STATE OF OKLAHOMA

1st Session of the 58th Legislature (2021)

SENATE BILL 779 By: Daniels

AS INTRODUCED

An Act relating to abortion; defining terms; specifying applicability of act; creating the Oklahoma Abortion-Inducing Drug Certification Program; limiting provision of abortion-inducing drugs to certain practitioners and procedures; directing State Board of Pharmacy to establish certain requirements for manufacturers, distributors and physicians; providing certification systems and requirements for manufacturers, distributors and physicians; requiring physician to maintain hospital admitting privileges or enter into certain written agreement; stating conditions of agreement; requiring Board to adopt certain reporting system; stating criteria of reporting system; requiring certain reporting of physicians; providing for reporting of adverse events; providing criminal penalties; providing for certain civil remedies, disciplinary sanctions and injunctive relief; specifying certain judicial procedures; directing Board to develop certain enforcement scheme; specifying criteria of enforcement scheme; providing for certain restitution; directing creation of certain public portal; requiring portal to list certain names and allow for certain complaints; providing for disposition of complaints; providing for confidentiality of complaints; providing certain construction and intent; authorizing certain intervention; providing severability; providing for codification; and providing an effective date.

BE IT ENACTED BY THE PEOPLE OF THE STATE OF OKLAHOMA:

SECTION 1. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 1-756.1 of Title 63, unless there is created a duplication in numbering, reads as follows:

As used in this act:

1. "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 pregnancy of a woman known to be pregnant, 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:

a. save the life or preserve the health of the unborn child,

b. remove a dead unborn child caused by spontaneous abortion, accidental trauma or a criminal assault on the pregnant woman or her unborn child,

c. remove an ectopic pregnancy, or

d. treat a maternal disease or illness for which the prescribed drug is indicated;

2. "Abortion-inducing drug" means a medicine, drug or any other substance prescribed or dispensed with the intent of terminating the pregnancy of a woman known to be pregnant, 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 does not apply to drugs that may be known to cause an abortion, but which are prescribed for other medical indications, such as chemotherapeutic agents and diagnostic drugs. The use of such drugs to induce abortion is also known as "medical", "medication", "RU-486", "chemical", "Mifeprex regimen" or "drug-induced" abortion;

3. "Adverse Event", according to the 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;

4. "Associated physician" means a person licensed to practice medicine in the state including medical doctors and doctors of osteopathy, that has entered into an associated physician agreement;

5. "Complication" means any adverse physical or psychological condition arising from the performance of an abortion which includes, but is not limited to, uterine perforation, cervical perforation, infection, heavy or uncontrolled bleeding, hemorrhage, blood clots resulting in pulmonary embolism or 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, metabolic disorder, shock, embolism, coma, placenta previa in subsequent pregnancies, preterm delivery in subsequent pregnancies, free fluid in the abdomen, hemolytic reaction due to the administration of ABO-incompatible blood or blood products, adverse reactions to anesthesia and other drugs, subsequent development of breast cancer, psychological complications such as depression, suicidal ideation, anxiety, sleeping disorders, death and any other adverse event as defined by the Food and Drug Administration criteria provided in the Medwatch Reporting System;

6. "Gestational age" means the time that has elapsed since the first day of the woman's last menstrual period, also known as "last menstrual period" or "LMP";

7. "Hospital" means an institution providing medical and surgical treatment and nursing care for sick or injured people, or institutions defined under Section 1-701 of Title 63 of the Oklahoma Statutes;

8. "Manufacturers and distributors" means individuals or entities that create, produce, supply, transport or sell drugs, which include:

a. any substances recognized by an official pharmacopoeia or formulary,

b. any substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease,

c. any substances other than food intended to affect the structure or any function of the body, or

d. any substances intended for use as a component of a medicine but not a device or a component, part or accessory of a device;

9. "Obstetrician/gynecologist", also known as OB/GYN, means a licensed physician who specializes in the care of women during pregnancy and childbirth and in the diagnosis and treatment of diseases of the female reproductive organs and specializes in other women's health issues such as menopause, hormone problems, contraception or birth control, and infertility;

10. "Physician" means any person licensed to practice medicine in this state. The term includes medical doctors and doctors of osteopathy;

11. "Pregnant" or "pregnancy" means that female reproductive condition of having an unborn child in the mother's uterus;

12. "Provide" or "provision" 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; and

13. "Unborn child" means an individual organism of the species homo sapiens, beginning at fertilization, until the point of being born-alive as defined in Title 1 U.S.C., Section 8(b).

