DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

CHAPTER 20 - AMBULATORY SURGICAL CENTER AND AMBULATORY SURGICAL CENTER WITH A CONVALESCENT CENTER

6 CCR 1011-1 Chap 20

[Editor's Notes follow the text of the rules at the end of this CCR Document.]

Adopted by the Board of Health on December 17, 2014

SECTION 1 - STATUTORY AUTHORITY AND APPLICABILITY

1.1 The statutory authority for the promulgation of these rules is set forth in section 25-1.5-103 and 25-3-101, *et seq.*, C.R.S.

1.2 An ambulatory surgical center, as defined herein, shall comply with all applicable federal and state statutes and regulations, including, but not limited to:

(A) This Chapter 20, Sections 1 through 24, and

(B) 6 CCR, 1011-1, Chapter 2, General Licensure Standards, unless otherwise modified herein.

1.3 An ambulatory surgical center with a convalescent center, as defined herein, shall comply with all applicable federal and state statutes and regulations, including, but not limited to:

(A) This Chapter 20, Sections 1 through 25, and

(B) 6 CCR 1011-1, Chapter 2, General Licensure Standards, unless otherwise modified herein.

1.4 These regulations incorporate by reference (as indicated within) materials originally published elsewhere. Such incorporation does not include later amendments to or editions of the referenced material. The Department of Public Health and Environment maintains copies of the complete text of the incorporated materials for public inspection during regular business hours, and shall provide certified copies of the incorporated material at cost upon request. Information regarding how the incorporated material may be obtained or examined is available from:

Division Director
Health Facilities and Emergency Medical Services Division
Colorado Department of Public Health and Environment
4300 Cherry Creek Drive South
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Phone: 303-692-2800

Copies of the incorporated materials have been provided to the State Publications Depository and Distribution Center, and are available for interlibrary loan. Any incorporated material may be examined at any state publications depository library.

SECTION 2 - DEFINITIONS

2.1 "Administrator" means an individual who has authority over the daily operations of an ambulatory surgical center or ambulatory surgical center with convalescent center or an individual who is designated by the governing body of an ambulatory surgical center. Such individual shall have sufficient authority to interpret and implement all policies of the owner or proprietor and must be sufficiently qualified to perform those tasks.

2.2 "Ambulatory Surgical Center" means a health care entity established for the primary purpose of providing medically necessary surgery, elective surgery, or preventive diagnostic procedures that do not require hospitalization but do require post surgical or post procedural observation and monitoring that generally will not exceed 24 hours from admission to discharge. For convenience in this Chapter 20 only, an ambulatory surgical center is also referred to as a "center."

(A) Offering multiple health services in the same building does not preclude or exempt a center from meeting the requirements of Chapter 20. The other health services being offered in the same building must be physically separated from the ambulatory surgical center.

(B) A licensed ambulatory surgical center may sublease space to another licensed ambulatory surgical center for use if all of the criteria set forth below are met. If the Department finds deficient practice by either licensee, it has the discretion to assign those deficiencies to both licensees.

(1) The licensed centers shall not operate at the same time or on the same days of the week;

(2) There shall be clear public signage stating the days and times each licensed center is in operation.

(3) There shall be a written agreement between the licensed centers that establishes the responsibilities of each party regarding services, supplies and equipment use, quality assurance and infection control. All agreements must comply with this chapter and any other applicable local, state and federal law;

(4) Each licensed center shall meet all license requirements either directly or by contract; and

(5) Each licensed center shall ensure that all information regarding its patients is kept confidential and safeguarded from access by the other center.

(C) The term "ambulatory surgical center" includes a clinic or practitioner's office if:

(1) It is certified as an ambulatory surgical center by the Centers for Medicaid and Medicare Services,

(2) It is operated or used by a practitioner or entity other than the primary practitioner(s), or

(3) It holds itself out to the public or other health care providers as an ambulatory surgical center, surgical center, surgicenter or similar facility using a similar name or variation thereof.

(D) The term “ambulatory surgical center” does not include:

(1) A practitioner’s private office or treatment rooms where the practitioner primarily consults with and treats patients including, but not limited to, practitioners organized as professional corporations, professional associations, professional limited liabilities companies, partnerships and sole proprietorships; or

(2) An outpatient surgery unit that is licensed as part of a hospital and located on a hospital campus as defined in 6 CCR 1011-1, Chapter 4; or

(3) An outpatient surgery center that is owned and operated by a hospital; licensed as an off campus location of the hospital; and has signage that clearly indicates the surgery center’s connection with the hospital.

(a) A licensed hospital provider of ambulatory surgical services may use the term “ambulatory surgery” or a similar term to indicate that ambulatory surgical services or an ambulatory surgery or surgical department is available or housed within the hospital as part of the facility's services. Such hospital shall not indicate to the public nor hold itself out to the public as an ambulatory surgical center (free standing or otherwise) unless the hospital entity actually possesses such a license.

2.3 “Convalescent Center” means a health care entity that provides post surgical, post procedural and/or post diagnostic medical and nursing services to patients for whom an uncomplicated recovery is anticipated and for whom acute hospitalization is not required. A convalescent center shall be licensed and operated only in conjunction with a licensed ambulatory surgical center.

2.4 “Department” means the Colorado Department of Public Health and Environment.

2.5 “Medical Director” means the physician responsible for planning, organizing, conducting and directing the medical affairs of the ambulatory surgical center. The medical director shall meet one of the following requirements in order to be considered qualified:

(A) Is board eligible or board certified in at least one of the services provided at the ambulatory surgical center and has had at least 12 months of experience or training in the care of patients in a surgical environment, or

(B) Has served for at least 12 months in a leadership role at a health facility during the prior five year period.

(1) In geographical areas where a medical director meeting the above criteria is not available, another licensed and credentialed physician may fill that role if approved to do so by the Department prior to initial appointment.

2.6 “Medical Staff” means a formal organization of physicians, dentists, podiatrists or other health professionals, who are appointed by the governing body to attend to patients within the ambulatory surgical center.

