Session of 2006

Substitute for HOUSE BILL No. 2829

By Committee on Health and Human Services

2-16

AN ACT concerning abortion clinics; providing for regulation, licensing 10 and standards for the operation thereof; providing penalties for viola-11 12 tions and authorizing injunctive actions. AN ACT concerning the 13 secretary of health and environment; providing for regulation 14 of clinics and facilities where office-based surgeries and special 15 procedures are performed. 16 17 Be it enacted by the Legislature of the State of Kansas: 18 Section 1. (a) As used in this section: 19 "Secretary" means the secretary of health and environment. 20 - (2) "Abortion clinic" means a facility, other than an accredited hos-21 pital, in which five or more first trimester surgical abortions in any month 22 or any second or third trimester abortions are performed. 23 "Department" means the department of health and environment. (4) "Physician" means a person licensed to practice medicine and 24 surgery in this state. 25 26 "Gestational age" shall have the meaning ascribed to such term under K.S.A. 65-6701 and amendments thereto. 27 - (6) "Viable" shall have the meaning ascribed to such term under 28 29 K.S.A. 65-6701 and amendments thereto. 30 (b) The secretary shall adopt rules and regulations for an abortion 31 clinic's physical facilities. At a minimum these rules and regulations shall 32 prescribe standards for: (1) Adequate private space that is specifically designated for inter-33 34 viewing, counseling and medical evaluations. 35 (2) Dressing rooms for staff and patients. 36 (3) Appropriate lavatory areas. 37 — (4) Areas for preprocedure hand washing. 38 (5) Private procedure rooms. 39 Adequate lighting and ventilation for abortion procedures. 40 -(7)Surgical or gynecologic examination tables and other fixed equipment. 41 42(8) Postprocedure recovery rooms that are supervised, staffed and

equipped to meet the patients' needs.

- 1 (9) Emergency exits to accommodate a stretcher or gurney.
- 2 (10) Areas for cleaning and sterilizing instruments.
- 3 (11) Adequate areas for the secure storage of medical records and 4 necessary equipment and supplies.
- 5 (12) The display in the abortion clinic, in a place that is conspicuous 6 to all patients, of the clinic's current license issued by the department.
- 7 (c) The secretary shall adopt rules and regulations to prescribe abor8 tion clinic supplies and equipment standards, including supplies and
 9 equipment that are required to be immediately available for use or in an
 10 emergency. At a minimum these rules and regulations shall:
- 11 (1) Prescribe required equipment and supplies, including medica-12 tions, required for the conduct, in an appropriate fashion, of any abortion 13 procedure that the medical staff of the clinic anticipates performing and 14 for monitoring the progress of each patient throughout the procedure 15 and recovery period.
- (2) Require that the number or amount of equipment and supplies
 at the clinic 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 abortion clinic or operated by clinic staff.
- 27 <u>(5) Require ultrasound equipment in those facilities that provide</u> 28 abortions after 12 weeks gestational age of the fetus.
- 29 <u>(6) Require that all equipment is safe for the patient and the staff,</u>
 30 meets applicable federal standards and is checked annually to ensure safety and appropriate calibration.
- 32 (d) The secretary shall adopt rules and regulations relating to abortion
 33 elinie personnel. At a minimum these rules and regulations shall require
 34 that:
- 35 (1) The abortion clinic designate a medical director of the abortion clinic who is licensed to practice medicine and surgery in Kansas.
- (2) Physicians performing surgery in an abortion clinic are licensed
 to practice medicine and surgery in Kansas, demonstrate competence in
 the procedure involved and are acceptable to the medical director of the
 abortion clinic.
- 41 (3)—A physician with admitting privileges at an accredited hospital in 42 this state is available.
- 43 (4) Another individual is present in the room during a pelvic exami-