SECTION 2. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 1-756.2 of Title 63, unless there is created a duplication in numbering, reads as follows:

This act applies to any physician, health care provider or other person who is providing abortion-inducing drugs for use within this state, or any manufacturer or distributor providing abortion-inducing drugs within this state.

SECTION 3. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 1-756.3 of Title 63, unless there is created a duplication in numbering, reads as follows:

A. The State Board of Pharmacy shall promulgate rules to create a certification program to oversee and regulate the provision of abortion-inducing drugs. Abortion-inducing drugs shall be transported and provided in this state only by manufacturers or distributors certified to do so under this program. The drugs shall only be provided to patients by physicians certified to do so under this program.

B. The program shall be known as the Oklahoma Abortion-Inducing Drug Certification Program.

C. Abortion-inducing drugs shall not be provided directly to the patient through the mail, or otherwise outside of the parameters of the Oklahoma Abortion-Inducing Drug Certification Program.

SECTION 4. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 1-756.4 of Title 63, unless there is created a duplication in numbering, reads as follows:

A. The State Board of Pharmacy shall establish the following requirements for manufacturers and distributors of abortion-inducing drugs, at a minimum:

1. Require completion of the certification process for physicians as described in paragraph 6 of this subsection, and for manufacturers and distributors, as described in paragraph 5 of this subsection;

2. Notify manufacturers and distributors of physicians certified under the Oklahoma Abortion-Inducing Drug Certification Program;

3. Develop a reporting system as specified in Section 8 of this act;

4. Prohibit shipment of abortion-inducing drugs to physicians who become de-certified from the Oklahoma Abortion-Inducing Drug Certification Program;

5. Audit newly certified manufacturers and distributors within ninety (90) calendar days after the manufacturer or distributor is authorized, and annually thereafter, to ensure that all processes and procedures are in place and functioning to support the requirements of the Oklahoma Abortion-Inducing Drug Certification Program;

6. If a manufacturer or distributor is found to be non-compliant, immediately suspend manufacturer's or distributor's certification until the manufacturer or distributor demonstrates full compliance; and

7. Enforce compliance according to Section 11 of this act.

B. The State Board of Pharmacy shall establish the following requirements for physicians providing abortion-inducing drugs, at a minimum:

1. Require completion of the certification process;

2. Audit newly certified physicians within ninety (90) calendar days after the physician is authorized, and annually thereafter, to ensure that all required processes and procedures are in place and functioning to support the requirements of the Oklahoma Abortion-Inducing Drug Certification Program;

3. If a physician is found to be non-compliant, immediately suspend the physician's certification until such time that the physician demonstrates full compliance; and

4. Enforce compliance according to Section 11 of this act.

SECTION 5. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 1-756.5 of Title 63, unless there is created a duplication in numbering, reads as follows:

The State Board of Pharmacy shall adopt a certification system for any manufacturer or distributor intending to provide abortion-

inducing drugs in the state. To be eligible to be certified under this section, manufacturers and distributors shall:

1. Be licensed by the Board;

2. Only distribute to physicians certified under this act;

3. Record each serial number from pharmaceutical packages distributed to each certified physician;

4. Abide by all applicable the standards of the Utilization Review Accreditation Commission (URAC) or National Association of the Boards of Pharmacy (NABP);

5. For online sales or orders, hold a current ".pharmacy" or ".pharma" domain and abide by all the standards required by the NABP to maintain the domain;

6. Follow all other applicable state or federal laws related to the distribution or delivery of legend drugs including abortion-inducing drugs; and

7. Follow 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 package serial numbers, proof of delivery and controlled returns of abortion-inducing drugs.

