COLORADO
Department of Public Health & Environment

Dedicated to protecting and improving the health and environment of the people of Colorado

To: Members of the State Board of Health

From: Laurie Schoder, Policy Analyst, Health Facilities and Emergency Medical Services Division

Through: D. Randy Kuykendall, MLS; Director *DRK*

Date: October 15, 2014

Subject: Proposed Amendments to 6 CCR 1011-1, Standards for Hospitals and Health Facilities, Chapter 20, Ambulatory Surgical Center, with a Request for the Rulemaking Hearing to occur on December 17, 2014

The Division is proposing amendments to Chapter 20, Ambulatory Surgical Center, in order to reflect current industry and Department standards, re-arrange the current rules into a more concise format and differentiate between centers that perform surgery under general anesthesia and centers that perform diagnostic procedures under mild sedation. In addition, the Division's proposed amendments include up-dated standards of care for the operation of convalescent centers, in anticipation of the repeal of 6 CCR 1011-1, Chapter 11, Convalescent Centers.

There are currently 11 licensed convalescent centers in Colorado. Each center has a patient capacity that ranges from 3 to 10 beds, for a total of 58 licensed convalescent center beds in the state. Each of these convalescent centers is operated in conjunction with an ambulatory surgery center. Therefore, the Division is proposing amending Chapter 20, Ambulatory Surgery Centers, to allow for the licensing of a convalescent center only in conjunction with an ambulatory surgical center license.

The Division has been meeting with stakeholders from currently licensed ambulatory surgical centers and convalescent centers, as well as representatives of the Colorado Hospital Association and all have agreed that the Department's proposal is an appropriate course of action. Although stakeholders have agreed on the general concepts contained in this proposal, the Division anticipates that there will be changes to the specific wording or formatting of this proposal prior to submission of the final rule-making packet for the requested December hearing.

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY

For Amendments to 6 CCR 1011-1, Standards for Hospitals and Health Facilities,
Chapter 20, Ambulatory Surgical Center
October 15, 2014

Basis and Purpose:

The amendments are proposed in order to reflect current industry and Department standards, re-arrange the current rules into a more concise format and differentiate between ambulatory surgical centers that perform surgery under general anesthesia and centers that perform diagnostic procedures under mild sedation. In addition, the Division's proposed amendments include up-dated standards of care for the operation of convalescent centers, in anticipation of the repeal of 6 CCR 1011-1, Chapter 11, Convalescent Centers.

These rules are promulgated pursuant to the following statutes:

Section 25-1.5-103, C.R.S. (2014).
Section 25-3-101,*et seq.*, C.R.S. (2014).

SUPPLEMENTAL QUESTIONS

Is this rulemaking due to a change in state statute?

_____ Yes
__X__ No

Is this rulemaking due to a federal statutory or regulatory change?

_____ Yes
__X__ No

Does this rule incorporate materials by reference?

__X__ Yes
_____ No

Does this rule create or modify fines or fees?

_____ Yes
__X__ No

REGULATORY ANALYSIS

For Amendments to 6 CCR 1011-1, Standards for Hospitals and Health Facilities,
Chapter 20, Ambulatory Surgical Center
October 15, 2014

1. A description of the classes of persons who will be affected by the rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the rule.

The classes of persons affected by the amendments will be the owners and operators of convalescent care centers, ambulatory surgical centers and their patients. The cost of the amendments will be borne by the convalescent centers and the ambulatory surgical centers. The affected health care entities, their patients and the Department will all benefit from amending this regulation to reflect current industry standards, streamline regulation and clarify Department expectations.

2. To the extent practicable, a description of the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected class of persons.

Because the rule does not reflect current standards of practice or current Department expectations, the proposed amendments should have a beneficial quantitative and qualitative impact on all affected parties.

3. The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

The Department anticipates only minimal costs associated with implementation and enforcement of the rule, primarily associated with revising existing paperwork and computerized numbering.

4. A comparison of the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.

Inaction would result in the continuation of out-dated and duplicative standards for ambulatory surgical centers, which could result in confusion and frustration for both patients and ambulatory surgical center staff. Amendment of this rule with the incorporation of new standards for convalescent centers will benefit the industry and public alike because they will have a clear understanding of the licensing requirements for both ambulatory surgical centers and convalescent centers.

5. A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

The Department has determined that there are no less costly or less intrusive methods for achieving the purpose of the proposed rule.

