

K.A.R. 28-34-126. Definitions. For the purposes of K.A.R. 28-34-126 through 28-34-144, the following terms shall have the meanings specified in this regulation. (a) "Admitting privileges" means permission extended by a hospital to a physician to allow the physician to admit a patient to that hospital either as active or courtesy staff.

(b) "Ancillary services" means laboratory, radiology, or pharmacy services.

(c) "Ancillary staff member" means an individual who performs laboratory, radiology, or pharmacy services at a facility.

(d) "Applicant" means a person who has applied for a license but who has not yet been granted a license to operate a facility.

(e) "Clinical privileges" means permission extended by a hospital to a physician to allow the physician to provide treatment to a patient in that hospital.

(f) "Health professional" means an individual, other than a physician, who is one of the following:

(1) A nurse licensed by the Kansas state board of nursing; or

(2) a physician assistant licensed by the Kansas state board of healing arts.

(g) "Licensee" means a person who has been granted a license to operate a facility.

(h) "Medical staff member" means an individual who is one of the following:

(1) A physician licensed by the Kansas state board of healing arts;


(2) a health professional; or

(3) an ancillary staff member.

(i) "Newborn child" means a viable child delivered during an abortion procedure.

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(j) "Person" means any individual, firm, partnership, corporation, company, association, or joint-stock association, and the legal successor thereof.

(k) "Risk manager" means the individual designated by the applicant or licensee to administer the facility's internal risk management program and to receive reports of reportable incidents within the facility.

(l) "Reportable incident" means an act by a medical staff member which:

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

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

(m) "Staff member" means an individual who provides services at the facility and who is compensated for those services.

(n) "Unborn child" means a living individual organism of the species homo sapiens, in utero, at any stage of gestation from fertilization to birth.


(o) "Viable" shall have the same meaning ascribed in K.S.A. 65-6701, and amendments thereto.

(p) "Volunteer" means an individual who provides services at the facility and who is not compensated for those services.

This regulation shall be effective on and after July 1, 2011. (Authorized by 2011 House substitute for SB 36, sec. 9; implementing 2011 House substitute for SB 36, sec.1; effective, T-_____, _____.)

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28-34-127. Application process. (a) Any person desiring to operate a facility shall apply for a license on forms provided by the department.

(b) Each applicant shall submit a fee of \$500 for a license. The applicable fee shall be submitted at the time of license application and shall not be refundable.

(c) Before initial licensing each applicant shall submit to the department the following information:

(1) Written verification from the applicable local authorities showing that the premises are in compliance with all local codes and ordinances, including all building, fire, and zoning requirements;

(2) written verification from the state fire marshal showing that the premises are in compliance with all applicable fire codes and regulations;

(3) documentation of the specific arrangements that have been made for the removal of biomedical waste and human tissue from the premises; and

(4) documentation that the facility is located within 30 miles of an accredited hospital.

(d) The granting of a license to any applicant may be denied by the secretary if the applicant is not in compliance with all applicable laws, rules, and regulations.

This regulation shall be effective on and after July 1, 2011. (Authorized by 2011 House substitute for SB 36, sec. 9; implementing 2011 House substitute for SB 36, secs. 2 and 9; effective, T-_____, _____.)

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28-34-129. Terms of a license. (a) Each license shall be effective for one year following the date of issuance.

(b) Each license shall be valid for the licensee and the address specified on the license.

When an initial, renewed, or amended license becomes effective, all licenses previously granted to the applicant or licensee at the same address shall become invalid.

(c) Only one physical location shall be described in each license.

(d) Any applicant may withdraw the application for a license.

(e) Any licensee may submit, at any time, a request to close the facility permanently and to surrender the license.

(f) If a facility is closed, any license granted for that facility shall become void.

This regulation shall be effective on and after July 1, 2011. (Authorized by 2011 House substitute for SB 36, sec. 9; implementing 2011 House substitute for SB 36, sec. 2; effective, T-_____, _____.)

