

Dear Stakeholders

The Division is proposing changes to Chapters 20 and 11. The changes are highlighted in yellow below.

Written comments regarding these changes should be provided by November 20, 2014 and directed to Laurie Schoder at laurie.schoder@state.co.us.

1 **DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT**

2 **Health Facilities and Emergency Medical Services Division**

3 **STANDARDS FOR HOSPITALS AND HEALTH FACILITIES**

4 **CHAPTER 20 - AMBULATORY SURGICAL CENTER AND AMBULATORY SURGICAL CENTER WITH A**
5 **CONVALESCENT CENTER**

6 **6 CCR 1011-1 Chap 20**
7 _____

8 **SECTION 1 - STATUTORY AUTHORITY AND APPLICABILITY**

9 ~~A.~~ 1.1 The statutory authority for the promulgation of these rules is set forth in section 25-1.5-103 and
10 25-3-101, *et seq.*, C.R.S.

11 ~~B.~~ 1.2 An ambulatory surgical center, as defined herein, shall comply with all applicable federal and
12 state statutes and regulations, including, but not limited to, ~~the following:~~

13 4(A) This Chapter ~~XX~~ 20, SECTIONS 1 THROUGH 24, AND

14 2(B) 6 CCR, 1011-1, Chapter 2, General Licensure Standards, unless otherwise modified
15 herein.

16 1.3 AN AMBULATORY SURGICAL CENTER WITH A CONVALESCENT CENTER, AS DEFINED HEREIN, SHALL
17 COMPLY WITH ALL APPLICABLE FEDERAL AND STATE STATUTES AND REGULATIONS, INCLUDING, BUT NOT
18 LIMITED TO:

19 (A) THIS CHAPTER 20, SECTIONS 1 THROUGH 25, AND

20 (B) 6 CCR 1011-1, CHAPTER 2, GENERAL LICENSURE STANDARDS, UNLESS OTHERWISE MODIFIED
21 HEREIN.

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

28 Division Director
29 Health Facilities and Emergency Medical Services Division
30 Colorado Department of Public Health and Environment
31 4300 Cherry Creek Drive South
32 Denver, CO 80246
33 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.

A: 2.2 “Ambulatory Surgical Center” means a HEALTH CARE ENTITY facility 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. ~~which operates exclusively for the purpose of providing surgical services to patients not requiring hospitalization.~~ FOR CONVENIENCE IN THIS CHAPTER 20 ONLY, AN AMBULATORY SURGICAL CENTER IS ALSO REFERRED TO AS A “CENTER.”

4(A) Offering multiple health services in the same building does not preclude or exempt a facility CENTER from meeting the requirements of Chapter XX 20. ~~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.

(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,

1 (2) IT IS OPERATED OR USED BY A PRACTITIONER OR ENTITY OTHER THAN THE PRIMARY
2 PRACTITIONER(S), OR

3 (3) IT HOLDS ITSELF OUT TO THE PUBLIC OR OTHER HEALTH CARE PROVIDERS AS AN
4 AMBULATORY SURGICAL CENTER, SURGICAL CENTER, SURGICENTER OR SIMILAR
5 FACILITY USING A SIMILAR NAME OR VARIATION THEREOF.

6 2(D) The term "ambulatory surgical center" does not include:

7 (1) A PRACTITIONER'S PRIVATE OFFICE OR TREATMENT ROOMS WHERE THE PRACTITIONER
8 PRIMARILY CONSULTS WITH AND TREATS PATIENTS INCLUDING, BUT NOT LIMITED TO,
9 PRACTITIONERS ORGANIZED AS PROFESSIONAL CORPORATIONS, PROFESSIONAL
10 ASSOCIATIONS, PROFESSIONAL LIMITED LIABILITIES COMPANIES, PARTNERSHIPS AND
11 SOLE PROPRIETORSHIPS; OR

12 (2) AN OUTPATIENT SURGERY UNIT THAT IS LICENSED AS PART OF A HOSPITAL AND
13 LOCATED ON A HOSPITAL CAMPUS AS DEFINED IN CHAPTER IV; OR

14 (3) AN OUTPATIENT SURGERY CENTER THAT IS OWNED AND OPERATED BY A HOSPITAL;
15 LICENSED AS AN OFF CAMPUS LOCATION OF THE HOSPITAL; AND HAS SIGNAGE THAT
16 CLEARLY INDICATES THE SURGERY CENTER'S CONNECTION WITH THE HOSPITAL.

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

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

20 ~~1) it holds itself out to the public or other health care providers as an ambulatory~~
21 ~~surgical center, surgical center, surgicenter or similar facility using a~~
22 ~~similar name or variation thereof, or;~~

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

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

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

39 **B2.3** "CONVALESCENT CENTER" MEANS A HEALTH CARE ENTITY THAT PROVIDES POST SURGICAL, POST
40 PROCEDURAL AND/OR POST DIAGNOSTIC MEDICAL AND NURSING SERVICES TO PATIENTS FOR WHOM AN
41 UNCOMPLICATED RECOVERY IS ANTICIPATED AND FOR WHOM ACUTE HOSPITALIZATION IS NOT REQUIRED.
42 A CONVALESCENT CARE CENTER SHALL BE LICENSED AND OPERATED ONLY IN CONJUNCTION WITH A
43 LICENSED AMBULATORY SURGICAL CENTER.

1 2.4 "Department" means the Colorado Department of Public Health and Environment.

2 2.5 "MEDICAL DIRECTOR" MEANS THE PHYSICIAN RESPONSIBLE FOR PLANNING, ORGANIZING, CONDUCTING
3 AND DIRECTING THE MEDICAL AFFAIRS OF THE AMBULATORY SURGICAL CENTER. THE MEDICAL DIRECTOR
4 SHALL MEET ONE OF THE FOLLOWING REQUIREMENTS IN ORDER TO BE CONSIDERED QUALIFIED:

5 (A) IS BOARD ELIGIBLE OR BOARD CERTIFIED IN AT LEAST ONE OF THE SERVICES PROVIDED AT THE
6 AMBULATORY SURGICAL CENTER AND HAS HAD AT LEAST 12 MONTHS OF EXPERIENCE OR
7 TRAINING IN THE CARE OF PATIENTS IN A SURGICAL ENVIRONMENT, OR

8 (B) HAS SERVED FOR AT LEAST 12 MONTHS IN A LEADERSHIP ROLE AT A HEALTH FACILITY DURING
9 THE PRIOR FIVE YEAR PERIOD.

10 (1) IN GEOGRAPHICAL AREAS WHERE A MEDICAL DIRECTOR MEETING THE ABOVE CRITERIA
11 IS NOT AVAILABLE, ANOTHER LICENSED AND CREDENTIALLED PHYSICIAN MAY FILL THAT
12 ROLE IF APPROVED TO DO SO BY THE DEPARTMENT PRIOR TO APPOINTMENT.

13 2.6 "MEDICAL STAFF" MEANS A FORMAL ORGANIZATION OF PHYSICIANS, DENTISTS, PODIATRISTS OR OTHER
14 HEALTH PROFESSIONALS, WHO ARE APPOINTED BY THE GOVERNING BODY TO ATTEND TO PATIENTS
15 WITHIN THE AMBULATORY SURGICAL CENTER.

16 C.2.7 "Medical Waste" means any infectious, pharmaceutical or trace chemotherapy waste generated
17 in a health care setting in the diagnosis, treatment, immunization, or care of humans or animals;
18 generated in autopsy or necropsy; generated during preparation of a body for final disposition
19 such as cremation or interment, generated in research pertaining to the production or testing of
20 microbiologicals; generated in research using human or animal pathogens; or related to accident,
21 suicide, or other physical trauma. Medical waste does not include fluids, tissues or body parts
22 removed from the whole body for the purposes of donation, research or other use, or those
23 returned to the person from whom they were removed, or their authorized representative, as long
24 as the material is rendered safe for handling. For purposes of these regulations, this does not
25 include medications reused in compliance with 6 CCR 1011-1 Chapter II, Part 7.200 *et. seq.*, or 6
26 CCR 1015-10.

27 SECTION 3 – AMBULATORY SURGICAL CENTER CLASSIFICATIONS

28 3.1 AN AMBULATORY SURGICAL CENTER SHALL BE ISSUED A LICENSE CONSISTENT WITH THE TYPE AND
29 EXTENT OF SERVICES PROVIDED, AS OUTLINED BELOW.

30 (A) CLASS C CENTER – A CLASS C CENTER SHALL HAVE AT LEAST ONE STERILE OPERATING ROOM
31 WITH THE CAPACITY TO ADMINISTER GENERAL ANESTHESIA TO PATIENTS. THE OPERATING
32 ROOM(S), AS WELL AS THE PRE AND POST SURGICAL AREAS, SHALL BE LOCATED IN A WAY THAT
33 PROVIDES CONTROL OVER THE MOVEMENT OF PATIENTS AND PERSONNEL. THIS CLASSIFICATION
34 OF OPERATING ROOM IS EQUIVALENT TO A CLASS C OPERATING ROOM AS DESCRIBED IN THE
35 GUIDELINES FOR DESIGN AND CONSTRUCTION OF HEALTH CARE FACILITIES, (2010 EDITION),
36 FACILITIES GUIDELINES INSTITUTE, WHICH IS INCORPORATED BY REFERENCE.

