

902 KAR 20:074. Operation and services; outpatient health care center.

RELATES TO: KRS 194A.030(1), 211.842-211.852, 216B.010, 216B.015, 216B.040, 216B.042, 216B.045-216B.055, 216B.075, 216B.105-216B.131, 216B.176, 216B.177, 216B.990, Chapter 311, Chapter 314, 29 C.F.R. 1910.1030(d)(2)(vii), 42 C.F.R. 413.65, 42 U.S.C. 1320d-2

STATUTORY AUTHORITY: KRS 194A.050(1), 216B.042, 216B.105

NECESSITY, FUNCTION, AND CONFORMITY: KRS 216B.105 and 216B.042 require the Cabinet for Health and Family Services to license and regulate health care facilities and health care services. This administrative regulation provides licensure requirements for the operation of and services provided by outpatient health care centers.

Section 1. Definitions.

- (1) "Campus" means the physical area on which the licensee's main administrative building, other areas and structures are located as well as that physical area located, immediately adjacent to and within 250 yards of the main administrative building.
- (2) "Main provider" means a licensed acute care hospital under which an outpatient health care center functions as a subordinate and integral part, and which is under the same name, ownership, and control as the outpatient health care center.
- (3) "Outpatient health care center" or "center" means a licensed health care facility that is designated in the Certificate of Need State Health Plan as a primary care center with outpatient diagnostic and surgical services, and which is certified by the Centers for Medicare and Medicaid Services under 42 C.F.R. 413.65 as a provider-based institution, with permanent facilities on a single campus that is operated under the supervision of an organized medical staff and is comprised of service components for the provision of primary care, ambulatory surgery, twenty-four (24) hour emergency care, and radiological and magnetic resonance imaging "MRI".

Section 2. Services. The center shall provide component services that include primary care services, 24-hour emergency services, diagnostic imaging including MRI, and ambulatory surgery services on a single campus that is located in a county that has no hospital, that has a population of 60,000 or more persons and that also is a medically-underserved area as determined by the Secretary of the Federal Department for Health and Human Services.

(1) A primary care component shall include the following services, which shall be provided in the center or shall be arranged through other providers with which the center has linkage agreements in accordance with Section 7 of this administrative regulation:

- (a) Basic health care services to patients of all ages during normal hours of operation;
- (b) A variety of preventative, diagnostic, and therapeutic services of sufficiently broad scope to provide for the usual and expected needs of patients in all age groups;
- (c) Coordinated services for all other health components in this administrative regulation; and
- (d) Services established in Section 8(1) of this administrative regulation.

(2) An ambulatory surgical care component shall include:

- (a) Ambulatory surgical services that, in the professional judgment of the surgeon and the facility's medical director, may be safely performed in the outpatient setting on a patient whose recovery under normal circumstances shall not require inpatient care, observation-hold, or convalescence in excess of twenty-three (23) hours;
- (b) Follow-up care and services as necessary for a surgical patient's recovery; and
- (c) Services established in Section 8(4) of this administrative regulation.

(3) An emergency medical services component shall include:

- (a) Twenty-four (24) hour emergency medical treatment by a board certified or board eligible emergency room physician seven (7) days per week;

- (b) A specific area for emergency treatment that shall be located adjacent to an exterior entrance and is immediately accessible to emergency transport vehicles;
- (c) Facilities sufficient to assure prompt diagnosis, treatment, and stabilization of injuries and trauma; and
- (d) Services established in Section 8(2) of this administrative regulation.

(4) A diagnostic imaging and MRI component shall include:

- (a) Radiologic and magnetic resonance imaging with permanent, fixed-site equipment licensed or registered pursuant to KRS 211.842 to 211.852 and 900 KAR 6:050, but shall not include any services for which a separate certificate of need is required;
- (b) Radiologic and imaging services shall be provided in accordance with protocols established by the center, which shall include a concise statement of the reason for the service; and
- (c) Services established in Section 8(3) of this administrative regulation.

Section 3. Administration and Operations.

(1) The licensee shall:

- (a) Be legally responsible for the center and for compliance with federal, state, and local laws and administrative regulations pertaining to the operation of the center;
- (b) Appoint a full-time administrator of the center whose qualifications, responsibilities, authority, and accountability shall be defined in writing and approved by the hospital governing authority; and
- (c) Be responsible for and assure compliance with this administrative regulation, and make immediately available for public inspection at the center all licensure and complaint inspection reports and plans of correction pertaining to the last three (3) year survey period.

