

- (24) Some women come to regret their decision to abort shortly after ingesting Mifeprex/mifepristone, the first drug in the chemical abortion regimen.
- (25) In recent years, physicians have developed a method to potentially reverse the effects of Mifeprex/mifepristone. This abortion pill reversal (or “rescue”) process, which has been discussed in a peer-reviewed study and is based on decades of the safe use of progesterone to stabilize and continue pregnancies.
- (26) Understanding the science behind the mechanism of action of Mifeprex/mifepristone has allowed physicians to design a specific “rescue” for a woman who has used Mifeprex/mifepristone to induce an abortion but has not yet ingested the second drug in the chemical abortion regimen. Since physicians know exactly how Mifeprex/mifepristone works (*i.e.*, by blocking progesterone, a hormone naturally created by the pregnant woman’s body), physicians know that treating a woman with progesterone can “kick off” the Mifeprex/mifepristone (*i.e.*, displace Mifeprex/mifepristone from the progesterone receptors). This allows the woman's body to respond naturally to the progesterone and to effectively fight the effects of the Mifeprex/mifepristone-induced blockage.
- (27) It has long been known that mifepristone acts reversibly at the molecular level of receptor binding. Progesterone and mifepristone compete for the binding site of the receptor, making the antiprogestosterone activity of mifepristone reversible.
- (28) In short, Mifeprex/mifepristone floods the progesterone receptors (thus, blocking progesterone). To block or “reverse” the effects of the Mifeprex/mifepristone, a pregnant woman is prescribed additional progesterone to outcompete and outnumber the mifepristone and restore adequate progesterone in her body to sustain the pregnancy.
- (29) Progesterone itself has been used safely in pregnancies for decades. It is used in *in vitro* fertilization, infertility treatments, and high-risk pregnancies (such as those experiencing pre-term labor). Using progesterone to reverse the effects of Mifeprex/mifepristone is a targeted response that is safe for the woman.
- (30) Statistics show that, as of January 2022, more than 3,000 lives have been saved following this reversal process and that babies born following this reversal process have a rate of birth defects no higher than the general population.
- (31) Studies show that following this reversal process or otherwise treating a woman with progesterone during pregnancy does not lead to increased mortality rates.
- (32) To facilitate reliable scientific studies and research on the safety and efficacy of abortion-inducing drugs, it is essential that the medical and public health communities have access to accurate information both on the efficacy and use of abortion-inducing drugs, as well as on resulting complications.

(33) Abortion “record keeping and reporting provisions that are reasonably directed to the preservation of maternal health and that properly respect a patient’s confidentiality and privacy are permissible.” *Planned Parenthood v. Danforth*, 428 U.S. 80 at 52, 79-81 (1976).

(34) The Supreme Court of the United States has explicitly permitted abortion and complication reporting provisions for three decades, most recently in *Dobbs v. Jackson Women’s Health Org.*, 597 U.S. __ (2022). Specifically, “[t]he collection of information with respect to actual patients is a vital element of medical research. . .” *Planned Parenthood v. Casey*, 505 U.S. 833 at 900-901 (1992).

(35) To promote its interest in maternal health and life:

(a) The State maintains an interest in:

1. Collecting certain demographic information on all drug-induced abortions performed _____ in _____ the State;
2. Collecting information on all abortion complications from all drug-induced abortions diagnosed or treated in the State; and
3. Compiling statistical reports based on abortion complication information collected pursuant to this Act for future scientific studies and public health research.

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

1. Protect the health and welfare of every woman considering a drug-induced abortion;
2. Ensure that a physician examines a woman prior to dispensing an abortion-inducing drug in order to confirm the gestational age of the unborn child prior to administering the abortion inducing drug, the intrauterine location of the unborn child, and that the unborn child is alive, since administration of Mifeprex/mifepristone following spontaneous miscarriage exposes the woman to unnecessary risks associated with both Mifeprex/mifepristone and misoprostol if not medically indicated;
3. Ensure that a physician does not prescribe or dispense an abortion-inducing drug beyond 70 days’ gestation;
4. Reduce “the risk that a woman may elect an abortion, only to discover later, with devastating psychological consequences, that her decision was not fully informed.” *Planned Parenthood v. Casey*, 505 U.S. 833, 882 (1992);

5. Ensure that women considering a drug-induced abortion receives comprehensive information on abortion-inducing drugs, including the potential to reverse the effects of the drugs should she change her mind, and that women submitting to an abortion do so only after giving voluntary and fully informed consent to the procedure; and
6. Promote the health and safety of women, by adding to the sum of medical and public health knowledge through the compilation of relevant data on drug-induced abortions performed in the State, as well as on all medical complications and maternal deaths resulting from these abortions.