6. A description of any alternative methods for achieving the purpose of the proposed rule that were seriously considered by the agency and the reasons why they were rejected in favor of the proposed rule.

The Department determined that there are no alternative methods for achieving the purpose of the proposed rule. Neither Departmental policies nor guidance would have the desired effect of amending the rules to reflect updated industry standards, consolidating or eliminating duplicative requirements and maintaining licensing standards for convalescent centers.

7. To the extent practicable, a quantification of the data used in the analysis; the analysis must take into account both short-term and long-term consequences.

The Department analyzed the type and number of health care entities affected by these amendments, as well as the number of in-patient beds involved. There are approximately 110 currently licensed ambulatory surgical centers and 11 licensed convalescent centers in Colorado. Each of these convalescent centers is already operated in conjunction with an ambulatory surgery center. Amendment of the ambulatory surgical standards to reflect current industry standards and Department expectations, along with incorporation of standards and licensing for convalescent centers makes sense in both the short term and long term.

STAKEHOLDER Comment

For Amendments to 6 CCR 1011-1, Standards for Hospitals and Health Facilities, Chapter 11, Convalescent Centers

The following individuals and/or entities were included in the development of these proposed rules: The Colorado Ambulatory Surgical Center Association, the Colorado Hospital Association, and representatives from currently licensed ambulatory surgical centers and convalescent centers.

The following individuals and/or entities will be notified of this proposed rule-making by the Board of Health on or before the date of publication of the notice in the Colorado Register: All currently licensed ambulatory surgical centers and convalescent care centers. The Division will send notice to persons and/or groups considered by the division to be interested parties to the proposed rule-making, and those who have requested notification/information from the division regarding the proposed rule-making? _X_Yes ____ No.

Summarize Major Factual and Policy Issues Encountered and the Stakeholder Feedback Received. If there is a lack of consensus regarding the proposed rule, please also identify the Department's efforts to address stakeholder feedback or why the Department was unable to accommodate the request. Thus far there have been no major factual or policy issues that the Division and stakeholders have been unable to resolve. All parties involved in the rule-making process thus far have agreed regarding the revisions to this Chapter; however, the Division is continuing to engage stakeholders and is amenable to making changes if needed.

Please identify health equity and environmental justice (HEEJ) impacts. Does this proposal impact Coloradoans equally or equitably? Does this proposal provide an opportunity to advance HEEJ? Are there other factors that influenced these rules?

The Division is unaware of any health equity or environmental justice impacts.

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

STANDARDS FOR HOSPITALS AND HEALTH FACILITIES

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

6 CCR 1011-1 Chap 20

SECTION 1 - STATUTORY AUTHORITY AND APPLICABILITY

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

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

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

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

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

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

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

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

Division Director
Health Facilities and Emergency Medical Services Division
Colorado Department of Public Health and Environment
4300 Cherry Creek Drive South
Denver, CO 80246
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 AN INDIVIDUAL WHO IS DESIGNATED BY THE GOVERNING AUTHORITY 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 PREVENTATIVE 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."

~~1~~(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,

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

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

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

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

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

~~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.~~

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

~~B~~2.3 "CONVALESCENT CENTER" MEANS A SEPARATE AND DISTINCT COMPONENT OF A LICENSED AMBULATORY SURGICAL CENTER THAT PROVIDES POST SURGICAL, POST PROCEDURAL AND/OR POST DIAGNOSTIC MEDICAL AND NURSING SERVICES TO PATIENTS FOR WHOM AN UNCOMPLICATED RECOVERY IS ANTICIPATED AND FOR WHOM ACUTE HOSPITALIZATION IS NOT REQUIRED. A CONVALESCENT CARE CENTER SHALL BE LICENSED AND OPERATED ONLY IN CONJUNCTION WITH A LICENSED AMBULATORY SURGICAL CENTER.

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

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

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

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

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

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

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

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

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

(B) CLASS A OR B CENTER – A CLASS A OR B CENTER SHALL HAVE A DEDICATED PROCEDURE ROOM(S) WITH THE CAPACITY TO PROVIDE OXYGEN AND PATIENT MONITORING IN A CLEAN ENVIRONMENT THAT SUPPORTS INFECTION CONTROL. THE PROCEDURE ROOM(S) SHALL ONLY BE USED FOR ENDOSCOPIC OR INTERVENTIONAL PROCEDURES OR NON-INVASIVE EXAMINATIONS/TREATMENTS UNLESS FIRST TERMINALLY CLEANED. LOW-RISK VERSUS HIGH-RISK EXPOSURE AREAS SHALL BE IDENTIFIED, ALONG WITH THE ATTIRE AND PERSONAL PROTECTIVE EQUIPMENT NECESSARY FOR EACH AREA. THIS CLASSIFICATION OF PROCEDURE ROOM IS EQUIVALENT TO CLASS A OR B OPERATING ROOMS AS DESCRIBED IN THE GUIDELINES FOR DESIGN AND CONSTRUCTION OF HEALTH CARE FACILITIES, (2010 EDITION), FACILITIES GUIDELINES INSTITUTE, WHICH IS INCORPORATED BY REFERENCE.

