

CABINET FOR HEALTH AND FAMILY SERVICES
Office of Inspector General
Division of Health Care
(Amended After Comments)

902 KAR 20:106. Operation and services; ambulatory surgical center.

RELATES TO: KRS 211.842-211.852, 216B.015, 216B.042, 216B.153, 216B.165, 216B.990(1), (2), (8), 311.400, 311.571, 311.710-311.810, 313.010(9), 313.030, 314.041, 314.042, 314.051, 333.030, 45 C.F.R. Part 160, Part 164, 42 U.S.C. 1320d-2—1320d-8

STATUTORY AUTHORITY: KRS 216B.042(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.042(1)(a) and (c) require the cabinet to promulgate administrative regulations necessary for the proper administration of the licensure function and to establish licensure standards and procedures to ensure safe, adequate, and efficient health facilities and health services. This administrative regulation establishes the licensure requirements for the operation and services of ambulatory surgical centers.

Section 1. Definitions.

- (1) "Admission" means the time after completion of the registration process and at the first instance of rendering medical care to the patient on the day of the scheduled procedure as a part, or in anticipation, of a surgery.
- (2) "Ambulatory surgical center" means a public or private institution that is:
 - (a) Hospital-based or freestanding;
 - (b) Operated under the supervision of an organized medical staff; and
 - (c) Established, equipped, and operated primarily for the purpose of providing surgical services to patients not requiring hospitalization and whose recovery under normal circumstances is not expected to require inpatient care.
- (3) "Cabinet" is defined by KRS 216B.015(6).
- (4) "Center" means an ambulatory surgical center.
- (5) "Licensee" means a person or business entity that has been issued and holds a valid ambulatory surgical center license from the cabinet.

Section 2. Administration and Operation.

- (1) Licensee.
 - (a) The licensee shall be legally responsible for operation of the center and for compliance with federal, state, and local laws and administrative regulations pertaining to operation of the center.
 - (b) The licensee shall develop written policies for the administration and operation of the center.
 - (c) Medical staff shall approve medical policies that include the following:
 1. Personnel practices and procedures that shall be readily available to personnel;
 2. Job descriptions for each level of personnel, including the authority, responsibilities, and actual work to be performed in each classification;
 3. Written infection control measures governing the use of aseptic techniques and procedures in all areas of the center;
 4. Sterilization of supplies;
 5. Disposal of patient waste and other potentially infectious materials;
 6. Examination by a pathologist of tissues removed during surgery, including the identification of tissues that require examination and tissues that are exempted by the medical staff team from examination ;

7. Procedures for consultation with other physicians, dentists, or podiatrists based on a patient's medical needs;
 8. A list of surgical procedures performed in the center;
 9. The center's privileging process, including the granting and withdrawal of medical staff surgical privileges, and privileges for the administration of anesthetics;
 10. Arrangement for transportation of patients who require hospital care;
 11. A surgical smoke safety and control policy that shall be available to staff in all areas where surgical smoke is generated; and
 12. Policies that assure compliance with KRS 216B.165.
- (2) Personnel and administration.
- (a) Administrator. The center shall have:
 1. An administrator responsible for the daily operation of the center; and
 2. A similarly qualified staff person for delegation of responsibilities in the administrator's absence.
 - (b) Current employee records shall be maintained and include:
 1. A resume of the employee's training and experience;
 2. Evidence of current licensure or registration, if required; and
 3. Evaluation of the employee's performance, including a report of any adverse incident involving the employee.
 - (c) Medical staff requirements. The center shall have an organized medical staff responsible for:
 1. The quality of medical care provided in the center;
 2. Oversight of the ethical and professional practices of its members; and
 3. Developing the center's medical care policies.
 - (d) Surgical procedures shall be performed by professionally qualified physicians, dentists, or podiatrists who:
 1. Are legally authorized under their scope of practice to perform the procedures; and
 2. Have been granted clinical privileges by the center's medical staff or governing body.
 - (e) Pharmaceutical, radiology, or laboratory services provided directly by the center or through an agreement with another entity shall be provided under the direction of a licensed pharmacist, a physician specializing as a radiologist, or a physician specializing as a pathologist, respectively, on a full-time, part-time, or regular consultative basis.
 - (f) The center shall employ registered nurses on a full-time basis for patient care in the operating and postanesthesia recovery rooms.
 - (g) The center shall employ other nursing personnel, aides, and technicians as necessary to meet the needs of the patients served by the center, including personnel responsible for supervision, indexing, and filing of medical records.
- (3) A center shall not retain a patient longer than twenty-four (24) hours from the time of admission to discharge.
- (4) The center shall not provide obstetric deliveries.
- (5) Physician coverage. A physician or a practitioner that performs surgical procedures shall be present in the center until all patients have been discharged and have left the center.
- (6) The center shall have a physician on the medical staff with admitting privileges at a nearby hospital who is responsible for admitting patients in need of inpatient care.
- (7) Medical records.
- (a) Content. The center shall maintain a complete, comprehensive, accurate, and legible medical record for each patient. The record shall include the following information:

1. Name and address of the person or agency responsible for the patient;
 2. Patient identification data, including the patient's:
 - a. Name;
 - b. Address;
 - c. Age;
 - d. Sex; and
 - e. Marital status;
 3. Date of admission and discharge;
 4. Name of the referring and attending physician, dentist, or podiatrist;
 5. A medical history and physical evaluation that was performed and entered into the medical record no more than thirty (30) days prior to surgery;
 6. A surgical consent form that has been signed by the patient or the patient's legal representative prior to the surgical procedure;
 7. All preoperative diagnostic studies and laboratory tests;
 8. Special examinations, such as consultations, clinical, laboratory, and x-ray;
 9. Nurses' notes;
 10. Complete medical record signed by the operating surgeon, including:
 - a. Anesthesia record;
 - b. Preoperative diagnosis;
 - c. Operative procedures and findings;
 - d. Postoperative diagnosis;
 - e. Condition of patient upon discharge;
 - f. Postoperative instructions; and
 - g. If required, tissue diagnosis by a pathologist on specimens surgically removed;
 11. Charts including records of temperature, pulse, respiration, and blood pressure; and
 12. Medication record including:
 - a. Name of medication;
 - b. Dosage;
 - c. Date and time of administration;
 - d. Method of administration;
 - e. Name of prescribing physician, dentist, or podiatrist;
 - f. Name of person who administered the medication; and
 - g. Any allergies or abnormal drug reaction.
- (b) Indexing. The center shall have a system of identification and filing to assure ready access to a patient's record by authorized personnel.
- (c) Ownership.
1. Medical records shall be the property of the center.
 2. The original medical record shall not be removed from the center except by court order or subpoena.
 3. Copies of a medical record or portions of the record may be used and disclosed. Use and disclosure shall be as established by paragraph (d) of this subsection.
- (d) Confidentiality and Security: Use and Disclosure.
1. The center shall maintain the confidentiality and security of medical records in compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 42 U.S.C. 1320d-2 to 1320d-8, and 45 C.F.R. Parts 160 and 164, as amended, including the security requirements mandated by subparts A and C of 45 C.F.R. Part 164, or as provided by applicable federal or state law.
 2. The center may use and disclose medical records. Use and disclosure shall be as established or required by HIPAA, 42 U.S.C. 1320d-2 to 1320d-8, and 45 C.F.R. Parts 160 and 164, or as established in this administrative regulation.

3. A center may establish higher levels of confidentiality and security than required by HIPAA, 42 U.S.C. 1320d-2 to 1320d-8, and 45 C.F.R. Parts 160 and 164.

(e) Medical records shall be made available if requested for inspection by a duly authorized representative of the cabinet.

(f) The attending physician, dentist, or podiatrist shall complete and sign a patient's medical record as soon as practicable after discharge, but not to exceed ten (10) days.

(g)

1. Orders for medication and treatment shall be dated, timed, and signed by the:

a. Prescribing physician, dentist, or podiatrist; or

b. Health care practitioner who receives the verbal order.

2. A verbal order shall be followed by a written order and signed by the prescribing physician, dentist, or podiatrist within forty-eight (48) hours, except that a prescription for a Schedule II drug shall be signed immediately.

3. A record of medication administered to the patient shall be included in the record and signed by the health care professional administering the medication.

(h) Retention of records. Medical records shall be retained for at least:

1. Six (6) years from the date of discharge; or

2. If a minor, three (3) years after the patient reaches the age of majority under state law, whichever is the longest.

(8) Bedrails shall be available for patients in the admitting and recovery units.

Section 3. Sanitary Environment. The center shall provide a sanitary environment to avoid sources and transmission of infection.

(1) An infection control committee composed of members of the medical and nursing staff shall be established and charged with responsibility for investigating, controlling, and preventing infections in the center.

