DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

STANDARDS FOR HOSPITALS AND HEALTH FACILITIES: CHAPTER 20 - AMBULATORY SURGICAL CENTER

6 CCR 1011-1 Chap 20

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

SECTION 1 - STATUTORY AUTHORITY AND APPLICABILITY

A. 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.

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

1. This Chapter XX.

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

C. 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

A. Ambulatory Surgical Center (ASC) means a facility which operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization.

1. Offering multiple health services in the same building does not preclude or exempt a facility from meeting the requirements of Chapter XX. The building space constituting the ambulatory surgical center must be used exclusively for ambulatory surgery and its directly related services. The other health services being offered in the same building must be physically separated from the ambulatory surgical center.

2. The term "ambulatory surgical center" does not include:

A. a facility that is licensed as part of a hospital, or;

B. a facility which is used as an office or clinic for the private practice of a physician(s), podiatrist(s), or dentist(s) except when:

1) 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, or;

2) it is operated or used by a person or entity different than the physician(s), podiatrists(s), or dentist(s), or;

3) patients are charged a fee for use of the facility in addition to the physician(s), podiatrist(s), or dentist(s) professional services; unless such fees are an integrated part of the office-based surgery program incentive allowance of a licensed sickness and accident insurer, a non-profit hospital, medical-surgical and health service corporation, or a health maintenance organization and the program incentive occurs in a setting that does not require licensure.

3. 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.

B. "Department" means the Colorado Department of Public Health and Environment.

C. "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. For purposes of these regulations, this does not include medications reused in compliance with 6 CCR 1011-1 Chapter II, Part 7.200 *et. seq.* or 6 CCR 1015-10.

SECTION 3 - GOVERNING BODY

A. Responsibility: The Governing Body shall provide facilities, personnel, and services necessary for the welfare and safety of the patients.

B. Duties: The Governing Body shall:

1. adopt by-laws in accordance with APPLICABLE legal requirements;

2. meet regularly and maintain accurate records of such meetings;

3. appoint committees consistent with the needs of surgical center;

4. appoint and delineate clinical and surgical privileges of practitioners based upon recommendations by the provider staff and other appropriate indicators of physician and other licensed practitioner competence;

5. establish a formal means of liaison with the provider staff;

6. approve by-laws, rules and regulations of the provider staff;

7. adopt appropriate policies on admissions, surgical procedures, and the timely completion of medical records;

8. conduct, with the active participation of the provider 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 facility policies and the granting or continuation of clinical privileges;

9. require that the facility's Quality Management Program ensure the adequate investigation, control and prevention of infections;

SECTION 4 - ADMINISTRATOR

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

B. Duties: The administrator shall be responsible for the development, implementation and administration of surgical center policies and procedures for employee and provider staff use. All policies and procedures shall be reviewed and approved by the governing body and/or updated as necessary but at least annually.

SECTION 5 - PROVIDER STAFF

A. Organization: The ambulatory surgical center shall have an organized provider staff.

1. The governing body shall appoint a member of the provider staff to act as medical director for the ambulatory surgical center. The medical director shall have the responsibility for directing the provision of services and for monitoring the quality of all medical care and services provided patients in the facility.

B. Duties: The provider staff or a delegated committee composed of members of the provider staff shall:

1. be responsible for the quality of all medical care provided patients in the facility;

2. hold meetings regularly and maintain accurate records of such meetings;

3. formulate, adopt, and enforce by-laws, rules, regulations and policies for the proper conduct of its activities and credentialing of its members;

4. recommend staff privileges to the Governing Body;

5. ensure professionally ethical conduct on the part of all members of the provider staff and initiate corrective measures as required;

6. establish a formal liaison with the governing body;

7. participate actively in the quality management program;

8. recommend admission and surgical procedure policies to the Governing Body;

SECTION 6 - MEDICAL RECORDS

A. Facilities: the center must develop and maintain a system for the proper collection, storage, and use of patient records. The facility shall maintain an individual record for each patient admitted.