Section 3. Definitions.

As used in this Act:

(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 a clinically diagnosable pregnancy, with knowledge that the termination by those means will with reasonable likelihood cause the death of the unborn child, or the act of prescribing an abortion-inducing drug with reasonable certainty that the drug will prevent growth or implantation, or otherwise cause the death of an unborn child, if ingested prior to confirmation of a clinically diagnosed pregnancy (i.e. “missed period pills”).

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 medically 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 the off-label use of drugs known to have abortion-inducing properties, which are prescribed specifically with the intent of causing an abortion, such as mifepristone (Mifeprex), misoprostol (Cytotec), and methotrexate. This definition includes the off-label use of drugs known to have abortion-inducing properties, which are prescribed without a diagnosed pregnancy (sometimes called “pre-prescribing” or “advanced prescribing”) for the purpose of causing an abortion at some future date rather than contemporaneously with a clinically diagnosed pregnancy. 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.).

The use of such drugs to induce abortion is also known as “medical,” “medication,” “RU-486,” “chemical,” “Mifeprex regimen,” “missed period pill,” “Plan C,” or “drug-induced” abortion.

(c) **“Adverse Event”** according to the U.S. Food and Drug Administration, means any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related. It does not include an adverse event or suspected adverse reaction that, had it occurred in a more severe form, might have caused death (21 CFR 312.32).

(d) **“Associated Physician”** means a person licensed to practice medicine in the state, including medical doctors and doctors of osteopathy, who has entered into a “Associated Physician Agreement.”

(e) **“Complication”** or **“Abortion Complication”** means only the following physical or psychological conditions which, in the reasonable medical judgment of a licensed healthcare professional, arise as a primary or secondary result of an induced abortion: uterine perforation, cervical laceration, infection, bleeding, vaginal bleeding that qualifies as a Grade 2 or higher adverse event according to the Common Terminology Criteria for Adverse Events (CTCAE), pulmonary embolism, deep vein thrombosis, failure to actually terminate the pregnancy, incomplete abortion (retained tissue), pelvic inflammatory disease, endometritis, missed ectopic pregnancy, cardiac arrest, respiratory arrest, renal failure, shock, amniotic fluid embolism, coma, free fluid in the abdomen, allergic reactions to anesthesia and abortion-inducing-drugs, psychological complications as diagnosed that are listed in the current Diagnostic and Statistical Manual (DSM) and any related complication arising under the following ICD 10 codes: O04.2, O04.5, O04.6, O04.7, O04.80, O04.81, O04.82, O04.84, O04.86, O04.87, O04.88, O07.0, O07.1, O07.2, O07.34, O07.38.

(f) **“Department”** means the Department of [Appropriate State Agency] of the State of [Name of State].

(g) **“Hospital”** means an institution providing medical and surgical treatment and nursing care for sick or injured people, and/or institutions defined under [*Insert applicable state codes defining hospital(s)*].

(h) **“Facility”** means any public or private hospital, clinic, center, medical school, medical training institution, healthcare business, physician’s office, infirmary, dispensary, ambulatory surgical center, or other institution or location or business wherein medical care or pharmaceuticals are provided to any person.

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

(j) **“Physician”** means any person licensed to practice medicine in this State. The term includes medical doctors and doctors of osteopathy.

(k) **“Pregnant”** or **“pregnancy”** means that female reproductive condition of having an unborn child in the uterus.

(l) **“Provide”** means, when used regarding abortion-inducing drugs, any act of giving, selling, dispensing, administering, transferring possession to or otherwise providing or prescribing an abortion-inducing drug.

(m) **“Qualified physician”** means a physician licensed in this State who has the ability to:

1. identify and document a viable intrauterine pregnancy,
2. assess the gestational age of pregnancy and to inform the patient of gestational age-specific risks,
3. diagnose ectopic pregnancy,
4. determine blood type and administer RhoGAM if a woman is Rh negative,
5. assess for signs of domestic abuse, reproductive control, human trafficking, and other signals of coerced abortion,
6. provide surgical intervention or has entered into a contract with another qualified physician to provide surgical intervention, and
7. supervise and bear legal responsibility for any agent, employee, or contractor who is participating in any part of procedure, including but not limited to, pre-procedure evaluation and care.

