A B O R T I O N - I N D U C I N G  D R U G S  
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Model Legislation & Policy Guide  
For the 2017 Legislative Year  

A M E R I C A N S  U N I T E D  F O R  L I F E  

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

Following the Food and Drug Administration’s (FDA) approval of the abortion drug RU-486 in September 2000, the abortion industry blatantly ignored the sanctioned protocol for the use and distribution of the dangerous drug, often providing RU-486 in a manner that directly conflicted with the standard of care prescribed by the FDA. This disregard for women’s health and safety is likely to continue – even in the wake of the newly lowered standard of care approved by the FDA in March 2016.¹

As a result, it is imperative that states enact legislation protecting women from the abortion industry’s systematic misuse of RU-486 and other abortion-inducing drugs. More than ever, it is vital that states ensure that women are fully informed about the inherent health risks of drug-induced abortions, that women are given accurate information about their unborn child’s development, that women are aware of alternatives to abortion, and that women are made aware that drug-induced abortions potentially may be reversed. Finally, states must enact specific reporting requirements for drug-induced abortions and their complications to facilitate more extensive medical research into and study of these deadly drugs.

The need for such requirements is underscored by the abortion industry’s increasing reliance on drug-induced abortions (referred to as “medical abortions” by pro-abortion advocates). Surveys document that drug-induced abortions account for an increasing percentage of abortions performed in the United States each year. For example, 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.² Given that many abortion providers quickly announced an expansion of their abortion drug businesses in response to the newly lowered standard of care, the annual percentage of drug-induced abortions will only increase.

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 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 see a physician), abortion providers are able to “serve” (and charge) more women in a day.

¹ Significant alterations to the FDA protocol that expose women at greater risks include an extension of the gestational limit from 49 days LMP to 70 days LMP, changed dosage and administration recommendations, allowing non-physicians to dispense abortion-inducing drugs, and an abandonment of the requirement that the second drug in the drug regimen be taken under the supervision of a healthcare provider.
That the abortion industry’s agenda is dominated by financial priorities rather than concern for women’s health has been confirmed in Iowa, where abortion providers first began using “webcam” or “telemed” services to provide RU-486 to women. Rather than meet with a 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 abortion drug process, a button is pushed and an electronic drawer opens that contains the drugs. Under this scheme, 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 the inconvenience of meeting with the women in person.

Importantly, medical evidence demonstrates that the current FDA-approved protocol carries significant risks and administering the drugs outside the current FDA protocol places women at even greater risk. Importantly, the drug manufacturer 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.”3 These adverse reactions include, but are not limited to abdominal pain, cramping, vomiting, headache, fatigue, uterine hemorrhage, viral infections, and pelvic inflammatory disease.4

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”).5 Of the reported deaths, eight were from severe bacterial infections. All eight women administered misoprostol (the second drug in the RU-486 regimen) in an off-label, unapproved manner – alarmingly now the same regimens used in the current FDA protocol.6

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.

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4 Id. at 12 (Table 3).
6 Id.
In order to better protect women against the risks and misuse of abortion-inducing drugs, AUL has drafted the *Abortion-Inducing Drugs Information and Reporting Act*.

For more information and drafting assistance, please contact AUL’s Legislative Coordinator at (202) 289-1478 or Legislation@AUL.org.

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ABORTION-INDUCING DRUGS INFORMATION AND REPORTING ACT

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

Section 1. Title.

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

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 RU-486, an abortion-inducing drug, 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.”

(2) The FDA does not treat Subpart H drugs in the same manner as drugs which undergo the typical approval process.

(3) In September 2000, the FDA prescribed a specific gestation, dosage, and administration protocol for RU-486.

(4) The approved FDA protocol for RU-486 was modified in March 2016; however, the new FDA guidelines maintain that certain distribution restrictions are still necessary because of the drug’s potential for serious complications.

(5) As approved by the FDA, the new administration protocol consists of mifepristone, followed by misoprostol taken 24 to 48 hours later, through seventy (70) 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 to confirm that a complete abortion has occurred.

(6) The new FDA protocol also requires that the distribution and use of RU-486 be under the supervision of a qualified healthcare provider 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).

(7) Court testimony by Planned Parenthood and other abortion providers has demonstrated that providers routinely and intentionally failed to follow the September 2000 FDA-approved protocol for RU-486. See, e.g., Planned Parenthood Cincinnati Region v. Taft, 459 F. Supp. 2d 626 (S.D. Oh. 2006).

(8) The use of RU-486 presents significant medical risks including, but not limited to, abdominal pain, cramping, vomiting, headache, fatigue, uterine hemorrhage, viral infections, and pelvic inflammatory disease.

