House File 2122 - Introduced

HOUSE FILE 2122
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A BILL FOR

An Act relating to certification requirements for the provision of abortion-inducing drugs, providing penalties, and providing effective date provisions.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF IOWA:

Section 1. NEW SECTION. **146F.1 Definitions.**

As used in this chapter, unless the context otherwise requires:

1. *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. *"Abortion"* includes the act of prescribing an abortion-inducing drug with reasonable certainty that the drug will prevent the growth or implantation, or otherwise cause the death of the unborn child, if the drug is ingested prior to confirmation of a clinically diagnosed pregnancy.

b. "Abortion" does not include any use, prescribing, or means if done with the intent described in any of the following:

(1) To save the life or preserve the health of the unborn child.

(2) To remove a dead unborn child resulting from a spontaneous abortion commonly known as a miscarriage.

(3) To remove an ectopic pregnancy.

(4) To treat a maternal disease or illness for which the prescribed drug is medically indicated.

2. *"Abortion complication"* or *"complication"* means only the following physical or psychological conditions which, in the reasonable medical judgment of a licensed health care provider, 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 produced by the United States national cancer institute, pulmonary embolism, deep vein thrombosis, failure to actually terminate the pregnancy, incomplete abortion or 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 and any termination of pregnancy with complications or abortion with complications diagnosis as specified in current international classification of diseases (ICD) ICD-10 codes.

3. *a. "Abortion-inducing drug"* means mifepristone, misoprostol, and any other medicine, drug, or other substance that is prescribed or dispensed with the intent of terminating a clinically diagnosable pregnancy with knowledge that the termination will with reasonable likelihood cause the death of the unborn child.

b. "Abortion-inducing drug" includes all of the following:

(1) The off-label use of drugs known to have abortion-inducing properties which are prescribed or dispensed specifically with the intent of terminating a clinically diagnosable pregnancy.

(2) The off-label use of drugs known to have abortion-inducing properties that are prescribed without a diagnosed pregnancy for the purpose of causing an abortion at a future time rather than contemporaneously with a clinically diagnosed pregnancy.

c. "Abortion-inducing drug" does not include drugs that may be known to cause an abortion but that are prescribed for other medical indications.

4. *"Adverse event"* means the same as defined in 21 C.F.R. §312.32.

5. *"Associated physician"* means a physician who has entered into an associated physician contract with another physician under this chapter to provide for hospital admitting privileges as required under this chapter.

6. *"Department"* means the department of inspections, appeals, and licensing.

7. *"Distributor"* means the same as wholesale distributor as defined in section 155A.3.

8. *"Facility"* means a public or private hospital, clinic, center, medical school, medical training institution, health care business, physician office, infirmary, dispensary, ambulatory surgical center, or other institution or location or business wherein medical care or pharmaceuticals are provided to any person.

9. *"Gestational age"* means the time that has elapsed since the first day of the pregnant woman's last menstrual period.

10. *"Health care provider"* means a person who is licensed, certified, or otherwise authorized or permitted by law of this state to administer health care in the ordinary course of business or in the practice of a profession.

11. *"Hospital"* means the same as defined in section 135B.1.

12. *"Manufacturer"* means the same as defined in section 155A.3.

13. *"Pharmacy"* means a pharmacy as defined in section 155A.3 located in that state that is also certified by the manufacturers of abortion-inducing drugs to dispense the drugs via prescription.

14. *"Physician"* means a person licensed to practice pursuant to chapter 148.

15. *"Pregnant"* or *"pregnancy"* means the female reproductive condition of having an unborn child in the female's uterus.

16. *"Provide"*, *"provided"*, or *"providing"* 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.

Sec. 2. NEW SECTION. **146F.2 Applicability.**

This chapter applies to any physician, health care provider, manufacturer, distributor, pharmacy, or other person providing abortion-inducing drugs within the state.

Sec. 3. NEW SECTION. **146F.3 Abortion-inducing drug certification program —— creation.**

1. The board of pharmacy shall create an abortion-inducing drug certification program to provide oversight and to regulate the provision of abortion-inducing drugs in the state.

2. Abortion-inducing drugs shall be transported and provided in the state at wholesale only by manufacturers or distributors certified under the program.

3. Abortion-inducing drugs shall only be provided to patients by physicians certified to prescribe and dispense the drugs under the program.

4. Abortion-inducing drugs shall not be provided directly to a patient outside of the program, including through the mail.