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

SECTION ~~3~~ 4 - GOVERNING BODY

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

~~B.~~4.2 Duties: The Governing Body shall:

~~1~~(A) adopt by-laws in accordance with ~~APPLICABLE~~ APPLICABLE legal requirements;

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

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

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

(E) MAINTAIN AN UP-TO-DATE ROSTER OF PROVIDERS CREDENTIALED BY THE CENTER THAT SPECIFIES THE APPROVED SURGICAL PRIVILEGES OF EACH PROVIDER. THE ROSTER SHALL BE AVAILABLE TO THE NURSING STAFF AT ALL TIMES;

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

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

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

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

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

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

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

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

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

SECTION 45- ADMINISTRATOR

~~A.~~ 5.1 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.~~ 5.2 Duties: The administrator shall be responsible for the development, implementation and administration of ~~surgical~~ center policies and procedures for employee and ~~provider~~ MEDICAL staff use. All policies and procedures shall be reviewed and approved by the governing body and/or updated as necessary but at least annually. THE ADMINISTRATOR SHALL DESIGNATE A QUALIFIED INDIVIDUAL TO ACT FOR HIM OR HER WHEN ABSENT SO THAT THE AMBULATORY SURGICAL CENTER HAS ADMINISTRATIVE DIRECTOR AT ALL TIMES.

SECTION ~~5~~6 - ~~PROVIDER~~ MEDICAL STAFF

~~A.~~ 6.1 Organization: The ambulatory surgical center shall have an organized ~~provider~~ MEDICAL 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.~~ 6.2 Duties: The ~~provider~~ MEDICAL staff or a delegated committee composed of members of the ~~provider~~ MEDICAL staff shall:

~~1~~(A) be responsible for the quality of all medical care provided patients in the ~~facility~~ CENTER;

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

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

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

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

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

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

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

SECTION ~~6~~7- ~~MEDICAL RECORDS~~ HEALTH INFORMATION MANAGEMENT

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

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

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

(2) PROVIDE FOR CONFIDENTIALITY, INTEGRITY AND SECURITY;

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

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

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

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

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

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

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

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

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

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

~~1~~(A) Medical records of minors shall be preserved for the period of minority plus ten (10) years (i.e., 28 years less age of minor at time of most recent patient care usage of the medical record).

~~2~~(B) ~~Facilities~~ CENTERS shall establish procedures for notification to patients whose records are to be destroyed prior to the destruction of such records.

~~3~~(C) ~~The~~ CENTERS SHALL BE SOLELY RESPONSIBLE ~~responsibility~~ for the destruction of all medical records. ~~shall be in the facilityinvolved but in no case shall records be destroyed prior to consultation with legal counsel;~~

~~4~~(D) Actual x-ray films, scans, and other imaging records shall be maintained by the ~~facility~~ CENTER for a period of five (5) years, if services are provided directly.

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

~~1~~(A) complete patient identification and a unique identification number;

~~2~~(B) admission and discharge dates;

~~3~~(C) chief complaint and admission diagnosis;

~~4~~(D) medical history and physical examination completed prior to surgery;

~~5~~(E) diagnostic tests, laboratory, x-ray, scans, and other radiological imaging reports and consultative findings when appropriate;

~~6~~(F) physician progress notes if appropriate;

~~7~~(G) properly executed informed consent;

~~8~~(H) a pre-anesthesia examination by a physician prior to surgery, a proper anesthesia record and a post-anesthesia evaluation;

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

~~10~~(J) a pathology report of tissue removed during surgery in accordance with ~~facility~~ CENTER policies;

~~11~~(K) all medication and treatment orders in writing and signed by the authorizing party. Telephone and verbal orders are designated as such, signed and dated by a legally designated person, and countersigned by the attending provider within a clearly designated time period established by the governing body; and

~~12~~(L) patient's condition on discharge, final diagnosis, and instructions given patient for follow-up care.