2.7 "Medical Waste" means any infectious, pharmaceutical or trace chemotherapy waste generated in a health care setting in the diagnosis, treatment, immunization, or care of humans or animals; generated in autopsy or necropsy; generated during preparation of a body for final disposition such as cremation or interment, generated in research pertaining to the production or testing of microbiologicals; generated in research using human or animal pathogens; or related to accident, suicide, or other physical trauma. Medical waste does not include fluids, tissues or body parts removed from the whole body for the purposes of donation, research or other use, or those returned to the person from whom they were removed, or their authorized representative, as long as the material is rendered safe for handling.

SECTION 3 - AMBULATORY SURGICAL CENTER CLASSIFCATIONS

3.1 An ambulatory surgical center shall be issued a license consistent with the type and extent of services provided, as outlined below.

(A) Class C Center – A Class C center shall have at least one sterile operating room with the capacity to administer general anesthesia to patients. The operating room(s), as well as the pre and post surgical areas, shall be located in a way that provides control over the movement of patients and personnel. This classification of operating room is equivalent to a Class C operating room as described in the Guidelines for Design and Construction of Health Care Facilities, (2010 Edition), Facilities Guidelines Institute, which is incorporated by reference.

(B) Class A or B Center – A Class A or B Center shall have a dedicated procedure room(s) with the capacity to provide oxygen and patient monitoring in a clean environment that supports infection control. The procedure room(s) shall only be used for endoscopic or interventional procedures or non-invasive examinations/treatments unless first terminally cleaned. Low-risk versus high-risk exposure areas shall be identified, along with the attire and personal protective equipment necessary for each area. This classification of procedure room is equivalent to Class A or B operating rooms as described in the Guidelines for Design and Construction of Health Care Facilities, (2010 Edition), Facilities Guidelines Institute, which is incorporated by reference.

SECTION 4 - GOVERNING BODY

4.1 Responsibility: The governing body shall provide facilities, personnel, and services necessary for the welfare and safety of the patients.

4.2 Duties: The governing body shall:

(A) Adopt bylaws in accordance with applicable legal requirements;

(B) Meet regularly and maintain accurate records of such meetings;

(C) Appoint committees consistent with the needs of center;

(D) Appoint and delineate clinical privileges of practitioners based upon recommendations by the medical staff and other appropriate indicators of physician and other licensed practitioner competence. Each member of the medical staff shall be granted privileges that are commensurate with the member's qualifications, experience, and present capabilities and that are within the practitioner's scope of practice;

(E) Maintain an up-to-date roster of providers credentialed by the center that specifies the approved surgical and/or procedural privileges of each provider. The roster shall be available to the nursing staff at all times;

(F) Establish a formal means of liaison with the medical staff;

(G) Approve bylaws, rules and regulations of the medical staff;

(H) Develop written policies and procedures in cooperation with the medical staff. The procedures shall address the acceptance, care, treatment, surgical and anesthesia services, discharge, referral and follow-up of all patients and all incidental operations of the center. The policies and procedures shall be available to all staff in the center and shall be followed by them at all times in the performance of their duties. The governing board shall also define the scope of services provided within the center;

(I) Conduct, with the active participation of the medical staff, an ongoing, comprehensive self-assessment of the quality of care provided, including the medical necessity of procedures performed, the appropriateness of care, and the appropriateness of utilization. This information shall provide a basis for the revision of center policies and the granting or continuation of clinical privileges;

(J) Adopt a national standard for infection control;

(K) Ensure the center maintains an adequate number of qualified personnel;

(L) Maintain effective quality control, quality improvement and data management;

(M) Appoint an administrator qualified by education and experience as defined in the job description developed by the center; and

(N) Appoint a member of the medical staff to act as medical director for the center.

SECTION 5 - ADMINISTRATOR

5.1 Responsibility: The administrator shall be the official representative of the governing body and the chief executive officer of the center. The administrator shall be delegated responsibility and authority in writing by the governing body for the management of the center and shall serve as liaison among the governing body, provider staff and other departments of the center.

5.2 Duties: The administrator shall be responsible for the development, implementation and administration of center policies and procedures for employee and medical staff use. All policies and procedures shall be reviewed and approved by the governing body and/or updated as necessary but at least annually. The administrator shall designate a qualified individual to act for him or her when absent so that the ambulatory surgical center has administrative direction at all times.

SECTION 6 - MEDICAL STAFF

6.1 Organization: The ambulatory surgical center shall have an organized medical staff.

6.2 Duties: The medical staff or a delegated committee composed of members of the medical staff shall:

(A) Be responsible for the quality of all medical care provided patients in the center;

(B) Ensure professionally ethical conduct on the part of all members of the medical staff and initiate corrective measures as required;

(C) Formulate, adopt and enforce bylaws, rules, regulations and policies for the proper conduct of its activities and credentialing of its members. The practitioners applying for staff privileges shall be required to sign an agreement to abide by the medical staff bylaws, code of conduct and applicable state laws, rules and regulations;

(D) Recommend medical staff privileges to the governing body;

(E) Hold meetings regularly and maintain accurate records of such meetings;

(F) Establish a formal liaison with the governing body;

(G) Participate actively in the quality management program; and

(H) Recommend admission and procedural policies to the governing body.

SECTION 7- HEALTH INFORMATION MANAGEMENT

7.1 Facilities: The center shall develop and maintain a system for the proper collection, storage, and use of patient health information. The center shall maintain an individual record for each patient admitted.

(A) Each center shall establish processes to obtain, manage and utilize information to enhance and improve individual and organizational performance in patient care, management and support processes. Such processes shall:

(1) Be planned and designed to meet the center's internal and external information needs;

(2) Provide for confidentiality, integrity and security;

(3) Provide education and training in information management principles to decision-makers and other center personnel who generate, collect and analyze information; and

(4) Provide for information in a timely and accurate manner.

(B) The administrator shall appoint in writing a qualified person responsible for the patient information system or similarly titled unit. This person shall meet the qualifications established for this position, in writing, by the governing body.