Sec. 4. NEW SECTION. **146F.4 Board of pharmacy — abortion-inducing drug certification program duties.**

1. The board of pharmacy shall require all of the following at a minimum from manufacturers, distributors, and pharmacies in the state that provide abortion-inducing drugs:

a. Completion of the certification process for manufacturers, distributors, physicians, and pharmacies as described under this chapter.

b. Notification by manufacturers, distributors, and pharmacies of the physicians certified under the program.

c. Compliance with reporting requirements as specified under this chapter.

d. Prohibited shipment of abortion-inducing drugs to physicians who are not certified under the program.

e. Auditing of newly certified manufacturers, distributors, and pharmacies within ninety calendar days following initial certification and annually thereafter, to ensure compliance with the processes and procedures required under the program.

f. Suspension of the certification of a manufacturer, distributor, or pharmacy found to be noncompliant until the manufacturer, distributor, or pharmacy demonstrates full compliance.

g. Enforcement of certification compliance in accordance

with this chapter.

2. The board of pharmacy shall require all of the following at a minimum from physicians in the state who provide abortion-inducing drugs:

a. Completion of the certification process.

b. Auditing of newly certified physicians within ninety calendar days following initial certification and annually thereafter, to ensure compliance with the processes and procedures required under the program.

c. Suspension of the certification of a physician found to be noncompliant until the physician demonstrates full compliance.

d. Enforcement of certification compliance in accordance with this chapter.

3. The board of pharmacy shall require that all manufacturers of abortion-inducing drugs submit a list of any manufacturers, distributors, pharmacies, and physicians that are certified or otherwise approved by the manufacturer of abortion-inducing drugs to dispense the drugs in the state.

Sec. 5. NEW SECTION. **146F.5 Certification program requirements for manufacturers, distributors, and pharmacies.**

1. The board of pharmacy shall create a certification program for manufacturers, distributors, and pharmacies intending to provide abortion-inducing drugs in the state.

2. To be eligible for certification under this section, a manufacturer, distributor, or pharmacy shall do all of the following, as applicable:

a. Be licensed by the board of pharmacy.

b. Only distribute abortion-inducing drugs to physicians certified under this chapter.

c. Record each national drug code, serial number, lot number, and expiration date from the pharmaceutical packages of abortion-inducing drugs distributed to each certified physician.

d. Only dispense abortion-inducing drugs to patients based

on prescriptions by physicians certified under this chapter.

e. Only dispense a prescription for abortion-inducing drugs to a patient if the prescription is accompanied by a patient agreement form signed by the patient.

f. Have available for examination the certification required by the manufacturer of abortion-inducing drugs.

g. Comply with all applicable standards of the utilization review accreditation commission and the national association of the boards of pharmacy.

h. For online sales or orders, hold a current pharmacy or pharma domain and comply with all standards required by the national association of the boards of pharmacy to maintain the domain.

i. Comply with all other applicable state and federal laws related to the distribution or delivery of legend drugs, including abortion-inducing drugs.

j. Comply with all acceptable processes and procedures to maintain a distribution or delivery system that is secure, confidential, and follows all processes and procedures, including those for storage, handling, shipping, tracking of national drug codes, serial numbers, lot numbers and expiration dates on products, proof of delivery, and controlled returns of abortion-inducing drugs.

Sec. 6. NEW SECTION. **146F.6 Certification program requirements for physicians.**

1. The board of pharmacy shall create a certification program for physicians intending to provide abortion-inducing drugs to pregnant women in the state. Physicians providing abortion-inducing drugs in other states shall not be automatically certified in Iowa but shall be fully certified under this chapter prior to providing any abortion-inducing drugs to any pregnant women in this state. To be eligible to be certified under this section, a physician shall comply with all of the following:

a. Hold a license to practice medicine in good standing in

the state.

b. Examine any pregnant woman in person prior to prescribing or dispensing an abortion-inducing drug.

c. Present and continually hold a current prescriber agreement form with the manufacturer of each abortion-inducing drug prescribed by the physician in accordance with guidelines of the United States food and drug administration.

d. Sign an annual dispensing agreement form developed and provided by the board of pharmacy before providing abortion-inducing drugs.

e. Obtain the signature of the pregnant woman to whom an abortion-inducing drug is dispensed on the patient agreement form required by the manufacturer of each abortion-inducing drug used in accordance with the guidelines of the United States food and drug administration.

f. Attach the signed patient agreement form to any prescription for an abortion-inducing drug issued to a certified pharmacy.