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

~~1~~(A) MAINTAIN a register of all ~~surgical operations~~ PROCEDURES performed BY PRACTITIONER (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~~(B) MAINTAIN A master patient index file.

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

(1) THE NUMBER OF VISITS,

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

(3) THE TYPES AND NUMBER OF PROCEDURES PERFORMED,

(4) THE AGE DISTRIBUTION OF PATIENTS,

(5) ALL COMPLICATIONS AND EMERGENCIES, AND

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

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

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

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

SECTION ~~7~~8- PERSONNEL

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

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

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

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

~~E.~~ 8.4 ~~In-service~~EDUCATION: ~~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.~~ ALL PERSONNEL SHALL RECEIVE AT LEAST 12 HOURS OF CONTINUING EDUCATION ANNUALLY, WHICH MUST INCLUDE, BUT NOT BE LIMITED TO, INFECTION CONTROL; FIRE, SAFETY AND EMERGENCY PROCEDURES.

~~F.~~ 8.5 Disease: Any personnel with communicable disease as defined by the Department shall return to work only after complying with the ~~facility's~~ CENTER'S infection control policy.

~~G.~~ 8.6 Records: Personnel records shall be maintained for each person employed in the ~~facility~~ CENTER and shall include, at a minimum, the following RECORDS:

~~1~~(A) an employment application THAT CONTAINS INFORMATION REGARDING EDUCATION, EXPERIENCE AND, IF APPLICABLE, REGISTRATION AND/OR LICENSURE INFORMATION FOR THE APPLICANT;

~~2~~(B) verification of references and/or credentials as required;

~~3~~(C) incident and/or accident reports;

(D) AN ADEQUATE PLAN FOR THE CONTINUOUS EVALUATION OF NURSING CARE, ALONG WITH A PLAN TO PERIODICALLY EVALUATE THE ADEQUACY OF THE CENTER TO MEET THE NEEDS OF ITS PATIENTS AND THE NECESSITY FOR IMPROVEMENT OR REVISION OF THE CENTER OR ITS SERVICES;

~~4~~(E) results of medical examinations required as a part of employment within the ~~facility~~ CENTER.

~~5~~(F) BACKGROUND CHECKS THAT, AT A MINIMUM, INCLUDE CHECKING THE DEPARTMENT OF REGULATORY AGENCIES WEBSITE TO ENSURE THAT AN ACTIVE LICENSE IN GOOD STANDING EXISTS. ANY ADMONISHMENTS OR ENFORCEMENT ACTIONS SHALL BE REVIEWED BY THE ADMINISTRATOR PRIOR TO HIRE; AND

~~6~~(G) DOCUMENTATION OF CONTINUING EDUCATION.

SECTION ~~8~~9 - ADMISSIONS

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

~~B~~ 9.2 Restrictions:

~~1~~(A) Surgical procedures shall be limited to the following:

~~a~~ (1) those in which the EXPECTED combined operating and recovery time does not exceed 24 hours from the time of admission; and

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

~~2~~(B) There shall be no pre-planned off-site transfers to a higher level of care and no transfers shall occur solely for the convenience of the ~~A~~AMBULATORY ~~S~~SURGICAL ~~C~~CENTER or its staff.

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

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

~~1~~ (A) The physicians performing the procedure shall document in writing that the patient is in good health or that any pre-existing health conditions are adequately controlled, require no special management and are such that performance of the procedure in ~~an ASC~~ A CENTER, rather than AN INPATIENT hospital setting, does not pose an increased risk to the patient.

~~2~~ (B) The patient or a responsible person acting on behalf of the patient must be able to strictly follow instructions related to ingestion of fluids or solids within the specified time frame prior to the surgery.

~~3~~ (C) If the patient is to receive sedation or anesthetic which will result in impaired mental status following surgery, the patient must be accompanied upon discharge by a responsible adult, unless exempted in writing by the attending physician.

~~4~~ (D) Patients who may require post-operative ventilation following surgery, either because of the procedure to be performed or because of a pre-existing condition, shall not be admitted for surgery.

~~5~~ (E) Surgery which requires the presence of special equipment, personnel, and/or facilities due to the risk of the operation involved shall not be performed in the center unless such equipment, personnel, and/or facilities are available in the ambulatory surgical center.