(9) The risk of complications increases with advancing gestational age and with the failure to complete the two-step dosage process for RU-486.

(10) Studies document that increased rates of complications (including incomplete abortion) occur even within the FDA-approved gestational limit.

(11) In July 2011, the FDA reported 2,207 adverse events after women used RU-486 for abortions. Among these events were 14 deaths, 612 hospitalizations, 339 blood transfusions, and 256 infections (including 48 “severe infections”).

(12) 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.

(13) “Off-label” or so-called “evidence-based” use of RU-486 may be deadly. To date, 14 women have reportedly died after administration of RU-486, with eight deaths attributed to severe bacterial infections. All eight of those women administered RU-486 in an “off-label” or “evidence-based” manner then advocated by abortion providers. The FDA has not been able to determine whether this off-label use led to the deaths.

(14) Medical evidence demonstrates that women who use abortion-inducing drugs risk more complications than those who undergo surgical abortions.

(15) 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).
The knowledgeable exercise of a woman’s decision to have an abortion depends on the extent to which the woman receives sufficient information to make an informed choice.

Some women come to regret their decision to abort shortly after ingesting mifepristone, the first drug in the RU-486 regimen.

In recent years, physicians have developed a method to potentially reverse the effects of mifepristone. This abortion pill reversal process, which has been discussed in a peer-reviewed study, is based upon a well-established medical regimen that is used in other areas of healthcare—specifically, methotrexate and “leucovorin rescue.”

Methotrexate, a chemotherapy drug, kills rapidly dividing cells (cancer cells). It works by blocking the action of folic acid. Typically, physicians allow the methotrexate to work for a day or two, and then give the patient a high dose of folic acid (leucovorin) to compensate for what has been lost. This high dosage of folic acid, in essence, “kicks” the methotrexate off of the cells. This flooding of the patient’s body with folic acid is called a “leucovorin rescue” and is a well-established medical procedure.

Understanding the science behind the mechanism of action of mifepristone has allowed physicians to design a specific "rescue" for a woman who has used mifepristone to induce an abortion, but has not yet ingested the second drug in the RU-486 regimen. Since physicians know exactly how mifepristone works (i.e., blocking progesterone), physicians know that treating a woman with progesterone can "kick off" the mifepristone (i.e., displace 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 mifepristone-induced blockage.

In short, mifepristone floods the progesterone receptors (thus, blocking progesterone). To block or “reverse” the effects of the mifepristone, a pregnant woman’s body is flooded with progesterone.

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 mifepristone is a targeted response that is safe for the woman.
[As of May 2016, it had been reported that at least one hundred seventy-five (175) babies had been born following this reversal process, with another one hundred (100) on the way (still in utero)].

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.

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).

Abortion and complication reporting provisions do not impose an “undue burden” on a woman’s right to choose whether or not to terminate a pregnancy. Specifically, “[t]he collection of information with respect to actual patients is a vital element of medical research, and so it cannot be said that the requirements serve no purpose other than to make abortions more difficult.” Planned Parenthood v. Casey, 505 U.S. 833 at 900-901 (1992).

To promote its interest in maternal health and life, the State of [Insert name of State] maintains an interest in:

a. Collecting certain demographic information on all drug-induced abortions performed in the State;

b. Collecting information on all complications from all drug-induced abortions performed in the State; and

c. Compiling statistical reports based on abortion complication information collected pursuant to this Act for future scientific studies and public health research.

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 [qualified healthcare provider] examines a woman prior to dispensing an abortion-inducing drug in order to confirm the gestational age of the fetus prior to administering the abortion inducing drug, the intrauterine
location of the fetus, and that the fetus is alive since administration of mifepristone with miscarriage is unnecessary and exposes the woman to unnecessary risks associated with both mifepristone and misoprostol;

(3) Ensure that a [qualified healthcare provider] does not prescribe or dispense an abortion-inducing drug beyond the FDA-approved gestational limit.

(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 every woman 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 every woman submitting to an abortion does so only after giving her 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 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 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 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.).

The use of such drugs to induce abortion is also known as “medical” or “drug-induced”
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) “Medical emergency” means that condition which, on the basis of the qualified
healthcare provider’s good faith clinical judgment, so complicates the medical condition of a
pregnant woman as to necessitate the immediate termination of her pregnancy to avert her death
or for which a delay will create serious risk of substantial and irreversible impairment of a major
bodily function.

(g) “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.”

(h) “Mifepristone” means the first drug used in the Mifeprex regimen.

(i) “Misoprostol” means the second drug used in the Mifeprex regimen.

