

## **902 KAR 20:360. Abortion facilities.**

RELATES TO: KRS Chapter 13B, 15.241, 213.101, 216B.010-216B.130, 216B.990, 311.710-311.830, 314.011(8), 314.042(8), Chapter 333, 29 C.F.R. 1910.1030, 40 C.F.R. Part 403, 42 C.F.R. Part 493

STATUTORY AUTHORITY: KRS 216B.0431

NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.0431 requires that the Cabinet for Health and Family Services regulate abortion facilities. This administrative regulation establishes the licensure requirements for abortion facilities.

### **Section 1. Definitions.**

- (1) "Abortion" is defined by KRS 311.720(1).
- (2) "Abortion facility" is defined by KRS 216B.015(1).
- (3) "Cabinet" is defined by KRS 216B.015(6).
- (4) "Volunteer" means a person who is not an employee of the abortion facility, but has direct patient health care responsibilities performed within the abortion facility, and excludes any individual whose only duties include ushering patients into the facility.

### **Section 2. Licenses.**

- (1) A license to operate an abortion facility shall not be required for a health facility licensed in accordance with 902 KAR 20:016 or 902 KAR 20:106.
- (2) A Kentucky-licensed acute-care hospital or ambulatory surgical center shall:
  - (a) Comply with the requirements of its respective licensure category and provide written notice of its intent to perform abortions to the Office of Inspector General, Division of Health Care, 275 East Main Street, Frankfort, Kentucky 40621;
  - (b) Comply with the reporting requirements of KRS 216B.0431; and
  - (c) Be exempt from any other licensure requirements of this administrative regulation.
- (3) An abortion facility license required by KRS 216B.0431 shall be conspicuously posted in a public area of the facility.
- (4) An applicant for licensure shall file with the Office of the Inspector General, Division of Health Care, 275 East Main Street, Frankfort, Kentucky 40621, an Application for License to Operate an Abortion Facility.
- (5) An applicant for a license shall, as a condition precedent to licensure or relicensure, be in compliance with the applicable federal and state laws and administrative regulations relating to an abortion facility and the requirements established in this subsection.
  - (a) Compliance with licensure administrative regulations shall be ascertained through an onsite inspection of the facility. A licensure inspection may be unannounced.
  - (b) A representative of the Office of Inspector General shall have access to the facility during the hours that the facility operates.
  - (c) A regulatory violation identified during an inspection shall be transmitted in writing to the facility by the Office of Inspector General.
  - (d) The facility shall submit a written plan for the elimination or correction of the regulatory violation to the Office of Inspector General within ten (10) calendar days.
    1. The plan shall specify the date by which each violation shall be corrected.
    2. Following a review of the plan, the Office of Inspector General shall notify the facility in writing of the acceptability of the plan.
    3. If a portion or all of the plan is unacceptable:
      - a. The Office of Inspector General shall specify the reasons for the unacceptability; and
      - b. The facility shall modify or amend the plan and resubmit it to the Office of Inspector General within ten (10) calendar days.
- (6) A licensee shall, as a condition of licensure or relicensure, be in compliance with the reporting requirements of KRS 213.101.

- (7) An unannounced inspection shall be conducted:
  - (a) On a complaint allegation; and
  - (b) Utilizing the procedures established in subsection (5) of this section.
- (8) A license shall remain in effect for one (1) year from the date of issuance unless otherwise expressly provided in the license certificate.
- (9) A license shall be renewed upon payment of the prescribed fee and compliance with the licensure administrative regulations.
- (10) Each license to operate shall be issued for the person or entity and premises named in the application.
- (11) A new application shall be filed if there is change of ownership as established by 902 KAR 20:008, Section 2(16).
  - (a) Upon the filing of a new application for a license because of change of ownership, the new license shall be automatically issued for the remainder of the current licensure period.
  - (b) An additional fee shall not be charged for the remainder of the licensure period.

### Section 3. Fee Schedule.

- (1) Annual fees. The annual licensure fee (including a renewal) for abortion facilities shall be \$155 for each licensed facility.
- (2) Fees shall be paid by check made payable to Kentucky State Treasurer and sent to Cabinet for Health and Family Services, Division of Health Care, 275 East Main Street, 4EA, Frankfort, Kentucky 40621.

