Session of 2011

House Substitute for SENATE BILL No. 36

By Committee on Federal and State Affairs

3-23

AN ACT concerning abortion; relating to licensure of abortion clinics.

Be it enacted by the Legislature of the State of Kansas:

Section 1. As used in sections 1 through 12, and amendments thereto:

(a) "Abortion" has the same meaning ascribed thereto in K.S.A. 65-6701, and amendments thereto.

(b) "Ambulatory surgical center" means an ambulatory surgical center as defined in K.S.A. 65-425, and amendments thereto.

(c) "Clinic" means any facility, other than a hospital or ambulatory surgical center, in which any second or third trimester, or five or more first trimester abortions are performed in a month.

(d) "Department" means the department of health and environment.

(e) "Facility" means any clinic, hospital or ambulatory surgical center, in which any second or third trimester, or five or more first trimester abortions are performed in a month.

(f) "Gestational age" has the same meaning ascribed thereto in K.S.A. 65-6701, and amendments thereto, and shall be determined pursuant to K.S.A. 65-6703, and amendments thereto.

(g) "Hospital" means a hospital as defined in subsection (a) or (b) of K.S.A. 65-425, and amendments thereto.

(h) "Physician" has the same meaning ascribed thereto in K.S.A. 65-6701, and amendments thereto.

(i) "Secretary" means the secretary of the department of health and environment.

Sec. 2. (a) A facility shall be licensed in accordance with sections 1 through 12, and amendments thereto.

(b) Any facility seeking licensure for the performance of abortions shall submit an application for such license to the department on forms and in the manner required by the secretary. Such application shall contain such information as the secretary may reasonably require, including affirmative evidence of the ability of the applicant to comply with such reasonable standards and rules and regulations adopted pursuant to section 9, and amendments thereto.

(c) Upon receipt of such application and verification by the department that the applicant is in compliance with all applicable laws and

rules and regulations, the secretary shall issue a license to the applicant.

(d) A license issued under this section shall be posted in a conspicuous place in a public area within the facility. The issuance of a license does not guarantee adequacy of individual care, treatment, personal safety, fire safety or the well-being of any occupant of such facility. A license is not assignable or transferable.

(e) A license shall be effective for one year following the date of issuance. A license issued under this section shall apply only to the premises described in the application and in the license issued thereon, and only one location shall be described in each license.

(f) At the time application for a license is made the applicant shall pay a license fee in the amount of $500. Fees paid pursuant to this section shall not be refunded by the secretary.

(g) The secretary may make exceptions to the standards set forth in law or in rules and regulations when it is determined that the health and welfare of the community require the services of the hospital or ambulatory surgical center and that the exceptions, as granted, will have no significant adverse impact on the health, safety or welfare of the patients of such hospital or ambulatory surgical center.

Sec. 3. Applicants for an annual license renewal shall file an application with the department and pay the license fee in accordance with section 2, and amendments thereto. Applicants for an annual license renewal shall also be subject to a licensing inspection in accordance with section 5, and amendments thereto.

Sec. 4. (a) No proposed facility shall be named, nor may any existing facility have its name changed to, the same or similar name as any other facility licensed pursuant to sections 1 through 12, and amendments thereto. If the facility is affiliated with one or more other facilities with the same or similar name, then the facility shall have the geographic area in which it is located as part of its name.

(b) Within 30 days after the occurrence of any of the following, a facility shall apply for an amended license by submitting such application to the department:

(1) A change of ownership either by purchase or lease; or

(2) a change in the facility's name or address.

Sec. 5. (a) The secretary shall make or cause to be made such inspections and investigations of each facility at least twice each calendar year and at such other times as the secretary determines necessary to protect the public health and safety and to implement and enforce the provisions of sections 1 through 12, and amendments thereto, and rules and regulations adopted pursuant to section 9, and amendments thereto. At least one inspection shall be made each calendar year without providing prior notice to the facility. For that purpose, authorized agents of the

secretary shall have access to a facility during regular business hours.

(b) Information received by the secretary through filed reports, inspections or as otherwise authorized under sections 1 through 12, and amendments thereto, shall not be disclosed publicly in such manner as to identify individuals. Under no circumstances shall patient medical or other identifying information be made available to the public, and such information shall always be treated by the department as confidential.