(2) The administrator shall:

- (a) Be responsible for the daily operations of the center and shall delegate that responsibility in his absence;
- (b) Assure the establishment and implementation of written policies and procedures covering all aspects of the center's operation and, if appropriate, shall be consistent with the policies and procedures of the main provider;
- (c) Serve as liaison between the center, its medical staff, and the main provider;
- (d) Hold at least quarterly, component and departmental staff meetings that shall include a discussion of administrative and patient care standards;
- (e) Ensure that a sufficient number of trained staff are available to meet the needs of all persons who receive services in the center; and
- (f) Appoint a licensed physician to serve as medical director who shall direct and coordinate all medical services and oversee implementation of patient care standards and policies, who may serve as the licensed physician in charge as established in Section 5(1)(a)1 of this administrative regulation.

Section 4. Policies and Procedures.

(1) Development of policies and procedures. The administrator shall assure development or adoption and implementation of the following policies and procedures:

- (a) Administrative standards and policies covering all aspects of the center's operation and specific to each component part, including at least the following:
 1. A description of organizational structure, staffing, and allocation of responsibility and accountability within each component part;
 2. A description of referral linkages with inpatient facilities and other providers;
 3. A description of the component services provided by the center;
 4. Policies and procedures for the guidance and control of personnel performance and quality assurance;

5. Policies and procedures for creation and maintenance of administrative and patient care records and reports;
6. Policies for expense and accrual-based revenue accounting system following generally-accepted accounting procedures;
7. Policies and procedures governing the use of aseptic techniques in all areas of the center;
8. Policies and procedures for sterilization of equipment and supplies;
9. Policies and procedures for disposal of patient waste and other potentially-infectious materials; and
10. Policies and procedures for granting and withdrawal of medical staff surgical privileges and privileges for the administration of anesthetics.

(b) Patient care policies and standards, which shall be developed by staff physicians and other qualified professional staff, for all medical aspects of the center including:

1. Written protocols for standing orders, rules of practice, and medical directives applying to each of the component services, which shall be signed by the administrator and staff physician;
2. Patient care policies and standards for patients held in the center's holding-observation area;
3. Patient care policies and standards for primary care services;
4. Patient care policies and standards for emergency medical services;
5. Patient care policies and standards for ambulatory surgical services; and
6. Patient care policies and standards for diagnostic imaging and magnetic resonance imaging services; and

(c) Patient rights policies which shall be developed and assure that each patient is:

1. Informed of the patient's rights and facility responsibilities, including procedures for handling patient grievances;
2. Informed of services available at the center and any charges not covered under Medicare, Medicaid, or other third-party payor arrangements;
3. Informed of his medical condition, unless medically contraindicated and documented in the medical record, and is afforded the opportunity to participate in the planning of medical treatment, the right to refuse treatment, and informed consent;
4. Encouraged and assisted to understand and exercise patient rights and the right to make grievances and receive a response to a grievance;
5. Assured confidentiality in treatment, care, and records, and is afforded the opportunity to approve or refuse release of records to any individual not involved in his care except as required by Kentucky law or third-party payment contract; and
6. Treated with consideration, respect, and full recognition of his dignity and individuality, including privacy in treatment, and in the care of his personal health needs.

(2) Accessibility of policies and procedures. Written policies and procedures shall be maintained in the facility in a readily-accessible electronic format or a written manual that is available and conveniently accessible to all staff employed in the component service.

Section 5. Personnel and Qualifications.