~~6~~ (F) 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.~~

9.5 DISCHARGE: PATIENTS SHALL BE IN A STABLE CONDITION WHICH WILL NOT ENDANGER THEIR CONTINUED WELL-BEING OR SHALL BE TRANSFERRED TO A LICENSED HOSPITAL, CONVALESCENT CENTER OR OTHER TREATMENT FACILITY. THERE SHALL BE WRITTEN PROCEDURES AND ASSIGNED RESPONSIBILITIES FOR IMPLEMENTING SUCH PROCEDURES, INCLUDING PROVISIONS FOR TRANSPORTATION. THE CENTER SHALL PROVIDE VERBAL AND WRITTEN PATIENT INSTRUCTIONS IN REGARD TO POST-OPERATIVE CARE, PHYSICIAN POST-OPERATIVE APPOINTMENT, AND PHYSICIAN CONTACT INFORMATION.

~~E~~ 9.6 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~~ (A) DISCLOSURE. Facilities offering surgical services which include an off-site pre-planned transfer to another licensed facility following post-operative recovery shall disclose in written form to the patient all the details of the transfer prior to admission to the facility. Disclosure includes, but is not limited to, the cost of the transfer, whether or not such costs shall be covered by insurance or other third party payer, and the details of the actual transfer, including, but not limited to, the mode of transport. Disclosure shall be made to the patient prior to the time for admission to the facility. The patient shall acknowledge such disclosure in writing, and the date thereof. Such disclosures on ~~facility~~

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

~~2~~ (B) Off-site pre-planned transfers shall be made only to other licensed facilities that can provide the level of care necessary to meet the needs of the patient. The 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.~~ (1) An ambulatory surgical center shall allow preplanned transfers only with the written consent of the patient and the written authorization of the attending or operating surgeon or physician. The attending or operating surgeon or physician shall approve such a transfer if there are assurances that the continuity of care for the patient shall be maintained and contact with the patient's attending physician is continuous.

~~3~~ (C) 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~~ MEDICAL staff from the ambulatory surgical center shall accompany the patient on the ambulance to provide continuity of care and a level of care that meets the peri-operative needs of the patient.

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

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

~~1~~ (A) The provisions of paragraph ~~(E)(1) and (2)~~ 8.6(A) and (B) shall apply to on-site pre-planned transfers. The provisions of paragraph ~~(E)(3),(4),and (5)~~ 8.6(C) and (D) shall not apply to on-site pre-planned transfers.

SECTION ~~9~~10 - LABORATORY AND RADIOLOGY

~~A~~ 10.1 Services: Clinical laboratory services shall be available as required by the needs of the patients as determined by the ~~provider~~ MEDICAL 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~~ 10.2 RADIOLOGICAL~~Y~~ SERVICES: Radiological services shall be provided as required by the needs of the patients as determined by the ~~provider~~ MEDICAL staff. Whether provided on-site or by contract, the radiological services shall meet Colorado rules and regulations pertaining to "Radiation Control," 6 CCR 1007-1.

~~1~~ (A) THE RADIOLOGICAL SERVICE SHALL BE DIRECTED BY A LICENSED RADIOLOGIST AND STAFFED BY QUALIFIED TECHNICAL PERSONNEL.

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

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

SECTION ~~10~~11 - ANESTHESIA

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

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

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

SECTION ~~11~~12 - EMERGENCY SERVICES

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

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

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

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

~~E~~ 12.5 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.

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

SECTION ~~12~~13 - NURSING SERVICES

~~A~~ 13.1 Nursing Administration : The ~~facility~~ CENTER 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 QUALIFIED BY EDUCATION AND EXPERIENCE TO BE responsible for oversight of all nursing services.

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

~~1~~ (A) delivery of appropriate nursing services to patients;

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

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

~~4~~ (D) establishment of a means of adequately assessing and planning the nursing care needs of patients and staffing to meet those needs; and

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

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

~~1~~ (A) at least one registered nurse shall be in the ~~facility~~ CENTER at all times whenEVER a patient is ~~in the facility~~ PRESENT;

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

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

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

~~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.~~

13.6 STAFFING: THE CENTER SHALL HAVE NURSING STAFF IN SUFFICIENT NUMBERS TO ENSURE THAT THE FOLLOWING SERVICES ARE PROVIDED:

(A) A REGISTERED NURSE, QUALIFIED BY EDUCATION AND EXPERIENCE SHALL BE PRESENT IN EACH OPERATING ROOM DURING OPERATIVE PROCEDURES. THIS NURSE'S DUTIES ARE PERFORMED OUTSIDE THE STERILE FIELD. THIS NURSE IS RESPONSIBLE FOR MANAGING ALL NURSING CARE

WITHIN THE OPERATING ROOM, OBSERVING THE SURGICAL TEAM FROM A BROAD PERSPECTIVE, AND ASSISTING THE TEAM AS NECESSARY.