Sec. 6. (a) When the secretary determines that a facility is in violation of any applicable law or rule and regulation relating to the operation or maintenance of such facility, the secretary, upon proper notice, may deny, suspend or revoke the license of such facility, or assess a monetary penalty after notice and an opportunity for hearing has been given to the licensee in accordance with the provisions of the Kansas administrative procedure act.

(b) Either before or after formal charges have been filed, the secretary and the facility may enter into a stipulation which shall be binding upon the secretary and the facility entering into such stipulation, and the secretary may enter its findings of fact and enforcement order based upon such stipulation without the necessity of filing any formal charges or holding hearings in the case. An enforcement order based upon a stipulation may order any disciplinary action authorized by this section against the facility entering into such stipulation.

(c) The secretary may temporarily suspend or temporarily limit the license of any facility in accordance with the emergency adjudicative proceedings under the Kansas administrative procedure act if the secretary determines that there is cause to believe that grounds exist under this section for immediate action authorized by this section against the facility and that the facility's continuation in operation would constitute an imminent danger to the public health and safety.

(d) Violations of sections 1 through 12, and amendments thereto, or of any rules and regulations adopted thereunder shall be deemed one of the following:

(1) Class I violations are those that the secretary determines to present an imminent danger to the health, safety or welfare of the patients of the facility or a substantial probability that death or serious physical harm could result therefrom. A physical condition or one or more practices, means, methods or operations in use in a facility may constitute such a violation. The condition or practice constituting a class I violation shall be abated or eliminated immediately unless a fixed period of time, as stipulated by the secretary, is required for correction. Each day such violation shall exist after expiration of such time shall be considered a subsequent violation.

(2) Class II violations are those, other than class I violations, that the

secretary determines to have a direct or immediate relationship to the health, safety or welfare of the facility's patients. The citation of a class II violation shall specify the time within which the violation is required to be corrected. Each day such violation shall exist after expiration of such time shall be considered a subsequent violation.

(3) Class III violations are those that are not classified as class I or II, or those that are against the best practices as interpreted by the secretary. The citation of a class III violation shall specify the time within which the violation is required to be corrected. Each day such violation shall exist after expiration of such time shall be considered a subsequent violation.

(e) The secretary shall consider the following factors when determining the severity of a violation:

(1) Specific conditions and their impact or potential impact on the health, safety or welfare of the facility's patients;

(2) efforts by the facility to correct the violation;

(3) overall conditions of the facility;

(4) the facility's history of compliance; and

(5) any other pertinent conditions that may be applicable.

(f) Any monetary penalty assessed by the secretary shall be assessed in accordance with the following fine schedule:

(1) For class I violations the following number of violations within a 24-month period shall result in the corresponding fine amount:

(A) One violation, a fine of not less than $200 and not more than $1,000;

(B) two violations, a fine of not less than $500 and not more than $2,000;

(C) three violations, a fine of not less than $1,000 and not more than $5,000; and

(D) four or more violations, a fine of $5,000;

(2) for class II violations the following number of violations within a 24-month period shall result in the corresponding fine amount:

(A) One violation, a fine of not less than $100 and not more than $200;

(B) two violations, a fine of not less than $200 and not more than $1,000;

(C) three violations, a fine of not less than $500 and not more than $2,000;

(D) four violations, a fine of not less than $1,000 and not more than $5,000; and

(E) five or more violations, a fine of $5,000;

(3) for class III violations the following number of violations within a 24-month period shall result in the corresponding fine amount:

(A) One violation, there shall be no fine;

(B) two violations, a fine of not less than $100 and not more than $500;

(C) three violations, a fine of not less than $200 and not more than $1,000;

(D) four violations, a fine of not less than $500 and not more than $2,000;

(E) five violations, a fine of not less than $1,000 and not more than $5,000; and

(F) six or more violations, a fine of $5,000.

Sec. 7. Except in the case of a medical emergency, as defined in K.S.A. 65-6701, and amendments thereto, an abortion performed when the gestational age of the unborn child is 22 weeks or more shall be performed in a licensed hospital or ambulatory surgical center. All other abortions shall be performed in a licensed hospital, ambulatory surgical center or facility.