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28-34-130. Renewals; amendments. (a) No earlier than 90 days before but no later than the renewal date, each licensee wishing to renew the license shall submit the following:

- (1) The nonrefundable license fee of \$500; and
- (2) an application to renew the license on the form provided by the department.
- (b) Each licensee shall submit a request for an amended license to the department within 30 days, as set forth in 2011 House substitute for SB 36, sec. 4.

This regulation shall be effective on and after July 1, 2011. (Authorized by 2011 House substitute for SB 36, sec. 9; implementing 2011 House substitute for SB 36, secs. 2, 3, and 4; effective, T-_____, _____.)

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K.A.R. 28-34-131. Operation of the facility. (a) Each applicant and each licensee shall be responsible for the operation of the facility.

(b) Each applicant and each licensee shall:

(1) Ensure compliance with all applicable federal, state, and local laws;

(2) serve as or designate a medical director who is a physician licensed by the Kansas state board of healing arts and who has no limitations to the license that would prohibit the physician's ability to serve in the capacity as a medical director of a facility; and

(3) ensure the following documents are conspicuously posted at the facility:

(A) The current facility license issued by the department; and

(B) the current telephone number and address of the department.

(c) Each applicant and each licensee shall ensure that written policies and procedures are developed and implemented for the operation of the facility. The policies and procedures shall include the following requirements:

(1) An organized recordkeeping system to meet the requirements in K.A.R. 28-34-144;

(2) documentation of personnel qualifications, duties, and responsibilities to meet the requirements in K.A.R. 28-34-132;

(3) that the facility is designed, constructed, equipped, and maintained to protect the health and safety of patients, staff, and visitors to meet the requirements in K.A.R. 28-34-133 through 28-34-136;

(4) ensure proper and adequate medical screening and evaluation of each patient to meet the requirements in K.A.R. 28-34-137;

(5) consent is obtained from each patient before the procedure;

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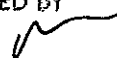
- (6) safe conduct of abortion procedures to meet the requirements in K.A.R. 28-34-138;
- (7) the appropriate use of anesthesia, analgesia and sedation to meet the requirements in K.A.R. 28-34-138;
- (8) ensure the use of appropriate precautions for any patient undergoing a second or third trimester abortion to meet the requirements in K.A.R. 28-34-138;
- (9) post-procedure care of patients to meet the requirements in K.A.R. 28-34-139;
- (10) identify and ensure a physician with admitting privileges at an accredited hospital located within 30 miles of the facility is available during facility hours of operation;
- (11) if indicated, the transfer of any patient and newborn child to a hospital to meet the requirements in K.A.R. 28-34-140;
- (12) follow-up and aftercare for each patient receiving an abortion procedure in the facility to meet the requirements in K.A.R. 28-34-141;
- (13) a written plan for risk management to meet the requirements in K.A.R. 28-34-142, including policies and procedures for staff member or volunteer reporting of any clinical care concerns; and
- (14) ensure that incidents that require reporting to the department are completed as required in K.A.R. 28-34-143.

This regulation shall be effective on and after July 1, 2011. (Authorized by 2011 House substitute for SB 36, sec. 9; implementing 2011 House substitute for SB 36, secs. 2 and 9; effective, T-_____, _____.)

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K.A.R. 28-34-132. Staff requirements. (a) Each applicant and each licensee shall ensure that each physician performing surgery in a facility is approved by the medical director, licensed to practice medicine and surgery in the state of Kansas, and demonstrates competence in the procedure involved in the physician's duties at the facility. Competence shall be demonstrated through both of the following means and methods:

- (1) Documentation of education and experience; and
- (2) observation by or interaction with the medical director.

(b) Each applicant and each licensee shall ensure the following:

(1) A physician with admitting privileges at an accredited hospital located within 30 miles of the facility is available.

(2) Any physician performing or inducing abortion procedures in the facility has clinical privileges at a hospital located within 30 miles of the facility.

(c) Each applicant and each licensee shall ensure that each individual who performs an ultrasound is one of the following:

(1) A physician licensed in the state of Kansas who has completed a course for the type of ultrasound examination the physician performs; or

(2) an individual who performs ultrasounds under the supervision of a physician and who meets all of the following requirements:

(A) Has completed a course in performing ultrasounds;

(B) has completed a training for the specific type of ultrasound examination the individual performs; and

(C) is not otherwise precluded by law from performing ultrasound examinations.