g. Inform the pregnant woman to whom the abortion-inducing drug is to be dispensed of gestational age-specific risks of using abortion-inducing drugs.

h. Screen the pregnant woman to whom the abortion-inducing drug is to be dispensed for coercion, abuse, and anxiety, and refer the pregnant woman to the appropriate health care provider for treatment consistent with the screening results.

i. Inform the pregnant woman to whom an abortion-inducing drug is to be dispensed that the pregnant woman may see the remains of the unborn child in the process of completing the abortion, that it may be possible to reverse the effects of the drug-induced abortion if the pregnant woman changes her mind but that time is of the essence, that studies show that babies born following the abortion reversal process do not have a higher rate of birth defects than the general population, and that studies show that following the reversal process or otherwise treating a pregnant woman with progesterone during

pregnancy does not lead to increased mortality rates.

j. Refrain from knowingly supplying abortion-inducing drugs to persons who present with any of the following:

(1) Absence of a pregnancy.

(2) Being post-seventy days gestation or post-ten weeks of pregnancy.

(3) Having risk factors medically contraindicated for taking abortion-inducing drugs, including but not limited to any of the following:

(a) An ectopic pregnancy.

(b) Problems with the adrenal glands near the kidneys.

(c) Being treated with long-term corticosteroid therapy.

(d) Allergic reactions to abortion-inducing drugs, mifepristone, misoprostol, or similar drugs.

(e) Bleeding problems, anemia, or taking anticoagulant drug products.

(f) Having inherited porphyria.

(g) Having an intrauterine device in place.

(h) Being Rh negative and requiring the administration of Rhogam before providing abortion-inducing drugs.

k. Provide or refer the pregnant woman for emergency surgical intervention in cases of an incomplete abortion, severe bleeding, or other medical complications, through maintenance of hospital admitting privileges or through a written agreement with an associated physician as specified in this chapter.

l. Ensure the pregnant woman access to medical facilities equipped to provide blood transfusions and resuscitation or other necessary treatments, if necessary.

m. Sign and ensure that the pregnant woman signs all required informed consent materials, provide the pregnant woman with a copy of the signed consent materials showing both signatures, and place the original signed consent materials in the pregnant woman's medical record.

n. Record the national drug code, serial number, lot number,

and expiration date from the package of each abortion-inducing drug provided to the pregnant woman in the pregnant woman's medical record.

o. Submit a written protocol of efforts that will be made to schedule the follow-up appointment with the pregnant woman within fourteen days to assure a completed abortion.

p. Report to the board of pharmacy and the United States food and drug administration any death associated with the physician's provision of abortion-inducing drugs to a pregnant woman with the following guidelines:

(1) The pregnant woman shall be referenced in the report by a nonidentifiable reference and the national drug code, lot number, and expiration date from the package of the abortion-inducing drug given, whether or not considered drug related.

(2) The report shall be submitted as soon as possible but no later than fifteen calendar days from the initial receipt of the information by the physician.

q. Submit a written protocol of how complications will be handled by the physician and a copy of any signed contract with an associated physician credentialed to handle certain complications specified in this chapter to the board of pharmacy.

r. Comply with all applicable state and federal laws regarding medical records retention, confidentiality, and privacy.

s. Agree to follow and document compliance with all other required conditions for performing abortions in the state.

2. The requirements under this subsection do not affect the other reporting requirements for a physician under the abortion-inducing drugs certification program or any other applicable law.

Sec. 7. NEW SECTION. **146F.7 Hospital admitting privileges —— associated physician agreements —— requirements.**

The board of pharmacy shall require all of the following of

physicians certified under this chapter:

1. Maintain hospital admitting privileges at one or more hospitals in the county or a contiguous county where the abortion-inducing drug is provided by the physician, and inform the pregnant woman of any hospital where the physician holds admitting privileges.

2. *a.* In lieu of subsection 1, enter into a written agreement with an associated physician in the county or a contiguous county where the abortion-inducing drug is provided to comply with the requirements for maintenance of hospital admitting privileges. A physician who enters into such written agreement shall ensure compliance with all of the following:

(1) The physician who provides an abortion-inducing drug shall notify the pregnant woman of the location of any hospital at which the associated physician has admitting privileges.

(2) The physician shall keep a copy of the written agreement at the physician's practice location.

(3) The physician shall submit a copy of the written agreement to the department as part of any required facility licensure.

(4) The written agreement shall be renewed annually.