SECTION 6. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 1-756.6 of Title 63, unless there is created a duplication in numbering, reads as follows:

The State Board of Pharmacy shall adopt a certification system for any physician intending to provide abortion-inducing drugs to patients in the state. Individuals or physicians providing abortion-inducing drugs in other states are not automatically certified in this state and shall be fully certified under this law prior to providing any abortion-inducing drugs to any pregnant women in this state. To be eligible to be certified under this section physicians shall:

1. Be licensed to practice medicine and in good standing in the state;

2. Examine any patient in-person prior to providing abortion-inducing drugs;

3. Sign an annual "Dispensing Agreement Form," to be developed and provided by the State Board of Pharmacy, before providing abortion-inducing drugs;

4. Inform the patient of gestational age-specific risks of using abortion-inducing drugs;

5. Assess for signs of domestic abuse, reproductive control, human trafficking and other signals of coerced abortion, per current state guidelines;

6. Adequately inform the patient of gestational age-specific age risks of using abortion-inducing drugs;

7. Inform the patient that she may see the remains of her unborn child in the process of completing the abortion;

8. Inform the patient that studies show that babies born following the abortion reversal process have a rate of birth defects no higher than the general population;

9. Inform the patient that studies show that following this reversal process or otherwise treating a woman with progesterone during pregnancy does not lead to increased mortality rates;

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

a. absence of a pregnancy,

b. being post-seventy days gestation or post-ten weeks of pregnancy, and

c. having risk factors associated with abortion-inducing drugs including, but not limited to:

(1) ectopic pregnancies,

(2) problems with the adrenal glands near the kidneys,

(3) being treated with long-term corticosteroid therapy,

(4) allergic reactions to abortion-inducing drugs, mifepristone, misoprostol or similar drugs,

(5) bleeding problems or is taking anticoagulant drug products,

(6) has inherited porphyria,

(7) has an intrauterine device in place, or

(8) being Rh Negative, requiring administration of Rhogam before providing abortion-inducing drugs;

11. Provide or refer for emergency surgical intervention in cases of incomplete abortion, severe bleeding, or other medical complications, through maintaining hospital admitting privileges or entering into a written agreement with an associated physician as specified in Section 7 of this act;

12. Assure patient access to medical facilities equipped to provide blood transfusions and resuscitation or other necessary treatments, if necessary;

13. Sign, and ensure that the patient signs, all legally required informed consent material, providing patient with a copy showing both signatures, and placing the original in the patient's medical record;

14. Record the serial number from each package of each abortion-inducing drug given to the patient in her medical record;

15. Submit a written protocol of how efforts will be made to schedule with the patient the medically indicted follow-up appointment within fourteen (14) days to assure a completed abortion;

16. Report to the State Board of Pharmacy, as well as the Food and Drug Administration, any death associated with abortion-inducing drugs with the following guidelines:

a. the patient shall be noted by a non-identifiable reference and the serial number from each package of abortion-inducing drug given, whether or not considered drug-related,

b. this shall be done as soon as possible but no later than fifteen (15) calendar days from the initial receipt of the information by the physician, and

c. this requirement does not affect the physician's other reporting and follow-up requirements under the Oklahoma Abortion-Inducing Drug Certification Program or any additional requirements by another department that oversees the abortion industry in this state;

17. Submit a written protocol of how complications will be handled by the certified physician and submit a copy of a signed contract with an associated physician credentialed to handle certain complications as outlined in Section 7 of this act;

18. Abide by all applicable state and federal laws regarding medical records retention, confidentiality and privacy; and

19. Agree to follow and document compliance with all other legally required conditions for performing abortion in the state where the patient presents for her appointment including, but not limited to, waiting periods, informed consent requirements, statistical reporting, parental consent or notification, and required inspections.

SECTION 7. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 1-756.7 of Title 63, unless there is created a duplication in numbering, reads as follows:

The State Board of Pharmacy shall also require the following of certified physicians:

1. Maintaining hospital admitting privileges at one or more hospitals in the county or contiguous county where the abortion-inducing drug was provided and informing the patient of any hospital where the physician holds admitting privileges.

2. Alternatively, the physician may enter into a written agreement with an associated physician in the county or contiguous county where the abortion-inducing drug was provided. The written agreement shall meet these conditions:

a. a physician who provides an abortion-inducing drug shall notify the patient of the location of the hospital at which the associated physician has admitting privileges,

b. the physician shall keep, at the location of his or her practice, a copy of the written agreement,

c. the physician shall submit a copy of the written agreement to the State Department of Health as part of any required clinic licensure,

d. the State Department of Health shall verify the validity of the document, and shall remove any

personal identifying information of the patient from the document before releasing the document in accordance with the following:

(1) the State Department of Health shall annually submit a copy of the written agreement described in this paragraph to each hospital located in the county or a county that is contiguous to the county where the abortion was performed, and

(2) the State Department of Health shall confirm to a member of the public, upon request, that the written agreement required to be submitted under this section for an abortion clinic has been received by the Department,

e. the agreement shall be renewed annually, or more often as required by the State Board of Pharmacy,

f. the agreement shall include a requirement that the physician provide to the patient and require the patient to sign all legally required informed consent material, and

g. the agreement shall require the adherence to all reporting requirements from the State Board of Pharmacy and the State Department of Health.