- nation or during the abortion procedure and if the physician is male then
 the other individual shall be female.
- 3 (5) A registered nurse, nurse practitioner, licensed practical nurse or
 4 physician assistant is present and remains at the clinic when abortions are
 5 performed to provide postoperative monitoring and care until each pa6 tient who had an abortion that day is discharged.
- 7 (6) Surgical assistants receive training in the specific responsibilities 8 of the services the surgical assistants provide.
- 9 (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.
- 13 (e) The secretary shall adopt rules and regulations relating to the 14 medical sercening and evaluation of each abortion clinic patient. At a 15 minimum these rules and regulations shall require:
- 16 (1) A medical history including the following:
- 17 (A) Reported allergies to medications, antiseptic solutions or latex.
- 18 (B) Obstetric and gynecologic history.
- 19 (C) Past surgeries.
- 20 <u>(2) A physical examination including a bimanual examination esti-</u> 21 mating uterine size and palpation of the adnexa.
- 22 <u>(3) The appropriate laboratory tests including:</u>
- (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.
- 26 (B) A test for anemia as indicated.
- 27 (C) Rh typing, unless reliable written documentation of blood type is 28 available.
- 29 (D)—Other tests as indicated from the physical examination.
- 30 (4) An ultrasound evaluation for all patients who elect to have an 31 abortion after 12 weeks gestational age of the fetus. The rules shall require 32 that if a person who is not a physician performs an ultrasound examina-33 tion, that person shall have documented evidence that the person com-34 pleted 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 re-36 37 sults with the patient before the abortion procedure is performed, in-38 eluding the probable gestational age of the fetus.
- (5) That the physician is responsible for estimating the gestational age of the fetus 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

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- prints of each ultrasound examination of a patient in the patient's medical
 history file.
- 3 (f) The secretary shall adopt rules and regulations relating to the 4 abortion procedure. At a minimum these rules and regulations shall 5 require:
- 6 (1) That medical personnel are available to all patients throughout 7 the abortion procedure.
- 9 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.
- 11 (3) Appropriate use of local anesthesia, analgesia and sedation if or-12 dered by the physician.
- 13 <u>(4) The use of appropriate precautions, such as the establishment of</u>
 14 intravenous access at least for patients undergoing second or third tri15 mester abortions.
- (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.
- 20 (g) The secretary shall adopt rules and regulations that prescribe minimum recovery room standards. At a minimum these rules and regulations
 22 shall require that:
- 23 <u>(1) Immediate postprocedure care consists of observation in a super-</u> 24 <u>vised recovery room for as long as the patient's condition warrants.</u>
 - (2) The clinic 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 abortion clinic 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 abortion clinic until all patients are discharged and to facilitate the transfer of emergency cases if hospitalization of the patient or viable fetus 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 such patient 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.

- 1 (6) Written instructions with regard to postabortion coitus, signs of
 2 possible problems and general aftercare are given to each patient. Each
 3 patient shall have specific instructions regarding access to medical care
 4 for complications, including a telephone number to call for medical
 5 emergencies.
- 6 (7) There is a specified minimum length of time that a patient re-7 mains in the recovery room by type of abortion procedure and gestational 8 age of the fetus.
- 9 (8) The physician assures that a licensed health professional from the
 10 abortion clinic makes a good faith effort to contact the patient by tele11 phone, with the patient's consent, within 24 hours after surgery to assess
 12 the patient's recovery.
- 13 <u>(9) Equipment and services are located in the recovery room to pro-</u> 14 vide appropriate emergency resuscitative and life support procedures 15 pending the transfer of the patient or viable fetus 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, if requested, sched uled within four weeks after the abortion, including a medical examina tion 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 abortions shall be consulted.
 - (i) The secretary shall adopt rules and regulations to prescribe minimum abortion clinic incident reporting. At a minimum these rules and regulations shall require that:
- (1) The abortion clinic records each incident resulting in a patient's or viable fetus' serious injury occurring at an abortion clinic 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 an abortion clinic and that creates a serious risk of substantial impairment of a major body organ.
- (2) If a patient's death occurs, other than a fetal death properly reported pursuant to law, the abortion clinic shall report such death to the department of health and environment not later than the next department business day.
- 39 <u>(3) Incident reports are filed with the department of health and environment and appropriate professional regulatory boards.</u>
- 41 (j) (1) The secretary shall adopt rules and regulations requiring each 42 abortion clinic to establish and maintain an internal risk management 43 program which, at a minimum, shall consist of: (A) A system for investi-

gation and analysis of the frequency and causes of reportable incidents within the clinic; (B) measures to minimize the occurrence of reportable incidents and the resulting injuries within the clinic; and (C) a reporting system based upon the duty of all health care providers staffing the clinic and all agents and employees of the clinic 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 clinic.

— (2)—As used in this subsection (j), "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 secretary shall make or cause to be made such inspections and investigations of abortion clinics at such intervals as the secretary determines necessary to protect the public health and safety and to implement and enforce the provisions of this act and rules and regulations adopted hereunder. For that purpose, authorized agents of the secretary shall have access to an abortion clinic during reasonable business hours.

(l) Information received by the secretary through filed reports, inspections or as otherwise authorized under this act 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.