(C) A current job description delineating duties and responsibilities shall be maintained for each medical records service position.

(D) The health information management administrator shall ensure that:

(1) Operative and procedure reports signed by the physician are recorded in the patient's health record immediately following the surgery or procedure or that a progress note is entered in the patient record to provide pertinent information;

(2) Postoperative information includes vital signs, level of consciousness, medications, blood or blood components, complications and management of those events, identification of direct providers of care, and discharge information from post-anesthesia care area; and

(3) All medical records are entered into a database and maintained on a current basis according to procedure and physician.

7.2 Security: Medical records shall be protected from loss, damage, unauthorized use and disclosure. If electronic medical records are utilized, there must be a back-up system for all data collected. An audit trail shall be maintained to track data entries and deletions, and include information regarding the data entered or deleted as well as the user responsible for the data entry or deletion.

7.3 Preservation: With the exception of medical records of minors (individuals under the age of 18 years) medical records shall be preserved as original records or on a technologically appropriate medium as administratively determined by the Department for no less than ten (10) years after the most recent patient care usage, after which time medical records may be destroyed at the discretion of the center. Accessibility of medical records to the Department to assure compliance and to patients or their legal representatives shall be maintained.

(A) Medical records of minors shall be preserved for the period of minority plus ten (10) years (i.e., 28 years less age of minor at time of most recent patient care usage of the medical record).

(B) Centers shall establish procedures for notification to patients whose records are to be destroyed prior to the destruction of such records.

(C) Centers shall be solely responsible for the destruction of all medical records.

(D) Actual x-ray films, scans, and other imaging records shall be maintained by the center for a period of five (5) years, if services are provided directly.

7.4 Content: The medical records shall contain sufficient accurate information to justify the diagnosis and warrant the treatment and end results including, but not limited to:

(A) Complete patient identification including a unique identification number;

(B) Admission and discharge dates;

(C) Chief complaint and admission diagnosis;

(D) Medical history and physical examination completed prior to surgery;

(E) Diagnostic tests, laboratory, x-ray, scans, and other radiological imaging reports and consultative findings when appropriate;

(F) Physician progress notes if appropriate;

(G) Properly executed informed consent;

(H) A pre-anesthesia examination by a physician prior to surgery, a proper anesthesia record and a post-anesthesia evaluation;

(I) A complete detailed description of operative procedures, findings and post-operative diagnosis recorded and signed by the attending physician;

(J) A pathology report of tissue removed during surgery in accordance with center policies;

(K) All medication and treatment orders in writing and signed by the authorizing party. Telephone and verbal orders are designated as such, signed and dated by a legally designated person, and countersigned by the attending provider within a clearly designated time period established by the governing body; and

(L) Patient's condition on discharge, final diagnosis, and instructions given to patient for follow-up care.

7.5 Other records: The center shall:

(A) Maintain a register of all procedures performed by practitioner (entered daily);

(B) Maintain a master patient index file; and

(C) Collect, retrieve and annually summarize the following medical statistical information:

(1) The number of patient visits,

(2) The basis of treatment (clinical diagnosis and/or problem for which the patient was treated),

(3) The types and number of procedures performed,

(4) The age distribution of patients,

(5) All complications and emergencies, and

(6) The number of times a patient was transferred from the center to a hospital.

The information shall be used to inform the governing body and as part of the center's ongoing quality management program. The beginning and ending dates for the annual summary shall be set in policy by the governing body.

(D) Nursing Records: Standard nursing practice and procedure shall be followed in the recording of medications and treatments, including operative and post-operative notes. Nursing notes shall include notation of the instructions given patients preoperatively and at the time of discharge. All nursing notes shall be entered as part of the patient's medical record. Entries shall be appropriately signed, including name and identifying title.

(E) Entries: All orders for diagnostic procedures, treatments, and medications shall be authenticated by the physician submitting them and entered in the medical record by technologically appropriate medium as administratively determined by the Department. Authentication may be by written signature, identifiable initials, computer key or other secure electronic means.

SECTION 8 - PERSONNEL

8.1 Orientation: The purpose and objectives of the center shall be explained to all personnel as part of an overall orientation program.

8.2 Policies: There shall be appropriate written personnel policies, rules and regulations governing the conditions of employment, the management of employees and the types of functions to be performed.

8.3 Job Description: There shall be written job descriptions for each position in the center including at least the title, authority, specific responsibilities and minimum qualifications. Each employee shall be provided a copy of his or her job description.

8.4 Staffing: Each service department of the center shall be under the direction of a person qualified by training, experience, and ability. Staffing levels shall be commensurate with the needs of the patients and center.

8.5 Education: All personnel shall receive at least 12 hours of continuing education annually, which must include, but not be limited to, infection control; fire, safety and emergency procedures.

8.6 Disease: Any personnel with communicable disease as defined by the Department shall return to work only after complying with the center's infection control policy.

8.7 Records: Personnel records shall be maintained for each person employed in the center and shall include, at a minimum, the following records:

(A) An employment application that contains information regarding education, experience and, if applicable, registration and/or licensure information for the applicant;

(B) Verification of references and/or credentials as required;

(C) Incident and/or accident reports;

(D) Evidence of periodic personnel performance evaluations;

(E) Results of medical examinations required as a part of employment within the center;

(F) Background checks for licensed individuals that includes verification, at the Department of Regulatory Agencies website, of an active license in good standing. Any admonishments or enforcement actions shall be reviewed by the administrator prior to hire; and

(G) Documentation of continuing education.

SECTION 9 - ADMISSIONS AND DISCHARGE

9.1 All persons admitted to the ambulatory surgical center shall be under the direct care of a member of the medical staff. The medical staff shall ensure the continuity of care for each patient including pre-operative, intra-operative, and post-operative care. All necessary instruction and education shall be provided to each patient prior to admission (for pre-surgical care) and discharge (for post-surgical care).