SECTION 8. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 1-756.8 of Title 63, unless there is created a duplication in numbering, reads as follows:

A. The State Board of Pharmacy shall adopt an electronically based reporting system for certified physicians to report annually the following:

1. The number of patients served;

2. Age of patients served;

3. Race of patients served;

4. County and state of residence of patients served;

5. If the patient resides outside the United States, city and country of residence;

6. County and state of service;

7. A list of staff attending patients including licensing numbers and evidence of other qualifications;

8. Each medication used or provided per patient, by date;

9. Any known complications or adverse events, and how they were addressed, by date; and

10. Unresolved cases.

B. This reporting system shall also be used by emergency department physicians and private physicians who treat post-abortion complications.

C. Physicians shall protect from disclosure any personally identifiable information of the patient in accordance with applicable federal and state law.

D. A certified physician shall also report to the State Board of Pharmacy, as well as the Medwatch Reporting System of the Food and Drug Administration (FDA), any complication or adverse event as defined according to the FDA criteria given in the Medwatch Reporting System.

E. A certified physician shall also report to the State Board of Pharmacy any death associated with abortion-inducing drugs with the following guidelines:

1. The patient shall be noted by a non-identifiable reference and the serial number from each package of abortion-inducing drug given, whether or not considered drug related;

2. This shall be done as soon as possible, but no later than fifteen (15) calendar days from the initial receipt of the information by the physician; and

3. These requirements are in addition to the physician's other reporting requirements under the Oklahoma Abortion-Inducing Drug Certification Program, or any requirements imposed by another state agency that oversees the abortion industry in this state.

F. The State Board of Pharmacy shall develop a system of reporting adverse events from the use of abortion-inducing drugs for

this state. The system shall require reporting of complications and adverse events including, but not limited to:

1. Death;

2. Blood loss including hemorrhage;

3. Infection including sepsis;

4. Blood transfusions;

5. Administer drug for an ectopic pregnancy; and

6. Other adverse effects requiring hospitalization or additional medical care.

G. The State Board of Pharmacy shall require the following providers and entities to report complications and adverse events in writing:

1. Physicians certified to provide abortion-inducing drugs;

2. Emergency room physicians;

3. Any doctor licensed in this state including an obstetrician/gynecologist who treats women with adverse effects;

4. Provision of certification requires that the physician shall also report adverse events and any patient deaths to the FDA; and

5. Other individuals or entities as determined by the State Board of Pharmacy.

SECTION 9. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 1-756.9 of Title 63, unless there is created a duplication in numbering, reads as follows:

A. Individuals or entities not certified under the Oklahoma Abortion-Inducing Drug Certification Program that provide drugs for the purpose of inducing abortion are in violation of this act.

B. Individuals or entities that provide abortion-inducing drugs to any person or entity that is not certified, or otherwise authorized, to provide abortion-inducing drugs under the Oklahoma Abortion-Inducing Drug Certification Program are in violation of this act.

C. A person who intentionally, knowingly, or recklessly violates any provision of this act is guilty of a misdemeanor.

D. 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 felony.

E. No civil or criminal penalty may be assessed against the pregnant woman upon whom the drug-induced abortion is attempted, induced or performed.

SECTION 10. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 1-756.10 of Title 63, unless there is created a duplication in numbering, reads as follows:

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; and

3. Provide a basis for recovery for the woman's survivors for the wrongful death of the woman.

B. 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.

C. 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.

D. 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.

E. A cause of action for injunctive relief against a person who has provided an abortion-inducing drug in violation of this act may be maintained by:

1. A woman to whom such an abortion-inducing drug was provided;

2. A person who is the spouse, parent or guardian of, or a current or former licensed health care provider of, a woman to whom such an abortion-inducing drug was provided; or

3. A prosecuting attorney with appropriate jurisdiction.

The injunction shall prevent the defendant from providing further abortion-inducing drugs in violation of this act.