(1) Personnel. The center shall have sufficient trained personnel to meet the needs of each patient who presents for treatment at the center, which shall include:

(a) At a minimum, a core center provider team to coordinate services for the component services, composed of at least one (1) licensed physician in charge, who may also serve as the center's medical director and the physician in charge of emergency medicine; one (1) full-time registered nurse, who shall provide services

within the scope of practice; and other nursing personnel, aides, and technicians as required to meet the needs of the patients, as follows:

1. A licensed physician shall be in charge in the center twenty-four (24) hours a day, seven (7) days a week, who shall be a physician in active practice and who shall be responsible for all medical aspects of the center's operation. The licensed physician in charge may provide direct medical services in accordance with KRS Chapter 311.
2. The center shall employ or have contractual or other linkage agreements with other physicians as necessary to meet the surgical needs of the center's patients, and who shall be qualified to practice general medicine (e.g., general practitioner, family practitioner, obstetrician/gynecologist, pediatrician, and internist), and who shall hold at least courtesy staff privileges at one (1) or more hospitals with which the center has a formal transfer agreement.
3. The registered nurse shall provide nursing services within the scope of practice pursuant to KRS Chapter 314.

(b) At a minimum, a core ambulatory surgery component provider team composed of one (1) licensed physician in charge; other licensed physicians, dentists, or podiatrists, as necessary to meet the surgical needs of the center's patients; an anesthesiologist or nurse anesthetist; a full-time registered nurse; and other nursing personnel, aides, and technicians as required to meet the needs of the patients, as follows:

1. A licensed physician shall be in charge of the ambulatory surgery component, and may also serve as the center's medical director. This physician shall be in active practice and shall either:
 - a. Have surgical privileges at the provider-based hospital or one (1) or more hospitals with which the center has a formal transfer agreement; or
 - b. Be a board-certified anesthesiologist in active practice and be employed full time by the center or have a contract to work full time at the center.
2. Surgical procedures shall be performed by physicians who are legally authorized to perform these procedures and have been granted privileges by the center through its medical staff or governing body.
3. The ambulatory surgery registered nurse shall be employed full-time and shall provide services within the scope of practice pursuant to KRS Chapter 314.
4. Other nursing personnel, aides, and technicians shall be employed to meet the needs of the patients. A registered nurse shall be available during the surgical procedure and if a patient is in recovery for patient care in the operating or post-anesthesia recovery room.

(c) At a minimum, the emergency medical component shall be composed of a licensed physician, board certified in emergency medicine or board eligible, who shall serve as director of emergency medicine; at least one (1) full-time registered nurse; and other physicians and medical staff who shall be available or on duty at all times for the emergency service, as follows:

1. A licensed physician shall be present in the center twenty-four (24) hours a day, seven (7) days a week, shall serve as director of emergency services and may also serve as the center's medical director. The director of emergency medicine shall assure creation and implementation of patient care policies, and assure at least the following:
 - a. Each patient presenting for or requesting care shall be evaluated by a qualified physician or registered nurse;
 - b. Qualified medical personnel shall be available to treat a patient presenting for or requesting emergency care;
 - c. At least one (1) physician shall be available on-site at all times to treat a patient;

- d. Establishment and maintenance of a manual of policies and procedures for emergency and nursing care provided in the emergency room;
- e. Nursing personnel shall be assigned to or available to cover the emergency service at all times; and
- f. Diagnostic and treatment equipment, drugs, and supplies shall be readily available for the provision of emergency services and shall be adequate in terms of the scope of services provided.

2. Physicians employed by or under contract with the center to provide emergency medical treatment shall be board certified in emergency medicine or board eligible.
3. Other nursing personnel, aides, and technicians shall be available in the emergency department to meet the needs of the patients who present for treatment.

(2) Center staffing and qualifications. In addition to the core service component staff requirements, the center shall employ sufficient numbers of qualified administrative and medical personnel to provide prompt and effective patient care and services, and shall assure at least the following:

- (a) A written job description for each position, which shall be reviewed and revised by the administrator as necessary;
- (b) An employee health program for mutual protection of employees and patients, including provisions for preemployment and periodic health examination;
- (c) A tuberculosis skin test of each staff member, which shall be implemented according to the following requirements be documented in the employee's personnel record and which shall:
 1. A test shall be initiated on each new staff member before or during the first week of employment. The results shall be documented in the employee's personnel record within the first month of employment, unless the employee documents a prior skin test of ten (10) or more millimeters of induration, or is currently receiving or has completed nine (9) months of therapy for latent tuberculosis infection (LTBI) or a course of multiple-drug chemotherapy for tuberculosis;
 2. There shall be a two (2) step skin testing for a new employee regardless of age whose initial test shows less than ten (10) millimeters of induration, unless the employee can document that he has had a tuberculosis skin test within one (1) year prior to his current employment;
 3. A staff member who has never had a skin test result of ten (10) or more millimeters induration shall be skin tested annually, on or before the anniversary of the last skin test;
 4. A staff member who has a skin test result of ten (10) or more millimeters induration on initial employment or annual testing shall receive a chest x-ray unless:
 - a. A chest x-ray within the previous two (2) months showed no evidence of tuberculosis; or
 - b. The individual can document the previous completion of a course of prophylactic treatment with Isoniazid. The employee shall be advised of the symptoms of the disease and instructed to report to his employer and to seek medical attention promptly if symptoms persist;
 5. The following shall be reported by the center administrator to the local health department having jurisdiction immediately upon becoming known:
 - a. Names of staff who convert from a skin test of less than ten (10) to a skin test of ten (10) millimeters or more induration at the time of employment; and
 - b. Chest x-rays suspicious for tuberculosis;
 6. A staff member whose skin test status changes on annual testing from less than ten (10) to ten (10) or more millimeters of induration shall be considered to be recently infected with *Mycobacterium tuberculosis*. A recently-infected person who has no sign or symptom of tuberculosis disease on chest x-ray or medical history

shall receive preventative therapy with Isoniazid for six (6) months, unless medically contraindicated, as determined by a licensed physician. Medication shall be administered only upon the written order of a physician or other ordering personnel acting within their statutory scope of practice. If an individual is unable to take Isoniazid therapy, the individual shall be advised of the clinical symptoms of the disease, and shall have an interval medical history and a chest x-ray taken and evaluated for tuberculosis every six (6) months during the two (2) years following conversion, for a total of five (5) x-rays; and

7. A staff member who documents completion of preventive treatment with Isoniazid shall be exempt from further screening requirements; and

(d) An employee file, which shall include at least the following information for each employee:

1. Name, address, Social Security number;
2. Evidence of current professional registration, certification, or licensure;
3. Complete record of training, experience, and in-service;
4. Records of performance evaluation;
5. Records of incidents and accidents in which the employee was involved; and
6. Documentation of current tuberculin screening.

(3) Personnel in-service training. Center personnel shall participate in quarterly in-service training programs relating to their respective job duties and activities, which shall include at least the following:

- (a) Job orientation for new personnel and recurring in-service training, including a requirement that each staff member shall be knowledgeable of the center's policies;
- (b) Quarterly in-service training for all staff emphasizing professional competence, quality assurance, policy development; and the physical, nutritional, environmental, and social components necessary for effective health care;
- (c) Quarterly in-service training pertaining to medical documentation and maintenance of medical records;
- (d) Reporting, identifying, and preventing abuse and neglect of children and adults; and
- (e) Maintaining privacy and confidentiality of patient-specific information and records.

Section 6. Medical Records.

(1) Maintenance of records. The center or the main provider shall maintain a medical record at the center for each patient to include at least the following:

- (a) Medical and social history, including data from other providers;
- (b) Description of each medical visit or contact, including identification of the condition or reason for the visit or contact, assessment performed, medical diagnosis, services provided, medications and treatments prescribed, and disposition;
- (c) Reports of all laboratory, x-ray, and other test findings;
- (d) Documentation pertaining to a patient referred to the center for treatment, including the reason for the referral, to whom the patient was referred, and information obtained from the referral source;
- (e) Physicians' orders, nurses' notes, and surgical and medical consent forms;
- (f) History and physical examination record prior to surgery;
- (g) For surgical patients, the complete medical record signed by the operating surgeon, including anesthesia record, preoperative diagnosis, operative procedures and findings, postoperative diagnosis and, if required, tissue diagnosis by a pathologist on specimens surgically removed;
- (h) Charts, including records of temperature, pulse, respiration, and blood pressure; and

- (i) Discharge summary completed at the time of discharge which includes condition on discharge and post-treatment instructions to the patient;
- (2) Confidentiality. Confidentiality of patient records shall be maintained at all times;
- (3) Transfer of records. The center shall establish systematic procedures to assist in continuity of care if the patient moves to another provider of care, and the center shall, upon proper release, transfer medical records or an abstract, if requested;
- (4) Attending signature. The attending physician shall complete and sign the medical record of each patient as soon as practicable after discharge, but not to exceed ten (10) days; and
- (5) Retention of records. Medical records shall be maintained by the center for a period of five (5) years following the last treatment, assessment, or visit made by the patient.