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(d) Each applicant and each licensee shall ensure that each physician assistant, each nursing, and each ancillary staff member employed by or contracted with the facility are licensed, if required by state law, are qualified, and provide services to patients consistent with the scope of practice of the individual's training and experience.

(e) Each applicant and each licensee shall ensure that each surgical assistant employed by or contracted with the facility receives training in the specific responsibilities of the services the surgical assistant provides in the facility.

(f) Each applicant and each licensee shall ensure that each volunteer receives training as identified by the medical director in the specific responsibilities the volunteer provides at the facility.

(g) Each applicant and each licensee shall ensure that at least one physician or registered nurse is certified in advanced cardiovascular life support and is present at the facility when any patient is present.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, sec. 9; effective, T-_____, _____.)

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K.A.R. 28-34-133. Facility environmental standards. (a) Each applicant and each licensee shall ensure that the facility is designed, constructed, equipped, and maintained to protect the health and safety of patients, staff members, volunteers, and visitors.

(b) Each facility shall include the following rooms and areas:

(1) At least one room with private space consisting of at least 80 square feet, designated for patient interviews, counseling, and medical examinations;

(2) designated dressing rooms for patients only, including a toilet, hand washing station, and storage for clothing and valuables;

(3) designated dressing rooms for staff members only, including a toilet, hand washing station, and storage for clothing and valuables;

(4) a toilet room adjacent to the recovery area, designated for patients only;

(5) a toilet room designated for the public only;

(6) separate facilities for pre-procedure handwashing by staff members;

(7) private procedure rooms consisting of at least 150 square feet, excluding fixed cabinet areas;

(8) a recovery area consisting of at least 80 square feet per patient in the area;

(9) a nurse station with visual observation of each patient in the recovery area;

(10) privacy for each patient in the recovery area with at least cubicle curtains around each patient gurney or bed;

(11) a waiting area for patients and visitors;

(12) an administrative area, including office space for the secure filing and storage of facility patient records;

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(13) a soiled workroom exclusive to the procedure rooms, including the following:

- (A) A hand washing station;
- (B) a work counter;
- (C) a clinical sink; and
- (D) receptacles for waste and soiled items;

(14) a clean workroom including the following:

- (A) A hand washing station;
- (B) counter space;
- (C) storage space for clean and sterile supplies;
- (D) and an area for cleaning and sterilizing instruments; and
- (E) physically separated from the soiled workroom; and

(15) a storage area designated for janitorial supplies and equipment consisting of at least 50 square feet per procedure room.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, sec. 9; effective, T-_____, _____.)

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K.A.R. 28-34-134. Health and safety requirements. (a) Each applicant and each licensee shall ensure that the facility meets the following health and safety requirements:

(1) The room temperature in each procedure room shall be between 68 and 73 degrees Fahrenheit during each abortion procedure.

(2) The room temperature in each patient recovery area shall be between 70 and 75 degrees Fahrenheit at all times.

(3) Fixed or portable lighting units shall be present in each examination, procedure, and recovery room or area, in addition to general lighting.

(4) Each emergency exit shall accommodate a stretcher or a gurney.

(5) The facility shall be maintained in a clean condition.

(6) The facility shall not be infested by insects and vermin.

(7) A warning notice shall be placed at the entrance to any room or area where oxygen is in use.

(8) Soiled linen and clothing shall be kept in covered containers in a separate area from clean linen and clothing.

(b) A written emergency plan shall be developed and implemented, including procedures for protecting the health and safety of patients and other individuals in any of the following circumstances:

(1) A fire;

(2) a natural disaster;

(3) loss of electrical power; or

(4) threat or incidence of violence.

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(c) An evacuation drill shall be conducted at least once every six months, including participation by all individuals in the facility at the time of the drill. Documentation shall be maintained at the facility for one year from the date of the drill and shall include the date and time of the drill.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, sec. 9; effective, T-_____, _____.)