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

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

SECTION ~~13~~14- PHARMACEUTICAL SERVICES

~~A~~ 14.1 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.

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

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

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

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

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

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

SECTION ~~14~~15 – SURGICAL AND PROCEDURAL 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.~~

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

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

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

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

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

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

(1) PATIENT IDENTITY USING TWO PATIENT IDENTIFIERS;

(2) TYPE OF PROCEDURE;

(3) IDENTIFICATION OF CORRECT SITE OR SIDE.

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

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

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

~~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~~ 15.6 ~~Janitors~~ ENVIRONMENTAL SERVICES Room: A separate ~~janitors'~~ room or equivalent SPACE shall be provided exclusively for the surgical and/or procedure rooms. It shall be equipped with shelves for supplies, mop clip boards, and a wall or floor-mounted mop sink. A hand-washing sink with soap and sanitary 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~~16 – ~~POST ANESTHESIA RECOVERY ROOM~~ PRE- AND POST-PROCEDURE AREAS

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

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

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

~~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.~~

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

(A) DIRECT VISUAL OBSERVATION OF ALL PATIENTS,

(B) MEDICATION ADMINISTRATION,

(C) CHARTING,

(D) TOILETING AND HAND WASHING,

(E) SUPPLY AND EQUIPMENT STORAGE,

(F) ADMINISTRATION OF OXYGEN, SUCTION AND RESUSCITATION; AND

(G) EMERGENCY CALL SYSTEM.

~~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 17 - INFECTION AND DISEASE CONTROL

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

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

(A) THE ADMISSION OF PATIENTS WITH SPECIFIC INFECTIOUS DISEASES;

(B) ANNUAL REVIEW OF CLINIC POLICIES AND PROCEDURES TO ENSURE COMPLIANCE WITH THE GOVERNING BOARD'S CHOSEN NATIONAL STANDARD FOR INFECTION CONTROL, AND ANY SPECIFIC RECOMMENDATIONS FROM LOCAL OR STATE PUBLIC HEALTH AGENCIES.

(C) ORIENTATION AND CONTINUING EDUCATION OF PERSONNEL ON THE CONTROL OF NOSOCOMIAL AND INFECTIOUS DISEASES, INCLUDING UNIVERSAL PRECAUTIONS;

(D) THE REPORTING OF COMMUNICABLE DISEASES AS REQUIRED BY APPLICABLE STATE AND FEDERAL LAWS AND REGULATIONS;

(E) CLEANING AND/OR DISINFECTION OF THE CENTER AND EQUIPMENT; AND

(F) EFFECTIVE CONTROL AND ERADICATION OF INSECTS AND RODENTS.

SECTION ~~16~~18 - PATIENT CARE UNIT

~~A~~ 18.1 An ambulatory surgical center shall maintain a distinct patient care area if the ambulatory surgical center provides surgical services for persons needing longer periods of care and/or observation beyond the recovery period and prior to discharge, 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~~ 18.2 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~~ 18.3 Each patient room shall contain at least one, appropriately sized patient bed equipped with a mattress protected by waterproof material and a pillow.

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

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

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

SECTION ~~17~~ 19 – EQUIPMENT AND SUPPLIES

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

(A) MONITORING EQUIPMENT, SUCTION APPARATUS, OXYGEN AND RELATED ITEMS SHALL BE AVAILABLE WITHIN THE SURGICAL/PROCEDURE AREAS AND RECOVERY AREAS.

(1) CENTERS THAT CONDUCT SURGERY OR PROCEDURES USING GENERAL ANESTHESIA SHALL HAVE CARDIAC PULMONARY RESUSCITATION EQUIPMENT.

(2) CENTERS THAT DO NOT USE GENERAL ANESTHESIA SHALL HAVE AT LEAST ONE AUTOMATED EXTERNAL DEFIBRILLATOR (AED).

(B) Sterilizing equipment of appropriate type shall be available and of sufficient capacity to adequately sterilize instruments and operating room materials as well as laboratory equipment and supplies. The sterilizing equipment shall have an approved recording

thermometer and safety features. The accuracy of such instrumentation and equipment shall be checked and calibrated periodically, preventive maintenance shall be provided as necessary and a log maintained.