(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 mother’s [woman’s] uterus.
(l)  “Qualified healthcare provider” means a healthcare provider licensed in this State 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.

(m)  “Qualified person” means an agent of the physician who is a psychologist, licensed social worker, licensed professional counselor, registered nurse, or physician.

(n)  “Unborn child” means the offspring of human beings from conception until birth.

Section 4.  Unlawful Distribution of Abortion-Inducing Drugs.

(a)  Because the failure and complication rates from a [medical or drug-induced] abortion increase with advancing gestational age; because the physical symptoms of [medical or drug-induced] 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 healthcare provider giving, selling, dispensing, administering, or otherwise providing or prescribing an abortion-inducing drug must first examine the woman and document, in the woman’s medical chart, the gestational age and intrauterine location of the pregnancy prior to giving, selling, dispensing, administering, or otherwise providing or prescribing an abortion-inducing drug.

(b)  Every pregnant woman to whom a qualified healthcare provider gives, sells, dispenses, administers, or otherwise provides or prescribes any abortion-inducing drug shall be provided with a copy of the drug’s final printing label (FPL).

(c)  Every qualified healthcare provider, other than a physician, giving, selling, dispensing, administering, or otherwise providing or prescribing an 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. Every pregnant woman to whom a qualified healthcare provider gives, sells, dispenses, administers, or otherwise provides or prescribes any abortion-inducing drug shall receive the name and phone number of the contracted physician.

(d)  The qualified healthcare provider giving, selling, dispensing, administering, or otherwise providing or prescribing any abortion-inducing drug or an agent of the qualified healthcare provider shall inform the patient that she may schedule an appointment to take each drug included in the regimen under the supervision of the qualified healthcare provider.

(e)  The qualified healthcare provider giving, selling, dispensing, administering, or otherwise providing or prescribing any abortion-inducing drug or an agent of the qualified healthcare
provider 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 healthcare provider or an agent of qualified healthcare provider 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. Informed Consent Requirements for Abortion-Inducing Drugs.

(a) No abortion-inducing drug shall be given, sold, dispensed, administered, or otherwise provided or prescribed without the voluntary and informed consent of the woman to whom the abortion-inducing drug is given, sold, dispensed, administered, or otherwise provided or prescribed.

(b) Except in the case of a medical emergency, consent to an abortion must be obtained at least [twenty-four (24) or insert existing state law requirement] hours before the abortion-inducing drug is given to, sold to, dispensed to, administered to, or otherwise provided or prescribed to the woman.

(c) A form created by the Department shall be used by a qualified healthcare provider to obtain the consent required prior to giving, selling, dispensing, administering, or otherwise providing or prescribing 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)(6) of this Section);

(2) The patient signs the “consent statement” described in subsection (e)(6) of this Section; and

(3) The qualified healthcare provider signs the “qualified healthcare provider declaration” described in subsection (e)(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 the gestational age;

(2) A detailed description of the [medical or drug-induced] abortion regimen or procedure;
A detailed list of the risks and hazards related to the specific [medical or drug-induced] abortion regimen or procedure to be used including, but not limited to hemorrhage (heavy bleeding); failure to remove all products of conception which may require an additional procedure; sepsis; sterility; and possible continuation of pregnancy;

That the risks of complications from a [medical or drug-induced] abortion, including incomplete abortion, increase with advancing gestational age;

That it may be possible to reverse the effects of the [medical or drug-induced] abortion should she change her mind, but that time is of the essence;

That information on and assistance with reversing the effects of abortion-inducing drugs are available in the state-prepared materials; and

A “consent statement” which must be signed by the patient. The consent statement must include, but is not limited to the following declarations, which must be individually initialed by the patient:

a. That the patient understands that the abortion-inducing drug regimen or procedure will end her pregnancy and will result in the death of her unborn child;

b. 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 or procedure;

c. That the patient understands that the [medical or drug-induced] abortion regimen or procedure to be used has specific risks and may result in specific complications;

d. That she has been given a copy of the final printing label (FPL) of the chosen abortion-inducing drug regimen or procedure to be used.

e. 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 regimen or procedure to be used, and the risks and complications inherent in the regimen or procedure to be used;

f. That she was specifically given “[i]nformation on the potential ability of qualified medical professionals to reverse the effects of an abortion obtained through the use of abortion-inducing drugs, such as mifepristone (brand name
“Mifeprex”), commonly referred to as “RU-486,” including information
directing women to obtain further information at
http://www.abortionpillreversal.com/ and by contacting (877) 558-0333 for
assistance in locating a medical professional that can aide in the reversal of an
abortion.”

g. 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].

h. That she has been given the name and phone number of the contracted
physician who has agreed to provide medical care and treatment in the event
of complications associated with the abortion-inducing drug regimen or
procedure;

i. That she has been informed that she may schedule an appointment to take
each drug included in the abortion-inducing regimen or procedure under the
direct supervision of the qualified healthcare provider;

j. That the qualified healthcare provider or an agent of the qualified healthcare
provider will schedule an in person follow-up visit for the woman at
approximately seven (7) to fourteen (14) days after administration of the
abortion-inducing drug regimen or procedure to confirm that the pregnancy is
completely terminated and to assess the degree of bleeding and other
complications; and

k. That the patient has received or been given sufficient information to give her
informed consent to the abortion-inducing drug regimen or procedure.