9.2 Restrictions:

(A) Surgical procedures shall be limited to the following:

(1) Those in which the expected combined operating and recovery time does not exceed 24 hours from the time of admission; and

(2) Those that do not generally result in extensive blood loss; require major or prolonged invasion of body cavities; directly involve major blood vessels or constitute an emergency or life-threatening procedure.

(B) There shall be no pre-planned, off-site transfers to a higher level of care and no transfers shall occur solely for the convenience of the ambulatory surgical center or its staff.

9.3 Identification: Each patient admitted to the center shall have a visible means of identification placed and maintained on his/her person until discharge. In cases of off-site pre-planned transfer such means of identification shall be maintained throughout the period of transfer and until such time as the patient becomes a patient of another licensed facility.

9.4 Admission Requirements: All admissions shall be in accordance with appropriate written policies and procedures which reflect the admission requirements established in this section, recommended by the medical staff and adopted by the governing body, specific to the ambulatory surgical center operations, that includes at least the following:

(A) The physicians performing the procedure shall document in writing that the patient is in good health or that any pre-existing health conditions are adequately controlled, require no special management and are such that performance of the procedure in a center, rather than an inpatient hospital setting, does not pose an increased risk to the patient.

(B) The patient or a responsible person acting on behalf of the patient must be able to strictly follow instructions related to ingestion of fluids or solids within the specified time frame prior to the surgery.

(C) If the patient is to receive sedation or anesthetic which will result in impaired mental status following surgery, the patient must be accompanied upon discharge by a responsible adult, unless exempted in writing by the attending physician.

(D) Patients who may require post-operative ventilation following surgery, either because of the procedure to be performed or because of a pre-existing condition, shall not be admitted for surgery.

(E) Surgery which requires the presence of special equipment, personnel, and/or facilities due to the risk of the operation involved shall not be performed in the center unless such equipment, personnel, and/or facilities are available in the center.

(F) When overnight care is provided, appropriate services shall be rendered within the defined capabilities of the organization.

9.5 Discharge: Patients shall be in a stable condition which will not endanger their continued well-being or shall be transferred to a licensed hospital, convalescent center or other treatment facility. There shall be written procedures and assigned responsibilities for implementing such procedures, including provisions for transportation. The center shall provide verbal and written patient instructions regarding post-operative or post-procedure care, physician follow-up, and physician contact information.

9.6 Off-Site Pre-Planned Transfers: Off-site pre-planned transfers of patients include those transfers of patients to other licensed health facilities, which are physically located off-site or off-campus, where it is known in advance that further post-surgical patient care will be needed. Off-site pre-planned transfers do not include discharges to the patient's place of residence where further care will be provided by home health or home care providers. Ambulatory surgical centers providing off-site pre-planned transfer service options shall adhere to the following requirements:

(A) Disclosure: Facilities offering surgical services which include an off-site pre-planned transfer to another licensed facility following post-operative recovery shall disclose in written form to the patient all the details of the transfer prior to admission to the facility. Disclosure includes, but is not limited to, the cost of the transfer, whether or not such costs shall be covered by insurance or other third party payer, and the details of the actual transfer, including, but not limited to, the mode of transport. Disclosure shall be made to the patient prior to the time for admission to the facility. The patient shall acknowledge such disclosure in writing, and the date thereof. Such disclosures on center policies regarding off-site pre-planned transfers shall be in addition to the requirements for informed consent.

(B) Off-site pre-planned transfers shall be made only to other licensed facilities that can provide the level of care necessary to meet the needs of the patient. The center shall have a written agreement with any and each licensed facility that admits patients for post-surgical care from a center. The center shall provide written discharge instructions, including patient progress information, to the receiving facility.

(1) An ambulatory surgical center shall allow preplanned transfers only with the written consent of the patient and the written authorization of the attending or operating surgeon or physician. The attending or operating surgeon or physician shall approve such a transfer if there are assurances that the continuity of care for the patient shall be maintained and contact with the patient's attending physician is continuous.

(C) All pre-planned transfers shall be by licensed ambulance. The center shall have a written agreement with the provider(s) of ambulance services. Such transfer agreements shall include the provision for an appropriate level of care commensurate with the needs of a post-surgical recovering patient. If necessary, as determined by the attending or operating physician, licensed medical staff from the ambulatory surgical center shall accompany the patient on the ambulance to provide continuity of care and a level of care that meets the peri-operative needs of the patient.

(D) Ambulatory surgical centers engaging in pre-planned transfers shall provide space at the entrance to the building to facilitate transfer. The center shall provide close-in parking that shall be accessible at all times and shall not be obstructed by other parked vehicles or any other architectural barriers. The space provided for ambulance access shall also contain adequate height clearance to accommodate a type I or a type III ambulance.

9.7 On-Site Pre-Planned Transfers: On-site pre-planned transfers of patients are also authorized where it is known in advance that further post-surgical patient care will be desired or needed. Such transfers are limited to those transfers of patients to convalescent centers licensed in accordance with section 25 or other licensed health facilities, located on-site or on campus and are physically connected to the ambulatory surgical center.

(A) The provisions of paragraph 9.6(A) and (B) shall apply to on-site pre-planned transfers. The provisions of paragraph 9.6(C) and (D) shall not apply to on-site pre-planned transfers.

SECTION 10 - LABORATORY AND RADIOLOGY

10.1 Laboratory Services: Clinical laboratory services shall be available as required by the needs of the patients as determined by the medical staff. Whether provided on-site or by contract, the laboratory shall meet the requirements of the "Clinical Laboratory Improvement Amendments of 1988," 42 USC § 263a, and the corresponding regulations at 42 CFR Part 493.

10.2 Radiological Services: Radiological services shall be provided as required by the needs of the patients as determined by the medical staff. Whether provided on-site or by contract, the radiological services shall meet Colorado rules and regulations pertaining to "Radiation Control," 6 CCR 1007-1.

(A) The radiological service shall be directed by a licensed radiologist or overseen by a qualified individual with appropriate education and experience who is appointed by the governing body.

(B) There shall be written policies governing all radiological procedures.