Sec. 8. (a) It shall be unlawful to operate a facility within Kansas without possessing a valid license issued annually by the secretary pursuant to section 2, and amendments thereto, with no requirement of culpable mental state.

(b) It shall be unlawful for a person to perform or induce an abortion in a facility unless such person is a physician, with clinical privileges at a hospital located within 30 miles of the facility, with no requirement of culpable mental state.

(c) Violation of subsection (a) or (b) is a class A nonperson misdemeanor and shall constitute unprofessional conduct under K.S.A. 65-2837, and amendments thereto.

Sec. 9. (a) The secretary shall adopt rules and regulations for the licensure of facilities for the performance of abortions.

(b) The secretary shall adopt rules and regulations concerning sanitation, housekeeping, maintenance, staff qualifications, emergency equipment and procedures to provide emergency care, medical records and reporting, laboratory, procedure and recovery rooms, physical plant, quality assurance, infection control, information on and access to patient follow-up care and any other areas of medical practice necessary to carry out the purposes of sections 1 through 12, and amendments thereto, for facilities for the performance of abortions. At a minimum these rules and regulations shall prescribe standards for:

(1) Adequate private space that is specifically designated for interviewing, counseling and medical evaluations;

(2) dressing rooms for staff and patients;

(3) appropriate lavatory areas;

(4) areas for preprocedure hand washing;

(5) private procedure rooms;

(6) adequate lighting and ventilation for abortion procedures;

(7) surgical or gynecologic examination tables and other fixed equipment;

(8) postprocedure recovery rooms that are supervised, staffed and equipped to meet the patients' needs;

(9) emergency exits to accommodate a stretcher or gurney;

(10) areas for cleaning and sterilizing instruments; and

(11) adequate areas for the secure storage of medical records and necessary equipment and supplies.

(c) The secretary shall adopt rules and regulations to prescribe facility supplies and equipment standards, including supplies and equipment, that are required to be immediately available for use or in an emergency. At a minimum these rules and regulations shall:

(1) Prescribe required equipment and supplies, including medications, required for the conduct, in an appropriate fashion, of any abortion procedure that the medical staff of the facility anticipates performing and for monitoring the progress of each patient throughout the procedure and recovery period;

(2) require that the number or amount of equipment and supplies at the facility is adequate at all times to assure sufficient quantities of clean and sterilized durable equipment and supplies to meet the needs of each patient;

(3) prescribe required equipment, supplies and medications that shall be available and ready for immediate use in an emergency and requirements for written protocols and procedures to be followed by staff in an emergency, such as the loss of electrical power;

(4) prescribe required equipment and supplies for required laboratory tests and requirements for protocols to calibrate and maintain laboratory equipment at the facility or operated by facility staff;

(5) require ultrasound equipment in facilities; and

(6) require that all equipment is safe for the patient and the staff, meets applicable federal standards and is checked annually to ensure safety and appropriate calibration.

(d) The secretary shall adopt rules and regulations relating to facility personnel. At a minimum these rules and regulations shall require that:

(1) The facility designate a medical director of the facility who is licensed to practice medicine and surgery in Kansas;

(2) physicians performing surgery in a facility are licensed to practice medicine and surgery in Kansas, demonstrate competence in the procedure involved and are acceptable to the medical director of the facility;

(3) a physician with admitting privileges at an accredited hospital located within 30 miles of the facility is available;

(4) another individual is present in the room during a pelvic

examination or during the abortion procedure and if the physician is male then the other individual shall be female;

(5) a registered nurse, nurse practitioner, licensed practical nurse or physician assistant is present and remains at the facility when abortions are performed to provide postoperative monitoring and care until each patient who had an abortion that day is discharged;

(6) surgical assistants receive training in the specific responsibilities of the services the surgical assistants provide; and

(7) volunteers receive training in the specific responsibilities of the services the volunteers provide, including counseling and patient advocacy as provided in the rules and regulations adopted by the director for different types of volunteers based on their responsibilities.