### Section 4. Appeals.

- (1) Notice of the denial, suspension, or revocation of a license, or application for a provisional license, or denial or rescission of a request for extension as set forth in Section 10(5) of this administrative regulation shall be made pursuant to the provisions of KRS Chapter 13B.
- (2) A licensee may appeal the denial, suspension, or revocation of the facility's license or its application for a provisional license to the Secretary of the Cabinet for Health and Family Services, 275 East Main Street, Frankfort, Kentucky 40621.
- (3) A hearing on the denial, suspension, or revocation of a license shall be conducted pursuant to the provisions of KRS Chapter 13B.

### Section 5. Administration and Operation.

- (1) Licensee.
  - (a) The licensee shall be legally responsible for the abortion facility and for compliance with federal, state, and local laws and regulations pertaining to the operation of the abortion facility.
  - (b) The licensee shall establish written policies for the administration and operation of the abortion facility.
  - (c) The licensee shall establish lines of authority and designate the staff person who shall be principally responsible for the daily operation of the abortion facility.
- (2) Policies.
  - (a) Administrative policies. The abortion facility shall have written administrative policies covering all aspects of the operation, including:
    - 1. A description of organizational structure, staffing, and allocation of responsibility and accountability;
    - 2. A description of referral linkages with inpatient facilities and other providers;
    - 3. Policies and procedures for the guidance and control of personnel performances;
    - 4. A description of services included in the program;
    - 5. A description of the administrative and patient care records and reports;

6. Procedures to be followed in the storage, handling, and administration of drugs and biologicals;
7. A policy to specify the provision of emergency medical services; and
8. Procedures to be followed in obtaining the voluntary and informed written consent of the pregnant woman as required by KRS 311.725 prior to performing an obstetric ultrasound in accordance with KRS 311.727.

(b) Patient rights policies. The abortion facility shall adopt written policies regarding the rights and responsibilities of patients. These patients' rights policies shall assure that each patient:

1. Is informed of these rights and of a procedure for handling patient grievances;
2. Is informed of services available at the abortion facility and of related charges, including any charges not covered under third-party payor arrangements;
3. Is informed of her medical condition, unless medically contraindicated (as documented in her medical record), and is afforded the opportunity to participate in the planning of her medical treatment and to refuse to participate in experimental research;
4. Is encouraged and assisted to understand and exercise her patient rights. To this end, she may voice grievances and recommend changes in policies and services. Upon the patient's request, the grievances and recommendations shall be conveyed within a reasonable time to an appropriate decision making level within the organization that has authority to take corrective action;
5. Is assured confidential treatment of her records and is afforded the opportunity to approve or refuse the release of her records to any individual not involved in her care, except as required by Kentucky law or thirdparty payment contract; and
6. Is treated with consideration, respect, and full recognition of her dignity and individuality, including privacy in treatment and in the care of her personal health needs.

(3) Personnel.

(a) A facility shall have a staff that is adequately trained and capable of providing appropriate service and supervision to the patients.

1. The licensee shall obtain written applications for employment from all employees. The licensee shall obtain and verify information on the application as to education, training, experience, appropriate licensure, if applicable, and health and personal background of each employee.
2. Prior to performing job duties, all employees and volunteers who have direct patient contact within the abortion facility shall have tuberculin testing conducted in accordance with 902 KAR 20:205.
3. A person shall be designated in writing at each facility to coordinate TB screening of personnel and any other TB control activities.
4. All professional and allied health professional staff members shall be currently certified with American Red Cross, American Heart Association, or an equivalent nationally recognized organization to perform cardiopulmonary resuscitation and capable of recognizing symptoms of distress.
5. An employee or volunteer of the facility while afflicted with any infected wounds, boils, sores, or an acute respiratory infection or any other contagious disease or illness shall not work in any capacity in which there is a likelihood of that person transmitting disease to other individuals.
6. Each facility shall have and execute a written orientation program to familiarize each new staff member with the facility and its policies and procedures, including:
  - a. Fire safety and other safety measures;
  - b. Medical emergencies;
  - c. Infection control; and