B. Personnel: A person knowledgeable in the management of medical records shall be responsible for the proper administration and functioning of the medical records section.

C. Security: Medical records shall be protected from loss, damage, unauthorized use and disclosure.

D. 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 facility. Accessibility of medical records to the Department to assure compliance and to patients or their legal representatives shall be maintained.

1. 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);

2. Facilities shall establish procedures for notification to patients whose records are to be destroyed prior to the destruction of such records;

3. The sole responsibility for the destruction of all medical records shall be in the facility involved but in no case shall records be destroyed prior to consultation with legal counsel;

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

E. 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:

1. complete patient identification and a unique identification number;

2. admission and discharge dates;

3. chief complaint and admission diagnosis;

4. medical history and physical examination completed prior to surgery;

5. diagnostic tests, laboratory, x-ray, scans, and other radiological imaging reports and consultative findings when appropriate;

6. physician progress notes if appropriate;

7. properly executed informed consent;

8. a pre-anesthesia examination by a physician prior to surgery, a proper anesthesia record and a post-anesthesia evaluation ;

9. a complete detailed description of operative procedures, findings and post-operative diagnosis recorded and signed by the attending physician;

10. a pathology report of tissue removed during surgery in accordance with facility policies;

11. 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

12. patient's condition on discharge, final diagnosis, and instructions given patient for follow-up care;

F. Other records: The facility shall maintain:

1. a register of all surgical operations performed (entered daily);

2. statistical information concerning all admissions, discharges, deaths and other information such as blood usage, surgery complications, etc, required for the effective administration of the facility

3. master patient index file.

G. 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.

H. 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 or computer key

SECTION 7 - PERSONNEL

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

B. 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.

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

D. 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 facility clientele and the facility.

E. In-service: There shall be an in-service program which keeps all employees abreast of changing methods and new techniques. Records including attendance and subject matter of each in-service shall be maintained.

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

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

1. an employment application;

2. verification of references and/or credentials as required;

3. incident and/or accident reports;

4. results of medical examinations required as a part of employment within the facility.

SECTION 8 - ADMISSIONS

A. Admissions and discharge: All persons admitted to the ambulatory surgical center shall be under the direct care of a member of the provider staff. The provider 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).

B. Restrictions:

1. Surgical procedures shall be limited to the following:

a. those in which the combined operating and recovery time does not exceed 24 hours from the time of admission; and

b. 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.

2. 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.

C. 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.

D. 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 provider staff and adopted by the governing body, specific to the ambulatory surgical center operations, that includes at least the following:

1. 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 an ASC, rather than a hospital setting, does not pose an increased risk to the patient.

2. 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.

3. 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.

4. 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.

5. 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 ambulatory surgical center.

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

7. The governing body of the facility shall provide clear notice to patients that the facility is a smoke-free environment.

E. OFF-SITE PRE-PLANNED TRANSFERS: Off-site pre-planned transfers of patients include those transfers of patients to other licensed health facilities, that 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.

1. 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 facility policies regarding off-site pre-planned transfers shall be in addition to the requirements for informed consent.

2. 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 ambulatory surgical center shall have a written agreement with any and each licensed facility that admits patients for post-surgical care from an ambulatory surgical center. The ambulatory surgical center shall provide written discharge instructions, including patient progress information, to the receiving facility.

a. 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.

3. All pre-planned transfers shall be by licensed ambulance. The ambulatory surgical 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 provider 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.

4. Ambulatory surgical centers engaging in pre-planned transfers shall provide space at the entrance to the building to facilitate transfer. The facility 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.

5. An ambulatory surgical center located above the ground level of the 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 horizontal position and a minimum of two attendants.

F. 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 needed. Such transfers are limited to those transfers of patients to other licensed health facilities, located on-site or on campus and are physically connected to the ambulatory surgical center.