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

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

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

~~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~~120 - HOUSEKEEPING ~~SERVICES~~ AND MAINTENANCE

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

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

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

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

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

~~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~~21 - LAUNDRY AND LINENS

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

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

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

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

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

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

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

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

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

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

~~J~~ 21.11 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 CENTER 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~~ 22 - WASTE MANAGEMENT ~~STORAGE AND DISPOSAL~~

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

~~B~~ 22.2 Refuse and Rubbish:

~~1~~(A) 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~~ 3 of this ~~rule~~ CHAPTER 20.

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

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

SECTION ~~24~~ 23 - COMPLIANCE WITH FGI GUIDELINES

Effective July 1, 2013, all ambulatory surgical centers shall be constructed in conformity with the standards adopted by the Director of the Division of Fire Prevention and Control (DFPC) at the Colorado Department of Public Safety. For construction initiated or systems installed on or after July 1, 2013, that affect patient health and safety and for which DFPC has no applicable standards, each ~~facility~~ CENTER shall conform to the relevant section(s) of the Guidelines for Design and Construction of Health Care Facilities, (2010 Edition), Facilities Guidelines Institute. The Guidelines for Design and Construction of Health Care Facilities, (2010 Edition), Facilities Guidelines Institute (FGI), is hereby incorporated by reference and excludes any later amendments to or editions of the Guidelines. The 2010 FGI Guidelines are available at no cost in a read only version at: http://fgiguidelines.org/digitalcopy.php ~~http://openpub.realread.com/rrserver/browser?title=/FGI/2010_Guidelines~~

SECTION ~~25~~ 24 - ~~DEPARTMENT OVERSIGHT~~ LICENSE FEES

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

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

~~1.~~ (A) 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.~~ (B) 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.~~ (C) Change of Ownership: A license applicant shall submit with an application for licensure a nonrefundable fee of $4,100.

~~4.~~ (D) Provisional License: The license applicant may be issued a provisional license upon submittal of a nonrefundable fee of $2,500. If a provisional license is issued, the provisional license fee shall be in addition to the initial or renewal license fee.

~~5.~~ (E) Conditional License: A ~~facility~~ CENTER that is issued a conditional license by the Department shall submit a nonrefundable fee ranging from 10 to 25 percent of its applicable renewal fee. The percentage shall be determined by the Department. If the conditional license is issued concurrent with the initial or renewal license, the conditional license fee shall be in addition to the initial or renewal license fee.

SECTION 25 – AMBULATORY SURGICAL CENTER WITH A CONVALESCENT CENTER

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

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

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

(A) THE HANDLING OF MEDICAL EMERGENCIES;

(B) COORDINATION OF CARE ACROSS MULTIPLE DISCIPLINES, AS APPLICABLE;

(C) INITIAL AND REVISED PATIENT ASSESSMENTS AND CARE PLANS; AND

(D) DISCHARGE PLANNING.

25.4 DIETARY SERVICES: THE CONVALESCENT CENTER SHALL PROVIDE FOOD SERVICE TO PATIENTS ADMITTED TO INPATIENT BEDS.

(A) PERSONS ASSIGNED TO FOOD PREPARATION AND SERVICE SHALL HAVE THE APPROPRIATE TRAINING NECESSARY TO STORE, PREPARE AND SERVE FOOD IN A MANNER THAT PREVENTS FOOD-BORNE ILLNESS

(B) MEALS SHALL BE PREPARED, STORED AND SERVED IN A MANNER THAT PREVENTS FOOD-BORNE ILLNESS.

(C) THE FOOD SERVICE AREA SHALL BE AN AREA SEPARATE FROM THE EMPLOYEE LOUNGE OR OTHER AREAS USED BY FACILITY PERSONNEL OR THE PUBLIC

(D) ALL FOOD SHALL BE PRE-PACKAGED AND REQUIRE MICROWAVE HEATING ONLY AND DISPOSABLE PRODUCTS FOR PREPARATION AND SERVICE SHALL BE USED UNLESS THE FACILITY DEVELOPS AND IMPLEMENTS POLICIES AND PROCEDURES FOR THE SAFE PREPARATION, STORAGE AND SERVING OF FOODS.

(E) CATERING AND ALTERNATIVE METHODS OF MEAL PROVISION SHALL BE ALLOWED IF PATIENT NEEDS AND THE INTENT OF THIS PART OF THE REGULATIONS ARE MET.