- d. Confidentiality of patient information and records.
- 7. In-service training programs shall be planned and provided for all employees and volunteers to ensure and maintain their understanding of their duties and responsibilities.
- 8. Records shall be maintained to reflect in-service training program content and individual attendance.
- 9. The following training shall be provided at least annually:
  - a. Infection control, to include as a minimum:
    - (i) Universal precautions against blood-borne diseases;
    - (ii) General sanitation; and
    - (iii) Personal hygiene such as hand washing, use of masks and gloves, and instruction to staff if there is a likelihood of transmitting a disease to patients or other staff members;
  - b. Fire protection, including:
    - (i) Evacuating patients;
    - (ii) Proper use of fire extinguishers; and
    - (iii) Procedures for reporting fires;
  - c. Confidentiality of patient information and records, and protecting patient rights; and
  - d. Licensing regulations.
- 10. Job descriptions.
  - a. Written job descriptions that adequately describe the duties of every position shall be maintained.
  - b. Each job description shall include:
    - (i) Position title;
    - (ii) Authority;
    - (iii) Specific responsibilities; and
    - (iv) Minimum qualifications.
  - c. Job descriptions shall be:
    - (i) Reviewed at least annually;
    - (ii) Kept current; and
    - (iii) Given to each employee and volunteer assigned to the position, including any revised job descriptions.
- 11. A personnel file shall be maintained for each employee and for each volunteer as follows:
  - a. The records shall be:
    - (i) Completely and accurately documented; and
    - (ii) Readily available and systematically organized to facilitate the compilation and retrieval of information; and
  - b. The file shall contain:
    - (i) A current job description that reflects the individual's responsibilities and work assignments; and
    - (ii) Documentation of the individual's orientation, in-service education, appropriate licensure, if applicable, and TB testing.
- (b) Clinical staff.
  - 1. Physicians, nurses, and allied health professionals shall constitute the clinical staff.
  - 2. The clinical staff shall meet at least quarterly to review and analyze their clinical experiences. Minutes shall be maintained of the meetings.
  - 3. Physicians.
    - a. Abortions shall be performed only by a physician who is:
      - (i) Licensed to practice medicine in Kentucky; and

- (ii) Properly qualified by training and experience to perform pregnancy termination procedures.
- b. A physician shall remain on the premises until all patients are discharged.
- (c) Nursing.
  - 1. Nursing care shall be under the supervision of a registered nurse currently licensed in Kentucky.
  - 2. A registered nurse shall be on duty to provide or supervise all nursing care of patients in preparation, during the termination procedure, the recovery period, and until all patients leave the facility.
  - 3. Licensed practical nurses, working under appropriate supervision and direction of a registered nurse, may be employed as components of the nursing staff.
- (d) Allied health professionals, working under appropriate direction and supervision, may be employed to work only within areas where their competency has been established.

#### Section 6. Patient Care.

- (1) An abortion facility shall not serve patients whose needs exceed the resources or capabilities of the facility.
- (2) The facility shall formulate and adhere to written patient care policies and procedures designed to ensure professional and safe care for patients, including the following:
  - (a) Admission criteria;
  - (b) Physician and nurse responsibilities for the services offered;
  - (c) Specific details regarding the preoperative procedures performed, to include history and physical examination, including:
    - 1. Verification of pregnancy;
    - 2. Estimation of gestational age;
    - 3. Identification of any preexisting conditions or complications; and
    - 4. An obstetric ultrasound as required by KRS 311.727;
  - (d) The actual abortion procedure, to include the use of:
    - 1. IVs;
    - 2. Fluids;
    - 3. Analgesia or anesthesia. General anesthesia shall be administered only by personnel acting within the limits of their statutory scope of practice; and
    - 4. Tissue examination and disposal;
  - (e) Postprocedure care and recovery room procedures to include emergency care;
  - (f) Provisions for the education of patient, family, and others, as appropriate in pre- and postprocedure care;
  - (g) Plans for follow-up patient care after discharge from the facility;
  - (h) Management and appropriate referral of high-risk conditions;
  - (i) Transfer of patients who, during the course of pregnancy termination, are determined to need care beyond that of the facility; and
  - (j) Infection control and sanitation procedures, including duties and responsibilities of the infection control committee. The infection control committee shall develop and implement specific patient care and administrative policies aimed at investigating, controlling, and preventing infections in the facility.

#### Section 7. Pharmaceutical Services. Pharmaceutical services shall be provided in accordance with accepted professional practice and federal, state, and local laws.

- (1) Emergency drugs.
  - (a) Emergency kit or emergency drugs. Each facility shall maintain an emergency kit or stock supply of drugs and medicines for use in treating the emergency needs of patients in compliance with the requirements of this paragraph.