1. The provisions of paragraph (E)(1) and (2) shall apply to on-site pre-planned transfers. The provisions of paragraph (E)(3),(4),and (5) shall not apply to on- site pre-planned transfers.

SECTION 9 - LABORATORY AND RADIOLOGY

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

B. RADIOLOGY SERVICES: Radiological services shall be provided as required by the needs of the patients as determined by the provider 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.

SECTION 10 - ANESTHESIA

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

SECTION 11 - EMERGENCY SERVICES

A. The center shall have policies and procedures which provide for adequate care of the facility's patients in the event of an emergency.

B. 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.

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

D. Emergency equipment and supplies shall be readily available on the premises.

E. An ambulatory surgical 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 ASC.

SECTION 12 - NURSING SERVICES

A. Nursing Administration: The facility shall have sufficient nursing personnel under the supervision of a nurse manager who is currently licensed by the State of Colorado as a professional registered nurse and who is responsible for oversight of all nursing services.

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

1. delivery of appropriate nursing services to patients;

2. 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;

3. coordination of nursing services with other patient services;

4. establishment of a means of adequately assessing and planning the nursing care needs of patients and staffing to meet those needs; and

5. staff development including orientation, inservice and continuing education which includes provisions for CPR certification or review.

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

1. at least one registered nurse shall be in the facility at all times when a patient is in the facility;

2. nursing personnel shall be assigned duties consistent with their education and experience.

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

E. Personnel 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.

F. In-service Education: All nursing personnel shall receive at least 12 hours of in-service education annually; which shall include, but not be limited to, infection control; fire, safety and emergency procedures.

G. Evaluation: There shall be an adequate plan of continuous evaluation of nursing care. The nurse manager shall periodically evaluate the adequacy of the facility to meet the nursing needs of its patients and shall participate in planning for needed improvements or revisions of facilities and services.

H. Circulating Nurse: A registered nurse, qualified by education and experience in operating room nursing, shall be present as a circulating nurse in each operating room during operative procedures.

SECTION 13 - PHARMACEUTICAL SERVICES

A. The ambulatory surgical center shall implement methods, procedures and controls which ensure the appropriation, acquisition, storage, dispensing and administration of drugs and biologicals in accordance with acceptable pharmaceutical practice and 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.

SECTION 14 - SURGICAL SERVICES

A. Location: The ambulatory surgical center shall have at least one operating room that has the capability of administering general anesthesia to patients and is located in a sterile environment within the facility. The operating room(s) and accessory areas shall be located so that in and out traffic is properly controlled. The ambulatory surgical center may have additional, appropriately equipped treatment and/or procedures rooms for surgical procedures not requiring general anesthesia.

1. If an ambulatory surgical center generally provides only surgical services that do not require general anesthesia, the facility may make application to the department for an appropriate modification of the requirements for a surgical suite provided that the facility can demonstrate the ability to implement a functional, sterile operating room whenever such use would be necessitated by patient needs.

2. The provisions of paragraph A.1.shall not apply to ambulatory surgical centers licensed prior to January 30, 1995.

B. Patient Preparation Area: A patient preparation area with adjacent toilet facilities must be provided near the surgical suite. This area must provide for the privacy and comfort of the patients and for storage of patient's clothing.

C. Surgical Privileges Roster: An up-to-date roster of staff providers specifying the approved surgical privileges of each shall be kept on file and shall be available to the nursing staff at all times.

D. Doorways and Corridors: The-minimum width of doors for patients and equipment shall be 3 feet. Doors to accommodate stretchers shall be at least 3 feet, 8 inches wide. The minimum width of corridors serving surgery suites and recovery and patient preparation areas must be at least 8 feet.

E. Operating Room(s)/surgical suites and treatment and procedures rooms: Each room shall be large enough to accommodate equipment and personnel for surgical procedures to be performed. If general anesthesia is to be administered during the surgery, the room shall contain a minimum of 225 square feet and; adequate provisions shall be made for an emergency communication system connecting the surgical suite to a control station.