(n) **“Unborn child”** means an individual organism of the species homo sapiens, beginning at fertilization, until the point of being born-alive as defined in section 8(b) of Title 1, U.S. Code.

Section 4. In-person Requirement.

Abortion-inducing drugs shall only be provided in-person by a qualified physician following procedures laid out in this Bill. It shall be unlawful for any manufacturer, supplier, pharmacy, physician, qualified physician, or any other person to provide any abortion-inducing drug via courier, delivery, or mail service.

Section 5. Distribution of Abortion-Inducing Drugs.

(a) Because the failure and complication rates from a chemical abortion increase with advancing gestational age; because the physical symptoms of 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 qualified physician providing an abortion-inducing drug must examine the woman in person, and prior to providing an abortion-inducing drug, must:

1. independently verify that a pregnancy exists,
2. determine the woman’s blood type, and if she is Rh negative, be able to and offer to administer RhoGAM at the time of the abortion,
3. provide any other medically indicated diagnostic tests such as iron or hemoglobin/hematocrit (H/H test) to determine if the woman has heightened risks of complications,

4. screen the woman for coercion, abuse, and anxiety, and refer her to the appropriate healthcare professional for treatment consistent with the screening results,
5. inform the patient that she may see the remains or her unborn child in the process of completing the abortion,
6. follow all informed consent practices required by this code and as required by [State], and
7. document, in the woman's medical chart, the gestational age and intrauterine location of the pregnancy, and whether she received treatment for Rh negativity or any other diagnostic tests, as diagnosed by the most accurate standard of medical care.

(b) A qualified physician providing an abortion-inducing drug must be credentialed and competent to manage complications, including emergency transfer, or must have a signed contract with an associated physician who is credentialed to handle complications and be able to produce that signed contract on demand by the pregnant woman or by the Department. Every pregnant woman to whom a qualified physician provides any abortion-inducing drug shall be given the name and phone number of the associated physician.

(c) The qualified physician providing any abortion-inducing drug, or an agent of the qualified physician, shall schedule a follow-up visit for the woman at approximately seven (7) to 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. The qualified 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 6. Prohibition on State Funding of Abortion-Inducing Drugs at Public Schools, Colleges, and Universities.

Abortion-inducing drugs shall not be provided on state grounds, or in any school building, including but not limited to, elementary, secondary, and institutions of higher education in [State], nor may funds appropriated to or collected by a public educational institution be spent to perform, refer for, or reimburse travel expenses for any abortion.

Section 7. Informed Consent Requirements for Abortion-Inducing Drugs.

(a) No abortion-inducing drug shall be provided without the informed consent of the pregnant woman as described in this section to whom the abortion-inducing drug is provided.

(b) Informed consent to a chemical abortion must be obtained at least [*twenty-four (24) or insert existing state law requirement*] hours before abortion-inducing drug are provided to the pregnant woman, except if in reasonable medical judgment, compliance with this

subsection would pose a greater risk of the death or substantial and irreversible physical impairment of a major bodily function, not including psychological or emotional conditions of the pregnant woman.

(c) A “consent form” created by the Department shall be used by a qualified physician to obtain the consent required prior to providing an abortion-inducing drug.

(d) A consent form is not valid, and consent is not sufficient unless:

1. The patient initials each entry, list, description, or declaration required to be on the consent form (as detailed in subsections (e)(1) through (e)(10) of this Section);
2. The patient signs the “acknowledgement of risks and consent statement” described in subsection (e)(6) of this Section; and
3. The qualified physician signs the “qualified physician declaration” described in subsection (g)(7) of this Section.