1. The emergency kit or stock supply of drugs and medicine shall be stored in such a manner as to prohibit its access by unauthorized personnel.
2. A listing of contents by drawer or shelf shall be placed on the cabinet or emergency cart to allow quick retrieval.
3. Contents shall correspond with the inventory list.
4. Drugs and equipment shall be available within the facility to treat, as a minimum, the following conditions:
  - a. Cardiac arrest;
  - b. Seizure;
  - c. Asthmatic attack;
  - d. Allergic reaction;
  - e. Narcotic toxicity;
  - f. Hypovolemic shock; or
  - g. Vasovagal shock.
- (b) Drug Reference Sources. Each facility shall maintain reference sources for identifying and describing drugs and medicines.
- (2) Administering drugs and medicines.
  - (a) Drugs and medicines shall not be administered to individual patients or to anyone within or outside the facility except by those authorized by law under orders of a physician or other ordering personnel acting within the limits of his or her statutory scope of practice.
  - (b) The orders shall be in writing and signed personally by the physician or other personnel who prescribes the drug or medicine.
- (3) Medicine storage.
  - (a) Medicines and drugs maintained in the facility for daily administration shall not be expired and shall be properly stored and safeguarded in enclosures of sufficient size that are not accessible to unauthorized persons.
  - (b) Refrigerators used for storage of medications shall maintain an appropriate temperature as determined by the requirements established on the label of medications.
  - (c) A thermometer accurate to  $\pm$  three (3) degrees Fahrenheit shall be maintained in these refrigerators.
  - (d) Only authorized personnel shall have access to storage enclosures.
  - (e) Controlled substances and ethyl alcohol, if stocked, shall be stored under double locks and in accordance with applicable state and federal laws.
- (4) Medicine preparation area.
  - (a) Medicines and drugs shall be prepared for administration in an area that contains a counter and a sink.
  - (b) This area shall be located in such a manner as to prevent contamination of medicines being prepared for administration.
- (5) Records. Records shall be kept of all stock supplies of controlled substances giving an accounting of all items received or administered.
- (6) Poisonous substances. All poisonous substances shall be plainly labeled and kept in a cabinet or closet separate from medicines and drugs to be prepared for administration.

#### Section 8. Laboratory Services.

- (1) Laboratory services shall be provided on site or through arrangement with a laboratory certified to provide the required procedures under 42 C.F.R. Part 493.
  - (a) Facilities for collecting specimens shall be available on site.
  - (b) If laboratory services are provided on site, the services shall be:
    1. Directed by a person who qualifies as a director under KRS 333.090 and 42 C.F.R. Part 493; and

2. Performed in compliance with KRS Chapter 333 and 42 C.F.R. Part 493 standards.
- (2) Prior to the procedure, laboratory tests shall include a recognized urine pregnancy test unless the physician identifies fetal heart beats or fetal movements on physical examination. If positive, the following additional tests shall be required:
  - (a) Urinalysis including albumin and glucose examination;
  - (b) Hematocrit or hemoglobin; and
  - (c) Determination of Rh factor with appropriate medical intervention.
- (3)
  - (a) Aspirated tissues shall be examined to verify that villi or fetal parts are present.
  - (b) If villi or fetal parts cannot be identified with certainty, the tissue specimen shall be sent for further pathologic examination and the patient alerted to the possibility of an ectopic pregnancy.
- (4) A written report of each laboratory test and examination shall be a part of the patient's record.
- (5) If a patient is bleeding profusely and a transfusion of red blood cells is necessary, she shall be administered fluids and transported immediately to a Kentucky-licensed acute care hospital.
- (6) All laboratory supplies shall be monitored for expiration dates, if applicable.