(C) Sufficient diagnostic and therapeutic radiological equipment shall be available to satisfy the objectives of the center.

SECTION 11 - ANESTHESIA

11.1 The use of flammable anesthetics in ambulatory surgical centers is prohibited.

11.2 The center shall provide anesthesia services commensurate with the services provided.

11.3 General or regional anesthesia or analgesia shall be administered only by a physician qualified by training, experience and ability in anesthesiology or a certified, registered nurse anesthetist who is recognized and included on the Advanced Practice Registry of the Colorado Board of Nursing. In the case of dental treatment, dentists may administer local anesthetics.

SECTION 12 - EMERGENCY SERVICES

12.1 The center shall have policies and procedures which provide for adequate care of its patients in the event of an emergency.

12.2 There shall be a policy and procedure for obtaining ambulance services when emergency services are needed, including notification of next of kin or responsible party.

12.3 In the event emergency services are necessary, the center shall have a written transfer agreement with a local hospital or ensure that every physician performing surgery at the center has admitting privileges at a local hospital.

12.4 Emergency equipment and supplies shall be readily available in the surgical and/or procedure room(s) and recovery room(s).

12.5 A center transferring a patient to a hospital on an emergency basis, shall submit to the receiving hospital at the time of transfer a copy of all medical records related to the patient's condition, including observations of the patient's signs and symptoms, preliminary diagnosis, treatment provided, results of any tests, and a copy of the informed written consent for the surgical procedure that was scheduled or performed at the center.

12.6 A center located above the ground level of a building that admits patients for which a pre-planned transfer is anticipated shall have elevators available for the transport of such patients. Elevators shall be large enough to accommodate an ambulance cot in a horizontal position and a minimum of two attendants.

SECTION 13 - NURSING SERVICES

13.1 Nursing Administration: The center shall have sufficient nursing personnel to meet the needs of the patients being served, under the supervision of a nurse manager who is currently licensed by the State of Colorado as a professional registered nurse and who is qualified by education and experience to be responsible for oversight of all nursing services.

13.2 The nurse manager shall be responsible for oversight of the following:

(A) Delivery of appropriate nursing services to patients;

(B) Development and maintenance of appropriate nursing service objectives, standards of nursing practice, nursing policy and procedure manuals, and written job descriptions for all levels of nursing personnel;

(C) Coordination of nursing services with other patient services;

(D) An adequate plan for the continuous evaluation of nursing care, along with a plan to periodically evaluate the adequacy of the center to meet the needs of its patients and the necessity for improvement or revision of the center or its services; and

(E) Staff development including orientation, in-service and continuing education which includes provisions for CPR certification or review.

13.3 Nursing Personnel: There shall be sufficient licensed and auxiliary nursing personnel on duty to meet the total nursing needs of patients.

(A) At least one registered nurse shall be in the center at all times whenever a patient is present;

(B) Nursing personnel shall be assigned duties consistent with their education and experience.

13.4 Medications and Treatments: Medications and treatments shall be administered in accordance with all applicable state and federal laws and acceptable standards of practice.

13.5 Staff Meetings: Meetings of nursing personnel shall be held regularly to discuss, review and evaluate nursing care. Written minutes of these meetings shall be maintained and distributed to personnel.

13.6 Staffing: The center shall have nursing staff in sufficient numbers to ensure that the following services are provided, depending on the procedure and method of sedation.

(A) A registered nurse, qualified by education and experience, shall be present in each operating room during operative procedures. This nurse’s duties are performed outside the sterile field. This nurse is responsible for managing all nursing care within the operating room, observing the surgical team from a broad perspective, and assisting the team as necessary.

(B) A registered nurse or certified registered nurse anesthetist, qualified by education and experience in peri-operative nursing, shall be present in each operating or procedure room during the course of the procedure and be dedicated solely to monitoring the patient during the procedure.

(1) For procedures where a sterile field is not required and deep sedation is administered by a certified registered nurse anesthetist who is responsible for monitoring the patient during the procedure, either a technician or a nurse may be used to provide minor assistance to the practitioner if it is within their scope of practice and meets nationally recognized standards of practice.

(2) For procedures where no more than moderate sedation (also known as conscious sedation) is used, a technician or nurse may provide minor assistance to the practitioner if it is within their scope of practice, is conducted within nationally recognized standards of practice and the patient is appropriately monitored throughout the procedure.

(C) A registered nurse, qualified by education and experience, shall be present in the recovery area when patients are recovering.

SECTION 14 - PHARMACEUTICAL SERVICES

14.1 The ambulatory surgical center shall implement methods, procedures and controls which ensure the appropriation, acquisition, storage, dispensing and administration of drugs and biological in accordance with the Colorado Board of Pharmacy regulations at 3 CCR 719-1 and other applicable state and federal laws and regulations, whether it provides its own pharmaceutical services or makes other legal and appropriate arrangements for obtaining necessary pharmaceuticals.

14.2 Medications shall not be administered to patients unless ordered by a physician or other legally authorized practitioner. The orders shall be in writing or, if given verbally, shall be promptly reduced to writing and signed by the practitioner in accordance with center procedure.

14.3 Medications maintained in the center shall be appropriately stored and safeguarded against diversion or access by unauthorized persons. Appropriate records shall be kept regarding the disposition of all medications.

14.4 Each center shall maintain reference sources for identifying and describing medications. Sources may be in electronic format or web-based.

14.5 Medication shall be administered only by a licensed nurse or physician.

14.6 Blood, blood products and parenteral solutions shall be administered only by physicians or registered nurses.

14.7 Adverse medication reactions shall be reported immediately to the physician responsible for the patient and documented in the medical record.

SECTION 15 - SURGICAL AND PROCEDURAL SERVICES

15.1 A qualified person designated by the administrator shall be responsible for the daily functioning and maintenance of the surgical and/or procedure room(s).

15.2 Surgical Site Identification: Each center shall develop a standardized method to ensure all patients are appropriately identified, all pertinent information is obtained, the surgery and surgical site are confirmed, and a surgical team time out is conducted prior to an incision being made.