37 (B) CLASS A OR B CENTER – A CLASS A OR B CENTER SHALL HAVE A DEDICATED PROCEDURE
38 ROOM(S) WITH THE CAPACITY TO PROVIDE OXYGEN AND PATIENT MONITORING IN A CLEAN
39 ENVIRONMENT THAT SUPPORTS INFECTION CONTROL. THE PROCEDURE ROOM(S) SHALL ONLY
40 BE USED FOR ENDOSCOPIC OR INTERVENTIONAL PROCEDURES OR NON-INVASIVE
41 EXAMINATIONS/TREATMENTS UNLESS FIRST TERMINALLY CLEANED. LOW-RISK VERSUS HIGH-
42 RISK EXPOSURE AREAS SHALL BE IDENTIFIED, ALONG WITH THE ATTIRE AND PERSONAL
43 PROTECTIVE EQUIPMENT NECESSARY FOR EACH AREA. THIS CLASSIFICATION OF PROCEDURE
44 ROOM IS EQUIVALENT TO CLASS A OR B OPERATING ROOMS AS DESCRIBED IN THE GUIDELINES

1 FOR DESIGN AND CONSTRUCTION OF HEALTH CARE FACILITIES, (2010 EDITION), FACILITIES
2 GUIDELINES INSTITUTE, WHICH IS INCORPORATED BY REFERENCE.

3 (1) A CIRCULATING NURSE IS NOT REQUIRED IN A CLASS A OR B CENTER UNLESS
4 MODERATE/DEEP PATIENT SEDATION IS USED OR STANDARD PRACTICE FOR THE
5 PROCEDURE DICTATES THE NEED FOR A CIRCULATING NURSE.

6 **SECTION 3 4 - GOVERNING BODY**

7 A.4.1 Responsibility: The Governing Body shall provide facilities, personnel, and services necessary for
8 the welfare and safety of the patients.

9 B.4.2 Duties: The Governing Body shall:

10 4(A) adopt by-laws in accordance with ~~APPLICABLE~~ APPLICABLE legal requirements;

11 2(B) meet regularly and maintain accurate records of such meetings;

12 3(C) appoint committees consistent with the needs of ~~surgical~~ center;

13 4(D) appoint and delineate clinical and surgical privileges of practitioners based upon
14 recommendations by the ~~provider~~ MEDICAL staff and other appropriate indicators of
15 physician and other licensed practitioner competence. EACH MEMBER OF THE MEDICAL
16 STAFF SHALL BE GRANTED PRIVILEGES THAT ARE COMMENSURATE WITH THE MEMBER'S
17 QUALIFICATIONS, EXPERIENCE, AND PRESENT CAPABILITIES AND THAT ARE WITHIN THE
18 PRACTITIONER'S SCOPE OF PRACTICE;

19 (E) MAINTAIN AN UP-TO-DATE ROSTER OF PROVIDERS CREDENTIALIAED BY THE CENTER THAT
20 SPECIFIES THE APPROVED SURGICAL AND/OR PROCEDURAL PRIVILEGES OF EACH PROVIDER.
21 THE ROSTER SHALL BE AVAILABLE TO THE NURSING STAFF AT ALL TIMES;

22 5(F) establish a formal means of liaison with the ~~provider~~ MEDICAL staff;

23 6(G) approve by-laws, rules and regulations of the ~~provider~~ MEDICAL staff;

24 7(H) ~~adopt appropriate policies on admissions, surgical procedures, and the timely completion~~
25 ~~of medical records~~ DEVELOP WRITTEN POLICIES AND PROCEDURES IN COOPERATION WITH THE
26 MEDICAL STAFF. THE PROCEDURES SHALL ADDRESS THE ACCEPTANCE, CARE, TREATMENT,
27 SURGICAL AND ANESTHESIA SERVICES, DISCHARGE, REFERRAL AND FOLLOW-UP OF ALL
28 PATIENTS AND ALL INCIDENTAL OPERATIONS OF THE CENTER. THE POLICIES AND PROCEDURES
29 SHALL BE AVAILABLE TO ALL STAFF IN THE CENTER AND SHALL BE FOLLOWED BY THEM AT ALL
30 TIMES IN THE PERFORMANCE OF THEIR DUTIES. THE GOVERNING BOARD SHALL ALSO DEFINE THE
31 SCOPE OF SERVICES PROVIDED WITHIN THE CENTER;

32 8(I) conduct, with the active participation of the ~~provider~~ MEDICAL staff, an ongoing,
33 comprehensive self-assessment of the quality of care provided, including the medical
34 necessity of procedures performed, the appropriateness of care, and the appropriateness
35 of utilization. This information shall provide a basis for the revision of ~~facility~~ CENTER
36 policies and the granting or continuation of clinical privileges;

37 9(J) ADOPT A NATIONAL STANDARD FOR INFECTION CONTROL; ~~require that the facility's Quality~~
38 ~~Management Program ensure the adequate investigation, control and prevention of~~
39 ~~infections and avoidable adverse outcomes;~~

40 (K) ENSURE THE CENTER MAINTAINS AN ADEQUATE NUMBER OF QUALIFIED PERSONNEL;

1 (L) MAINTAINS EFFECTIVE QUALITY CONTROL, QUALITY IMPROVEMENT AND DATA MANAGEMENT;

2 (M) APPOINT AN ADMINISTRATOR QUALIFIED BY EDUCATION AND EXPERIENCE AS DEFINED IN THE JOB
3 DESCRIPTION DEVELOPED BY THE CENTER; AND

4 (N) APPOINT A MEMBER OF THE MEDICAL STAFF TO ACT AS MEDICAL DIRECTOR FOR THE CENTER.

5 SECTION 45- ADMINISTRATOR

6 A. 5.1 Responsibility: The administrator shall be the official representative of the governing body and the
7 chief executive officer of the surgical center. The administrator shall be delegated responsibility
8 and authority in writing by the governing body for the management of the surgical center and shall
9 provide liaison among the governing body, provider staff and other departments of the surgical
10 center.

11 B. 5.2 Duties: The administrator shall be responsible for the development, implementation and
12 administration of surgical center policies and procedures for employee and provider MEDICAL staff
13 use. All policies and procedures shall be reviewed and approved by the governing body and/or
14 updated as necessary but at least annually. THE ADMINISTRATOR SHALL DESIGNATE A QUALIFIED
15 INDIVIDUAL TO ACT FOR HIM OR HER WHEN ABSENT SO THAT THE AMBULATORY SURGICAL CENTER HAS
16 ADMINISTRATIVE DIRECTION AT ALL TIMES.

17 SECTION 56 --PROVIDER MEDICAL STAFF

18 A. 6.1 Organization: The ambulatory surgical center shall have an organized provider MEDICAL staff.

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

23 B. 6.2 Duties: The provider MEDICAL staff or a delegated committee composed of members of the
24 provider MEDICAL staff shall:

25 4(A) be responsible for the quality of all medical care provided patients in the facility CENTER;

26 2(B) ENSURE PROFESSIONALLY ETHICAL CONDUCT ON THE PART OF ALL MEMBERS OF THE MEDICAL
27 STAFF AND INITIATE CORRECTIVE MEASURES AS REQUIRED; ~~hold meetings regularly and~~
28 ~~maintain accurate records of such meetings;~~

29 3(C) formulate, adopt, and enforce by-laws, rules, regulations and policies for the proper
30 conduct of its activities and credentialing of its members. THE PRACTITIONERS APPLYING
31 FOR STAFF PRIVILEGES SHALL BE REQUIRED TO SIGN AN AGREEMENT TO ABIDE BY THE MEDICAL
32 STAFF BYLAWS, CODE OF CONDUCT AND APPLICABLE STATE LAWS, RULES AND REGULATIONS;

33 4(D) recommend MEDICAL staff privileges to the Governing Body;

34 5(E) HOLD MEETINGS REGULARLY AND MAINTAIN ACCURATE RECORDS OF SUCH MEETINGS ensure
35 professionally ethical conduct on the part of all members of the provider staff and initiate
36 corrective measures as required;

37 6(F) establish a formal liaison with the governing body;

38 7(G) participate actively in the quality management program; AND

1 8(H) recommend admission and surgical procedureAL policies to the Governing Body;

2 **SECTION 67- MEDICAL RECORDS-HEALTH INFORMATION MANAGEMENT**

3 A. 7.1 Facilities: The center must develop and maintain a system for the proper collection, storage, and
4 use of patient records. The facility CENTER shall maintain an individual record for each patient
5 admitted.

6 (A) EACH CENTER SHALL ESTABLISH PROCESSES TO OBTAIN, MANAGE AND UTILIZE INFORMATION TO
7 ENHANCE AND IMPROVE INDIVIDUAL AND ORGANIZATIONAL PERFORMANCE IN PATIENT CARE,
8 MANAGEMENT AND SUPPORT PROCESSES. SUCH PROCESSES SHALL:

9 (1) BE PLANNED AND DESIGNED TO MEET THE CENTER'S INTERNAL AND EXTERNAL
10 INFORMATION NEEDS;

11 (2) PROVIDE FOR CONFIDENTIALITY, INTEGRITY AND SECURITY;

12 (3) PROVIDE EDUCATION AND TRAINING IN INFORMATION MANAGEMENT PRINCIPLES TO
13 DECISION-MAKERS AND OTHER CENTER PERSONNEL WHO GENERATE, COLLECT AND
14 ANALYZE INFORMATION; AND

15 (4) PROVIDER FOR INFORMATION IN A TIMELY AND ACCURATE MANNER.

16 (B) THE ADMINISTRATOR SHALL APPOINT IN WRITING A QUALIFIED PERSON RESPONSIBLE FOR THE
17 PATIENT INFORMATION SYSTEM OR SIMILARLY TITLED UNIT. THIS PERSON SHALL MEET THE
18 QUALIFICATIONS ESTABLISHED FOR THIS POSITION, IN WRITING, BY THE GOVERNING BODY.

19 (C) A CURRENT JOB DESCRIPTION DELINEATING DUTIES AND RESPONSIBILITIES SHALL BE
20 MAINTAINED FOR EACH MEDICAL RECORDS SERVICE POSITION.