#### Section 9. Medical Waste Disposal.

- (1) Sharp wastes.
  - (a) Sharp wastes, including needles, scalpels, razors, or other sharp instruments used for patient care procedures, shall be segregated from other wastes and placed in puncture resistant containers immediately after use.
  - (b) A needle or other contaminated sharp shall not be recapped, purposely bent, broken, or otherwise manipulated by hand as a means of disposal, except as permitted by Centers for Disease Control and Occupational Safety and Health Administration guidelines at 29 C.F.R. 1910.1030(d)(2)(vii).
  - (c) A sharp waste container shall be incinerated on or off site, or be rendered nonhazardous.
- (2) Disposable waste.
  - (a) All disposable waste shall be:
    1. Placed in a suitable bag or closed container so as to prevent leakage or spillage; and
    2. Handled, stored, and disposed of in such a way as to minimize direct exposure of personnel to waste materials.
  - (b) The abortion facility shall establish specific written policies regarding handling and disposal of waste material.
  - (c) Pathological waste, such as tissues, organs, body parts, and bodily fluids, shall be incinerated.
  - (d) Blood, blood specimens, used blood tubes, or blood products shall be:
    1. Disposed of by incineration;
    2. Autoclaved before disposal; or
    3. Carefully poured down a drain connected to sanitary sewer, subject to limitations in paragraph (e) of this subsection.
  - (e) Any wastes conveyed to a sanitary sewer shall comply with applicable federal, state, and local pretreatment law, including 40 C.F.R. 403 and relevant local ordinances.
  - (f) Any incinerator used for the disposal of waste shall be in compliance with 401 KAR 59:023 or 401 KAR 61:013.

#### Section 10. Emergency Care.

(1) As required by KRS 216B.0435, an abortion facility shall enter into a written agreement with a Kentucky-licensed acute-care hospital and a local, Kentucky-licensed Class I ambulance service for the transport and treatment of a patient with unforeseen complications related to an abortion facility procedure.

(2) Each written agreement shall be filed with the cabinet pursuant to KRS 216B.0435(4) within ten (10) calendar days of finalization.

(3) A transfer agreement between the abortion facility and a Kentucky-licensed acute-care hospital shall:

(a) Be with a hospital located:

1. In the same county as the abortion facility; or
2. No further than twenty (20) minutes normal driving time from the abortion facility;

(b) Be a legally binding contractual document;

(c) Be signed by individuals authorized to execute the agreement on behalf of the abortion facility and hospital, who shall certify they have such authority;

(d) Require transfer of a patient if deemed medically necessary by the physician attending to the patient;

(e) Identify responsibilities of the abortion facility in which the abortion facility shall, at a minimum:

1. At the time of transfer, provide the hospital with complete and accurate information regarding the patient being transferred to the hospital;
2. Notify the hospital of the impending transfer of a patient and receive confirmation of the availability of appropriate facilities, services, and staff necessary for the care of the patient;
3. At the time of transfer, provide the hospital with copies of relevant portions of the patient's clinical record;
4. Transfer with the patient, the patient's medical records, demographic information, insurance information, and other information deemed necessary or otherwise required by law to facilitate the provision of medical care when the patient arrives at the hospital; and
5. Arrange for the immediate transfer of the patient's personal effects, including a document listing of the effects; and

(f) Identify responsibilities of the hospital in which the hospital shall, at a minimum:

1. Provide prompt and appropriate evaluation and treatment of a patient transferred to the hospital pursuant to the transfer agreement;
2. Accept responsibility for the patient's care when the patient is received by the hospital;
3. Direct charges performed by the hospital to the patient or patient's third-party payer; and
4. Acknowledge receipt of the patient's personal effects in writing signed by an authorized representative of the hospital and deliver the receipt to the abortion facility.

(4) A transport agreement between the abortion facility and a Kentucky-licensed Class I ambulance service capable of responding immediately to a call for emergency transport shall:

(a) Be with an ambulance service located:

1. In the same county as the abortion facility; or
2. No further than five (5) miles or ten (10) minutes normal driving time from the abortion facility;

(b) Be signed by individuals authorized to execute the agreement on behalf of the abortion facility and ambulance service, who shall certify they have such authority; and



(c) Identify responsibilities of the ambulance service in which the ambulance service shall agree, at a minimum to:

1. Provide services in accordance with all federal and state laws and administrative regulations applicable to emergency service entities;
2. Employ sufficient staff, including paramedics and emergency medical technicians, to provide patient care and operate vehicles and equipment in accordance with industry standards and applicable laws and administrative regulations;
3. Require all responding medical personnel to familiarize themselves with the floor plan of the abortion facility to minimize the time required to locate the patient in the facility and exit the facility with the patient as expeditiously as possible;
4. Acknowledge the existence of, and its familiarity with the terms of, the transfer agreement between the abortion facility and an acute care hospital; and
5. Transport the patient to the hospital that is party to the transfer agreement, unless otherwise directed by the patient.