(e) The consent form shall include, but is not limited to, the following:

1. The probable gestational age of the unborn child as determined by both patient history and by ultrasound results used to confirm gestational age;
2. A detailed description of the steps to complete the chemical abortion;
3. A detailed list of the risks related to the specific abortion-inducing drug or drugs to be used including, but not limited to hemorrhage (heavy bleeding); failure to remove all tissue of the unborn child which may require an additional procedure; sepsis; sterility; and possible continuation of pregnancy;
4. Information about Rh incompatibility, including that if she has an Rh-negative blood type, she should receive an injection of Rh immunoglobulin (brand name RhoGAM) at the time of the abortion to prevent Rh incompatibility in future pregnancies, which can lead to complications and miscarriage in future pregnancies;
5. That the risks of complications from a chemical abortion, including incomplete abortion, increase with advancing gestational age, and that infection and hemorrhage are the most common causes of deaths related to chemical abortions
6. That it may be possible to reverse the effects of the chemical abortion should she change her mind, but that time is of the essence;
7. That she may see the remains or her unborn child in the process of completing the abortion;
8. That initial studies suggest that children born after reversing the effects of Mifeprex/mifepristone have no greater risk of birth defects than the general population;

9. That initial studies suggest that there is no increased risk of maternal mortality after reversing the effects of Mifeprex/mifepristone;
10. That information on and assistance with reversing the effects of abortion-inducing drugs are available in the state-prepared materials; and

(f) An “acknowledgment of risks and consent statement” which must be signed by the patient. The statement must include, but is not limited to the following declarations, which must be individually initialed by the patient:

1. That the patient understands that the abortion-inducing drug regimen or procedure is intended to end her pregnancy and will result in the death of her unborn child;
2. That the patient is not being forced to have an abortion, that she has the choice not to have the abortion, and that she may withdraw her consent to the abortion-inducing drug regimen even after she has begun the abortion-inducing drug regimen;
3. That the patient understands that the chemical abortion regimen or procedure to be used has specific risks and may result in specific complications;
4. That the patient has been given the opportunity to ask questions about her pregnancy, the development of her unborn child, alternatives to abortion, the abortion-inducing drug or drugs to be used, and the risks and complications inherent to the abortion-inducing drug or drugs to be used;
5. That she was specifically told that “Information on the potential ability of qualified medical professionals to reverse the effects of an abortion obtained through the use of abortion-inducing drugs is available at www.abortionpillreversal.com, or you can contact (877) 558-0333 for assistance in locating a medical professional that can aid in the reversal of an abortion.”
6. That she has been provided access to state-prepared, printed materials on informed consent for abortion [*and*] the state-prepared and maintained website on informed consent for abortion [*and the state-prepared informational DVD on informed consent for abortion, if applicable*], [and any other resources made available by the state, including adoption or parenting support, ability to obtain child support, etc.].
7. If applicable, that she has been given the name and phone number of the associated physician who has agreed to provide medical care and treatment in the event of complications associated with the abortion-inducing drug regimen or procedure;
8. That the qualified physician will schedule an in-person follow-up visit for the patient at approximately seven (7) to fourteen (14) days after providing the abortion-inducing drug or drugs to confirm that the pregnancy is completely terminated and to assess the degree of bleeding and other complications;

9. That the patient has received or been given sufficient information to give her informed consent to the abortion-inducing drug regimen or procedure, and
 10. That the patient has a private right of action to sue the qualified physician under the laws of [State] if she feels that she has been coerced or misled prior to obtaining an abortion, and how to access state resources regarding her legal right to obtain relief.
 11. That she will be given a copy of the forms and materials with all signatures as required by this Act, including in Sections 7(c), 7(f), 7(g), and 8(a) to take home, as well as all other forms of informed consent required by [State].
- (g) A “qualified physician declaration,” which must be signed by the qualified physician, stating that the qualified physician has explained the abortion-inducing drug or drugs to be used, has provided all of the information required in subsections (e)(1) through (e)(10) of this Section, and has answered all of the woman’s questions.

Section 8. Information Required in State-Prepared Materials.

(a) The Department shall cause to be published in the state-prepared, printed materials on informed consent for abortion [*and*] the state-prepared and maintained website on informed consent for abortion, [*and the state-prepared informational DVD, if applicable*] required under [*Insert reference(s) to state statutes, administrative rules, or other authority related to informed consent for abortion*] the following statement:

“Information on the potential ability of qualified medical professionals to reverse the effects of an abortion obtained through the use of abortion-inducing drugs is available at www.abortionpillreversal.com, or you can contact (877) 558-0333 for assistance in locating a medical professional that can aide in the reversal of an abortion.”

(b) On an annual basis, the Department shall review and update, if necessary, the statement required in subsection (a) of this Section.

(c) As part of the informed consent counseling required in Sec. 7 of this Bill, the qualified physician will inform the pregnant woman about abortion pill reversal and provide her with the state-prepared materials and website link as proscribed by Sec. 8(a) of this Bill.

Section 9. State Public Information Campaigns.