(A) At a minimum, all surgical sites involving laterality, multiple structures (i.e., fingers, toes, lesions) or multiple levels (i.e., spine) shall be marked.

(1) The marking shall be made by an individual that is familiar with the patient and is involved with the patient's procedure such as the surgeon or a licensed individual who performs duties in collaboration with the surgeon (ie, registered nurse, advance practice nurse or physician assistant).

(2) Whenever possible, the marking shall involve the patient and take place when the patient is awake and aware.

(B) The surgical time out shall include, at a minimum, unanimous confirmation by the entire surgical team of the following factors:

(1) Patient identity using two patient identifiers;

(2) Type of procedure;

(3) Identification of correct site or side.

15.3 Scrub Area: The scrub area shall be adjacent to the operating room to permit immediate access to the room after scrubbing. The scrub area shall be no more than 10 feet from the entrance to the operating room. Scrub sink(s) with electronic sensors, knee or foot controls shall be installed in the scrub area.

15.4 Clean-up Facilities: Clean and soiled utility rooms shall be arranged and provided with equipment necessary for proper patient care and for the processing of soiled equipment, including a decontamination or sterilization system that is appropriate to the procedures being performed, and storage cabinets and work counters with sinks. Equipment for sterilizing instruments and supplies shall be conveniently located and of adequate capacity for the workload. Records shall be maintained to assure quality control, including date, time and temperature of each batch of sterilized supplies and equipment.

15.5 Staff Dressing Rooms: Separate staff dressing rooms shall be provided for men and women; each containing a toilet, hand-sink, and clothing storage. For centers with five or less surgical and/or procedure rooms, unisex dressing rooms are acceptable. Showers shall be provided where there is more than minimal possibility of exposure to blood or body fluids and secretions.

15.6 Environmental Services Room: A separate room or equivalent space shall be provided exclusively for the surgical and/or procedure rooms. It shall be equipped with shelves for supplies, mop clip boards, and a wall or floor-mounted mop sink. A hand washing sink with soap and sanitary hand washing facilities will be available nearby. There shall be room also for a waste container, drum of disinfectant detergent, mop carts and buckets, etc.

SECTION 16 - PRE AND POST PROCEDURE AREAS

16.1 The center shall be arranged and organized in a manner that ensures the comfort, safety, hygiene, privacy and dignity of its patients.

16.2 A separate area shall be provided where patients can change their clothing before and after the surgery or procedure. This area shall include holding room(s), lockers, and toilets.

16.3 Recovery Room(s): Centers that perform surgery or procedures with anesthesia, shall have post-anesthesia recovery room(s) for its patients. Beds, stretchers or recliners may be utilized if they offer the appropriate level of safety and comfort to the patient(s).

(A) The recovery room(s) shall accommodate provision of the following activities or services:

(1) Direct visual observation of all patients,

(2) Medication administration,

(3) Charting,

(4) Toileting and hand washing,

(5) Supply and equipment storage,

(6) Administration of oxygen, suction and resuscitation; and

(7) Emergency call system.

SECTION 17 - INFECTION AND DISEASE CONTROL

17.1 The ambulatory surgical center shall have a multi-disciplinary infection control committee charged with the responsibility of investigation and recommendations for the prevention and control of infection and communicable disease.

17.2 The infection control committee shall develop and implement policies and procedures related to infection and disease control including, but not limited to:

(A) The admission of patients with specific infectious diseases;

(B) Annual review of clinic policies and procedures to ensure compliance with the governing body's chosen national standard for infection control, and any specific recommendations from local or state public health agencies.

(C) Orientation and continuing education of personnel on the control of nosocomial and infectious diseases, including universal precautions;

(D) The reporting of communicable diseases as required by applicable state and federal laws and regulations;

(E) Cleaning and/or disinfection of the center and equipment; and

(F) Effective control and eradication of insects and rodents.

SECTION 18 - PATIENT CARE UNIT

18.1 An ambulatory surgical center shall maintain a distinct patient care area if the ambulatory surgical center provides surgical services for persons needing longer periods of care and/or observation beyond the recovery period and prior to discharge. Patient rooms shall have direct exit to the corridor or exit way and shall have a maximum of two beds per room.

18.2 Each patient room shall be a minimum of 100 square feet for a one-bed occupancy and 80 square feet per bed for a two-bed occupancy, exclusive of closets or lockers. In a two-bed patient room, privacy shall be provided by cubicle curtains or other appropriate partitions.

18.3 Each patient room shall contain at least one, appropriately sized patient bed equipped with a mattress protected by waterproof material and a pillow.

18.4 Each patient room shall be in an area that is visible to the staff at the nursing station and shall be equipped with a nurse call system.

18.5 A patient bathroom, with toilet and sink shall be provided in the immediate vicinity of the patient bedroom(s). Immediate vicinity means in the patient bedroom, adjacent to the patient bedroom or directly across the corridor from the patient bedroom.

18.6 Patient rooms shall be equipped with medical and personal care equipment that is necessary to meet the needs of the patient.

SECTION 19 - EQUIPMENT AND SUPPLIES

19.1 Equipment shall be in good working order and shall be available in sufficient quantity to ensure adequate patient care based upon the procedures to be performed in the center.

(A) Monitoring equipment, suction apparatus, oxygen, cardiac pulmonary resuscitation equipment and related items shall be available within the surgical, procedural and recovery areas.

(B) Sterilizing equipment of appropriate type shall be available and of sufficient capacity to adequately sterilize instruments and operating room materials as well as laboratory equipment and supplies. The sterilizing equipment shall have an approved recording thermometer and safety features. The accuracy of such instrumentation and equipment shall be checked and calibrated periodically according to the manufacturer's recommendations. The center shall have records documenting the maintenance of this equipment.

(C) Centers using laser equipment shall maintain written documentation of a safety and maintenance program related to the use of the laser equipment.