(5) A licensed abortion facility applying for a renewal license or an applicant for a provisional license may submit a request in writing for extensions of time to comply with the transfer or transport agreement requirements to the cabinet's Office of Inspector General in accordance with the provisions of this subsection.

(a) Any request shall:

1. Be in writing;
2. Contain a certification under oath that the party seeking the extension of time has exhausted all reasonable efforts to obtain a transfer or transport agreement for a continuous ninety (90) calendar day period prior to the request; and
3. Contain a detailed description of the efforts taken to secure the agreements.

(b) In deciding to grant or deny the request for an extension of time, the inspector general shall consider all factors the inspector general deems relevant under the circumstances, but at least the following factors:

1. Whether the abortion facility or applicant made, and continues to make, a good faith effort to obtain a transfer or transport agreement;
2. Whether the abortion facility or applicant can provide the same level of patient care and safety via alternative health services during any extension period; and
3. Regulatory compliance history at the abortion facility and at any other health care facility owned, in whole or in part, by the applicant or any other individual or entity having an ownership interest with the facility.

(c) If the request is granted, the extension of time shall be effective for a time-period of ninety (90) calendar days from the date of issuance.

(d) If the request is granted for a transfer agreement, the transport agreement need not comply with subsection (4)(c)4. and 5. of this section for the duration of the extension of time.

(e) The inspector general may rescind a previously granted extension of time at any time upon determining that the applicant or abortion facility has not met, or is not meeting, the conditions of paragraph (b) of this subsection.

(f) If a request for an extension is denied, an applicant or licensee shall have ten (10) calendar days to submit a written request for reconsideration to the inspector general, whose decision shall be final. The licensee or applicant for provisional license may appeal a denial in accordance with Section 4 of this administrative regulation.

Section 11. Equipment and Supplies. There shall be appropriate equipment and supplies maintained for the patients to include:

- (1) A bed or recliner suitable for recovery;
- (2) Oxygen with flow meters and masks or equivalent;
- (3) Mechanical suction;

- (4) Resuscitation equipment to include resuscitation bags and oral airways;
- (5) Emergency medications, intravenous fluids, and related supplies and equipment;
- (6) A clock with a sweep second hand;
- (7) Sterile suturing equipment and supplies;
- (8) Adjustable examination light;
- (9) Containers for soiled linen and waste materials with covers;
- (10) Refrigerator; and
- (11) Appropriate equipment for the administering of general anesthesia, if applicable.

Section 12. Consultation. Arrangements shall be made for consultation or referral services to be available as needed.

### Section 13. Quality Improvement.

- (1) The facility shall establish and implement a written plan for a quality improvement program for patient care that shall:
  - (a) Specify the individual responsible for coordinating the quality improvement program; and
  - (b) Provide for ongoing monitoring of staff and patient care services.
- (2) There shall be an ongoing process for monitoring and evaluating the following:
  - (a) Patient care services;
  - (b) Staffing;
  - (c) Infection prevention and control;
  - (d) Housekeeping;
  - (e) Sanitation;
  - (f) Safety;
  - (g) Maintenance of physical plant and equipment;
  - (h) Patient care statistics; and
  - (i) Discharge planning services.
- (3) Evaluation of patient care throughout the facility shall be criteria-based so that certain actions shall be taken or triggered if specific quantified, predetermined levels of outcomes or potential problems are identified.
- (4) The quality improvement process shall incorporate quarterly review of a minimum of five (5) percent of medical records of patients undergoing procedures during a given quarter, but not less than five (5) records shall be reviewed.
- (5)
  - (a) The quality improvement process shall include evaluation by patients of care and services provided by the facility.
  - (b) If the families of patients are involved in the care and services provided by the facility, the quality improvement process shall include a means for obtaining input from families of patients.
- (6) The administrator shall review the findings of the quality improvement program to ensure that effective corrective actions have been taken, including as a minimum:
  - (a) Policy revisions;
  - (b) Procedural changes;
  - (c) Educational activities; and
  - (d) Follow-up on recommendations, which may include that additional actions are no longer indicated or needed.
- (7) The quality improvement program shall identify and establish indicators of quality care specific to the facility that shall be monitored and evaluated.
- (8) The results of the quality improvement program shall:
  - (a) Be submitted to the licensee for review at least annually; and
  - (b) Include at least the deficiencies found and recommendations for corrections or improvements.

(9) Deficiencies that jeopardize patient safety shall be reported immediately in writing to the licensee.