(e) The secretary shall adopt rules and regulations relating to the medical screening and evaluation of each facility patient. At a minimum these rules and regulations shall require:

(1) A medical history including the following:

(A) Reported allergies to medications, antiseptic solutions or latex;

(B) obstetric and gynecologic history; and

(C) past surgeries;

(2) a physical examination including a bimanual examination estimating uterine size and palpation of the adnexa;

(3) the appropriate laboratory tests including:

(A) For an abortion in which an ultrasound examination is not performed before the abortion procedure, urine or blood tests for pregnancy performed before the abortion procedure;

(B) a test for anemia as indicated;

(C) Rh typing, unless reliable written documentation of blood type is available; and

(D) other tests as indicated from the physical examination;

(4) an ultrasound evaluation for all patients who elect to have an abortion of an unborn child. The rules shall require that if a person who is not a physician performs an ultrasound examination, that person shall have documented evidence that the person completed a course in the operation of ultrasound equipment as prescribed in rules and regulations. The physician or other health care professional shall review, at the request of the patient, the ultrasound evaluation results with the patient before the abortion procedure is performed, including the probable gestational age of the unborn child; and

(5) that the physician is responsible for estimating the gestational age of the unborn child based on the ultrasound examination and obstetric standards in keeping with established standards of care regarding the estimation of fetal age as defined in rules and regulations and shall verify the estimate in the patient's medical history. The physician shall keep

original prints of each ultrasound examination of a patient in the patient's medical history file.

(f) The secretary shall adopt rules and regulations relating to the abortion procedure. At a minimum these rules and regulations shall require:

(1) That medical personnel is available to all patients throughout the abortion procedure;

(2) standards for the safe conduct of abortion procedures that conform to obstetric standards in keeping with established standards of care regarding the estimation of fetal age as defined in rules and regulations;

(3) appropriate use of local anesthesia, analgesia and sedation if ordered by the physician;

(4) the use of appropriate precautions, such as the establishment of intravenous access at least for patients undergoing second or third trimester abortions; and

(5) the use of appropriate monitoring of the vital signs and other defined signs and markers of the patient's status throughout the abortion procedure and during the recovery period until the patient's condition is deemed to be stable in the recovery room.

(g) The secretary shall adopt rules and regulations that prescribe minimum recovery room standards. At a minimum these rules and regulations shall require that:

(1) Immediate postprocedure care consists of observation in a supervised recovery room for as long as the patient's condition warrants;

(2) the facility arrange hospitalization if any complication beyond the management capability of the staff occurs or is suspected;

(3) a licensed health professional who is trained in the management of the recovery area and is capable of providing basic cardiopulmonary resuscitation and related emergency procedures remains on the premises of the facility until all patients are discharged;

(4) a physician or a nurse who is advanced cardiovascular life support certified shall remain on the premises of the facility until all patients are discharged and to facilitate the transfer of emergency cases if hospitalization of the patient or viable unborn child is necessary. A physician or nurse shall be readily accessible and available until the last patient is discharged;

(5) a physician or trained staff member discusses Rho(d) immune globulin with each patient for whom it is indicated and assures it is offered to the patient in the immediate postoperative period or that it will be available to her within 72 hours after completion of the abortion procedure. If the patient refuses, a refusal form approved by the department shall be signed by the patient and a witness and included in the medical record;

(6) written instructions with regard to postabortion coitus, signs of possible problems and general aftercare are given to each patient. Each patient shall have specific instructions regarding access to medical care for complications, including a telephone number to call for medical emergencies;

(7) there is a specified minimum length of time that a patient remains in the recovery room by type of abortion procedure and gestational age of the unborn child;

(8) the physician assures that a licensed health professional from the facility makes a good faith effort to contact the patient by telephone, with the patient's consent, within 24 hours after surgery to assess the patient's recovery; and

(9) equipment and services are located in the recovery room to provide appropriate emergency resuscitative and life support procedures pending the transfer of the patient or viable unborn child to the hospital.

(h) The secretary shall adopt rules and regulations that prescribe standards for follow-up visits. At a minimum these rules and regulations shall require that:

(1) A postabortion medical visit is offered and scheduled within four weeks after the abortion, if accepted by the patient, including a medical examination and a review of the results of all laboratory tests;

(2) a urine pregnancy test is obtained at the time of the follow-up visit to rule out continuing pregnancy. If a continuing pregnancy is suspected, the patient shall be evaluated and a physician who performs or induces abortions shall be consulted; and

(3) the physician performing or inducing the abortion, or a person acting on behalf of the physician performing or inducing the abortion, shall make all reasonable efforts to ensure that the patient returns for a subsequent examination so that the physician can assess the patient's medical condition. A brief description of the efforts made to comply with this requirements, including the date, time and identification by name of the person making such efforts, shall be included in the patient's medical record.