(a) The Department of Education shall display a public awareness sign developed under (c) in every restroom in public secondary schools and institutions of higher education.

(b) Emergency rooms and emergency care facilities shall display a public awareness sign developed under (c) in waiting areas and patient facilities.

(c) The required public awareness sign must be at least 8.5 inches by 11 inches in size, must be printed in at least a 16-point type, and must state substantially the following in English and Spanish:

“Information on the potential ability of qualified medical professionals to reverse the effects of an abortion obtained through the use of abortion-inducing drugs is available at www.abortionpillreversal.com and (*state’s website*), or you can contact (877) 558-0333 for assistance in locating a medical professional that can aide in the reversal of an abortion.”

(d) The Department shall direct all hospital emergency rooms and emergency care facilities to post a sign in each patient room that is at least 8.5 inches by 11 inches in size, printed in at least 16-point type, and state substantially the following in English and Spanish:

“If you have had an abortion, including if you have taken abortion pills obtained online, please tell the doctor so your medical treatment can be as effective as possible.”

Section 10. Reporting on Abortion-Inducing Drugs and Chemical Abortions.

(a) For the purpose of promoting maternal health and adding to the sum of medical and public health knowledge through the compilation of relevant data, a report of each [*medical or drug-induced*] abortion performed shall be made to the Department on forms prescribed by it. The reports shall be completed by the hospital or other [*licensed*] facility in which the abortion-inducing drug was provided or prescribed; signed by the qualified physician who gave, sold, dispensed, administered, or otherwise provided or prescribed the abortion-inducing drug; and transmitted to the Department within fifteen (15) days after each reporting month. The Department shall update forms as needed to reflect changes to diagnostic and reimbursement coding classifications.

(b) Each report shall include, at minimum, the following information:

1. Identification of the qualified physician who provided the abortion-inducing drug;
2. Whether the chemical abortion was completed at the hospital or [*licensed*] facility in which the abortion-inducing drug was provided or at an alternative location;
3. The referring physician, agency, or service, if any;
4. The pregnant woman’s county, state, and country of residence;
5. The pregnant woman's age and race;
6. The number of previous pregnancies, number of live births, and number of previous abortions of the pregnant woman;

7. The probable gestational age of the unborn child as determined by both patient history and by ultrasound results used to confirm the gestational age, and the date of the ultrasound and gestational age determined on that date;
8. The abortion-inducing drug or drugs used, the date each was provided to the pregnant woman, and the reason for the abortion, if known;
9. Preexisting medical condition(s) of the pregnant woman which would complicate her pregnancy, if any;
10. Whether the woman returned for a follow-up examination to determine completion of the abortion procedure and to assess bleeding and the date and results of any such follow-up examination, and what reasonable efforts were made by the qualified physician to encourage that she return for a follow-up examination if she did not.
11. Whether the woman suffered any abortion complications, and what specific abortion complication(s) as defined in Section 3(e) that led to the diagnosis or treatment of abortion complications.
12. The amount billed to cover the treatment for specific complications, including whether the treatment was billed to Medicaid, private insurance, private pay, or other method. This should include ICD-10 diagnosis code(s) reported, any other treatment or procedure codes reported, charges for any physician, hospital, emergency room, prescription or other drugs, laboratory tests, and any other costs for treatment rendered.

(c) Reports required under this subsection shall not contain:

1. The name of the pregnant woman;
2. Common identifiers such as her social security number or [*motor vehicle operator's license number*]; or
3. Other information or identifiers that would make it possible to identify, in any manner or under any circumstances, a woman who has obtained or seeks to obtain a chemical abortion.

(d) If a qualified physician provides an abortion-inducing drug to a pregnant woman for the purpose of inducing an abortion as authorized in Sections 4 and 5 of this Act, and if the qualified physician knows that the woman who uses the abortion-inducing drug for the purpose of inducing an abortion experiences, during or after the use of the abortion-inducing drug, an abortion complication or an adverse event, the qualified 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 Department [*and to the State Medical Board*].

(e) Any physician, qualified physician, associated physician, or other healthcare provider who diagnoses or treats a woman, either contemporaneously to or at any time after the

procedure, for an adverse event or abortion complication subsequent to a chemical abortion shall make a report of the adverse event or complication to the Department on forms prescribed by it. The reports shall be completed by the hospital or other facility in which the adverse event or abortion complications diagnosis or treatment was provided; signed by the physician, qualified physician, or other healthcare provider who diagnosed or treated the abortion complication or adverse event; and transmitted to the Department within (15) days after each reporting month.