(2) Nondisposable sterile supplies shall be reprocessed if the integrity of the pack has not been maintained.

(3) The center shall:

(a) Have suitable equipment for rapid and routine sterilization of supplies, utensils, and equipment; and

(b) Maintain a sterile storage area for the equipment to be kept in a clean, convenient, and orderly manner.

(4) Continuing education shall be provided to all center personnel on the cause, effect, transmission, prevention, and elimination of infections.

Section 4. Surgical Services.

(1) The center shall operate exclusively for the purpose of providing surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed twenty-four (24) hours following admission.

(2) The center shall have at least one (1) operating room.

(3) A patient shall be examined:

(a) By a physician, dentist, or podiatrist acting within the professional's scope of practice; and

(b) Immediately prior to surgery to evaluate risks pertaining to:

1. Anesthesia; and

2. The procedure to be performed.

(4) A registered nurse shall:

(a) Be available to circulate at all times; and

(b) Supervise each operating room .

(5) The center shall have on file a list of all physicians, dentists, and podiatrists who have been granted surgical privileges by the center's medical staff or governing body, including the scope of the privileges granted to each practitioner.

- (6) The center shall maintain a complete and up-to-date operating room register.
- (7) The following equipment shall be available in the center:
 - (a) Oxygen;
 - (b) Mechanical ventilatory assistance equipment including airways, manual breathing bag, and ventilator;
 - (c) Cardiac defibrillator;
 - (d) Cardiac monitoring equipment;
 - (e) Tracheostomy set;
 - (f) Laryngoscopes and endotracheal tubes;
 - (g) Suction equipment; and
 - (h) Emergency medical equipment and supplies specified by the medical staff.
- (8)
 - (a) In accordance with KRS 216B.153, a center that utilizes an energy-generating device shall make use of a smoke evacuation system:
 1. That effectively captures and neutralizes surgical smoke at the site of origin and before the smoke can make ocular contact or contact with the respiratory tract of the occupants of the room; and
 2. During any surgical procedure that is likely to produce surgical smoke.
 - (b) The cabinet shall impose fines in accordance with KRS 216B.990(8) for each violation of noncompliance with KRS 216B.153 only if the violation has not been remedied after the center has had an opportunity to correct the violation through the filing of a plan of correction in accordance with 902 KAR 20:008, Section 2(13).
- (9) The center shall have arrangements for obtaining an adequate supply of blood in a timely manner to meet the center's needs.
- (10) A physician's, dentist's, or podiatrist's orders shall be in writing and signed by the physician, dentist, or podiatrist.
- (11) Except for cases requiring only local infiltration anesthetics, a physician anesthesiologist, a physician qualified to administer anesthesia, a dentist qualified to administer anesthesia, or a certified registered nurse anesthetist shall administer the anesthetics and remain present during the surgical procedures and until the patient is fully recovered from the anesthetics.
- (12)
 - (a) The physician, dentist, or podiatrist in charge of the patient shall be responsible for seeing that tissue removed during surgery is delivered to the center's pathologist.
 - (b) The pathologist's report on any tissue removed during surgery shall be included in the patient's medical record unless the center's medical staff have adopted a written policy exempting certain types of removed tissue from examination.
- (13) Voluntary interruption of pregnancies. An ambulatory surgical center shall comply with the applicable Kentucky statutes concerning the voluntary interruption of pregnancies, including KRS 311.710 to 311.810.

Section 5. Postanesthesia Recovery Services.

- (1) The center shall have at least one (1) postanesthesia recovery unit.
- (2) There shall be adequate staff available in the recovery unit so that no patient is left alone at any time.
- (3) A registered nurse shall be present in the recovery unit during the time that a patient is recovering from anesthesia.
- (4) A registered nurse shall be available to the recovery unit at all times.
- (5) A registered nurse or health care professional staffing the postanesthesia recovery unit shall be adequately trained in all aspects of postoperative and postanesthetic care.
- (6) The recovery unit nurse shall record a nursing note on each patient to document the following:

- (a) Postoperative abnormalities or complications;
 - (b) Pulse;
 - (c) Respiration;
 - (d) Blood pressure;
 - (e) Presence or absence of swallowing reflex;
 - (f) Cyanosis; and
 - (g) The general condition of the patient.
- (7) Available equipment shall include the following:
- (a) Suction machine;
 - (b) Stethoscope;
 - (c) Sphygmomanometer;
 - (d) Emergency crash cart;
 - (e) Necessary drugs; and
 - (f) Oxygen.
- (8)
- (a) The center shall provide suitable accommodations for its patients.
 - (b) There shall be adequate floor space, furnishings, bed linens, and other utensils, equipment and supplies reasonably required for the proper care of the patients.