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K.A.R. 28-34-135. Equipment; supplies; drugs and medications. (a) Each applicant and each licensee shall ensure that supplies, equipment, drugs, and medications are immediately available for use or in an emergency.

(b) Equipment and supplies shall be maintained in the amount required to assure sufficient quantities of clean and sterilized durable equipment to meet the needs of each patient during any abortion procedure and for monitoring each patient throughout the procedure and recovery period.

(c) Each applicant and each licensee shall ensure that the following equipment and supplies are maintained in the facility for airway management:

- (1) An oxygen source with flowmeter;
- (2) simple face masks, in sizes for infants, children, and adults;
- (3) pediatric and adult masks for assisting ventilation;
- (4) self-inflating bag with reservoir, 500 cc and 1000 cc;
- (5) suction, either wall or machine;
- (6) suction catheters, Yankauer, 8, 10, and 14F;
- (7) oral airways, infant to adult sizes;
- (8) nasal cannulas in infant, child, and adult sizes 1-3;
- (9) options for intubation, if needed;
- (10) laryngoscope handle with batteries;
- (11) miller blades, 0, 1, 2, and 3;
- (12) endotracheal tubes, uncuffed, 3.0, 3.5, 4.0, 4.5, 5.0, 6.0, 7.0, and 8.0;
- (13) stylets, small and large; and

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(14) adhesive tape to secure airway.

(d) Each applicant and each licensee shall ensure that the following supplies are maintained in the facility for fluid management:


- (1) Intraosseous needles, 15 or 18 gauge;
- (2) intravenous catheters, 18, 20, 22, and 24 gauge;
- (3) butterfly needles, 23 gauge;
- (4) intravenous boards, tape, alcohol swabs, and tourniquets;
- (5) pediatric drip chambers and tubing;
- (6) D5 ½ normal saline; and
- (7) isotonic fluids, either normal saline or lactated Ringer's solution.

(e) Each applicant and each licensee shall ensure that the following miscellaneous equipment and supplies are maintained in the facility:

- (1) Blood pressure cuffs, preemie, infant, child, and adult;
- (2) nasogastric tubes, 8, 10, and 14F; and
- (3) sphygmomanometer manual.

(f) Each applicant and each licensee may maintain the following optional equipment and supplies in the facility:

- (1) Portable monitor/defibrillator, with settings less than 10;
- (2) pediatric defibrillation paddles;
- (3) pediatric electrocardiogram (EKG) skin electrode contacts, peel and stick;

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(4) pulse oximeter with reusable sensors for older children and non-reusable sensors for small children;

(5) device to check serum glucose;

(6) strips to check urine for glucose and blood; and

(7) central lines over guidewire catheters, 3, 4, and 5F.

(g) Each applicant and each licensee shall ensure that all equipment is safe for each patient and for the staff.

(h) Each applicant and each licensee shall ensure that each item of equipment is installed and used according to the manufacturer's recommendations for use.

(i) Each applicant and each licensee shall ensure that each item of equipment is checked annually to ensure safety and appropriate calibration.

(j) Each applicant and each licensee shall ensure that equipment and supplies are clean and sterile, if applicable, before each use.

(k) Each applicant and each licensee shall ensure that the facility meets the following requirements for equipment:

(1) All equipment shall be clean, functional, and maintained in accordance with the manufacturer's instructions.

(2) The following equipment shall be available at all times:

(A) Ultrasound equipment;

(B) intravenous equipment;

(C) laboratory equipment;

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- (D) patient resuscitation and suction equipment;
- (E) equipment to monitor vital signs in each room in which an abortion is performed;
- (F) a surgical or gynecologic examination table;
- (G) equipment to measure blood pressure;
- (H) a stethoscope;
- (I) a scale for weighing a patient; and
- (J) additional equipment for any abortion procedure performed after the first trimester, including ultrasound equipment, drugs to support cardiopulmonary function, and equipment to monitor cardiopulmonary status.

(I) Each applicant and each licensee shall ensure that equipment and appropriate medications are located in the recovery area as needed for the provision of appropriate emergency resuscitative and life support procedures pending the transfer to a hospital of a patient or a newborn child.