(7) A “qualified healthcare provider declaration,” which must be signed by the
qualified healthcare provider, stating that the qualified healthcare provider or
another qualified person has explained the abortion-inducing drug regimen or
procedure to be used, has provided all of the information required in subsections
(e)(1) through (e)(6) of this Section, and has answered all of the woman’s
questions. .


(a) The Department shall cause to be published in the state-prepared, printed materials on
informed consent for abortion [and] state-prepared and maintained website on informed consent
for abortion[, and the state-prepared informational DVD] 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, such as mifepristone (brand name “Mifeprex”), commonly referred to as “RU-486,” including information directing women to obtain further information at http://www.abortionpillreversal.com/ and by contacting (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 5(a) of this Section.

Section 7. Reporting on Abortion-Inducing Drugs and [Medical or Drug-Induced] 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 given, sold, dispensed, administered, or otherwise provided or prescribed; signed by the qualified healthcare provider 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.

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

   (1) Identification of the qualified healthcare provider who gave, sold, dispensed, administered, or otherwise provided or prescribed the abortion-inducing drug;

   (2) Whether the abortion drug regimen or procedure was completed at the hospital or [licensed] facility in which the abortion-inducing drug was given, sold, dispensed, administered, or otherwise provided or prescribed or at an alternative location;

   (3) The referring physician, agency, or service, if any;

   (4) The county and state in which the woman resides;

   (5) The woman's age and race;
(6) The number of the woman’s previous pregnancies, number of live births, and number of previous abortions;

(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. The report will include the date of the ultrasound and gestational age determined on that date;

(8) The abortion-inducing drug used and the date it was given, sold, dispensed, administered, or otherwise provided or prescribed to the woman; and

(9) Preexisting medical condition(s) of the woman which would complicate her pregnancy, if any; and

(10) Whether the patient 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.

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

(1) The name of the 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 drug-induced abortion.

(d) If a qualified healthcare provider provides an abortion-inducing drug to another for the purpose of inducing an abortion as authorized in Sections 4 and 5 of this Act, and if the qualified healthcare provider 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 adverse event, the qualified healthcare provider 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].

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

(e) The Department shall prepare a comprehensive annual statistical report for the [Legislature] based upon the data gathered from reports under this Section. The statistical report
shall not lead to the disclosure of the identity of any qualified healthcare provider, physician, or person filing a report under this Section nor of any woman who is the subject of the report. The aggregated data shall also be made independently available to the public by the Department in a downloadable format.

(f) 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. The aggregated data shall also be made independently available to the public by the Department in a downloadable format.

(g) Reports filed pursuant this Section shall not be deemed public records and shall remain confidential, except that disclosure may be made to law enforcement officials upon an order of a court after application showing good cause. The court may condition disclosure of the information upon any appropriate safeguards it may impose.

(h) 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.

(i) Statistical information that may reveal the identity of a woman obtaining or seeking to obtain a drug-induced abortion shall not be maintained by the Department, any other state department, agency, office, or any employee or contractor thereof.

(j) The Department or an employee or contractor of the Department shall not disclose to a person or entity outside the Department the reports or the contents of the reports required under this Section, in a manner or fashion so as to permit the person or entity to whom the report is disclosed to identify, in any way or under any circumstances, the qualified healthcare provider who prescribed the [medical or drug-induced] abortion and filed the report or the woman who is the subject of the report.

(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 [and the State Medical Board] shall compile and retain all reports it receives under this Section. All reports the Department [and 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 Department [or 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 Department [and the State Medical Board] receives under this provision.]

(m) 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.

Section 8. Production of Reporting Forms.

The Department shall create 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 or until the effective date of this Act, whichever is later.

Section 9. 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 attempted, induced, or performed.

Section 10. 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]; and

(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 attempted, induced, or 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 attempted, induced, or 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 11. 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 12. 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 Act is challenged.

Section 13. 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 14. Effective Date.

This Act takes effect on [Insert date].
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 2016* is available online at AUL.org.

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

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