SECTION 11. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 1-756.11 of Title 63, unless there is created a duplication in numbering, reads as follows:

A. The State Board of Pharmacy shall develop an enforcement scheme to enforce this act, which includes:

1. When an individual or entity provides abortion-inducing drugs without first seeking certification under this act, the State Board of Pharmacy shall:

a. immediately report the illegal act to local law enforcement, or other applicable state and local agencies for investigation or other appropriate action, where appropriate,

b. impose a fine of no less than Five Million Dollars ($5,000,000.00) for manufacturers or distributors and Two Hundred Fifty Thousand Dollars ($250,000.00) for physicians;

2. When a certified manufacturer or distributor or physician is determined to be in noncompliance, suspend certification until compliance is proven to the satisfaction of the State Board of Pharmacy;

3. Where a current or previously certified manufacturer or distributer is found to have intentionally or knowingly violated this act, or refuses to bring operations into compliance within ninety (90) calendar days, remove certification and prohibit continued provision of abortion-inducing drugs by the manufacturer or distributor until compliance is demonstrated to the satisfaction of the State Board of Pharmacy;

4. When a certified manufacturer, distributor or physician is in noncompliance, suspend all annual recertification until compliance is demonstrated to the satisfaction of the State Board of Pharmacy; and

5. Where a current or previously certified manufacturer, distributer or physician is found to have intentionally or knowingly violated this act, or refuses to bring operations into compliance:

a. immediately suspend the manufacturer's, distributor's or physician's certification until full compliance is demonstrated,

b. for certified manufacturers or distributors, impose fines of not less than One Million Dollars ($1,000,000.00) per offense,

c. for certified physicians, impose fines of not less than One Hundred Thousand Dollars ($100,000.00) per offense,

d. permanently revoke the certification of the offender if offender fails to demonstrate compliance within ninety (90) calendar days,

e. impose remedial actions, which may include additional education, additional reporting or other actions as required by the State Board of Pharmacy,

f. in the case of a licensed manufacturer or distributor, recommend sanctioning to the appropriate disciplinary committee of the State Board of Pharmacy,

g. in the case of a licensed physician, report the violation to the appropriate medical licensing board,

h. publicly report any disciplinary actions, consistent with the practices of the State Board of Pharmacy,

i. permanently revoke the certification of the offender,

j. in the case of a licensed manufacturer or distributor, recommend permanent revocation of licensure,

k. in the case of a licensed physician, recommend appropriate sanctioning to the appropriate medical licensing board, and

l. publicly report any disciplinary actions consistent with the practices of the State Board of Pharmacy.

B. Individuals have a Private Right of Action to seek restitution in any court of law with appropriate jurisdiction for any and all damages suffered due to a violation of this act.

SECTION 12. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 1-756.12 of Title 63, unless there is created a duplication in numbering, reads as follows:

A. The State Board of Pharmacy shall develop on its website a complaint portal for patients, pharmacy, nursing and medical professionals and the public to submit information about potential violations offered at no charge to the parties named in this subsection.

B. The portal shall list the names of manufacturers and distributors that are certified under the program, as well as the physicians that are certified under the program.

C. The portal shall allow the party to make a complaint anonymously.

D. The State Board of Pharmacy shall review each complaint and determine a disposition including referral to another appropriate state agency, within thirty (30) days.

E. Confidentiality of the originator of the complaint shall be protected at all times except for intra-state referrals for investigation.

SECTION 13. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 1-756.13 of Title 63, unless there is created a duplication in numbering, reads as follows:

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.

SECTION 14. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 1-756.14 of Title 63, unless there is created a duplication in numbering, reads as follows:

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 15. NEW LAW A new section of law to be codified in the Oklahoma Statutes as Section 1-756.15 of Title 63, unless there is created a duplication in numbering, reads as follows:

If any one or more provisions, sections, subsections, sentences, clauses, phrases or words of this act or the application thereof to any person or circumstance is found to be unconstitutional, the same is hereby declared to be severable and the balance of this act shall remain effective notwithstanding such unconstitutionality. The Legislature hereby declares that it would have passed this act, and each provision, section, subsection, sentence, clause, phrase or word thereof, irrespective of the fact that any one or more provisions, sections, subsections, sentences, clauses, phrases or words be declared unconstitutional.

SECTION 16. This act shall become effective November 1, 2021.

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