Section 7. Linkage Agreements. The center shall have linkages through written agreements.

- (1) Linkage agreements. Linkage agreements shall be established with other providers of other levels of care which may be medically indicated to supplement the services available in the center and shall include:

- (a) Hospitals;
- (b) Emergency medical transportation services in the service area;
- (c) In-patient care facilities; and
- (d) Other agreements as necessary.

- (2) Inpatient agreements. Linkage agreements with inpatient care facilities shall incorporate provisions for:
 - (a) Appropriate referral and acceptance of patients from the center;
 - (b) Provisions for appropriate coordination of discharge planning with center staff; and
 - (c) Provisions for the center to receive a copy of the discharge summary for each patient referred to the center.
- (3) Transfer agreements. The written transfer agreements shall include designation of responsibility for:
 - (a) Transfer of information;
 - (b) Provision of transportation;
 - (c) Sharing of services, equipment, and personnel;
 - (d) Provision of total care or portions thereof in relation to facility and agency capability; and
 - (e) Patient record confidentiality.

Section 8. Provision of Services. The center shall provide the following component services on its campus:

- (1) Primary care component. The center shall provide at least the following services during scheduled hours of operation that reasonably accommodate various segments of the population:
 - (a) Medical diagnostic and treatment services of sufficiently broad scope to accommodate the basic health needs of all age groups;
 - (b) Preventive health services of sufficiently broad scope to provide for the usual and expected health needs of persons in all age groups;
 - (c) Educational offerings in the appropriate use of health services, preventive health services, and health maintenance;
 - (d) Chronic illness management;
 - (e) Laboratory, x-ray, and treatment services shall be provided directly or arranged through other providers; and
 - (f) Supplemental services may also be provided for pharmacy, dentistry, optometry, nutrition, and counseling.
- (2) Emergency services component. The center shall have written policies for operation of the emergency component and shall assure the following:

- (a) A patient presenting for or requesting emergency care shall be evaluated and triaged by a registered nurse or emergency department physician in accordance with the center's formal operating policies and procedures;
- (b) The physician, in conjunction with the administrator and other medical staff, shall establish and maintain policies and procedures for emergency and nursing care, which shall assure that:
 - 1. Emergency services shall at all times be under the direction of a licensed physician;
 - 2. Sufficient medical staff shall be available and on site at all times to perform emergency medical care in accordance with accepted standards of practice; and
 - 3. Current medical staff schedules and telephone numbers shall be posted in the emergency treatment area;
- (c) Sufficient nursing and medical personnel shall be assigned to or designated to cover the provision of emergency services at all times;
- (d) Appropriate facilities shall be provided to assure prompt diagnosis and emergency treatment for patients requiring emergency care on arrival;
- (e) Adequate diagnostic and treatment equipment, drugs, and supplies shall be readily available for the provision of emergency services;
- (f) Adequate medical records shall be kept for each patient seen in the emergency department, which shall include at least:
 - 1. A log listing the patient visits to the emergency department in chronological order, including:
 - a. Patient identification;
 - b. Means of arrival;
 - c. Person transporting patient;
 - d. Time of arrival;
 - e. History of present complaint and physical findings;
 - f. Laboratory and x-ray reports, if applicable;
 - g. Diagnosis;
 - h. Treatment ordered and details of treatment provided;
 - i. Patient disposition; and
 - j. Record of referrals.
 - 2. Instructions to the patient or family for those not admitted to the center; and
 - 3. Signatures of attending medical staff member, and nurse if applicable.

(3) Diagnostic imaging and MRI services. The center shall have written policies for the operation of the component and shall assure the following:

- (a) The center shall have diagnostic radiology facilities currently licensed or registered pursuant to KRS 211.842 to 211.852, the Kentucky Radiation Control Act of 1978;
- (b) The center shall employ or contract with a radiologist on at least a consulting basis to:
 - 1. Function as the director of the department; and
 - 2. Interpret films requiring specialized knowledge for accurate reading;
- (c) The center shall employ and have on duty sufficient personnel to supervise and conduct services, including one (1) certified radiation operator who shall be on duty or on call at all times;
- (d) Written policies and procedures governing radiologic services and administrative routines that support sound radiologic practices;
- (e) Signed reports shall be filed in the patient's record, and duplicate copies kept in the department;
- (f) Radiologic services shall be performed only upon written order of qualified personnel in accordance with their scope of practice and the center's protocols and

bylaws, and the order shall contain a concise statement of the reason for the service or examination;