21 (D) THE HEALTH INFORMATION MANAGEMENT ADMINISTRATOR SHALL ENSURE THAT:

22 (1) OPERATIVE AND PROCEDURE REPORTS SIGNED BY THE PHYSICIAN ARE RECORDED IN
23 THE PATIENT'S HEALTH RECORD IMMEDIATELY FOLLOWING THE SURGERY OR
24 PROCEDURE OR THAT A PROGRESS NOTE IS ENTERED IN THE PATIENT RECORD TO
25 PROVIDE PERTINENT INFORMATION;

26 (2) POSTOPERATIVE INFORMATION INCLUDES VITAL SIGNS, LEVEL OF CONSCIOUSNESS,
27 MEDICALS, BLOOD OR BLOOD COMPONENTS, COMPLICATIONS AND MANAGEMENT OF
28 THOSE EVENTS, IDENTIFICATION OF DIRECT PROVIDERS OF CARE, AND DISCHARGE
29 INFORMATION FROM POST-ANESTHESIA CARE AREA; AND

30 (3) ALL MEDICAL RECORDS ARE ENTERED INTO A DATA BASE AND MAINTAINED ON A
31 CURRENT BASIS ACCORDING TO PROCEDURE AND PHYSICIAN.

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

34 C 7.2. Security: Medical records shall be protected from loss, damage, unauthorized use and disclosure.
35 IF ELECTRONIC MEDICAL RECORDS ARE UTILIZED, THERE MUST BE A BACK-UP SYSTEM FOR ALL DATA
36 COLLECTED. AN AUDIT TRAIL SHALL BE MAINTAINED TO TRACK DATA ENTRIES AND DELETIONS, AND
37 INCLUDE INFORMATION REGARDING THE DATA ENTERED OR DELETED AS WELL AS THE USER RESPONSIBLE
38 FOR THE DATA ENTRY OR DELETION.

- 1 D 7.3. Preservation: With the exception of medical records of minors (individuals under the age of 18
2 years) medical records shall be preserved as original records or on a technologically appropriate
3 medium as administratively determined by the Department for no less than ten (10) years after
4 the most recent patient care usage, after which time medical records may be destroyed at the
5 discretion of the **facility CENTER**. Accessibility of medical records to the Department to assure
6 compliance and to patients or their legal representatives shall be maintained.
- 7 4(A) Medical records of minors shall be preserved for the period of minority plus ten (10) years
8 (i.e., 28 years less age of minor at time of most recent patient care usage of the medical
9 record).
- 10 2(B) **Facilities CENTERS** shall establish procedures for notification to patients whose records
11 are to be destroyed prior to the destruction of such records.
- 12 3(C) **The CENTERS SHALL BE SOLELY RESPONSIBLE responsibility for the destruction of all medical**
13 **records. shall be in the facility involved but in no case shall records be destroyed prior to**
14 **consultation with legal counsel;**
- 15 4(D) Actual x-ray films, scans, and other imaging records shall be maintained by the **facility**
16 **CENTER** for a period of five (5) years, if services are provided directly.
- 17 E. 7.4 Content: The medical records shall contain sufficient accurate information to justify the diagnosis
18 and warrant the treatment and end results including, but not limited to:
- 19 4(A) complete patient identification and a unique identification number;
- 20 2(B) admission and discharge dates;
- 21 3(C) chief complaint and admission diagnosis;
- 22 4(D) medical history and physical examination completed prior to surgery;
- 23 5(E) diagnostic tests, laboratory, x-ray, scans, and other radiological imaging reports and
24 consultative findings when appropriate;
- 25 6(F) physician progress notes if appropriate;
- 26 7(G) properly executed informed consent;
- 27 8(H) a pre-anesthesia examination by a physician prior to surgery, a proper anesthesia record
28 and a post-anesthesia evaluation;
- 29 9(I) a complete detailed description of operative procedures, findings and post-operative
30 diagnosis recorded and signed by the attending physician;
- 31 10(J) a pathology report of tissue removed during surgery in accordance with **facility** **CENTER**
32 **policies;**
- 33 11(K) all medication and treatment orders in writing and signed by the authorizing party.
34 Telephone and verbal orders are designated as such, signed and dated by a legally
35 designated person, and countersigned by the attending provider within a clearly
36 designated time period established by the governing body; and
- 37 12(L) patient's condition on discharge, final diagnosis, and instructions given patient for follow-
38 up care.

1 F. 7.5 Other records: The facility CENTER shall maintain:

2 4(A) MAINTAIN a register of all surgical operations PROCEDURES performed BY PRACTITIONER
3 (entered daily);

4 2 statistical information concerning all admissions, discharges, deaths and other
5 information such as blood usage, surgery complications, etc, required for the effective
6 administration of the facility

7 3(B) MAINTAIN A master patient index file.

8 4(C) COLLECT, RETRIEVE, AND ANNUALLY SUMMARIZE THE FOLLOWING MEDICAL STATISTICAL
9 INFORMATION:

10 (1) THE NUMBER OF VISITS,

11 (2) THE BASIS OF TREATMENT (CLINICAL DIAGNOSIS AND/OR PROBLEM FOR WHICH THE
12 PATIENT WAS TREATED),

13 (3) THE TYPES AND NUMBER OF PROCEDURES PERFORMED,

14 (4) THE AGE DISTRIBUTION OF PATIENTS,

15 (5) ALL COMPLICATIONS AND EMERGENCIES, AND

16 (6) THE NUMBER OF TIMES A PATIENT WAS TRANSFERRED FROM THE CENTER TO A
17 HOSPITAL.

18 THE INFORMATION SHALL BE USED TO INFORM THE GOVERNING BODY AND TO UTILIZE AS PART OF THE
19 CENTER'S ONGOING QUALITY MANAGEMENT PROGRAM. THE BEGINNING AND ENDING DATES FOR THE
20 ANNUAL SUMMARY SHALL BE SET IN POLICY BY THE GOVERNING BODY.

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

26 H (E) Entries: All orders for diagnostic procedures, treatments, and medications shall be
27 authenticated by the physician submitting them and entered in the medical record by
28 technologically appropriate medium as administratively determined by the Department.
29 Authentication may be by written signature, identifiable initials, or computer key OR OTHER
30 SECURE ELECTRONIC MEANS.

31 SECTION 78- PERSONNEL

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

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

- 1 ~~C~~. 8.3 Job Description: There shall be written job descriptions for each position in the facility CENTER
2 including at least the title, authority, specific responsibilities and minimum qualifications. Each
3 employee shall be provided a copy of his or her job description.
- 4 ~~D~~. 8.4 Staffing: Each service department of the center shall be under the direction of a person qualified
5 by training, experience, and ability. Staffing levels shall be commensurate with the needs of the
6 patients and CENTER facility clientele and the facility.
- 7 ~~E~~. 8.4 In-service EDUCATION: There shall be an in-service program which keeps all employees abreast of
8 changing methods and new techniques. Records including attendance and subject matter of each
9 in-service shall be maintained. ALL PERSONNEL SHALL RECEIVE AT LEAST 12 HOURS OF CONTINUING
10 EDUCATION ANNUALLY, WHICH MUST INCLUDE, BUT NOT BE LIMITED TO, INFECTION CONTROL; FIRE,
11 SAFETY AND EMERGENCY PROCEDURES.
- 12 ~~F~~. 8.5 Disease: Any personnel with communicable disease as defined by the Department shall return to
13 work only after complying with the facility's CENTER'S infection control policy.
- 14 ~~G~~. 8.6 Records: Personnel records shall be maintained for each person employed in the facility CENTER
15 and shall include, at a minimum, the following RECORDS:
- 16 4(A) an employment application THAT CONTAINS INFORMATION REGARDING EDUCATION,
17 EXPERIENCE AND, IF APPLICABLE, REGISTRATION AND/OR LICENSURE INFORMATION FOR THE
18 APPLICANT;
- 19 2(B) verification of references and/or credentials as required;
- 20 3(C) incident and/or accident reports;
- 21 (D) EVIDENCE OF PERIODIC PERFORMANCE EVALUATIONS;
- 22 4(E) results of medical examinations required as a part of employment within the facility
23 CENTER.
- 24 5(F) BACKGROUND CHECKS THAT, AT A MINIMUM, INCLUDE CHECKING THE DEPARTMENT OF
25 REGULATORY AGENCIES WEBSITE TO ENSURE THAT AN ACTIVE LICENSE IN GOOD STANDING
26 EXISTS. ANY ADMONISHMENTS OR ENFORCEMENT ACTIONS SHALL BE REVIEWED BY THE
27 ADMINISTRATOR PRIOR TO HIRE; AND
- 28 6(G) DOCUMENTATION OF CONTINUING EDUCATION.