(i) The secretary shall adopt rules and regulations to prescribe minimum facility incident reporting. At a minimum these rules and regulations shall require that:

(1) The facility records each incident resulting in a patient's or viable unborn child's serious injury occurring at a facility and shall report them in writing to the department within 10 days after the incident. For the purposes of this paragraph, ''serious injury'' means an injury that occurs at a facility and that creates a serious risk of substantial impairment of a major body organ;

(2) if a patient's death occurs, other than an unborn child's death

properly reported pursuant to law, the facility shall report such death to the department of health and environment not later than the next department business day; and

(3) incident reports are filed with the department of health and environment and appropriate professional regulatory boards.

(j) (1) The secretary shall adopt rules and regulations requiring each facility to establish and maintain an internal risk management program which, at a minimum, shall consist of:

(A) A system for investigation and analysis of the frequency and causes of reportable incidents within the facility;

(B) measures to minimize the occurrence of reportable incidents and the resulting injuries within the facility; and

(C) a reporting system based upon the duty of all health care providers staffing the facility and all agents and employees of the facility directly involved in the delivery of health care services to report reportable incidents to the chief of the medical staff, chief administrative officer or risk manager of the facility.

(2) As used in this subsection, the term ''reportable incident'' means an act by a health care provider which:

(A) Is or may be below the applicable standard of care and has a reasonable probability of causing injury to a patient; or

(B) may be grounds for disciplinary action by the appropriate licensing agency.

(k) The rules and regulations adopted by the secretary pursuant to this section do not limit the ability of a physician or other health care professional to advise a patient on any health issue. The secretary periodically shall review and update current practice and technology standards under sections 1 through 12, and amendments thereto, and based on current practice or technology adopt by rules and regulations alternative practice or technology standards found by the secretary to be as effective as those enumerated in sections 1 through 12, and amendments thereto.

(l) The provisions of sections 1 through 12, and amendments thereto, and the rules and regulations adopted pursuant thereto shall be in addition to any other laws and rules and regulations which are applicable to facilities defined as clinics under section 1, and amendments thereto.

(m) In addition to any other penalty provided by law, whenever in the judgment of the secretary of health and environment any person has engaged, or is about to engage, in any acts or practices which constitute, or will constitute, a violation of this section, or any rules and regulations adopted under the provisions of this section, the secretary shall make application to any court of competent jurisdiction for an order enjoining such acts or practices, and upon a showing by the secretary that such person has engaged, or is about to engage, in any such acts or practices, an

injunction, restraining order or such other order as may be appropriate shall be granted by such court without bond.

Sec. 10. (a) No abortion shall be performed or induced by any person other than a physician licensed to practice medicine in the state of Kansas. When RU-486 (mifepristone) or any drug is used for the purpose of inducing an abortion, the drug must be administered by or in the same room and in the physical presence of the physician who prescribed, dispensed or otherwise provided the drug to the patient.

(b) The physician inducing the abortion, or a person acting on behalf of the physician inducing the abortion, shall make all reasonable efforts to ensure that the patient returns 12 to 18 days after the administration or use of such drug for a subsequent examination so that the physician can confirm that the pregnancy has been terminated and assess the patient's medical condition. 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 patient's medical record.

(c) A violation of this section shall constitute unprofessional conduct under K.S.A. 65-2837, and amendments thereto.

Sec. 11. Nothing in sections 1 through 12, and amendments thereto, shall be construed as creating or recognizing a right to abortion. Notwithstanding any provision of this section, a person shall not perform an abortion that is prohibited by law.

Sec. 12. The provisions of sections 1 through 12, and amendments thereto, are declared to be severable, and if any provision, or the application thereof, to any person shall be held invalid, such invalidity shall not affect the validity of the remaining provisions of sections 1 through 12, and amendments thereto.

Sec. 13. This act shall take effect and be in force from and after its publication in the statute book.