(1) Each applicant and each licensee shall maintain an emergency kit or a stock supply of drugs and medications for the use of the physician in treating the emergency needs of patients, as required in subsection (m) of this regulation.

(2) The emergency kit or medication shall be stored in such a manner as to prohibit access by unauthorized personnel.

(3) Contents of the emergency kit or stock supplies of medications shall be regularly reviewed to ensure proper inventory control with removal or replacement of expired drugs and medications.

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
(4) Drugs and equipment shall be available within the facility to treat the following conditions consistent with standards of care:

- (A) Cardiac arrest;
- (B) a seizure;
- (C) an asthma attack;
- (D) allergic reaction;
- (E) narcotic or sedative toxicity;
- (F) hypovolemic shock;
- (G) vasovagal shock; and
- (H) anesthetic reactions.

(m) The following medications shall be maintained at the facility:

(1) Aqueous epinephrine – 1:1000 and 1:10,000 {1:1000 = 1 gram/1000 cc or 1 mg/cc and is available as both 1 cc glass vials which must be cracked and 30 cc multiple dose vials} {1:10,000 = 1 gram/10,000 cc or 0.1 mg/cc comes as a 10 cc bristojet};

- (2) atropine sulfate;
- (3) dextrose in water – 50%;
- (4) sodium bicarbonate – 1 meg/cc (approximately);
- (5) lorazepam or diazepam;
- (6) phenobarbital;
- (7) antibiotics, parenteral, including ampicillin, gentamycin, and ceftriaxone;
- (8) methylprednisolone or dexamethasone;

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(9) naloxone (1 mg/cc);

(10) activated charcoal;

(11) albuterol concentrated for inhalation (5 mg/cc) {also supplied premixed with 2.5 mg/2.5 cc};

(12) lidocaine 2% (20 mg/cc); and


(13) Benadryl (50 mg/cc).

(n) Drugs and medications shall be administered to individual patients only by a facility physician or a facility health professional.

(o) If a stock of controlled drugs is to be maintained at the facility, the applicant or licensee shall ensure that the facility is registered by the Kansas board of pharmacy. Each applicant and each licensee shall ensure the proper safeguarding and handling of controlled substances within the facility, and shall ensure that all possible control measures are observed and that any suspected diversion or mishandling of controlled substances is reported immediately.

(p) Records shall be kept of all stock supplies of controlled substances giving an accounting of all items received or administered.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, sec. 9; effective, T-_____, _____.)

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K.A.R. 28-34-136. Ancillary services. (a) Each applicant and each licensee shall document that the facility maintains a certificate of compliance from the centers for medicare and medicaid services pursuant to section 353 of the public health services act, 42 U.S.C. 263a, as revised by the clinical laboratory and current clinical laboratory improvement amendments for the purpose of performing examinations or procedures.

(b) Each applicant and each licensee shall ensure that the facility meets the following requirements for radiology services:

(1) Allow only trained and qualified individuals to operate radiology equipment;

(2) document annual checks and calibration of radiology equipment and maintain records of the annual checks and calibrations;

(3) ensure that all radiology and diagnostic procedures are provided only on the order of a physician; and

(4) maintain signed and dated clinical reports of the radiological findings in each patient's record.

(c) Each applicant and each licensee shall ensure that written policies and procedures are developed and implemented relating to drugs, including the following:

(1) Storage of drugs;

(2) security of drugs;

(3) labeling and preparation of drugs;

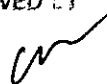
(4) administration of drugs; and

(5) disposal of drugs.

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(d) Each applicant and each licensee shall ensure that all drugs and medications shall be ordered pursuant to a written order from a facility physician or a facility health professional.

(e) Each applicant and each licensee shall ensure that each adverse drug reaction is reported to the physician responsible for the patient and is documented in the patient record.

(f) Each applicant and each licensee shall ensure that each drug and each medication requiring refrigeration is stored in a refrigerator that is used only for drug and medication storage.

(g) Each applicant and each licensee shall ensure that there is a mechanism for the ongoing review and evaluation of the quality and scope of laboratory, radiology, and pharmaceutical services.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, sec. 9; effective, T-_____, _____.)