29 SECTION 89 - ADMISSIONS

- 30 A 9.1 Admissions and discharge: All persons admitted to the ambulatory surgical center shall be under
31 the direct care of a member of the provider MEDICAL staff. The provider MEDICAL staff shall ensure
32 the continuity of care for each patient including pre-operative, intra-operative, and post-operative
33 care. All necessary instruction and education shall be provided to each patient prior to admission
34 (for pre-surgical care) and discharge (for post-surgical care).
- 35 B 9.2 Restrictions:
- 36 4(A) Surgical procedures shall be limited to the following:
- 37 a (1) those in which the EXPECTED combined operating and recovery time does not
38 exceed 24 hours from the time of admission; and

- 1 b (2) those that do not generally result in extensive blood loss; require major or
2 prolonged invasion of body cavities; directly involve major blood vessels; or
3 constitute an emergency or life threatening procedure.
- 4 2(B) There shall be no pre-planned off-site transfers to a higher level of care and no transfers
5 shall occur solely for the convenience of the ~~A~~AMBULATORY ~~S~~SURGICAL ~~C~~CENTER or its
6 staff.
- 7 9.3 Identification: Each patient admitted to the center shall have a visible means of identification
8 placed and maintained on his/her person until discharge. In cases of off-site pre-planned transfer
9 such means of identification shall be maintained throughout the period of transfer and until such
10 time as the patient becomes a patient of another licensed facility.
- 11 9.4 Admission Requirements: All admissions shall be in accordance with appropriate written policies
12 and procedures which reflect the admission requirements established in this section,
13 recommended by the ~~provider~~ MEDICAL staff and adopted by the governing body, specific to the
14 ambulatory surgical center operations, that includes at least the following:
- 15 4 (A) The physicians performing the procedure shall document in writing that the patient is in
16 good health or that any pre-existing health conditions are adequately controlled, require
17 no special management and are such that performance of the procedure in ~~an ASC A~~
18 CENTER, rather than ~~an INPATIENT~~ hospital setting, does not pose an increased risk to the
19 patient.
- 20 2 (B) The patient or a responsible person acting on behalf of the patient must be able to strictly
21 follow instructions related to ingestion of fluids or solids within the specified time frame
22 prior to the surgery.
- 23 3 (C) If the patient is to receive sedation or anesthetic which will result in impaired mental
24 status following surgery, the patient must be accompanied upon discharge by a
25 responsible adult, unless exempted in writing by the attending physician.
- 26 4 (D) Patients who may require post-operative ventilation following surgery, either because of
27 the procedure to be performed or because of a pre-existing condition, shall not be
28 admitted for surgery.
- 29 5 (E) Surgery which requires the presence of special equipment, personnel, and/or facilities
30 due to the risk of the operation involved shall not be performed in the center unless such
31 equipment, personnel, and/or facilities are available in the ambulatory surgical center.
- 32 6 (F) When overnight care is provided, appropriate services shall be rendered within the
33 defined capabilities of the organization.
- 34 ~~7. The governing body of the facility shall provide clear notice to patients that the facility is a~~
35 ~~smoke-free environment.~~
- 36 9.5 DISCHARGE: PATIENTS SHALL BE IN A STABLE CONDITION WHICH WILL NOT ENDANGER THEIR CONTINUED
37 WELL-BEING OR SHALL BE TRANSFERRED TO A LICENSED HOSPITAL, CONVALESCENT CENTER OR OTHER
38 TREATMENT FACILITY. THERE SHALL BE WRITTEN PROCEDURES AND ASSIGNED RESPONSIBILITIES FOR
39 IMPLEMENTING SUCH PROCEDURES, INCLUDING PROVISIONS FOR TRANSPORTATION. THE CENTER SHALL
40 PROVIDE VERBAL AND WRITTEN PATIENT INSTRUCTIONS IN REGARD TO POST-OPERATIVE CARE, PHYSICIAN
41 POST-OPERATIVE APPOINTMENT, AND PHYSICIAN CONTACT INFORMATION.
- 42 9.6 OFF-SITE PRE-PLANNED TRANSFERS: Off-site pre-planned transfers of patients include those
43 transfers of patients to other licensed health facilities, that are physically located off-site or off-

1 campus, where it is known in advance that further post-surgical patient care will be needed. Off-
2 site pre-planned transfers do not include discharges to the patient's place of residence where
3 further care will be provided by home health or home care providers. Ambulatory surgical centers
4 providing off-site pre-planned transfer service options shall adhere to the following requirements.

5 4 (A) DISCLOSURE. Facilities offering surgical services which include an off-site pre-planned
6 transfer to another licensed facility following post-operative recovery shall disclose in
7 written form to the patient all the details of the transfer prior to admission to the facility.
8 Disclosure includes, but is not limited to, the cost of the transfer, whether or not such
9 costs shall be covered by insurance or other third party payer, and the details of the
10 actual transfer, including, but not limited to, the mode of transport. Disclosure shall be
11 made to the patient prior to the time for admission to the facility. The patient shall
12 acknowledge such disclosure in writing, and the date thereof. Such disclosures on facility
13 CENTER policies regarding off-site pre-planned transfers shall be in addition to the
14 requirements for informed consent.

15 2 (B) Off-site pre-planned transfers shall be made only to other licensed facilities that can
16 provide the level of care necessary to meet the needs of the patient. The ambulatory
17 surgical center shall have a written agreement with any and each licensed facility that
18 admits patients for post-surgical care from an ambulatory surgical center. The ambulatory
19 surgical center shall provide written discharge instructions, including patient progress
20 information, to the receiving facility.

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

27 3 (C) All pre-planned transfers shall be by licensed ambulance. The ambulatory surgical center
28 shall have a written agreement with the provider(s) of ambulance services. Such transfer
29 agreements shall include the provision for an appropriate level of care commensurate
30 with the needs of a post-surgical recovering patient. If necessary, as determined by the
31 attending or operating physician, licensed provider MEDICAL staff from the ambulatory
32 surgical center shall accompany the patient on the ambulance to provide continuity of
33 care and a level of care that meets the peri-operative needs of the patient.

34 4 (D) Ambulatory surgical centers engaging in pre-planned transfers shall provide space at the
35 entrance to the building to facilitate transfer. The facility CENTER shall provide close-in
36 parking that shall be accessible at all times and shall not be obstructed by other parked
37 vehicles or any other architectural barriers. The space provided for ambulance access
38 shall also contain adequate height clearance to accommodate a type I or a type III
39 ambulance.

40 ~~5. An ambulatory surgical center located above the ground level of the building that admits~~
41 ~~patients for which a pre-planned transfer is anticipated shall have elevators available for~~
42 ~~the transport of such patients. Elevators shall be large enough to accommodate an~~
43 ~~ambulance cot in horizontal position and a minimum of two attendants.~~

44 F 9.7 ON-SITE PRE-PLANNED TRANSFERS: On-site pre-planned transfers of patients are also
45 authorized where it is known in advance that further post-surgical patient care will be DESIRED OR
46 needed. Such transfers are limited to those transfers of patients to CONVALESCENT CENTERS OR
47 other licensed health facilities, located on-site or on campus and are physically connected to the
48 ambulatory surgical center.

1 4 (A) The provisions of paragraph ~~(E)(1) and (2)~~ 89.6(A) and (B) shall apply to on-site pre-
2 planned transfers. The provisions of paragraph ~~(E)(3),(4),and (5)~~ 89.6(C) and (D) shall
3 not apply to on-site pre-planned transfers.

4 **SECTION 910 - LABORATORY AND RADIOLOGY**

5 A 10.1 Services: Clinical laboratory services shall be available as required by the needs of the patients
6 as determined by the ~~provider~~ MEDICAL staff. Whether provided on-site or by contract, the
7 laboratory shall meet the requirements of the "Clinical Laboratory Improvement Amendments of
8 1988," and the corresponding regulations (42 USC § 263a and 42 CFR Part 493).

9 B 10.2 ~~RADIOLOGICAL~~-SERVICES: Radiological services shall be provided as required by the needs
10 of the patients as determined by the ~~provider~~-MEDICAL staff. Whether provided on-site or by
11 contract, the radiological services shall meet Colorado rules and regulations pertaining to
12 "Radiation Control," 6 CCR 1007-1.

13 ~~4 (A) THE RADIOLOGICAL SERVICE SHALL BE DIRECTED BY A LICENSED RADIOLOGIST AND STAFFED BY~~
14 ~~QUALIFIED TECHNICAL PERSONNEL.~~

15 ~~2 (B) THERE SHALL BE WRITTEN POLICIES GOVERNING ALL RADIOLOGICAL PROCEDURES.~~

16 ~~3 (C) SUFFICIENT DIAGNOSTIC AND THERAPEUTIC RADIOLOGICAL EQUIPMENT SHALL BE AVAILABLE TO~~
17 ~~SATISFY THE OBJECTIVES OF THE CENTER.~~

18 **SECTION ~~4011~~ - ANESTHESIA**

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

20 B 11.2 ~~THE AMBULATORY SURGICAL CENTER SHALL PROVIDE ANESTHESIA SERVICES COMMENSURATE WITH THE~~
21 ~~SERVICES PROVIDED BY THE CENTER.~~

22 ~~C 11.3 GENERAL OR REGIONAL ANESTHESIA OR ANALGESIA SHALL BE ADMINISTERED ONLY BY A PHYSICIAN~~
23 ~~QUALIFIED BY TRAINING, EXPERIENCE AND ABILITY IN ANESTHESIOLOGY OR A REGISTERED NURSE~~
24 ~~ANESTHETIST GRADUATED FROM A CERTIFIED SCHOOL. IN THE CASE OF DENTAL TREATMENT, DENTISTS~~
25 ~~MAY ADMINISTER LOCAL ANESTHETICS.~~

26 **SECTION ~~4412~~ - EMERGENCY SERVICES**

27 A 12.1 The center shall have policies and procedures which provide for adequate care of ~~the facility's~~ ITS
28 patients in the event of an emergency.

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

31 ~~C 12.3~~ In the event emergency services are necessary, the ~~ASC CENTER~~ shall have a written transfer
32 agreement with a local hospital or ensure that every physician performing surgery at the ~~ASC~~
33 ~~CENTER~~ has admitting privileges at a local hospital.

34 ~~D 12.4~~ Emergency equipment and supplies shall be readily available ~~on the premises~~ IN THE SURGICAL
35 ~~AND/OR PROCEDURE ROOM(S) AND RECOVERY ROOM(S).~~

36 ~~E 12.5~~ An ambulatory surgical center transferring a patient to a hospital on an emergency basis, shall
37 submit to the receiving hospital at the time of transfer a copy of all medical records related to the
38 patient's condition, including observations of the patient's signs and symptoms, preliminary

1 diagnosis, treatment provided, results of any tests, and a copy of the informed written consent for
2 the surgical procedure that was scheduled or performed at the **ASC CENTER**.