Section 6. Pharmaceutical Services.

- (1) The center shall have a licensed pharmacy or have arrangements for promptly obtaining prescribed drugs and biologicals from a pharmacy.
- (2)
- (a) The center shall have appropriate methods and procedures for the storage, control, and administration of drugs and biologicals developed with the advice of a licensed pharmacist.
 - (b) The pharmacist shall properly label drugs for individual patients.
- (3) Licensed medical or nursing personnel shall administer medications in accordance with the established standards of practice set forth for:
- (a) Podiatrists licensed in accordance with KRS 311.400;
 - (b) Physicians licensed in accordance with KRS 311.571;
 - (c) Dentists licensed in accordance with KRS 313.030;
 - (d) Dental specialists defined by KRS 313.010(9); or
 - (e) Nurses licensed in accordance with KRS 314.041, 314.042, or 314.051.
- (4) Controlled substances.
- (a) Controlled substances shall be kept under double lock (i.e., in a locked box in a locked cabinet). There shall be a controlled substances record that includes the:
 1. Name of the patient;
 2. Date and time;
 3. Kind of controlled substance;
 4. Dosage and method of administration of the controlled substance;
 5. Name of the physician or practitioner who prescribed the controlled substance; and
 6. Name of the nurse who administered the controlled substance.
 - (b) In addition to the requirements established in paragraph (a) of this subsection, there shall be a recorded and signed:
 1. Schedule II controlled substances count daily conducted by a member of the nursing staff; and
 2. Schedule III, IV, and V controlled substances count once per week by a member of the nursing staff.

Section 7. Radiology Services.

- (1) The center shall provide radiology services directly through an:

- (a) Agreement with a licensed hospital; or
 - (b) Independent radiology service.
- (2) The radiology service shall have a current license or registration pursuant to KRS 211.842 to 211.852.
- (3) If radiology services are provided directly by the center:
- (a) The radiology department shall be free of hazards for patients and personnel. Proper safety precautions shall be maintained against:
 - 1. Fire and explosion hazards;
 - 2. Electrical hazards; and
 - 3. Radiation hazards;
 - (b) A physician specializing in radiology shall supervise the department and interpret films that require specialized knowledge for accurate reading;
 - (c) Signed reports shall be promptly entered into the medical record and duplicate copies kept in the department; and
 - (d) Orders for radiology procedures shall be made by a physician, dentist, or podiatrist.

Section 8. Laboratory Services.

- (1) The center shall provide laboratory services directly through:
- (a) Its own licensed laboratory;
 - (b) An agreement with a laboratory in a licensed hospital; or
 - (c) An agreement with a licensed laboratory nearby.
- (2) The medical laboratory providing services to the center shall be licensed pursuant to KRS 333.030, unless it is a part of a licensed hospital.
- (3) Laboratory examinations shall be made only upon the request of a physician, dentist, or podiatrist.
- (4)
- (a) The laboratory shall provide tissue pathology and diagnostic cytology examinations.
 - (b) Tissues removed from a patient during surgery shall be examined by a physician specializing in pathology if required by the center's written policies.
- (5) Laboratory and tissue pathology reports shall be signed and entered into the medical record.

Section 9. Utilization Review.

- (1) The center shall have in effect a plan for utilization review of the center's services on at least a quarterly basis by a committee of physicians, dentists, or podiatrists who have no financial interest in the center.
- (2) Reviews shall be made of the center's admissions and professional services, including utilization of surgical services and tissue reports.
- (8 Ky.R. 251; eff. 11-5-1981; 12 Ky.R. 611; eff. 12-10-1985; 18 Ky.R. 824; eff. 10-16-1991; 32 Ky.R. 1152; 1400; eff. 3-2-2006; 35 Ky.R. 1919; 2443; eff. 6-5-2009; Crt eff. 4-30-2019; 48 Ky.R. 2298, 3005; eff. 8-25-2022.)

ADAM MATHER, Inspector General
ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: May 6, 2022

FILED WITH LRC: May 11, 2022 at 1:45 p.m.

CONTACT PERSON: Krista Quarles, Policy Analyst, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-6746; fax 502-564-7091; email CHFSregs@ky.gov.