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K.A.R. 28-34-137. Patient screening and evaluation. (a) Each applicant and each licensee shall ensure written policies and procedures are developed and implemented for the medical screening and evaluation of patients. A medical screening and evaluation shall be completed on each patient before an abortion procedure is performed.

(b) The medical screening and evaluation shall consist of the following:

(1) A medical history shall be completed, including the following:

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

(B) obstetric and gynecologic history;

(C) past surgeries;

(D) medication currently being taken by the patient; and

(E) any other medical conditions.

(2) A physical examination shall be performed by a physician, including a bimanual examination to estimate uterine size and palpation of the adnexa.

(3) An ultrasound evaluation shall be completed for any patient who elects to have an abortion of an unborn child. The physician shall estimate 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 the age of the unborn child and shall verify the estimate in the patient's medical history. The physician shall keep the original prints of each ultrasound examination for each patient in the patient's medical history file.

(4) The appropriate laboratory tests shall be completed, including the following:

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

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which shall be completed before the abortion procedure;

(B) a test for anemia as indicated;

(C) determination of Rh factor or Rh typing, unless the patient provides written documentation of blood type acceptable to the physician; and

(D) other tests recommended by the physician or the medical director on the basis of the physical examination, which may include tests for chlamydia and gonorrhea and other cultures, syphilis serology, and a papanicolaou procedure.

(c) Each licensee shall ensure that another individual is present in the room during a pelvic examination or an abortion procedure. If the physician conducting the examination or the procedure is male, the other individual in the room shall be female.

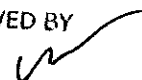
(d) The physician or health care professional shall review, at the request of the patient, the ultrasound evaluation results with the patient before the abortion procedure is performed, including the probable gestational age of the unborn child.

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K.A.R. 28-34-138. Abortion procedure. (a) Each applicant and each licensee shall ensure that written policies and procedures are developed and implemented for the following procedures:

(1) Safe conduct of abortion procedures that conform to obstetric standards in keeping with established standards of care regarding the estimation of the gestational age of the unborn child;

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

(3) the use of appropriate precautions, including the establishment of intravenous access for any patient undergoing a second or third trimester abortion, unless the physician determines that establishing intravenous access is not appropriate for the patient and documents that fact in the medical record of the patient.

(b) Each licensee shall ensure that the following procedures are followed for each patient before performance of an abortion:

(1) Information is provided to the patient on the abortion procedure, including alternatives, risks, and potential complications.

(2) Written consent is signed and dated by the patient.

(c) Each licensee shall ensure that a physician and at least one health professional is available to each patient throughout the abortion procedure.

(d) Each licensee shall ensure that an infection control program is established which includes the following:

(1) Measures for surveillance, prevention, and control of infections;

(2) policies and procedures outlining infection control and aseptic techniques to be

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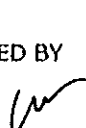
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followed by staff members and volunteers; and

(3) training on infection control and aseptic techniques for all staff members and volunteers.

(e) Each licensee shall ensure that each abortion is performed according to the facility's policies and procedures and in compliance with all applicable laws, rules, and regulations.

(f) Each licensee shall ensure that health professionals monitor each patient's vital signs throughout the abortion procedure to ensure the health and safety of the patient.

(g) Each licensee shall ensure that the following steps are performed if an abortion procedure results in the delivery of a newborn child:

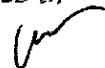
- (1) Resuscitative measures are used to support life;
- (2) the newborn child is transferred to a hospital; and
- (3) resuscitative measures and the transfer to a hospital are documented.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, sec. 9; effective, T-_____, _____.)

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K.A.R. 28-34-139. Recovery procedures; discharge. (a) Each applicant and each licensee shall ensure written policies and procedures are developed and implemented for the post-procedure care of patients, which shall include the following:

(1) Each patient shall remain in the recovery area at least two hours following the abortion procedure and as necessary based on the physician's evaluation of the patient's medical condition.

(2) Immediate post-procedure care for each patient shall consist of observation in a supervised recovery area.