3 **F 12.6** **AN AMBULATORY SURGICAL CENTER LOCATED ABOVE THE GROUND LEVEL OF A BUILDING THAT ADMITS**
4 **PATIENTS FOR WHICH A PRE-PLANNED TRANSFER IS ANTICIPATED SHALL HAVE ELEVATORS AVAILABLE FOR**
5 **THE TRANSPORT OF SUCH PATIENTS. ELEVATORS SHALL BE LARGE ENOUGH TO ACCOMMODATE AN**
6 **AMBULANCE COT IN A IN HORIZONTAL POSITION AND A MINIMUM OF TWO ATTENDANTS.**

7 **SECTION 4213 - NURSING SERVICES**

8 **A 13.1** **Nursing Administration** : The **facility CENTER** shall have sufficient nursing personnel under the
9 supervision of a nurse manager who is currently licensed by the State of Colorado as a
10 professional registered nurse and who is **QUALIFIED BY EDUCATION AND EXPERIENCE TO BE**
11 responsible for oversight of all nursing services.

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

13 4 (A) delivery of appropriate nursing services to patients;

14 2 (B) development and maintenance of appropriate nursing service objectives, standards of
15 nursing practice, nursing policy and procedure manuals, and written job descriptions for
16 all levels of nursing personnel;

17 3 (C) coordination of nursing services with other patient services;

18 4 (D) **establishment of a means of adequately assessing and planning the nursing care needs**
19 **of patients and staffing to meet those needs; AN ADEQUATE PLAN FOR THE CONTINUOUS**
20 **EVALUATION OF NURSING CARE, ALONG WITH A PLAN TO PERIODICALLY EVALUATE THE**
21 **ADEQUACY OF THE CENTER TO MEET THE NEEDS OF ITS PATIENTS AND THE NECESSITY FOR**
22 **IMPROVEMENT OR REVISION OF THE CENTER OR ITS SERVICES; and**

23 5 (E) staff development including orientation, inservice and continuing education which
24 includes provisions for CPR certification or review.

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

27 4 (A) at least one registered nurse shall be in the **facility CENTER** at all times whenever a
28 patient is **in the facility PRESENT;**

29 2 (B) nursing personnel shall be assigned duties consistent with their education and
30 experience.

31 **D 13.4** **Medications and Treatments:** Medications and treatments shall be administered in accordance
32 with all applicable laws and acceptable standards of practice.

33 **E 13.5** **Personnel STAFF Meetings** : Meetings of nursing personnel shall be held regularly to discuss,
34 review and evaluate nursing care. Written minutes of these meetings shall be maintained and
35 distributed to personnel.

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

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

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

8 **13.6 STAFFING:** THE CENTER SHALL HAVE NURSING STAFF IN SUFFICIENT NUMBERS TO ENSURE THAT THE
9 FOLLOWING SERVICES ARE PROVIDED, DEPENDING ON THE PROCEDURE AND METHOD OF SEDATION.

10 (A) A REGISTERED NURSE, QUALIFIED BY EDUCATION AND EXPERIENCE, SHALL BE PRESENT IN EACH
11 OPERATING ROOM DURING OPERATIVE PROCEDURES. THIS NURSE'S DUTIES ARE PERFORMED
12 OUTSIDE THE STERILE FIELD. THIS NURSE IS RESPONSIBLE FOR MANAGING ALL NURSING CARE
13 WITHIN THE OPERATING ROOM, OBSERVING THE SURGICAL TEAM FROM A BROAD PERSPECTIVE,
14 AND ASSISTING THE TEAM AS NECESSARY.

15 (B) A REGISTERED NURSE OR CERTIFIED REGISTERED NURSE ANESTHETIST, QUALIFIED BY
16 EDUCATION AND EXPERIENCE IN PERI-OPERATIVE NURSING, SHALL BE PRESENT IN EACH
17 OPERATING OR PROCEDURE ROOM DURING THE COURSE OF THE PROCEDURE AND BE DEDICATED
18 SOLELY TO MONITORING THE PATIENT DURING THE PROCEDURE.

19 (C) A REGISTERED NURSE, QUALIFIED BY EDUCATION AND EXPERIENCE, SHALL BE PRESENT IN THE
20 RECOVERY AREA WHEN PATIENTS ARE RECOVERING.

21 (D) FOR CLASS A OR B PROCEDURES WHERE NO MORE THAN LIGHT SEDATION IS USED:

22 (1) A TECHNICIAN MAY BE USED WITHIN THEIR SCOPE OF PRACTICE.

23 (2) A TECHNICIAN OR RN MAY PROVIDE MINOR ASSISTANCE TO THE PRACTITIONER AS LONG
24 AS IT IS CONDUCTED WITHIN NATIONALLY RECOGNIZED STANDARDS OR PRACTICE AND
25 THE PATIENT IS BEING APPROPRIATELY MONITORED THROUGHOUT THE PROCEDURE.

26 **SECTION 14.14- PHARMACEUTICAL SERVICES**

27 A 14.1 The ambulatory surgical center shall implement methods, procedures and controls which ensure
28 the appropriation, acquisition, storage, dispensing and administration of drugs and biologicals in
29 accordance with acceptable pharmaceutical practice and applicable state and federal laws and
30 regulations, whether it provides its own pharmaceutical services or makes other legal and
31 appropriate arrangements for obtaining necessary pharmaceuticals.

32 14.2 MEDICATIONS SHALL NOT BE ADMINISTERED TO PATIENTS UNLESS ORDERED BY A PHYSICIAN OR OTHER
33 PRACTITIONERS WITH PRESCRIPTIVE AUTHORITY. THE ORDERS SHALL BE IN WRITING OR, IF GIVEN
34 VERBALLY, SHALL BE PROMPTLY REDUCED TO WRITING AND SIGNED BY THE PRACTITIONER IN
35 ACCORDANCE WITH CENTER PROCEDURE.

36 14.3 MEDICATIONS MAINTAINED IN THE CENTER SHALL BE APPROPRIATELY STORED AND SAFEGUARDED
37 AGAINST DIVERSION OR ACCESS BY UNAUTHORIZED PERSONS. APPROPRIATE RECORDS SHALL BE KEPT
38 REGARDING THE DISPOSITION OF ALL MEDICATIONS.

39 14.4 EACH CENTER SHALL MAINTAIN REFERENCE SOURCES FOR IDENTIFYING AND DESCRIBING MEDICATIONS.
40 SOURCES MAY BE IN ELECTRONIC FORMAT OR WEB-BASED.

41 14.5 MEDICATION SHALL BE ADMINISTERED ONLY BY A LICENSED NURSE OR PHYSICIAN.

1 14.6 BLOOD, BLOOD PRODUCTS AND PARENTERAL SOLUTIONS SHALL BE ADMINISTERED ONLY BY PHYSICIANS
2 OR REGISTERED NURSES.

3 14.7 ADVERSE MEDICATION REACTIONS SHALL BE REPORTED IMMEDIATELY TO THE PHYSICIAN RESPONSIBLE
4 FOR THE PATIENT AND DOCUMENTED IN THE MEDICAL RECORD.

5 **SECTION 4415 – SURGICAL AND PROCEDURAL SERVICES**

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

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

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

19 15.1 A QUALIFIED PERSON DESIGNATED BY THE ADMINISTRATOR SHALL BE RESPONSIBLE FOR THE DAILY
20 FUNCTIONING AND MAINTENANCE OF THE SURGICAL AND/OR PROCEDURE ROOM(S).

21 15.2 SURGICAL SITE IDENTIFICATION: EACH CENTER SHALL DEVELOP A STANDARDIZED METHOD TO ENSURE
22 ALL PATIENTS ARE APPROPRIATELY IDENTIFIED, ALL PERTINENT INFORMATION IS OBTAINED, THE SURGERY
23 AND SURGICAL SITE ARE CONFIRMED, AND A SURGICAL TEAM TIME OUT IS CONDUCTED PRIOR TO AN
24 INCISION BEING MADE.

25 (A) AT A MINIMUM, ALL SURGICAL SITES INVOLVING LATERALITY, MULTIPLE STRUCTURES (IE,
26 FINGERS, TOES, LESIONS) OR MULTIPLE LEVELS (IE, SPINE) SHALL BE MARKED.

27 (1) THE MARKING SHALL BE MADE BY AN INDIVIDUAL THAT IS FAMILIAR WITH THE PATIENT
28 AND IS INVOLVED WITH THE PATIENT'S PROCEDURE SUCH AS THE SURGEON OR A
29 LICENSED INDIVIDUAL WHO PERFORMS DUTIES IN COLLABORATION WITH THE SURGEON
30 (IE, REGISTERED NURSE, ADVANCE PRACTICE NURSE OR PHYSICIAN ASSISTANT).

31 (2) WHENEVER POSSIBLE, THE MARKING SHALL INVOLVE THE PATIENT AND TAKE PLACE
32 WHEN THE PATIENT IS AWAKE AND AWARE.

33 (B) THE SURGICAL TIME OUT SHALL INCLUDE, AT A MINIMUM, UNANIMOUS CONFIRMATION BY THE
34 ENTIRE SURGICAL TEAM OF THE FOLLOWING FACTORS:

35 (1) PATIENT IDENTITY USING TWO PATIENT IDENTIFIERS;

36 (2) TYPE OF PROCEDURE;

37 (3) IDENTIFICATION OF CORRECT SITE OR SIDE.

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

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

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

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

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

16 G. ~~Reserved~~

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

20 † 15.3 Scrub Area : The scrub area shall be adjacent to the operating room to permit immediate access
21 to the room after scrubbing. The scrub area shall be no more than 10 feet from the entrance to
22 the operating room. Scrub sink(s) with ELECTRONIC SENSORS, knee or foot controls shall be
23 installed in the scrub area.