(g) Reports of interpretations shall be written or dictated and signed by the radiologist;

(h) Only a certified radiation operator, under the direction of medical staff, if necessary, shall use any x-ray apparatus or material. Uses shall include application, administration, and removal of radioactive elements, disintegration products, and radioactive isotopes. A certified radiation operator under the direction of a physician may administer medications allowed within his professional scope of practice and the context of radiological services and procedures being performed; and

(i) The radiology department shall be free of hazards for patients and personnel. Proper safety precautions shall be maintained against fire and explosion hazards, electrical hazards, and radiation hazards.

(4) Ambulatory surgical component services. The center shall have written policies for the operation of the component and shall assure the following:

(a) The patient or the patient's legal representative shall sign a written informed consent prior to all surgical operations;

(b) A medical history and physical evaluation shall be performed and entered into the medical record no more than thirty (30) days prior to surgery on a patient;

(c) Pertinent preoperative diagnostic studies and laboratory tests shall be performed and made a part of the medical record prior to surgery. The preoperative diagnosis shall be recorded in the medical record;

(d) A patient shall be examined by a physician immediately prior to surgery to evaluate the risk of anesthesia and of the procedure to be performed, taking into account site of service, the invasive nature of the procedure, and the need for extended postoperative recovery time or monitoring;

(e) The center shall employ a registered nurse who shall serve as operating room supervisor;

(f) A registered nurse shall be available to circulate in the operating room at all times.

(g) A list of physicians with surgical privileges at the center and the privileges assigned to each by the medical staff shall be on file;

(h) The operating room shall have an up-to-date operating room register;

(i) The operating room shall have medically-appropriate supplies and equipment available at all times to meet the needs of the patients, including the following:

1. Oxygen;

2. Mechanical ventilator assistance equipment including airways, manual breathing bag, and ventilator;

3. Cardiac defibrillator;

4. Cardiac monitoring equipment;

5. Tracheostomy set;

6. Laryngoscopes;

7. Endotracheal tubes;

8. Suction equipment; and

9. Emergency medical equipment and supplies specified by the medical staff;

(j) The operating room shall have on hand, or make arrangements for obtaining, an adequate supply of blood in a timely manner to meet the needs of each patient;

(k) Operating room administrative regulations shall be posted;

(l) Physicians' orders shall be in writing and signed by the physician;

(m) Except for cases requiring only local infiltration anesthetics, a physician qualified to administer anesthesia, a dentist qualified to administer anesthesia, or a registered nurse anesthetist acting under the direction of the operating surgeon shall administer the anesthetics and shall remain present during the surgical procedure and until the patient is discharged to home or observation;

(n) The patient's attending physician shall be responsible for assuring that tissue removed during surgery is delivered to the center's pathologist and that an examination and report is made on the tissue, if required by the center's written policies;

(o) Voluntary interruption of pregnancy. The center shall comply with the applicable Kentucky statutes, including KRS 311.710 to 311.810;

(p) The center shall have written surgery policies and protocols that shall include:

1. Infection control policies addressing the use of aseptic techniques and procedures for surgical patients;
2. Protocols for sterilization of surgical equipment and supplies;
3. Protocols for disposal of patient waste and other potentially-infectious materials;
4. Protocol for obtaining pathological examination of tissues removed during surgery; and
5. Policies for granting and withdrawing surgical privileges and privileges for the administration of anesthetics.

(q) The center shall have the following postanesthesia recovery services:

1. At least one (1) postanesthesia recovery unit;
2. Adequate staff available in the recovery unit so that no patient is left alone at any time;
3. At least one (1) licensed physician shall be present until all surgical patients are discharged;
4. A registered nurse shall be present in the recovery unit while a patient is recovering from anesthesia;
5. A registered nurse shall be available to the recovery unit at all times;
6. A person staffing the postanesthesia recovery unit shall be adequately trained in all aspects of postoperative and postanesthetic care; and
7. The recovery unit nurse shall record a nursing note on the patient, noting 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.