(3) The vital signs and bleeding of each patient shall be monitored by a physician or a health professional.

(b) Each licensee shall ensure that a physician or an individual designated by a physician shall discuss Rho(d) immune globulin with each patient for whom it is indicated and assure that it is offered to the patient in the immediate post-procedure period or that it will be available to the patient within 72 hours after completion of the abortion procedure. If the patient refuses the Rho(d) immune globulin, the refusal shall be documented on a form approved by the department, signed by the patient and a witness, and filed in the medical record of the patient.

(c) At the time of discharge from the facility, each patient shall receive the following written information:

- (1) Signs of possible complications;
- (2) when to access medical care in response to complications;
- (3) the telephone number to call in an emergency;
- (4) instructions and precautions for resuming vaginal intercourse; and

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(5) any other instructions specific to a patient's abortion or condition.

(d) Each licensee shall ensure that a physician signs the discharge order for each patient.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, sec. 9; effective, T-_____, _____.)

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K.A.R. 28-34-140. Transfers. (a) Each applicant and each licensee shall ensure that written policies and procedures are developed and implemented for the transfer of patients and newborn children to a hospital.

(b) Each licensee shall ensure that a physician arranges the transfer of a patient to a hospital if any complications beyond the medical capability of the health professionals occurs or is suspected.

(c) Each licensee shall ensure that a physician arranges the transfer of a newborn child to a hospital if the child requires emergency care.

(d) A physician or a nurse who is certified in advanced cardiovascular life support shall remain on the premises of the facility to facilitate the transfer of an emergency case if hospitalization of a patient or a newborn child is required.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, sec. 9; effective, T-_____, _____.)

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K.A.R. 28-34-141. Follow-up contact and care. Each applicant and each licensee shall ensure that written policies and procedures are developed and implemented for follow-up and aftercare for each patient receiving an abortion procedure in the facility, including the following: (a) With the consent of the patient, a health professional from the facility shall contact the patient by telephone within 24 hours after the procedure to assess the patient's recovery.

(b) Each patient shall be offered a follow-up visit and, if requested by the patient, shall be scheduled no more than four weeks after completion of the procedure. The follow-up visit shall include the following:

(1) A physical examination; and

(2) a review of all laboratory tests performed as required in K.A.R. 28-34-137.

(c) A urine pregnancy test shall be obtained. If a continuing pregnancy is suspected, a physician who performs abortion procedures shall be consulted.

(d) The physician who performs or induces the abortion, or an individual designated by the physician, shall make all reasonable efforts to ensure that the patient returns for a subsequent examination so the physician can assess the patient's medical condition. A description of the efforts made to comply with this regulation, including the date, time, and name of the individual making the efforts, shall be included in the patient's medical record.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, sec. 9; effective, T-_____, _____.)

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K.A.R. 28-34-142. Risk management. (a) Each applicant and each licensee shall develop and implement a written risk management plan.

(b) The risk management plan shall be reviewed and approved annually by the licensee.

(c) Findings, conclusions, recommendations, actions taken, and results of actions taken shall be documented and reported through procedures established within the risk management plan.

(d) All patient services, including those services provided by outside contractors or consultants, shall be periodically reviewed and evaluated in accordance with the risk management plan.

(e) Each risk management plan shall include the following:

(1) Section I. A description of the system implemented by the facility for investigation and analysis of the frequency and causes of reportable incidents within the facility;

(2) Section II. A description of the measures used by the facility to minimize the occurrence of reportable incidents and the resulting injuries within the facility;

(3) Section III. A description of the facility's implementation of a reporting system based upon the duty of all medical staff members staffing the facility and all agents and staff members of the facility directly involved in the delivery of health care services to report reportable incidents; and

(4) Section IV. A description of the organizational elements of the plan, including the following:

(A) Name and address of the facility;

(B) name and title of the facility's risk manager; and

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(C) description of involvement and organizational structure of medical staff members as related to the risk management program, including names and titles of medical staff members involved in investigation and review of reportable incidents.