24 ‡ 15.4 Clean-up Facilities: Clean and soiled utility rooms shall be arranged and provided with equipment
25 necessary for proper patient care and for the processing of soiled equipment, including a
26 ~~pressurized steam sterilizer or equivalent, or a sterilizer~~ DECONTAMINATION or sterilization system
27 that is appropriate to the procedures being performed, and storage cabinets and work counters
28 with sinks. EQUIPMENT FOR STERILIZING INSTRUMENTS AND SUPPLIES SHALL BE CONVENIENTLY
29 LOCATED AND OF ADEQUATE CAPACITY FOR THE WORKLOAD. RECORDS SHALL BE MAINTAINED TO
30 ASSURE QUALITY CONTROL, INCLUDING DATE, TIME AND TEMPERATURE OF EACH BATCH OF STERILIZED
31 SUPPLIES AND EQUIPMENT.

32 ¶ 15.5 Staff Dressing Rooms: SEPARATE STAFF DRESSING ROOMS SHALL be provided for both men and
33 women; each containing a toilet, handsink, and ~~provisions for storage of clothing~~ STORAGE. FOR
34 CENTERS WITH LESS THAN FOUR SURGICAL AND/OR PROCEDURE ROOMS, UNISEX DRESSING ROOMS ARE
35 ACCEPTABLE. SHOWERS SHALL BE PROVIDED WHERE THERE IS MORE THAN MINIMAL POSSIBILITY OF
36 EXPOSURE TO BLOOD OR BODY FLUIDS AND SECRETIONS.

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

41 1. ~~outdoor air intakes shall be located as far away from exhausts as practical, but not less~~
42 ~~than 25 feet from the exhausts from any ventilating systems, combustion equipment,~~
43 ~~medical-surgical vacuum system or plumbing vent or areas which may collect noxious~~
44 ~~fumes. The bottom of all outdoor air intakes shall be located as high as practical but not~~

1 less than 3 feet above grade level, or, if installed through the roof, 3 feet above the roof
2 level;

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

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

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

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

15 P. Reserved

16 Q 15.6 Janitors ENVIRONMENTAL SERVICES Room: A separate janitors room or equivalent SPACE shall be
17 provided exclusively for the surgical and/or procedure rooms. It shall be equipped with shelves for
18 supplies, mop clip boards, and a wall or floor-mounted mop sink. A hand-washing sink with soap
19 and sanitary handwashing facilities will be available nearby. There shall be room also for a waste
20 container, drum of disinfectant detergent, mop carts and buckets, etc.

21 SECTION 1516 – POST ANESTHESIA RECOVERY ROOM PRE- AND POST-PROCEDURE AREAS

22 16.1 THE CENTER SHALL BE ARRANGED AND ORGANIZED IN A MANNER THAT ENSURES THE COMFORT, SAFETY,
23 HYGIENE, PRIVACY AND DIGNITY OF ITS PATIENTS.

24 16.2 A SEPARATE AREA SHALL BE PROVIDED WHERE PATIENTS CAN CHANGE THEIR CLOTHING BEFORE AND
25 AFTER THE SURGERY OR PROCEDURE. THIS AREA SHALL INCLUDE HOLDING ROOM(S), LOCKERS, AND
26 TOILETS.

27 A 16.3 Recovery Room(s): Recovery room(s) for post-anesthesia recovery that meet the needs of
28 surgical patients shall be provided. CENTERS THAT PERFORM SURGERY OR PROCEDURES WITH
29 ANESTHESIA, SHALL HAVE POST-ANESTHESIA RECOVERY ROOM(S) FOR ITS PATIENTS. BEDS,
30 STRETCHERS OR RECLINERS MAY BE UTILIZED IF THEY OFFER THE APPROPRIATE LEVEL OF SAFETY AND
31 COMFORT TO THE PATIENT(S).

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

36 16.4 THE RECOVERY ROOM(S) MUST ACCOMMODATE PROVISION OF THE FOLLOWING ACTIVITIES OR SERVICES:

37 (A) DIRECT VISUAL OBSERVATION OF ALL PATIENTS,

38 (B) MEDICATION ADMINISTRATION,

39 (C) CHARTING,

- 1 (D) TOILETING AND HAND WASHING,
- 2 (E) SUPPLY AND EQUIPMENT STORAGE,
- 3 (F) ADMINISTRATION OF OXYGEN, SUCTION AND RESUSCITATION; AND
- 4 (G) EMERGENCY CALL SYSTEM.

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

7 **SECTION 17 - INFECTION AND DISEASE CONTROL**

8 **17.1** THE AMBULATORY SURGICAL CENTER SHALL HAVE A MULTI-DISCIPLINARY INFECTION CONTROL
9 COMMITTEE CHARGED WITH THE RESPONSIBILITY OF INVESTIGATION AND RECOMMENDATIONS FOR THE
10 PREVENTION AND CONTROL OF INFECTION AND COMMUNICABLE DISEASE.

11 **17.2** THE INFECTION CONTROL COMMITTEE SHALL DEVELOP AND IMPLEMENT POLICIES AND PROCEDURES
12 RELATED TO INFECTION AND DISEASE CONTROL INCLUDING, BUT NOT LIMITED TO:

- 13 (A) THE ADMISSION OF PATIENTS WITH SPECIFIC INFECTIOUS DISEASES;
- 14 (B) ANNUAL REVIEW OF CLINIC POLICIES AND PROCEDURES TO ENSURE COMPLIANCE WITH
15 THE GOVERNING BOARD'S CHOSEN NATIONAL STANDARD FOR INFECTION CONTROL, AND
16 ANY SPECIFIC RECOMMENDATIONS FROM LOCAL OR STATE PUBLIC HEALTH AGENCIES.
- 17 (C) ORIENTATION AND CONTINUING EDUCATION OF PERSONNEL ON THE CONTROL OF
18 NOSOCOMIAL AND INFECTIOUS DISEASES, INCLUDING UNIVERSAL PRECAUTIONS;
- 19 (D) THE REPORTING OF COMMUNICABLE DISEASES AS REQUIRED BY APPLICABLE STATE AND
20 FEDERAL LAWS AND REGULATIONS;
- 21 (E) CLEANING AND/OR DISINFECTION OF THE CENTER AND EQUIPMENT; AND
- 22 (F) EFFECTIVE CONTROL AND ERADICATION OF INSECTS AND RODENTS.

23 **SECTION ~~18~~18 - PATIENT CARE UNIT**

24 **A 18.1** An ambulatory surgical center shall maintain a distinct patient care area if the ambulatory surgical
25 center provides surgical services for persons needing longer periods of care and/or observation
26 beyond the recovery period and prior to discharge, ~~but not to exceed 24 hours~~. Patient rooms
27 shall have direct exit to the corridor or exit way and shall have a maximum of two beds per room.

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

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

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

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

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

6 **SECTION 4719 – EQUIPMENT AND SUPPLIES**

7 19.1 EQUIPMENT SHALL BE IN GOOD WORKING ORDER AND SHALL BE AVAILABLE IN SUFFICIENT QUANTITY TO
8 ENSURE ADEQUATE PATIENT CARE BASED UPON THE PROCEDURES TO BE PERFORMED IN THE CENTER.

9 (A) MONITORING EQUIPMENT, SUCTION APPARATUS, OXYGEN, CARDIAC PULMONARY RESUSCITATION
10 EQUIPMENT AND RELATED ITEMS SHALL BE AVAILABLE WITHIN THE SURGICAL, PROCEDURAL AND
11 RECOVERY AREAS.

12 (B) Sterilizing equipment of appropriate type shall be available and of sufficient capacity to
13 adequately sterilize instruments and operating room materials as well as laboratory
14 equipment and supplies. The sterilizing equipment shall have an approved recording
15 thermometer and safety features. The accuracy of such instrumentation and equipment
16 shall be checked and calibrated periodically, preventive maintenance shall be provided
17 as necessary and a log maintained.

18 (C) CENTERS USING LASER EQUIPMENT SHALL MAINTAIN WRITTEN DOCUMENTATION OF A SAFETY
19 AND MAINTENANCE PROGRAM RELATED TO THE USE OF THE LASER EQUIPMENT.

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

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

25 ~~C 19.3 Sterilizing Equipment: Sterilizing equipment of appropriate type shall be available and of
26 sufficient capacity to adequately sterilize instruments and operating room materials as well as
27 laboratory equipment and supplies. The sterilizing equipment shall have an approved recording
28 thermometer and safety features. The accuracy of such instrumentation and equipment shall be
29 checked and calibrated periodically, preventive maintenance shall be provided as necessary and
30 a log maintained.~~

31 **SECTION 48120 - HOUSEKEEPING SERVICES AND MAINTENANCE**

32 A 20.1 Organization: Each facility CENTER shall provide housekeeping services which ensure a pleasant,
33 safe and sanitary environment. ~~The facility shall be kept clean and orderly.~~ IF THE CENTER
34 CONTRACTS WITH AN OUTSIDE VENDOR TO PROVIDE HOUSEKEEPING SERVICES, THERE SHALL BE A
35 WRITTEN AGREEMENT REGARDING THE SERVICES AND THE CENTER SHALL BE ULTIMATELY RESPONSIBLE
36 FOR QUALITY CONTROL OF THE CONTRACTOR.

37 B 20.2 Written Policies and Procedures: ~~Appropriate w~~Written policies and procedures shall be
38 established and ~~followed~~ APPROVED BY THE INFECTION CONTROL COMMITTEE which ensure adequate
39 cleaning and/or disinfection of the physical ~~facility~~ STRUCTURE and equipment.

40 C 20.3 Storage: All cleaning materials, solutions, cleaning compounds, and hazardous substances, shall
41 be properly identified and stored ~~in a safe place~~ ACCORDANCE WITH THE MANUFACTURERS'
42 INSTRUCTIONS.

1 **20.4** CLEANING METHODS SHALL MINIMIZE THE DISPERSION OF DUST PARTICLES THAT MAY CONTAIN MICRO-
2 ORGANISMS IN CLEAN/STERILE AREAS.