(5) The written agreement shall include a requirement that the associated physician present and continually hold any certifications required by the manufacturers of abortion-inducing drugs.

(6) The written agreement shall include a requirement that the associated physician provide to the pregnant woman and require the pregnant woman to sign all informed consent materials required by the state.

(7) The written agreement shall require the compliance by the associated physician with all reporting requirements and any other required conditions for performing abortions in the state.

b. (1) The board of pharmacy shall verify the validity of the written agreement and shall provide a copy of each written

agreement to the department.

(2) The department shall annually submit a copy of each written agreement to each hospital located in the county or a county that is contiguous to the county where an abortion was performed.

(3) The department shall confirm to a member of the public, upon request, that the written agreement required under this section has been received by the department.

Sec. 8. NEW SECTION. **146F.8 Reporting system — annual reports — reports of abortion complications or adverse events — requirements for certified physicians and others.**

1. The board of pharmacy shall adopt an electronically based reporting system for physicians certified under this chapter to report annually all of the following regarding the provision of abortion-inducing drugs:

a. The number of pregnant women provided abortion-inducing drugs.

b. The age of each pregnant woman provided abortion-inducing drugs.

c. The race of each pregnant woman provided abortion-inducing drugs.

d. The county and state of residence of each pregnant woman provided abortion-inducing drugs.

e. If a pregnant woman resides outside of the United States, the city and country of residence of each such pregnant woman provided abortion-inducing drugs.

f. The county and state in which each pregnant woman was provided abortion-inducing drugs.

g. A list of the staff attending the pregnant woman provided abortion-inducing drugs, including licensing numbers and evidence of other qualifications.

h. The abortion-inducing drug provided for each pregnant woman, by date.

i. Any known abortion complications or adverse events experienced by a pregnant woman following provision of the

abortion-inducing drug, and how the abortion complications or adverse events were addressed, by date.

j. Any unresolved cases.

2. Emergency department physicians and other physicians who treat abortion complications or adverse events shall also report these instances to the reporting system.

3. A physician reporting under this section shall protect from disclosure any personally identifiable information of the pregnant woman in accordance with applicable federal and state law.

4. A certified physician shall also report to the board of pharmacy, as well as the MedWatch reporting system of the United States food and drug administration any abortion complication or adverse event as defined by the United States food and drug administration in the MedWatch reporting system.

5. A certified physician shall also report to the board of pharmacy any death of a pregnant woman associated with abortion-inducing drugs in accordance with the following guidelines:

a. The pregnant woman shall be identified by a nonidentifiable reference and the national drug code, serial number, lot number, and expiration date from each package of the abortion-inducing drug provided, whether or not the death is considered drug related.

b. The report shall be submitted as soon as possible but no later than fifteen calendar days from the initial receipt of the information by the physician.

6. The reporting requirements under this section are in addition to any other reporting requirements applicable to a physician under this chapter or any other required conditions for performing an abortion in the state.

7. The board of pharmacy shall develop a system of reporting abortion complications and adverse events resulting from the use of abortion-inducing drugs in the state.

a. The system shall require reporting of abortion

complications and adverse events, including but not limited to death, blood loss including hemorrhage, infection including sepsis, blood transfusions, administration of drugs for an ectopic pregnancy, and other adverse effects requiring hospitalization or additional medical care.

b. All of the following persons shall report abortion complications and adverse events in writing to the system:

(1) Physicians certified to provide abortion-inducing drugs.

(2) Emergency department physicians.

(3) Any physician licensed in the state who treats women with adverse abortion complications or adverse effects.

(4) Other persons as determined by the board of pharmacy.

c. A person required report so shall also report adverse events and patient deaths to the United States food and drug administration.

Sec. 9. NEW SECTION. **146F.9 Violations — penalties — remedies.**

1. A manufacturer, distributor, physician, or pharmacist shall not provide abortion-inducing drugs without being certified as required by this chapter.

2. A manufacturer, distributor, physician, or pharmacist who knowingly, intentionally, or recklessly violates this chapter is guilty of a class "D" felony.

3. A manufacturer, distributor, physician, or pharmacist who knowingly, intentionally, or recklessly violates this chapter by fraudulent use of an abortion-inducing drug, with or without the knowledge of the pregnant woman, is guilty of an aggravated misdemeanor.

4. *a.* In addition to any other remedies available under common or state law, failure to comply with the requirements of this chapter shall result in all of the following:

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

(2) A basis for a professional disciplinary action by the

appropriate licensing board or other entity.