F. Equipment: The following equipment must be available in the facility: 1) cardiac monitor, 2) resuscitator, 3) defibrillator, 4) aspirator, 5) tracheotomy set and equipment for airway maintenance, and 6) pediatric-sized equipment, if pediatric patients are served.

G. Reserved

H. Ancillary Areas: In addition to operating room(s), the following physically separated areas shall be provided within the suite and shall be separated by doors and/or walls: 1) scrub area, 2) cleanup room, 3) instrument and supply storage, 4) janitor's facilities.

I. 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 knee or foot controls shall be installed in the scrub area.

J. 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 pressurized steam sterilizer or equivalent, or a sterilizer or sterilization system that is appropriate to the procedures being performed, and storage cabinets and work counters with sinks.

K. Staff Dressing Rooms: Shall be provided for both men and women, each containing a toilet, handsink, and provisions for storage of clothing.

L. Ventilation: Operating rooms or surgical suites shall be provided with a minimum ventilation rate as required in Section 24 by mechanical supply and exhaust system. The air may be recirculated, provided the recirculated air passes through the final filters. The mechanical ventilation system may be shut down during off hours.

1. outdoor air intakes shall be located as far away from exhausts as practical, but not less than 25 feet from the exhausts from any ventilating systems, combustion equipment, medical-surgical vacuum system or plumbing vent or areas which may collect noxious fumes. The bottom of all outdoor air intakes shall be located as high as practical but not less than 3 feet above grade level, or, if installed through the roof, 3 feet above the roof level;

2. all air supplied to operating rooms and recovery rooms shall be delivered at or near the ceiling of the area served.

M. Filters: All ventilation or air-conditioning systems serving surgery suites shall have a minimum of two filter beds. Filter bed No. 1 shall be located upstream of the air conditioning equipment and shall have a minimum efficiency of 25 percent. Filter bed No. 2 shall be downstream of the supply fan and air-conditioning equipment and humidifying equipment. However, if a steam humidifying system is provided, it may be downstream of the final filter. Filter bed No. 2 shall have a minimum efficiency of 90 percent of 1-5 micron size particles. Each filter bed serving sensitive areas shall have a manometer installed across each filter bed.

N. Exhaust: At least two (2) exhaust outlets shall be provided in each operating room, with the lower perimeter of the outlet situated between three to four inches off the floor.

O. Lighting: General and spot illumination shall be provided in each operating room.

P. Reserved

Q. Janitors Room: A separate janitors' room or equivalent shall be provided exclusively for the surgical suite. 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 handwashing facilities will be available nearby. There shall be room also for a waste container, drum of disinfectant detergent, mop carts and buckets, etc.

SECTION 15 - POST ANESTHESIA RECOVERY ROOM

A. Recovery Room(s): Recovery room(s) for post-anesthesia recovery that meet the needs of surgical patients shall be provided.

B. Recovery Area and Equipment: The surgical recovery rooms must provide for: 1) direct visual observation of all patients, 2) medicine administration facilities, 3) charting facilities, 4) toilet facilities, 5) storage space for supplies and equipment, 6) oxygen, 7) emergency call system, and 8) hand washing facilities.

C. Bed Space: There must be at least 3 feet on each side or between recovery beds and space at the foot of the bed for work. and/or circulation.

SECTION 16 - PATIENT CARE UNIT

A. 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, but not to exceed 24 hours. Patient rooms shall have direct exit to the corridor or exit way and shall have a maximum of two beds per room.

B. Each patient room shall be a minimum of100 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.

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

D. 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.

E. 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.

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

SECTION 17 - SUPPLIES

A. 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.

B. 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.

C. Sterilizing Equipment: 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, preventive maintenance shall be provided as necessary and a log maintained.