3 **20.5** THE CENTER SHALL HAVE WRITTEN POLICIES AND PROCEDURES REGARDING A PREVENTIVE MAINTENANCE
4 PROGRAM TO ENSURE THAT THE PHYSICAL PLANT AND EQUIPMENT ARE KEPT IN GOOD REPAIR AND TO
5 PROVIDE FOR THE SAFETY, WELFARE AND COMFORT OF THE CENTER OCCUPANTS.

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

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

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

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

12 **SECTION 1921 - LAUNDRY AND LINENS**

13 ~~21.1~~ ~~Written provisions shall be made for the proper handling of linens and washable goods~~ THE
14 CENTER SHALL HAVE WRITTEN POLICIES AND PROCEDURE REGARDING THE HANDLING OF LINENS AND
15 LAUNDRY.

16 A 21.2 Outside Laundry: Laundry that is sent out shall be sent to a commercial or hospital laundry. A
17 contract for laundry services performed by commercial laundries for ambulatory surgical centers
18 shall include applicable standards of this Section **19 21.**

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

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

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

26 E 21.6 Packaging: The linens to be returned from the outside laundry to the facility CENTER shall be
27 completely wrapped or covered to protect against contamination.

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

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

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

33 I 21.10 Contaminated Linens: Contaminated linens shall be afforded appropriate special treatment by the
34 laundry.

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

37 **SECTION 20 – MAINTENANCE**

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

4 **SECTION 21 - INCINERATION**

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

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

12 C. ~~Refuse Incinerators: Refuse incinerators are prohibited.~~

13 **SECTION 22 - PEST CONTROL**

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

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

19 **SECTION 23 22 - WASTE MANAGEMENT STORAGE AND DISPOSAL**

20 A 22.1 ~~Sewage and Sewer Systems:~~ All sewage shall be discharged into a public sewer system.

21 B 22.2 Refuse and Rubbish:

22 4(A) Medical waste shall be disposed of in accordance with the Department's Regulations
23 Pertaining to Solid Waste Sites and Facilities at 6 CCR 1007-2, Part 1, Section 13,
24 Medical Waste. These regulations are incorporated by reference in accordance with
25 Section 1. ~~C 3 of this rule~~ CHAPTER 20.

26 2 (B) All garbage and refuse not treated as sewage shall be collected in ~~approved IMPERVIOUS~~
27 ~~containers with liners in such manner as not to become a nuisance,~~ and shall be
28 removed from the ~~facility CENTER~~ once a day. The ~~facility CENTER~~ shall have a paved
29 outside area for storage of garbage and refuse containers. Refuse incinerators are
30 prohibited.

31 (C) ~~ALL PERSONNEL SHALL WASH THEIR HANDS AFTER HANDLING REFUSE AS SPECIFIED BY THE~~
32 ~~CENTER'S INFECTION AND DISEASE CONTROL POLICIES AND PROCEDURES.~~

33 **SECTION 24 23 - COMPLIANCE WITH FGI GUIDELINES**

34 Effective July 1, 2013, all ambulatory surgical centers shall be constructed in conformity with the
35 standards adopted by the Director of the Division of Fire Prevention and Control (DFPC) at the Colorado
36 Department of Public Safety. For construction initiated or systems installed on or after July 1, 2013, that
37 affect patient health and safety and for which DFPC has no applicable standards, each ~~facility CENTER~~
38 shall conform to the relevant section(s) of the Guidelines for Design and Construction of Health Care
39 Facilities, (2010 Edition), Facilities Guidelines Institute. The Guidelines for Design and Construction of
40 Health Care Facilities, (2010 Edition), Facilities Guidelines Institute (FGI), is hereby incorporated by

1 reference and excludes any later amendments to or editions of the Guidelines. The 2010 FGI Guidelines
2 are available at no cost in a read only version at: [HTTP://FGIGUIDELINES.ORG/DIGITALCOPY.PHP](http://FGIGUIDELINES.ORG/DIGITALCOPY.PHP)
3 http://openpub.realread.com/rserver/browser?title=/FGI/2010_Guidelines

4 **SECTION 25 24 - DEPARTMENT OVERSIGHT LICENSE FEES**

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

6 **24.1 AN APPLICANT FOR AN AMBULATORY SURGICAL CENTER LICENSE SHALL SUBMIT, IN THE FORM AND**
7 **MANNER SPECIFIED BY THE DEPARTMENT, A LICENSE APPLICATION WITH THE CORRESPONDING NON**
8 **REFUNDABLE FEE AS SET FORTH BELOW:**

- 9 4- (A) Initial license: ~~(when such initial licensure is not a change of ownership).~~ A license
10 applicant shall submit with an application for licensure a nonrefundable fee of \$6,600.
- 11 2- (B) Renewal license: A license applicant shall submit with an application for licensure a
12 nonrefundable fee as follows: Base: \$1,440; Per Operating or Procedure Room: \$200.
13 The renewal fee shall not exceed \$3,000.
- 14 3- (C) Change of Ownership: A license applicant shall submit with an application for licensure a
15 nonrefundable fee of \$4,100.
- 16 4- (D) Provisional License: The license applicant may be issued a provisional license upon
17 submittal of a nonrefundable fee of \$2,500. If a provisional license is issued, the
18 provisional license fee shall be in addition to the initial or renewal license fee.
- 19 5- (E) Conditional License: A **facility CENTER** that is issued a conditional license by the
20 Department shall submit a nonrefundable fee ranging from 10 to 25 percent of its
21 applicable renewal fee. The percentage shall be determined by the Department. If the
22 conditional license is issued concurrent with the initial or renewal license, the conditional
23 license fee shall be in addition to the initial or renewal license fee.

24 **SECTION 25 – AMBULATORY SURGICAL CENTER WITH A CONVALESCENT CENTER**

25 **25.1 GENERAL:** IN ADDITION TO COMPLIANCE WITH THE PRECEDING SECTIONS 1 THROUGH 24, AN
26 **AMBULATORY SURGICAL CENTER WITH A CONVALESCENT CENTER SHALL ALSO COMPLY WITH THIS**
27 **SECTION 25 REGARDING THE OPERATION AND MAINTENANCE OF THE CONVALESCENT CENTER.**

28 **25.2 PATIENT TRANSFER:** A LICENSED AMBULATORY SURGICAL CENTER WITH A CONVALESCENT CENTER
29 **SHALL PROVIDE FOR THE PROMPT AND SAFE TRANSFER OF PATIENTS BETWEEN THE AMBULATORY**
30 **SURGICAL CENTER AND THE CONVALESCENT CENTER. EACH PATIENT TRANSFERRED FROM THE**
31 **AMBULATORY SURGICAL CENTER TO THE CONVALESCENT CENTER SHALL HAVE A VISIBLE MEANS OF**
32 **IDENTIFICATION ON HIS OR HER PERSON.**

33 **25.3 PATIENT CARE SERVICES:** THE CONVALESCENT CENTER SHALL HAVE WRITTEN POLICIES AND
34 **PROCEDURES REGARDING THE PROVISION OF DIRECT PATIENT CARE THAT INCLUDES, BUT IS NOT LIMITED**
35 **TO:**

- 36 (A) THE HANDLING OF MEDICAL EMERGENCIES;
- 37 (B) COORDINATION OF CARE ACROSS MULTIPLE DISCIPLINES, AS APPLICABLE;
- 38 (C) INITIAL AND REVISED PATIENT ASSESSMENTS AND CARE PLANS; AND
- 39 (D) DISCHARGE PLANNING.