— (m) (1)—No person shall operate an abortion clinic in this state unless such clinic holds a currently valid license as an abortion clinic under this act. Each such clinic shall be required annually to obtain a license from the department. The secretary shall adopt rules and regulations providing for the issuance of such licenses. At a minimum such rules and regulations shall require compliance with the standards adopted pursuant to this act. The secretary shall establish by rules and regulations the fee for such licenses in the amount required to cover costs of implementation and enforcement of this act.

(2) The department shall deny, suspend or revoke a license in any case in which it finds that there has been a substantial failure to comply with the requirements established under this act and rules and regulations adopted pursuant thereto, a failure to report any information required to be reported under subsections (i) and (j) or a failure to maintain a risk management program as required under subsection (j), after notice and an opportunity for hearing to the applicant or licensee in accordance with the provisions of the Kansas administrative procedure act.

42 — (n) The rules and regulations adopted by the secretary pursuant to 43 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 this act 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 this act.

(o) The provisions of this act 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 abortion clinics under this section.

(p) 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.

[Section 1. As used in this act:

- [(a) "Board" means the state board of healing arts.
- [(b) "Local anesthesia" means the administration of an anesthetic agent into a localized part of the human body by topical application or local infiltration in close proximity to a nerve, which produces a transient and reversible loss of sensation.
- [(c) "Minimal sedation" means the administration of oral sedative or oral analysis drugs in doses appropriate for the unsupervised treatment of insomnia, anxiety or pain.
- [(d) "Minor surgery" means surgery which can be safely and comfortably performed on a patient who has received local or topical anesthesia, without more than minimal sedation and where the likelihood of complications requiring hospitalization not reasonably foreseen.
- [(e) "Office-based surgery" means any surgery or other special procedure requiring anesthesia, analgesia or sedation which is performed by a physician in a clinical location other than a medical facility licensed pursuant to K.S.A. 65-425, and amendments thereto, and which results in a patient stay of less than 24 hours. The term does not include minor surgery.
- [(f) "Physician" means a person licensed by the board of healing arts to practice medicine and surgery in the state of Kansas.
- [(g) "Secretary" means the secretary of health and environment.

- [(h) "Special procedure" means a patient care service which requires contact with the human body with or without instruments in a potentially painful manner, for a diagnostic or therapeutic procedure requiring anesthesia services. The term does not include minor surgery.
- [(i) "Surgery" means a manual or operative procedure which involves the excision or resection, partial or complete, destruction, incision or other structural alteration of human tissue by any means, including the use of lasers, performed upon the human body for the purpose of preserving health, terminating a pregnancy, diagnosing or treating disease, repairing injury, correcting deformity or defects, prolonging life or relieving suffering, or for aesthetic, reconstructive or cosmetic purposes. Surgery includes, but is not limited to, incision or curettage of tissue or an organ, suture or other repair of tissue or an organ, a closed or open reduction of a fracture, extraction of tissue from the uterus and insertion of natural or artificial implants.
- [(j) "Topical anesthesia" means an anesthetic agent applied directly or by spray to the skin or mucous membranes, intended to produce a transient and reversible loss of sensation to a circumscribed area.
- [Sec. 2. (a) The secretary, by rules and regulations, shall establish standards for clinics and other facilities, in consultation with the state board of healing arts, where office-based surgery or special procedures, or both, are performed. Such standards shall promote the safety of patients, including, but not limited to, standards addressing:
- 28 [(1) Qualifications and supervision of nonphysician personnel 29 excluding licensed nurses and registered nurse anesthetists;
 - [(2) facility safety and sanitation;
- **[(3) equipment requirements, sanitation, testing and** 32 **maintenance**;
 - [(4) patient screening, assessment and monitoring;
 - [(5) selection of procedures to be performed;
 - [(6) anesthesia services:
 - [(7) peri-operative care;
 - [(8) emergencies and patient transfers; and
- 38 [(9) quality assurance and peer review.
 - [(b) In adopting standards pursuant to this section, the secretary, in consultation with the state board of healing arts, shall give consideration to standards adopted for the purposes of regulating ambulatory surgical centers licensed pursuant to K.S.A. 65-425 et seq. and amendments thereto and shall give consideration to the

guidelines for office-based surgery and special procedures approved by the Kansas medical society house of delegates on May 5, 2002, and any subsequently approved guidelines, and to guidelines for office-based surgery and special procedures approved by the state board of healing arts.