(3) A basis for recovery following a pregnant woman's death for the woman's survivors pursuant to a wrongful death action.

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

c. (1) If judgment is rendered in favor of the plaintiff, the court shall also award reasonable attorney fees in favor of the plaintiff.

(2) 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 award reasonable attorney fees in favor of the defendant.

5. A civil or criminal penalty shall not be assessed against a pregnant woman upon whom a drug-induced abortion is attempted, induced, or performed.

Sec. 10. NEW SECTION. **146F.10 Enforcement by the board of pharmacy.**

1. The board of pharmacy shall enforce this chapter by any of the following means:

a. When a manufacturer, distributor, physician, or pharmacist intentionally or knowingly provides abortion-inducing drugs without first seeking certification under this chapter in violation of this chapter, the board of pharmacy shall do all of the following:

(1) Immediately report the illegal act to local law enforcement or other applicable state and local agencies for investigation and other appropriate action, where appropriate.

(2) Impose a fine of no less than five million dollars for manufacturers, distributors, or pharmacies and two hundred fifty thousand dollars for physicians.

b. When a certified manufacturer, distributor, pharmacy,

or physician is determined to be in noncompliance, suspend certification until full compliance is demonstrated to the satisfaction of the board of pharmacy.

c. When a current or previously certified manufacturer, distributor, or pharmacy is found to have intentionally or knowingly violated this chapter or refuses to be fully compliant within ninety calendar days, suspend certification and prohibit continued provision of abortion-inducing drugs by the manufacturer, distributor, or pharmacy until full compliance is demonstrated to the satisfaction of the board of pharmacy.

d. When a certified manufacturer, distributor, pharmacy, or physician is in noncompliance, suspend all annual recertifications until compliance is demonstrated to the satisfaction of the board of pharmacy.

e. When a current or previously certified manufacturer, distributor, pharmacy, or physician is found to have intentionally or knowingly violated this chapter or refuses to be fully compliant:

(1) Immediately suspend the manufacturer's, distributor's, pharmacy's, or physician's certification until full compliance is demonstrated.

(2) For certified manufacturers, distributors, or pharmacies, impose fines of not less than one million dollars per offense.

(3) For certified physicians, impose fines of not less than one hundred thousand dollars per offense.

(4) Permanently revoke the certification of the offender if the offender fails to demonstrate full compliance within ninety calendar days.

(5) Impose remedial actions, which may include additional education, additional reporting, or other actions as required by the board of pharmacy.

(6) In the case of a licensed manufacturer, distributor, or pharmacy, recommend sanctioning to the appropriate licensing

board or other entity.

(7) In the case of a physician, report the violation and recommend appropriate sanctioning to the board of medicine.

(8) Publicly report any disciplinary actions consistent with the practices of the appropriate licensing board or other entity.

(9) Permanently revoke the certification of the offender.

(10) In the case of a licensed manufacturer, distributor, or pharmacy, recommend permanent revocation of licensure.

(11) In the case of a licensed physician, recommend appropriate sanctioning to the board of medicine.

2. A person shall have a private right of action to seek restitution in any court of law with appropriate jurisdiction for any damages suffered due to a violation of this chapter.

Sec. 11. NEW SECTION. **146F.11 Online public portal.**

1. The board of pharmacy shall develop on its internet site a complaint portal for patients, pharmacies, health care providers, and the public to submit information about potential violations at no cost.

2. The portal shall list the names of manufacturers, distributors, pharmacies, and physicians certified under the program.

3. The portal shall allow a person to make a complaint anonymously.

4. The board of pharmacy shall review each complaint and determine a disposition, including a referral to another appropriate entity, within thirty days of receipt of the complaint.

5. Confidentiality of the originator of the complaint shall be protected at all times except for intrastate referrals for investigation.

Sec. 12. NEW SECTION. **146F.12 Construction.**

1. This chapter shall not be construed as creating or recognizing a right to abortion.

2. It is not the intention of this chapter to make lawful an

abortion that is otherwise unlawful.

3. This chapter does not repeal, replace, or otherwise invalidate existing federal or state laws, regulations, or policies.

Sec. 13. NEW SECTION. **146F.13 Right to enforce or intervene by attorney general.**

The attorney general may bring an action to enforce compliance with this chapter or intervene as a matter of right in any case in which the constitutionality of this chapter is challenged.

Sec. 14. NEW SECTION. **146F.14 Severability.**

If any provision of this chapter or its application to any person or circumstance is held invalid, the invalidity does not affect other provisions or applications of this chapter which can be given effect without the invalid provision or application, and to this end the provisions of this chapter are severable.