19.2 Storage, Maintenance and Distribution: There shall be safe and sanitary storage, maintenance and distribution of sterile supplies and equipment, in accordance with adequate written policies and procedures which also govern shelf life.

19.3 Segregation: Sterile supplies and equipment shall not be mixed with unsterile supplies, shall be stored in dust proof and moisture free units, and shall be properly labeled.

SECTION 20 - HOUSEKEEPING AND MAINTENANCE

20.1 Organization: Each center shall provide housekeeping services which ensure a pleasant, safe and sanitary environment. If the center contracts with an outside vendor to provide housekeeping services, there shall be a written agreement regarding the services and the center shall be ultimately responsible for quality control of the contractor.

20.2 Written Policies and Procedures: Written policies and procedures shall be established, approved by the infection control committee, and followed to ensure adequate cleaning and/or disinfection of the physical structure and equipment.

20.3 Storage: All cleaning materials, solutions, cleaning compounds, and hazardous substances, shall be properly identified and stored in accordance with the manufacturers' instructions.

20.4 Cleaning methods shall minimize the dispersion of dust particles that may contain micro-organisms in clean/sterile areas.

20.5 The center shall have and follow written policies and procedures regarding a preventive maintenance program to ensure that the physical plant and equipment are kept in good repair and to provide for the safety, welfare and comfort of the center occupants.

SECTION 21 - LAUNDRY AND LINENS

21.1 The center shall have and follow written policies and procedures regarding the handling of linens and laundry.

21.2 Outside Laundry: Laundry that is sent out shall be sent to a commercial or hospital laundry. A contract for laundry services performed by commercial laundries for ambulatory surgical centers shall include applicable standards of this Section 21.

21.3 Storage: If soiled linen is not processed on a daily basis, a separate, properly ventilated storage area shall be provided.

21.4 Processing: The laundry processing area shall be arranged to allow for an orderly, progressive flow of laundry from the soiled to the clean area.

21.5 Washing Temperatures: The water temperature and duration of washing cycle shall be consistent with the temperature and duration recommended by the manufacturers of the laundry chemicals being used.

21.6 Packaging: The linens to be returned from the outside laundry to the center shall be completely wrapped or covered to protect against contamination.

21.7 Soiled Linen Transportation: Soiled linen shall be enclosed in an impervious bag and removed from surgery units after each procedure.

21.8 Soiled Linen Carts: Carts, if used to transport soiled linen, shall be constructed of impervious materials, cleaned and disinfected after each use.

21.9 Clean Linen Storage Room: Adequate provisions shall be made for storage of clean linen.

21.10 Contaminated Linens: Contaminated linens shall be afforded appropriate special treatment by the laundry to ensure cleanliness.

21.11 Procedures: Adequate procedures for the handling of all laundry and for the positive identification, proper packaging and storage of sterile linens shall be developed and followed.

SECTION 22 - WASTE MANAGEMENT

22.1 Sewage: All sewage shall be discharged into a public sewer system.

22.2 Refuse and Rubbish:

(A) Medical waste shall be disposed of in accordance with the Department's Regulations P pertaining to Solid Waste Disposal Sites and Facilities at 6 CCR 1007-2, Part 1, Section 13, Medical Waste. These regulations are incorporated by reference in accordance with Section 1.4 of this Chapter 20.

(B) All garbage and refuse not treated as sewage shall be collected in impervious containers with liners and shall be removed from the center once a day. The center shall have a paved outside area for storage of garbage and refuse containers. Refuse incinerators are prohibited.

(C) All personnel shall wash their hands after handling refuse as specified by the center's infection and disease control policies and procedures.

SECTION 23 - COMPLIANCE WITH FGI GUIDELINES

Effective July 1, 2013, all ambulatory surgical centers shall be constructed in conformity with the standards adopted by the Director of the Division of Fire Prevention and Control (DFPC) at the Colorado Department of Public Safety. For construction initiated or systems installed on or after July 1, 2013, that affect patient health and safety and for which DFPC has no applicable standards, each center shall conform to the relevant section(s) of the Guidelines for Design and Construction of Health Care Facilities, (2010 Edition), Facilities Guidelines Institute. The Guidelines for Design and Construction of Health Care Facilities, (2010 Edition), Facilities Guidelines Institute (FGI), is hereby incorporated by reference and excludes any later amendments to or editions of the Guidelines. The 2010 FGI Guidelines are available at no cost in a read only version at: HTTP://FGIGUIDELINES.ORG/DIGITALCOPY.PHP

SECTION 24 - LICENSE FEES

24.1 As part of the licensing process described at 6 CCR 1011-1, Chapter 2, sections 2.4 through 2.7, an applicant for an ambulatory surgical center license shall submit, in the form and manner specified by the Department, a license application with the corresponding nonrefundable fee as set forth below:

(A) Initial license: A license applicant shall submit with an application for licensure a nonrefundable fee of $6,600.

(B) Renewal license: A license applicant shall submit an application for licensure with a nonrefundable fee as shown in the table below. The total renewal fee shall not exceed $3,000.

(1) A license applicant that is accredited by an accrediting organization recognized by the Centers for Medicare and Medicaid Services as having deeming authority may be eligible for a 10 percent discount off the base renewal license fee. In order to be eligible for this discount, the license applicant shall authorize its accrediting organization to submit directly to the Department copies of all surveys and plan(s) of correction for the previous license year, along with the most recent letter of accreditation showing the license applicant has full accreditation status.

BASE FEE	BASE FEE WITH DEEMING DISCOUNT	PROCEDURE ROOM FEE
$1,440	$1,295	$200 PER ROOM

(C) Change of Ownership: The new owner shall submit with an application for licensure a nonrefundable fee of $4,100.

(D) Provisional License: The license applicant may be issued a provisional license upon submittal of a nonrefundable fee of $2,500. If a provisional license is issued, the provisional license fee shall be in addition to the initial or renewal license fee.

(E) Conditional License: A center that is issued a conditional license by the Department shall submit a nonrefundable fee ranging from 10 to 25 percent of its applicable renewal fee.