Each report shall include, at minimum, the following information:

1. The date the woman presented for treatment;
2. The age and race of the woman;
3. The woman's state and county of residence;
4. The number of previous pregnancies, number of live births, and number of previous abortions of the woman;
5. The date the abortion was performed, and type of abortion;
6. Identification of the physician who performed the abortion, the facility where the abortion was performed or the drug was prescribed, and the referring physician, agency, or service, if any;
7. The specific complication(s) that led to the treatment, including the following physical or psychological conditions which, in the reasonable medical judgment of a licensed healthcare professional, arise as a primary or secondary result of an induced abortion: uterine perforation, cervical laceration, infection, bleeding, vaginal bleeding that qualifies as a Grade 2 or higher adverse event according to the Common Terminology Criteria for Adverse Events (CTCAE), pulmonary embolism, deep vein thrombosis, failure to actually terminate the pregnancy, incomplete abortion (retained tissue), pelvic inflammatory disease, endometritis, missed ectopic pregnancy, cardiac arrest, respiratory arrest, renal failure, shock, amniotic fluid embolism, coma, free fluid in the abdomen, allergic reactions to anesthesia and abortion-inducing-drugs, psychological complications as diagnosed that are listed in the current Diagnostic and Statistical Manual (DSM) and any related complication arising under the following ICD 10 codes: 004.2, 004.5, 004.6, 004.7, 004.80, 004.81, 004.82, 004.84, 004.86, 004.87, 004.88, 007.0, 007.1, 007.2, 007.34, 007.38.
8. Whether the patient obtained abortion-inducing drugs via mail order or Internet website, and, if so, information identifying the name of the source, URL address, or telemedicine provider.
9. Whether the abortion was completed at the hospital or [*licensed*] facility in which the abortion-inducing drug was provided or at an alternative location;

(f) The Department shall prepare a comprehensive annual statistical report for the [*Legislature*] based upon the data gathered from reports under this Section. The aggregated data shall also be made available to the public by the Department in a downloadable format.

(g) The Department shall summarize aggregate data from the reports required under this Act and submit the data to the U.S. Centers for Disease Control and Prevention (CDC) for the purpose of inclusion in the annual Vital Statistics Report.

(h) Reports filed pursuant to this Section shall be deemed public records and shall be available to the public in accordance with the confidentiality and public records reporting laws of [State]. Original copies of all reports filed under this subsection shall be available to the [State medical board], [State Board of Pharmacy], state law enforcement offices, and child protective services for use in the performance of their official duties.

(i) Absent a valid court order or judicial subpoena, neither the Department, any other state department, agency, or office nor any employees thereof shall compare data concerning abortions or abortion complications maintained in an electronic or other information system file with data in any other electronic or other information system, the comparison of which could result in identifying, in any manner or under any circumstances, a woman obtaining or seeking to obtain a drug-induced abortion.

(j) The Department and any other state department, agency, office, or any employee or contractor thereof shall not maintain statistical information that may reveal the identity of a woman obtaining or seeking to obtain a drug-induced abortion.

(k) Original copies of all reports filed under this Section shall be available to the Department [*and the State Medical Board*] for use in the performance of its official duties.

(l) The Department shall communicate the reporting requirements in this Section to all medical professional organizations, licensed physicians, hospitals, emergency rooms, abortion facilities [*or other appropriate term such as "reproductive health center"*], Department [*of Health*] clinics, ambulatory surgical facilities, and other healthcare facilities operating in the State.

1. Any physician, including emergency medical personnel, who diagnoses or treats a woman for abortion complications or adverse event arising from an abortion, shall file a written report as required by Section 10 of this Act with the Department.
2. A physician filing a written report with the Department after diagnosing or treating a woman for abortion complications or otherwise in an emergency capacity shall make reasonable efforts to include all the required information that may be obtained without violating the privacy of the woman.
3. The reports required in section (a) shall be completed by the hospital or other [licensed] facility in which the abortion-inducing drug was given, sold, dispensed, administered, or otherwise provided or prescribed; signed by the qualified physician who gave, sold, dispensed, administered, or otherwise provided or prescribed the abortion-inducing drug; and transmitted to the Department within fifteen (15) days after each reporting month. However, if an abortion is for a female who is [*age of a minor under state law that constitutes a crime if pregnant and must be reported as child abuse*], the healthcare provider shall transmit the form in the manner prescribed by section (a) to the Department and separately to the [*appropriate state child abuse department*] within three (3) days after the abortion is performed.