Sec. 15. EFFECTIVE DATE. This Act, being deemed of immediate importance, takes effect upon enactment.

EXPLANATION

The inclusion of this explanation does not constitute agreement with the explanation's substance by the members of the general assembly.

This bill relates to certification requirements relating to the provision of abortion-inducing drugs.

The bill provides definitions used in the bill and creates a new Code chapter that applies to any physician, health care provider, manufacturer, distributor, pharmacy, or other person providing abortion-inducing drugs within the state.

The bill provides that the board of pharmacy shall create an abortion-inducing drug certification program to provide oversight and to regulate the provision of abortion-inducing drugs in the state. Abortion-inducing drugs shall be transported and provided in the state at wholesale only by certified manufacturers or distributors; abortion-inducing drugs shall only be provided to patients by certified

physicians; and abortion-inducing drugs shall not be provided directly to a patient outside of the program including through the mail.

The bill directs the board of pharmacy to establish a certification system with certain minimum measures relating to manufacturers, distributors, pharmacies, and physicians who provide abortion-inducing drugs in the state. The bill specifies requirements of manufacturers, distributors, physicians, and pharmacists who provide abortion-inducing drugs in the state under the state certification program.

The bill requires that a physician certified under the bill either shall maintain hospital admitting privileges at one or more hospitals in the county or a contiguous county where the abortion-inducing drug is provided by the physician or enter into a written agreement with an associated physician who has such privileges. The bill specifies the requirements for such written agreement.

The bill requires the board of pharmacy to create an electronically based reporting system for physicians certified under the bill to report annually certain information regarding the provision of abortion-inducing drugs. The bill also requires emergency department physicians and other physicians who treat abortion complications or adverse events to report these instances to the reporting system.

The bill requires certified physicians to report to the board of pharmacy, as well as the MedWatch reporting system of the United States food and drug administration, any abortion complication or adverse event as defined by the United States food and drug administration in the MedWatch reporting system. The bill requires certified physicians to report to the board of pharmacy any death of a pregnant woman associated with abortion-inducing drugs. The reporting requirements under the bill are in addition to any other reporting requirements applicable to a physician under the bill or any other required conditions for performing abortions in the state.

The bill requires the board of pharmacy to develop a system of reporting abortion complications and adverse events resulting from the use of abortion-inducing drugs in the state. Physicians certified to provide abortion-inducing drugs, emergency department physicians, and any physicians licensed in the state who treat women with adverse abortion complications or adverse effects, and other persons as determined by the board of pharmacy shall report abortion complications and adverse events to the system. A person required to do so shall also report adverse events and patient deaths to the United States food and drug administration.

The bill provides penalties and remedies for violations of the bill. A manufacturer, distributor, physician, or pharmacist who intentionally, knowingly, or recklessly violates the bill is guilty of a class "D" felony. A class "D" felony is punishable by confinement for no more than five years and a fine of at least $1,025 but not more than $10,245.

A manufacturer, distributor, physician, or pharmacist who intentionally, knowingly, or recklessly violates the bill by fraudulent use of an abortion-inducing drug, with or without the knowledge of the pregnant woman, is guilty of an aggravated misdemeanor. An aggravated misdemeanor is punishable by confinement for no more than two years and a fine of at least $855 but not more than $8,540.

In addition to any other remedies available under common or state law, failure to comply with the requirements of the bill provides a basis for a civil malpractice action for actual and punitive damages; a basis for a professional disciplinary action by the appropriate licensing board or other entity; and a basis for recovery following a pregnant woman's death for the woman's survivors pursuant to a wrongful death action. A civil or criminal penalty shall not be assessed against a pregnant woman upon whom a drug-induced abortion is attempted, induced, or performed.

The bill requires the board of pharmacy to enforce the

provisions of the bill by specified means.

The bill directs the board of pharmacy to develop a complaint portal on its internet site for patients, pharmacies, health care providers, and the public to submit information about potential violations of the bill at no cost.

The bill is not to be construed as creating or recognizing a right to abortion or to make lawful an abortion that is otherwise unlawful, and does not repeal, replace, or otherwise invalidate existing federal or state laws, regulations, or policies.

The bill provides that the attorney general may bring an action to enforce compliance with the bill or intervene as a matter of right in any case in which the constitutionality of the bill is challenged.

The bill includes a severability clause. The bill takes effect upon enactment.