- [(c) Any rules and regulations adopted by the secretary pursuant to this act shall provide for protection of the identities of patients and health care providers.
- [(d) Rules and regulations required by this section shall be adopted as temporary regulations within 60 days of the effective date of this act with corresponding permanent rules and regulations adopted on or before January 1, 2007.
- [Sec. 3. (a) A correction order may be issued by the secretary or the secretary's designee to a clinic or facility which performs office-based surgery or special procedures, or both, whenever a duly authorized representative of the secretary inspects or investigates such clinic or facility and determines that the clinic or facility is not in compliance with the standards adopted by the secretary by rule and regulation pursuant to section 2 and amendments thereto. The correction order shall be served upon the clinic or facility either personally or by certified mail, return receipt requested. The correction order shall be in writing, shall state the specific deficiency and shall specify a time of 30 days for correction of the deficiency, unless the deficiency is of such an extreme hazard to the health and safety of a patient that immediate correction is required. In such an extreme case correction of the deficiency in less than 30 days may be ordered by the secretary or the secretary's designee.
- [(b) When the time period set forth in the correction order has passed, the clinic or facility shall be reinspected for compliance. If the clinic or facility is still in noncompliance, the correction order will become an open record at this time and the secretary or the secretary's designee may restrict the performance of any office-based surgeries or special procedures, or both, at the noncompliant clinic or facility until compliance is found and may level a civil penalty against such clinic or other facility pursuant to section 4, and amendments thereto. If the secretary determines that the continued performance of office-based surgeries and special procedures at the noncompliant clinic or facility poses a threat of potential harm to patients, the secretary may exercise injunctive authority until such time as a hearing may be conducted in accordance with the provisions of the Kansas administrative procedure act.

- [Sec. 4. (a) Any clinic or facility which remains noncompliant to the correction order and continues to violate any provision of the rules and regulations adopted under this act may incur a civil penalty in an amount not more than \$5,000 for every such violation. In the case of a continuing violation, every day such violation continues shall be deemed a separate violation.
- [(b) The secretary, upon a finding that a clinic or facility has violated any provision of rules and regulations adopted under this act may impose a penalty within the limits provided in this section. In determining the amount of the civil penalty, the secretary shall take into consideration all relevant circumstances, including, but not limited to, the extent of harm caused by the violation, the nature and persistence of the violation, the length of time over which the violation occurs and any corrective actions taken.
- [(c) No penalty shall be imposed under this section until written notice and an opportunity for hearing have been provided to the clinic or facility alleged to have committed the violation. Such notice shall state the violation, the penalty to be imposed and the right of the clinic or facility to a hearing on the matter. Such clinic or facility, within 15 days after service of the order, may make written request to the secretary for a hearing thereon. The hearing shall be conducted in accordance with the provisions of the Kansas administrative procedure act.
- [(d) Any action of the secretary pursuant to this section is subject to review in accordance with the act for judicial review and civil enforcement of agency actions.
- [Sec. 5. Any clinic or facility where office-based surgery or special procedures, or both, are performed at the time rules and regulations adopted under this act take effect shall be given reasonable time, as determined by the secretary under the particular circumstances, but not to exceed 30 days from the effective date of such rules and regulations, within which to comply with such rules and regulations.
- [Sec. 6. (a) The secretary shall conduct unannounced inspections of any clinic or facility where office-based surgery or special procedures are performed at least every five years on a routine basis. As soon as possible after the effective date of this act and after the effective dates of the adoption of the new rules and regulations under this act, the secretary shall conduct unannounced inspections of any clinic or facility in which abortions are performed. Upon receipt of a complaint, the secretary shall conduct an inspection in a timely manner.
- [(b) The secretary shall assess a fee for the inspection of any

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clinic or facility where office-based surgery or special procedures are performed. The fee shall cover all of the cost of the inspection and be paid by the clinic or facility being inspected to the department of health and environment. The secretary shall adopt rules and regulations establishing the fees to be charged for such inspections.

- [(c) The board of healing arts shall forward all complaints it receives regarding clinics or facilities where office-based surgery or special procedures are performed to the secretary.
- [(d) The secretary shall forward the results of all inspections to the board of healing arts or the state board of nursing, or both, as 12 appropriate, when such clinic or facility is out of compliance.
- 13 [Sec. 7. Rules and regulations adopted pursuant to sections 1 through 6, and amendments thereto, shall not apply to those fa-14 15 cilities accredited by the joint commission on accreditation of health care organizations.] 16
- 17 Sec. 2 [8]. This act shall take effect and be in force from and after 18 its publication in the statute book.