The percentage shall be determined by the Department. If the conditional license is issued concurrent with the initial or renewal license, the conditional license fee shall be in addition to the initial or renewal license fee.

SECTION 25 - AMBULATORY SURGICAL CENTER WITH A CONVALESCENT CENTER

25.1 General: An ambulatory surgical center with a convalescent center shall comply with the preceding sections 1 through 24 which shall apply to the operation and maintenance of the ambulatory surgical center and the convalescent center. In addition, an ambulatory surgical center with a convalescent center shall comply with this Section 25.

25.2 Patient Transfer: A licensed ambulatory surgical center with a convalescent center shall provide for the prompt and safe transfer of patients between the ambulatory surgical center and the convalescent center. Each patient transferred from the ambulatory surgical center to the convalescent center shall have a visible means of identification on his or her person.

25.3 Patient Care Services: The convalescent center shall have and follow written policies and procedures regarding the provision of direct patient care that includes, but is not limited to:

(A) The handling of medical emergencies;

(B) Coordination of care across multiple disciplines, as applicable;

(C) Initial and revised patient assessments and care plans; and

(D) Discharge planning.

25.4 Dietary Services: The convalescent center shall provide food service to admitted patients.

(A) Persons assigned to food preparation and service shall have the appropriate training necessary to store, prepare and serve food in a manner that prevents food-borne illness

(B) Meals shall be prepared, stored and served in a manner that prevents food-borne illness.

(C) The food service area shall be an area separate from the employee lounge or other areas used by facility personnel or the public.

(D) All food shall be pre-packaged and require microwave heating only and disposable products for preparation and service shall be used unless the facility develops and implements policies and procedures for the safe preparation, storage and serving of foods.

(E) Catering and alternative methods of meal provision shall be allowed if patient needs and the intent of this part of the regulations are met.

25.5 Contracted Services: All contracted services shall be documented by a written agreement. The written agreement shall include the names of the owner or corporate officers authorized to sign the agreement and the center shall be ultimately responsible for quality control of the contracted services.

25.6 Compliance with FGI Guidelines: Effective July 1, 2013, all convalescent centers shall be constructed in conformity with the standards adopted by the Director of the Division of Fire Prevention and Control (DFPC) at the Colorado Department of Public Safety. For construction initiated or systems installed on or after July 1, 2013, that affect patient health and safety and for which DFPC has no applicable standards, each center shall conform to the relevant section(s) of the Guidelines for Design and Construction of Health Care Facilities, (2010 Edition), Facilities Guidelines Institute. The Guidelines for Design and Construction of Health Care Facilities, (2010 Edition), Facilities Guidelines Institute (FGI), is hereby incorporated by reference and excludes any later amendments to or editions of the Guidelines. The 2010 FGI Guidelines are available at no cost in a read only version at: HTTP://FGIGUIDELINES.ORG/DIGITALCOPY.PHP

25.7 License Fees: For new license applications received or renewal licenses that expire on or after March 1, 2015, an applicant for an ambulatory surgical center with a convalescent center license shall comply with the licensing process described at 6 CCR 1011-1, Chapter 2, sections 2.4 through 2.7 and submit, in the form and manner specified by the Department, a license application with the corresponding nonrefundable fee as set forth below:

(A) Initial license:

(1) An applicant for an initial ambulatory surgical center with convalescent center license shall submit with an application for licensure a nonrefundable fee of $6,960.

(2) A current ambulatory surgical center licensee that applies to add a convalescent center to the license prior to the expiration of the surgical center license shall submit an application for initial licensure of the convalescent center along with a nonrefundable fee of $360. Upon expiration of the existing surgical center license term, the licensee shall follow the procedure set forth below for a renewal license.

(B) Renewal license: A license applicant shall submit an application for licensure with a nonrefundable fee as shown in the table below. The total renewal fee shall not exceed $3,360.

(1) A license applicant that is accredited by an accrediting organization recognized by the Centers for Medicare and Medicaid Services as having deeming authority may be eligible for a 10 percent discount off the base ambulatory surgical center renewal fee. In order to be eligible for this discount, the license applicant shall authorize its accrediting organization to submit directly to the Department copies of all surveys and plan(s) of correction for the previous license year, along with the most recent letter of accreditation showing the license applicant has full accreditation status.

ASC BASE FEE	ASC BASE FEE WITH DEEMING DISCOUNT	CONVALESCENT CENTER FEE	PROCEDURE ROOM FEE
$1,440	$1,295	$360	$200 PER ROOM

(C) Change of Ownership: The new owner shall submit with an application for licensure a nonrefundable fee of $4,460.

(D) Provisional License: The license applicant may be issued a provisional license upon submittal of a nonrefundable fee of $2,860. If a provisional license is issued, the provisional license fee shall be in addition to the initial or renewal license fee.

(E) Conditional License: A center that is issued a conditional license by the Department shall submit a nonrefundable fee ranging from 10 to 25 percent of its applicable renewal fee. The percentage shall be determined by the Department. If the conditional license is issued concurrent with the initial or renewal license, the conditional license fee shall be in addition to the initial or renewal license fee.

Editor's Notes

6 CCR 1011-1 has been divided into separate chapters for ease of use. Versions prior to 05/01/2009 are located in the main section, 6 CCR 1011-1. Prior versions can be accessed from the All Versions list on the rule's current version page. To view versions effective on or after 05/01/2009, select the desired chapter, for example 6 CCR 1011-1 Chap 04 or 6 CCR 1011-1 Chap 18.

History

Chapter 20 entire rule eff. 03/01/2008.

Section 8.D.1 eff. 03/02/2011.

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Section 11.C emer. rule eff. 11/30/2012.

Section 11.C eff. 03/17/2013.

Sections 14.G, 14.P, 24 eff. 08/14/2013; Chapter 20 Sections 2.D, 25.B repealed eff. 08/14/2013.

Section 25.A.2 eff. 08/14/2014.

Entire rule eff. 02/14/2015.

Sections 24.1(B), 25.7(B) eff. 03/17/2017.