25.5 PHARMACEUTICAL SERVICES: THE CONVALESCENT CENTER SHALL COMPLY WITH THE PHARMACEUTICAL SERVICES REQUIREMENTS SET FORTH IN SECTION 14 OF THIS CHAPTER 20.

25.6 INFECTION CONTROL: THE CONVALESCENT CENTER SHALL COMPLY WITH THE INFECTION CONTROL REQUIREMENTS SET FORTH IN SECTION 17 OF THIS CHAPTER 20.

25.7 PATIENT CARE UNIT: THE CONVALESCENT CENTER SHALL COMPLY WITH THE PATIENT CARE UNIT REQUIREMENTS SET FORTH IN SECTION 18 OF THIS CHAPTER 20

25.8 HOUSEKEEPING AND MAINTENANCE: THE CONVALESCENT CENTER SHALL COMPLY WITH THE HOUSEKEEPING AND MAINTENANCE REQUIREMENTS SET FORTH IN SECTION 20 OF THIS CHAPTER 20.

25.9 LAUNDRY AND LINENS: THE CONVALESCENT CENTER SHALL COMPLY WITH THE LAUNDRY AND LINENS REQUIREMENTS SET FORTH IN SECTION 21 OF THIS CHAPTER 20.

25.10 WASTE MANAGEMENT: THE CONVALESCENT CENTER SHALL COMPLY WITH THE LAUNDRY AND LINENS REQUIREMENTS SET FORTH IN SECTION 22 OF THIS CHAPTER 20.

25.11 CONTRACTED SERVICES: ALL CONTRACTED SERVICES SHALL BE DOCUMENTED BY A WRITTEN AGREEMENT. THE WRITTEN AGREEMENT SHALL INCLUDE THE NAMES OF THE OWNER OR CORPORATE OFFICERS AUTHORIZED TO SIGN THE AGREEMENT AND THE CENTER SHALL BE ULTIMATELY RESPONSIBLE FOR QUALITY CONTROL OF THE CONTRACTED SERVICES.

25.12 COMPLIANCE WITH FGI GUIDELINES:

EFFECTIVE FEBRUARY 1, 2015, ALL CONVALESCENT CENTERS SHALL BE CONSTRUCTED IN CONFORMITY WITH THE STANDARDS ADOPTED BY THE DIRECTOR OF THE DIVISION OF FIRE PREVENTION AND CONTROL (DFPC) AT THE COLORADO DEPARTMENT OF PUBLIC SAFETY. FOR CONSTRUCTION INITIATED OR SYSTEMS INSTALLED ON OR AFTER JULY 1, 2013, THAT AFFECT PATIENT HEALTH AND SAFETY AND FOR WHICH DFPC HAS NO APPLICABLE STANDARDS, EACH FACILITY CENTER SHALL CONFORM TO THE RELEVANT SECTION(S) OF THE GUIDELINES FOR DESIGN AND CONSTRUCTION OF HEALTH CARE FACILITIES, (2010 EDITION), FACILITIES GUIDELINES INSTITUTE. THE GUIDELINES FOR DESIGN AND CONSTRUCTION OF HEALTH CARE FACILITIES, (2010 EDITION), FACILITIES GUIDELINES INSTITUTE (FGI), IS HEREBY INCORPORATED BY REFERENCE AND EXCLUDES ANY LATER AMENDMENTS TO OR EDITIONS OF THE GUIDELINES. THE 2010 FGI GUIDELINES ARE AVAILABLE AT NO COST IN A READ ONLY VERSION AT:
HTTP://FGIGUIDELINES.ORG/DIGITALCOPY.PHP
~~HTTP://OPENPUB.REALREAD.COM/RRSERVER/BROWSER?TITLE=/FGI/2010_GUIDELINES~~

25.13 LICENSE FEES: FOR NEW LICENSE APPLICATIONS RECEIVED OR RENEWAL LICENSES THAT EXPIRE ON OR AFTER MARCH 1, 2015, AN APPLICANT FOR AN AMBULATORY SURGICAL CENTER WITH A CONVALESCENT CENTER LICENSE SHALL SUBMIT, IN THE FORM AND MANNER SPECIFIED BY THE DEPARTMENT, A LICENSE APPLICATION WITH THE CORRESPONDING NON REFUNDABLE FEE AS SET FORTH BELOW

(A) INITIAL LICENSE: A LICENSE APPLICANT SHALL SUBMIT WITH AN APPLICATION FOR LICENSURE A NONREFUNDABLE FEE OF $6,960.

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

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

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

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

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