- 1 **25.4** **DIETARY SERVICES:** THE CONVALESCENT CENTER SHALL PROVIDE FOOD SERVICE TO PATIENTS
2 ADMITTED TO INPATIENT BEDS.
- 3 (A) PERSONS ASSIGNED TO FOOD PREPARATION AND SERVICE SHALL HAVE THE APPROPRIATE
4 TRAINING NECESSARY TO STORE, PREPARE AND SERVE FOOD IN A MANNER THAT PREVENTS
5 FOOD-BORNE ILLNESS
- 6 (B) MEALS SHALL BE PREPARED, STORED AND SERVED IN A MANNER THAT PREVENTS FOOD-BORNE
7 ILLNESS.
- 8 (C) THE FOOD SERVICE AREA SHALL BE AN AREA SEPARATE FROM THE EMPLOYEE LOUNGE OR
9 OTHER AREAS USED BY FACILITY PERSONNEL OR THE PUBLIC.
- 10 (D) ALL FOOD SHALL BE PRE-PACKAGED AND REQUIRE MICROWAVE HEATING ONLY AND DISPOSABLE
11 PRODUCTS FOR PREPARATION AND SERVICE SHALL BE USED UNLESS THE FACILITY DEVELOPS
12 AND IMPLEMENTS POLICIES AND PROCEDURES FOR THE SAFE PREPARATION, STORAGE AND
13 SERVING OF FOODS.
- 14 (E) CATERING AND ALTERNATIVE METHODS OF MEAL PROVISION SHALL BE ALLOWED IF PATIENT
15 NEEDS AND THE INTENT OF THIS PART OF THE REGULATIONS ARE MET.
- 16
- 17 **25.5** **PHARMACEUTICAL SERVICES:** THE CONVALESCENT CENTER SHALL COMPLY WITH THE PHARMACEUTICAL
18 SERVICES REQUIREMENTS SET FORTH IN SECTION 14 OF THIS CHAPTER 20.
- 19 **25.6** **INFECTION CONTROL:** THE CONVALESCENT CENTER SHALL COMPLY WITH THE INFECTION CONTROL
20 REQUIREMENTS SET FORTH IN SECTION 17 OF THIS CHAPTER 20.
- 21
- 22 **25.7** **PATIENT CARE UNIT:** THE CONVALESCENT CENTER SHALL COMPLY WITH THE PATIENT CARE UNIT
23 REQUIREMENTS SET FORTH IN SECTION 18 OF THIS CHAPTER 20
- 24 **25.8** **HOUSEKEEPING AND MAINTENANCE:** THE CONVALESCENT CENTER SHALL COMPLY WITH THE
25 HOUSEKEEPING AND MAINTENANCE REQUIREMENTS SET FORTH IN SECTION 20 OF THIS CHAPTER 20.
- 26 **25.9** **LAUNDRY AND LINENS:** THE CONVALESCENT CENTER SHALL COMPLY WITH THE LAUNDRY AND LINENS
27 REQUIREMENTS SET FORTH IN SECTION 21 OF THIS CHAPTER 20.
- 28 **25.10** **WASTE MANAGEMENT:** THE CONVALESCENT CENTER SHALL COMPLY WITH THE LAUNDRY AND LINENS
29 REQUIREMENTS SET FORTH IN SECTION 22 OF THIS CHAPTER 20.
- 30 **25.11** **CONTRACTED SERVICES:** ALL CONTRACTED SERVICES SHALL BE DOCUMENTED BY A WRITTEN
31 AGREEMENT. THE WRITTEN AGREEMENT SHALL INCLUDE THE NAMES OF THE OWNER OR CORPORATE
32 OFFICERS AUTHORIZED TO SIGN THE AGREEMENT AND THE CENTER SHALL BE ULTIMATELY RESPONSIBLE
33 FOR QUALITY CONTROL OF THE CONTRACTED SERVICES.
- 34 **25.12** **Compliance with FGI Guidelines:** Effective July 1, 2013, all convalescent centers shall be
35 constructed in conformity with the standards adopted by the Director of the Division of Fire
36 Prevention and Control (DFPC) at the Colorado Department of Public Safety. For construction
37 initiated or systems installed on or after July 1, 2013, that affect patient health and safety and for
38 which DFPC has no applicable standards, each facility center shall conform to the relevant
39 section(s) of the Guidelines for Design and Construction of Health Care Facilities, (2010 Edition),
40 Facilities Guidelines Institute. The Guidelines for Design and Construction of Health Care
41 Facilities, (2010 Edition), Facilities Guidelines Institute (FGI), is hereby incorporated by reference
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3 **25.13 LICENSE FEES:** FOR NEW LICENSE APPLICATIONS RECEIVED OR RENEWAL LICENSES THAT EXPIRE ON OR
4 AFTER MARCH 1, 2015, AN APPLICANT FOR AN AMBULATORY SURGICAL CENTER WITH A CONVALESCENT
5 CENTER LICENSE SHALL SUBMIT, IN THE FORM AND MANNER SPECIFIED BY THE DEPARTMENT, A LICENSE
6 APPLICATION WITH THE CORRESPONDING NON REFUNDABLE FEE AS SET FORTH BELOW

7 **(A) INITIAL LICENSE:**

8 (1) AN APPLICANT FOR AN INITIAL AMBULATORY SURGICAL CENTER WITH CONVALESCENT
9 CENTER LICENSE SHALL SUBMIT WITH AN APPLICATION FOR LICENSURE A
10 NONREFUNDABLE FEE OF \$6,960.

11 (2) A CURRENT AMBULATORY SURGICAL CENTER LICENSEE THAT APPLIES TO ADD A
12 CONVALESCENT CENTER TO THE LICENSE PRIOR TO THE EXPIRATION OF THE SURGICAL
13 CENTER LICENSE SHALL SUBMIT AN APPLICATION FOR INITIAL LICENSURE OF THE
14 CONVALESCENT CENTER ALONG WITH A NONREFUNDABLE FEE OF \$360. UPON
15 EXPIRATION OF THE EXISTING SURGICAL CENTER LICENSE TERM, THE LICENSEE SHALL
16 FOLLOW THE PROCEDURE SET FORTH BELOW FOR A RENEWAL LICENSE.

17 **(B) RENEWAL LICENSE:** A LICENSE APPLICANT SHALL SUBMIT WITH AN APPLICATION FOR LICENSURE
18 A NONREFUNDABLE FEE AS FOLLOWS: BASE: \$1,800; PER OPERATING OR PROCEDURE ROOM:
19 \$200. THE RENEWAL FEE SHALL NOT EXCEED \$3,360.

20 **(C) CHANGE OF OWNERSHIP:** A LICENSE APPLICANT SHALL SUBMIT WITH AN APPLICATION FOR
21 LICENSURE A NONREFUNDABLE FEE OF \$4,460.

22 **(D) PROVISIONAL LICENSE:** THE LICENSE APPLICANT MAY BE ISSUED A PROVISIONAL LICENSE UPON
23 SUBMITTAL OF A NONREFUNDABLE FEE OF \$2,860. IF A PROVISIONAL LICENSE IS ISSUED, THE
24 PROVISIONAL LICENSE FEE SHALL BE IN ADDITION TO THE INITIAL OR RENEWAL LICENSE FEE.

25 **(E) CONDITIONAL LICENSE:** A CENTER THAT IS ISSUED A CONDITIONAL LICENSE BY THE
26 DEPARTMENT SHALL SUBMIT A NONREFUNDABLE FEE RANGING FROM 10 TO 25 PERCENT OF ITS
27 APPLICABLE RENEWAL FEE. THE PERCENTAGE SHALL BE DETERMINED BY THE DEPARTMENT. IF
28 THE CONDITIONAL LICENSE IS ISSUED CONCURRENT WITH THE INITIAL OR RENEWAL LICENSE, THE
29 CONDITIONAL LICENSE FEE SHALL BE IN ADDITION TO THE INITIAL OR RENEWAL LICENSE FEE.

30 * * * * *

31 **DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT**

32 **Health Facilities and Emergency Medical Services Division**

33 **STANDARDS FOR HOSPITALS AND HEALTH FACILITIES: CHAPTER 11 - CONVALESCENT**
34 **CENTERS - REPEALED**

35 **6 CCR 1011-1 Chap 11**

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39
40
41 These chapters of regulation incorporate by reference (as indicated within) material originally published
42 elsewhere. Such incorporation, however, excludes later amendments to or editions of the referenced
43 material. Pursuant to 24-4-103 (12.5), C.R.S., the Health Facilities Division of the Colorado Department of
44 Public Health and Environment maintains copies of the incorporated texts in their entirety which shall be
45 available for public inspection during regular business hours at:
46 Division Director

1 Colorado Department of Public Health and Environment
2 Health Facilities Division
3 4300 Cherry Creek Drive South
4 Denver, Colorado 80222-1530
5 Main switchboard: (303) 692-2800

6 Certified copies of material shall be provided by the division, at cost, upon request. Additionally, any
7 material that has been incorporated by reference after July 1, 1994 may be examined in any state
8 publications depository library. Copies of the incorporated materials have been sent to the state
9 publications depository and distribution center, and are available for interlibrary loan.

11 DEFINITIONS

12 Convalescent Center — Convalescent center means a health facility planned, organized, operated, and
13 maintained to offer facilities and services to inpatients requiring restorative care and treatment, and that is
14 either an integral patient care unit of a general hospital or a facility physically separated from, but
15 maintaining an affiliation with, all services in a general hospital.

16 Convalescence is considered to be period of recovery after injury or illness, either mental or physical,
17 and/or following excessive strain on psychological process which produce exhaustion or fatigue. It is a
18 gradual process which may be interrupted by relapses or for necessary therapy. In some cases the
19 recovery may be only partial, but in any event, important mental and physical improvements in the
20 patient, regardless of the injury or disease, is required criterion of convalescence. Thus a license for a
21 Convalescence Center will be used only when a facility demonstrates that their services and condition of
22 patients are such that there is some promise of full or partial recovery to a former state of well-being and
23 that the facility has arrangements and programs to promote this return. Code of Colorado Regulations 2

25 1.1 LICENSE

26 All Convalescent Centers shall be licensed in accordance with the requirements specified in Chapter II.

28 1.2 APPLICABILITY OF OTHER SECTIONS.

29 Convalescent Centers shall conform to all applicable sections of Chapter IV, General Hospital, with
30 regard to area and operational requirements, environmental sanitation, physical plant maintenance,
31 safety, food service, and patient care units and services.

33 1.3 FACILITIES AND SERVICES

34 The facilities and services shall include provision for prompt transfer of patients between the General
35 Hospital and the Convalescent Center, utilization of the General Hospital's diagnostic and treatment
36 facilities, and sharing of knowledge and skills between personnel in the General Hospital and
37 Convalescent Center.

39 1.4 INTEGRATION WITH GENERAL HOSPITAL

40 When the Convalescent Center and the General Hospital have separate and distinct governing boards or
41 authorities, an integrated affiliation shall be established by written agreement.

42 1.5 WRITTEN AGREEMENT

43 The written agreement shall include names of the owner or corporate officers authorized to sign the
44 agreement, and accurate, clear statements which reflect that the operations provide: 1) Continuity and
45 evaluation of patient care; 2) Emergency care of patients; 3) Administrative and medical staff organization
46 and integration; 4) Review and appraisal of the quality and appropriateness of medical care including the
47 frequency with which patients are to be seen by their physicians; and 5) Procedural policies.

49 1.6 COMPLIANCE WITH FGI GUIDELINES

50 Effective July 1, 2013, all convalescent centers shall be constructed in conformity with the standards
51 adopted by the Director of the Division of Fire Prevention and Control (DFPC) at the Colorado
52 Department of Public Safety. For construction initiated or systems installed on or after July 1, 2013, that
53 affect patient health and safety and for which DFPC has no applicable standards, each facility shall
54 conform to the relevant section(s) of the Guidelines for Design and Construction of Health Care Facilities,
55 (2010 Edition), Facilities Guidelines Institute. The Guidelines for Design and Construction of Health Care
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