Section 11. Production of Reporting Forms.

The Department shall create and distribute the forms required by this Act within sixty (60) days after the effective date of this Act. No provision of this Act requiring the reporting of information on forms published by the Department shall be applicable until ten (10) days after the requisite forms are first created and distributed or until the effective date of this Act, whichever is later.

Section 12. 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) A [person] who intentionally, knowingly, or recklessly violates any provision of this Act by fraudulent use of an abortion-inducing drug, with or without the knowledge of the pregnant woman, is guilty of a [Insert appropriate penalty/offense classification].
- (c) A [person] who intentionally or knowingly offers or provides abortion doula services, with the intent that the services will be used, or are reasonably likely to be used, for an unlawful abortion is guilty of a [Insert appropriate penalty/offense classification].
- (d) A [person] who intentionally or knowingly provides a referral to an unlawful abortion provider, with the intent that the referral will result, or is reasonably likely to result, in an unlawful abortion, regardless of whether the referrer receives compensation, is guilty of a [Insert appropriate penalty/offense classification].
- (e) A [person] who intentionally or knowingly obtains or possesses abortion-inducing drugs with the intent to deliver it to another person is guilty of a [Insert appropriate penalty/offense classification].
- (f) A non-parent or guardian [adult] who intentionally, knowingly, or recklessly transports a minor with the intent to conceal an unlawful abortion from the parent(s) and/or guardian(s) of that minor, or to procure an unlawful abortion, or to obtain abortion-inducing drugs for that minor, is guilty of a [Insert appropriate penalty/offense classification].
- (g) No criminal penalty may be assessed against the pregnant woman upon whom the drug-induced abortion is attempted, induced, or performed.

[Drafter’s Note: When determining appropriate penalty/offense classification, the state should consider mandatory minimums, extradition for violators living outside of the state,

elevated sentencing, automatic triggering of state licensing penalties, etc. Please reach out and our team can help you identify the appropriate classifications for your state.]

Section 13. Civil Remedies.

(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, and injunctive, declaratory, or any other appropriate relief;
2. Provide a basis for recovery for the woman's [insert language used in existing state law for surviving relatives] for the wrongful death of the woman under the [state's *Wrongful Death Act*].

(b) Notwithstanding any other provision of law, a woman upon whom the drug-induced abortion has been attempted, induced, or performed, or her parent or guardian if she is a minor girl at the time of the attempted or completed abortion, may bring an action under this Act at any time from the point of the alleged violation until [XX years] after the alleged violation, or from the point that harm is discovered until [XX years] after the initial discovery of harm.

[Drafter's Note: insert timeframe and language consistent with existing state laws re: criminal and civil statutes of limitations.]

(c) Notwithstanding any other provision of law, an action under this subchapter may be commenced, and relief may be granted, in a judicial proceeding without regard to whether the person commencing the action has sought or exhausted available administrative remedies;

(d) 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 attempted, induced, or performed.

(e) 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.

(f) 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 may render judgment for reasonable attorney's fees in favor of the defendant against the plaintiff.

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

Section 14. 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 provide a basis for a professional disciplinary action under [state's *Medical Malpractice Act*, state's applicable medical, nursing, or pharmacy licensure board, an existing admitting privileges or emergency transfer agreement, or any other governing body overseeing the individual's professional status in this state].

(b) No professional sanction may be assessed against the pregnant woman upon whom the drug-induced abortion is attempted, induced, or performed.

Section 15. 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 otherwise unlawful.

(c) Nothing in this Act repeals, replaces, or otherwise invalidates existing federal or [State] laws, regulations, or policies.

[Drafter's Note: If the bill explicitly *does* repeal existing law (as for states with an FDA reference), this needs to be edited to state the repealed provision.]

Section 16. Right of Intervention.

(a) 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 Act is challenged, or

(b) The [state] Attorney General may bring an action to enforce compliance with this Act or intervene as a matter of right in any case in which the constitutionality of this Act is challenged.

Section 17. 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 18. Effective Date.

This Act takes effect on *[Insert date]*.

Compiled by the Chemical Abortion National Coalition – we are here to connect you with the resources you need:



Resources and References:

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