(f) The standards-of-care determinations shall include the following:

(1) Each facility shall assure that analysis of patient care incidents complies with the definition of a "reportable incident". Each facility shall use categories to record its analysis of each incident, and those categories shall be in substantially the following form:

(A) Standards of care met;

(B) standards of care not met, but with no reasonable probability of causing injury;

(C) standards of care not met, with injury occurring or reasonably probable; or

(D) possible grounds for disciplinary action by the appropriate licensing agency.

(2) Each reported incident shall be assigned an appropriate standard-of-care determination. Separate standard-of-care determinations shall be made for each involved medical staff member and each clinical issue reasonably presented by the facts. Any incident determined to meet paragraph (f)(1)(C) or (D) of this regulation shall be reported to the appropriate licensing agency.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, sec. 9; effective, T-_____, _____.)

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K.A.R. 28-34-143. Reporting requirements. In addition to the reporting requirements for risk management required in K.A.R. 28-34-142, each licensee shall ensure that the following incidents are reported to the department, on a form provided by the department:

(a) Each incident resulting in serious injury of a patient or a viable unborn child shall be reported to the department within 10 days after the incident.

(b) The death of a patient, other than the death of an unborn child, shall be reported to the department not later than the next department business day.

This regulation shall be effective on and after July 1, 2011. (Authorized by and implementing 2011 House substitute for SB 36, sec. 9; effective, T-_____, _____.)

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K.A.R. 28-34-144. Records. (a) Each applicant and each licensee shall maintain an organized recordkeeping system that provides for identification, security, confidentiality, control, retrieval, and preservation of all staff member and volunteer records, patient medical records, and facility information.

(b) Each applicant and each licensee shall ensure that only individuals authorized by the applicant or licensee have access to patient medical records.

(c) All records shall be available at the facility for review by the secretary or the authorized agent of the secretary.

(d) For staff member and volunteer records, each applicant and each licensee shall ensure that an individual record is maintained at the facility. The record shall include all of the following information:

(1) The employee's or volunteer's name, position, title, and the first and last date of employment or volunteer service;

(2) verification of qualifications, training, or licensure, if applicable;

(3) documentation of cardiopulmonary resuscitation certification, if applicable;

(4) if a physician, documentation of verification of competence, as required in K.A.R. 28-34-132, signed and dated by the medical director;

(5) documentation of ultrasound training required in K.A.R. 28-34-132;

(6) if a surgical assistant, documentation of training required in K.A.R. 28-34-132; and

(7) if a volunteer, documentation of training required in K.A.R. 28-34-132.

(e) For patient records, each licensee shall ensure that an individual record is maintained at the facility for each patient. The record shall include all of the following information:

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(1) Patient identification, including the following:

(A) Name, address, and date of birth; and

(B) name and telephone number of an individual to contact in an emergency;

(2) medical history as required in K.A.R. 28-34-137;

(3) the physical examination required in K.A.R. 28-34-137;

(4) laboratory test results required in K.A.R. 28-34-137;

(5) ultrasound results required in K.A.R. 28-34-137;

(6) the physician's estimated gestational age of the unborn child as required in K.A.R. 28-34-137;

(7) Each consent form signed by the patient;

(8) a record of all orders issued by a physician, physician assistant, or nurse practitioner;

(9) a record of all medical, nursing, and health-related services provided to the patient;

(10) a record of all adverse drug reactions as required in K.A.R. 28-34-136; and

(11) documentation of the efforts to contact the patient within 24-hours of the procedure and offer and schedule a follow-up visit no more than four weeks after the procedure, as required in K.A.R. 28-34-141.

(c) For facility records, each applicant and each licensee shall ensure that a record is maintained for the documentation of the following:

(1) All facility, equipment, and supply requirements specified in K.A.R. 28-34-133 through 28-34-136;

(2) ancillary services documentation required in K.A.R. 28-34-136;

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(3) risk management activities required in K.A.R. 28-34-142; and

(4) submission of all reports required in K.A.R. 28-34-143.

This regulation shall be effective on and after July 1, 2011. (Authorized by 2011 House substitute for SB 36, sec 9; implementing 2011 House substitute for SB 36, secs. 5 and 9; effective, T-_____, _____.)

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