#### Section 14. Medical Records.

(1) Medical records shall be maintained for all patients examined or treated in the abortion facility.

(2) The medical records shall be:

- (a) Completely and accurately documented;
- (b) Readily available; and
- (c) Systematically organized to facilitate the compilation and retrieval of information.

(3) All information shall be centralized in the patient's medical record.

(4) All entries shall be legibly written or typed, dated, and signed.

(5) The medical record shall include the following information:

(a) A face sheet with patient identification data, including:

- 1. Name;
- 2. Address;
- 3. Telephone number;
- 4. Social Security number;
- 5. Date of birth; and
- 6. Name, address and telephone number of the person to be notified if an emergency occurs;

(b) Signed consent for the procedure;

(c) Date of initial examination;

(d) Date of abortion;

(e) Referring and attending physicians' names and phone numbers, if applicable;

(f) Complete medical history to include medications currently being taken;

(g) Physical examination, to the extent necessary to determine the health status of the patient, within fifteen (15) days of the procedure, including detail of findings of pelvic examination and estimated gestational age, according to the first day of the last menstrual period;

(h) Results of diagnostic tests and examinations, including:

- 1. X-ray;
- 2. Electrocardiography;
- 3. Clinical laboratory;
- 4. Pathology;
- 5. Consultations; or
- 6. Ultrasound;

(i) Preoperative diagnosis;

(j) Counselor's notes, if applicable;

(k) Physician's orders;

(l) Complete record of abortion procedure to include:

- 1. Vital signs, including temperature, pulse, respiration, and blood pressure prior to and following the procedure;
- 2. Name of procedure performed;
- 3. Anesthetic agent utilized;
- 4. Name of attending physician performing the procedure;
- 5. Names of clinical assistants in attendance, including:
  - a. Other physicians;
  - b. Physician's assistants;
  - c. Anesthetists;
  - d. Nurses; or
  - e. Specially-trained technicians; and

- 6. Signature of physician performing the procedure;
  - (m) Nurses' notes;
  - (n) Progress notes to include a postanesthesia note if general anesthesia is utilized;
  - (o) Attending physician's description of gross appearance of tissue removed;
  - (p) Final diagnosis;
  - (q) Condition on discharge;
  - (r) Post-op orders and follow-up care; and
  - (s) Documented verification that the woman has received information and was offered printed materials as required by KRS 311.725.
- (6) The attending physician shall complete and sign the medical record within seventy-two (72) hours following discharge.
- (7) Confidentiality of all patient records shall be maintained at all times.
- (8) Transfer of records. The abortion facility shall:
- (a) Establish systematic procedures to assist in continuity of care if the patient moves to another source of care; and
  - (b) Upon proper release, transfer medical records or an abstract thereof if requested.
- (9) Retention of records. After patient's death or discharge, the complete medical record shall be placed in an inactive file and retained for six (6) years or, in case of a minor, three (3) years after the patient reaches the age of majority under state law, whichever is the longest.

#### Section 15. Infection Control.

- (1) There shall be an infection control program developed to prevent, identify, and control infections.
- (2) Written policies and procedures pertaining to the operation of the infection control program shall be:
  - (a) Established;
  - (b) Reviewed at least annually; and
  - (c) Revised as necessary.
- (3) A practical system shall be developed for reporting, evaluating, and maintaining records of infections among patients and personnel.
- (4) The system shall include assignment of responsibility for:
  - (a) The ongoing collection and analysis of data; and
  - (b) The implementation of required follow-up actions.
- (5) Corrective actions shall be:
  - (a) Taken on the basis of records and reports of infections and infection potentials among patients and personnel; and
  - (b) Documented.
- (6) All new employees shall be instructed on:
  - (a) The importance of infection control and personal hygiene; and
  - (b) Their responsibility in the infection control program.
- (7) The facility shall document that in-service education in infection prevention and control is provided to all services and program components.
- (8) Adequate space shall be provided for storage, maintenance, and distribution of sterile supplies and equipment.
- (9) Sterile supplies and equipment shall:
  - (a) Not be mixed with unsterile supplies;
  - (b) Be stored in dust-proof and moisture-free units; and
  - (c) Be properly labeled.
- (10) Sterilizing equipment of appropriate type shall be available and of adequate capacity to properly sterilize instruments and materials.
- (11) The sterilizing equipment shall have approved control and safety features.