SECTION 18 - HOUSEKEEPING SERVICES

A. Organization: Each facility shall provide housekeeping services which ensure a pleasant, safe and sanitary environment. The facility shall be kept clean and orderly.

B. Written Policies and Procedures: Appropriate written policies and procedures shall be established and followed which ensure adequate cleaning and/or disinfection of the physical facility and equipment.

C. Storage: All cleaning materials, solutions, cleaning compounds, and hazardous substances, shall be properly identified and stored in a safe place.

D. Clinical Areas: Clinical areas shall be maintained at a high level of cleanliness at all times.

E. Dry Dusting and Sweeping: Dry dusting and sweeping shall be prohibited in clean/sterile areas.

F. Rubbish and Refuse Containers: All rubbish and refuse containers in treatment areas shall be impervious, lined and clean.

G. Handwashing: All personnel shall wash their hands after handling refuse, pursuant to established ASC facility policy.

SECTION 19 - LAUNDRY AND LINENS

Written provisions shall be made for the proper handling of linens and washable goods.

A. 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 19.

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

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

D. 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.

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

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

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

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

I. Contaminated Linens: Contaminated linens shall be afforded appropriate special treatment by the laundry.

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

SECTION 20 - MAINTENANCE

A. Written Policies and Procedures: There shall be written policies and procedures for a preventive maintenance program which is implemented to keep the entire facility and equipment in good repair and to provide for the safety, welfare and comfort of the occupants of the building(s).

SECTION 21 - INCINERATION

A. Agreement: If there is no pathological incinerator on the premises, the facility must have an agreement with another facility that has an approved pathological incinerator for the proper disposal of pathological waste.

B. Incinerator for Pathological Waste: Any pathological waste incinerator must meet the applicable Colorado Air Quality Control Commission's regulations at 5 CCR 1001-3, 5 CCR 1001-5, and 5 CCR 1001-8. Part B. The Colorado Air Quality Control Commission regulations are incorporated by reference in accordance with Section 1.C of this rule.

C. Refuse Incinerators: Refuse incinerators are prohibited.

SECTION 22 - PEST CONTROL

A. Pest Control: Adequate written policies and procedures shall be developed and implemented to provide for effective control and eradication of insects and rodents.

B. Outer Air Openings: All openings to the outer air shall be effectively protected against the entrance of insects and rodents, etc., by self-closing doors, closed windows, screens, controlled air currents or other effective means.

SECTION 23 - WASTE STORAGE AND DISPOSAL

A. Sewage and Sewer Systems: All sewage shall be discharged into a public sewer system

B. Refuse and Rubbish:

1. Medical waste shall be disposed of in accordance with the Department's Regulations Pertaining to Solid Waste 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.C of this rule.

2. All garbage and refuse not treated as sewage shall be collected in approved containers with liners in such manner as not to become a nuisance, and shall be removed from the facility once a day. The facility shall have a paved outside area for storage of garbage and refuse containers.

SECTION 24 - 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 facility 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://openpub.realread.com/rrserver/browser?title=/FGI/2010_Guidelines

SECTION 25 - DEPARTMENT OVERSIGHT

A. LICENSURE FEES. Fees shall be submitted to the Department as specified below.

1. Initial license (when such initial licensure is not a change of ownership). A license applicant shall submit with an application for licensure a nonrefundable fee of $6,600.

2. Renewal license. A license applicant shall submit with an application for licensure a nonrefundable fee as follows: Base: $1,440; Per Operating or Procedure Room: $200. The renewal fee shall not exceed $3,000.

3. Change of Ownership. A license applicant shall submit with an application for licensure a nonrefundable fee of $4,100.

4. 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.

5. Conditional License. A facility 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.

Chapter 20 Section 8.D.1 eff. 03/02/2011.

Chapter 20 entire rule eff. 11/30/2012.

Chapter 20 Section 11.C emer. rule eff. 11/30/2012.

Chapter 20 Section 11.C eff. 03/17/2013.

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