(r) The ambulatory surgery component shall assure the following equipment is available to the operating area:

1. Suction machine;
2. Stethoscope;
3. Sphygmomanometer;
4. Emergency crash cart;
5. Necessary drugs; and
6. Oxygen.

(s) The surgical center shall provide suitable accommodations for its patients, including:

1. Adequate floor space, furnishings, bed linens, and utensils, equipment, and supplies reasonably required for the proper care and comfort of patients accommodated;
2. Holding-observation and convalescent accommodations within the following limitations:
 - a. Holding-observation and convalescent accommodations shall not exceed twenty-three (23) hours postadmission for medical observation, recuperation, or convalescence in anticipation of discharge to the patient's home;

- b. The decision to hold a patient shall be the responsibility of a physician on the medical staff of the center, who shall document the reason for and duration of the hold in the patient's medical record and shall date and sign the entry; and
- c. A physician or registered nurse shall be on duty at the center, if a patient is held in the center's accommodations beyond regularly scheduled hours.

(5) Physical and sanitary environment.

- (a) The condition of the physical plant and the overall environment shall be maintained in such a manner that the safety and well-being of patients, personnel, and visitors are assured.
- (b) There shall be an infection control committee charged with the responsibility of investigating, controlling, and preventing infections. This committee shall develop written infection control policies that are consistent with Centers for Disease Control guidelines and include:
 1. Prevention of disease transmission to and from patients, visitors, and employees, including:
 - a. Universal blood and body fluid precautions;
 - b. Precautions against airborne transmittal of infections; and
 - c. Work restrictions for employees with infectious diseases;
 2. Use of environmental cultures. Culture testing results shall be recorded and reported to the Infection Control Committee; and
 3. Cleaning, disinfection, and sterilization methods used for equipment and the environment.
- (c) The center shall provide in-service education programs on the cause, effect, transmission, prevention, and elimination of infections.
- (d) The center's buildings, equipment, and surroundings shall be kept in a condition of good repair, neat, clean, free from accumulation of dirt, rubbish, and foul, stale, or musty odors.
- (e) Hazardous cleaning solutions, compounds, and substances shall be labeled, stored in closed metal containers, and kept separate from other cleaning materials.
- (f) The facility shall be kept free from insects and rodents, and their nesting places, and entrances shall be eliminated.
- (g) Garbage and trash:
 1. Shall be stored in areas separate from those used for preparation and storage of food;
 2. Shall be removed from the premises regularly; and
 3. Containers shall be cleaned on a regular basis.
- (h) Sharp wastes:
 1. 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.
 2. A needle or other contaminated sharp shall not be purposely bent, broken, or otherwise manipulated by hand as a means of disposal, except as permitted by Occupational Safety and Health Administration guidelines at 29 C.F.R. 1910.1030(d)(2)(vii).
 3. A sharp waste container shall be incinerated or shall be rendered nonhazardous.
 4. Nondisposable sharps, such as large-bore needles or scissors, shall be placed in a puncture-resistant container for transport to the Central Medical and Surgical Supply Department in accordance with 902 KAR 20:009, Section 22.
- (i) Disposable waste:
 1. Disposable waste shall be placed in a suitable bag or closed container so as to prevent leakage or spillage, and shall be handled, stored, and disposed of in such a way as to minimize direct exposure of personnel to waste materials.

2. The center shall establish specific written policies regarding handling and disposal of waste material.
3. The following wastes shall receive special handling:
 - a. Microbiology laboratory waste including a viral or bacterial culture, contaminated swab, or a specimen container or test tube used for microbiologic purposes shall be incinerated, autoclaved, or otherwise rendered nonhazardous; and
 - b. Pathological waste including a tissue specimen from a surgical or necropsy procedure shall be incinerated.

(6) Utilization review and medical audit. In order to determine the appropriateness of the services delivered, the center shall establish procedures for the medical audit and utilization review of services provided in the center. The center may use professional capabilities and assistance obtainable from other agencies and sources. There shall be a written plan for utilization review developed by the center including frequency of review and composition of the body conducting the review.

(32 Ky.R. 2407; 33 Ky.R. 814; 1083; eff. 10-13-2006; Crt eff. 4-30-2019.)