#### Section 16. Linen and Laundry.

- (1) An adequate supply of clean linen or disposable materials shall be maintained to ensure a change of linen on procedure tables between patients.
- (2) Provisions for proper laundering of linen and washable goods shall be made.
- (3) Soiled and clean linen shall be handled and stored separately.
- (4) Storage shall be in covered containers.
- (5) A sufficient supply of cloth or disposable towels shall be available so that a fresh towel is used after each hand washing.
- (6) Towels shall not be shared.

#### Section 17. Housekeeping.

- (1) A facility shall be kept neat, clean, and free from odors.
- (2) Accumulated waste material shall be removed daily or more often if necessary.
- (3) There shall be frequent cleaning of floors, walls, ceilings, woodwork, and windows.
- (4) The premises shall be kept free from rodent and insect infestation.
- (5) Bath and toilet facilities shall be maintained in a clean and sanitary condition at all times.
- (6) Cleaning materials and supplies shall be stored in a safe manner.
- (7) All harmful agents shall be locked in a closet or cabinet used for this purpose only.

#### Section 18. Refuse and Waste Disposal.

- (1) All garbage and waste shall be collected, stored, and disposed of in a manner designed to prevent the transmission of disease.
- (2) Containers shall be washed and sanitized before being returned to work areas.
- (3) Disposable type containers shall not be reused.
- (4) Containers for garbage and refuse shall be:
  - (a) Covered and stored outside; and
  - (b) Placed on an approved platform to prevent:
    1. Overturning by animals;
    2. The entrance of flies; or
    3. The creation of a nuisance.
- (5) All solid waste shall be disposed of at sufficient frequencies in a manner so as not to create a rodent, insect, or other vermin problem.
- (6) Immediately after emptying, containers for garbage shall be cleaned.
- (7) All medical waste shall be managed in accordance with Section 9 of this administrative regulation.

#### Section 19. Outside Areas.

- (1) All outside areas, grounds, and adjacent buildings shall be kept free of rubbish, grass, and weeds that may serve as a:
  - (a) Fire hazard; or
  - (b) Haven for insects, rodents, and other pests.
- (2) Outside stairs, walkways, ramps, and porches shall be maintained free from accumulations of water, ice, snow, and other impediments.

#### Section 20. Disaster Preparedness.

- (1) All staff shall be knowledgeable of a written plan and procedure for meeting potential disasters and emergencies such as fires or severe weather.
- (2) The plan shall be posted.
- (3) Staff shall be trained in:
  - (a) Properly reporting a fire;
  - (b) Extinguishing a small fire;
  - (c) Evacuation from the building; and
  - (d) Procedures for fire safety, including fire drills.

- (4) All fire protection and alarm systems and other firefighting equipment shall be inspected and tested at least once each year, and more often if necessary to maintain them in serviceable condition.

Section 21. Facility Specifications.

- (1) An abortion facility shall provide a functionally safe and sanitary environment for patients, personnel, and the public.
- (2) An abortion facility shall include space for the following functions:
  - (a) Reception and waiting;
  - (b) Administrative activities such as patient admission, record storage, and business affairs;
  - (c) Patient dressing and storage of personal items;
  - (d) Preoperative evaluation, including:
    1. Physical examination;
    2. Laboratory testing; and
    3. Preparation for anesthesia;
  - (e) Performance of surgical procedures;
  - (f) Preparation and sterilization of instruments;
  - (g) Storage of equipment, drugs, and fluids;
  - (h) Postanesthetic recovery; and
  - (i) Janitorial and utility support.

Section 22. Injunctive Relief. The Office of Inspector General shall refer instances where administrative penalties and legal sanctions have failed to prevent or cause a discontinuance of a violation of KRS Chapter 216B to the secretary of the cabinet for action in accordance with KRS 15.241.

Section 23. Incorporation by Reference.

- (1) Form OIG 240, "Application for License to Operate an Abortion Facility", June 2017, is incorporated by reference.
  - (2) This material may be inspected, copied or obtained subject to applicable copyright law, at the Office of Inspector General, Division of Health Care, 275 East Main Street, Frankfort, Kentucky 40621, Monday through Friday, 8 a.m. to 4:30 p.m.
- (25 Ky.R. 1293; Am. 2168; 2388; eff. 3-17-1999; 44 Ky.R. 371; eff. 10-11-2017; Cert eff. 7-18-2024.)