DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities Regulation Division

STANDARDS FOR HOSPITALS AND HEALTH FACILITIES

CHAPTER IV - GENERAL HOSPITALS

6 CCR 1011-1 Chap 04

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

Copies of these regulations may be obtained at cost by contacting:

Division Director

Colorado Department of Public Health and Environment

Health Facilities Division

4300 Cherry Creek Drive South

Denver, Colorado 80222-1530

Main switchboard: (303) 692-2800

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

Division Director

Colorado Department of Public Health and Environment

Health Facilities Division

4300 Cherry Creek Drive South

Denver, Colorado 80222-1530

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

Part 1. STATUTORY AUTHORITY AND APPLICABILITY

1.100

1.101 STATUTORY AUTHORITY

(1) Authority to establish minimum standards through regulation and to administer and enforce such regulations is provided by Sections 25-1.5-103 and 25-3-101, C.R.S., et seq.

1.102 APPLICABILITY

(1) All hospitals shall meet applicable federal and state statutes and regulations, including but not limited to:

(a) 6 CCR 1011-1, Chapter II, except as noted below:

(i) Notwithstanding 6 CCR 1011-1, Chapter II, Section 2.3.2, hospital services/departments provided for under this Chapter IV shall not require a separate license if they are on the hospital campus. Services that are subject to separate licensure including, but not limited to, assisted living residences, hospices, hospital units, home care agencies, long term care facilities, and end stage renal dialysis treatment centers, shall not be considered part of the hospital campus.

(b) This Chapter IV, except as noted below:

(i) facilities that are federally certified or are undergoing federal certification under 42 CFR 482, et seq., as long term hospitals shall meet the requirements of this chapter, except that they shall not be required to have an emergency department, obstetric services or anesthesia services.

(ii) Facilities that have 25 inpatient beds or less and are federally certified or undergoing federal certification under 42 CFR 485.600, et seq., as critical access hospitals shall meet the requirements of this chapter, except that the staffing qualifications, level of staffing, hours of operation, and quality management requirements shall not exceed the requirements established in the aforementioned federal regulations.

(2) Contracted services shall meet the standards established herein.

(3) When differing standards are imposed by federal, state, or local jurisdictions, the most stringent standard shall apply.

Part 2. DEFINITIONS

2.100

(1) "Anesthetizing location" means any area of a facility that has been designated to be used for the administration of nonflammable inhalation anesthetic agents in the course of examination or treatment, including the use of such agents for relative analgesia.

(2) "Care plan" means a plan of care, treatment and services designed to meet the needs of the patient.

(3) "Cord blood unit" means neonatal blood collected from the placenta and/or the umbilical cord of a single newborn baby after separation from the baby.

(4) "Critical care unit" means a designated area of the hospital containing a grouping of single bedrooms or enclosures accommodating not more than 6 beds each, and providing specialized facilities and services to care for patients who require continuing, acute observation and concentrated, highly proficient care.

(5) "Department" means the Department of Public Health and Environment.

(6) "Dietary services equipment" means an article used in the operation of dietary services, such as, but not limited to a freezer, grinder, hood, ice maker, oven, mixer, range, slicer, or ware-washing machine. "Dietary services equipment" does not include items used for handling or storing large quantities of packaged foods received from a supplier in a cased or over-wrapped lot, such as forklifts, hand trucks, dollies, pallets, racks and skids.

(7) "Distinct part" means a physically distinguishable portion from the larger hospital institution that is separately certified by the Centers for Medicaid and Medicaid Services as a nursing facility, a skilled nursing facility or a psychiatric or rehabilitation unit for the purposes of exclusion from prospective payment systems.

(8) "Food-contact surfaces" means those surfaces of equipment and utensils with which food normally comes in contact, and those surfaces from which food may drain, drip, or splash back onto surfaces in contact with food. This excludes ventilation hoods.

(9) "General hospital" means a health facility that, under an organized medical staff, offers and provides twenty-four hours per day, seven days per week, inpatient services, emergency medical and surgical care, continuous nursing services, and necessary ancillary services, to individuals for the diagnosis or treatment of injury, illness, pregnancy, or disability.

(a) A general hospital may offer and provide, but is not limited to, outpatient, preventive, therapeutic, surgical, diagnostic, rehabilitative, or any other supportive services for periods of less than twenty-four hours per day.

(b) Services provided by a general hospital may be provided directly or by contractual agreement. Direct inpatient services shall be provided on the licensed premises of the general hospital.

(c) A general hospital may provide services on its campus and on off-campus locations.

(d) Non-direct care services (such as billing functions) necessary for the successful operation of the facility that are not on the hospital campus may be incorporated under the license.

(10) "Investigational drug" in accordance with 21 CFR 312.3 means a new drug or biological drug that is used in a clinical investigation. [1] The term also includes a biological product that is used in vitro for diagnostic purposes. The terms "investigational drug" and "investigational new drug" are deemed to be synonymous.

[1] The Text of 21 CFR 312.3 is available for public inspection during regular business hours at Colorado Department of Public Health and Environment, Health facilities and Emergency Medical Services Division, 4300 Cherry Creek Drive South, Denver CO 80246-1530. Copies are also available on the web at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.3

(11) "Governing board" means the board of trustees, directors, or other governing body in whom the ultimate authority and responsibility for the conduct of the hospital is vested.

(12) "Hospital campus" means the hospital's main buildings including areas and structures that are not strictly contiguous to the main building excluding parking lots and other parcels dedicated to the public's use. In order to be part of the hospital campus, any adjoining areas shall be under the same hospital operational control and ownership as described on the hospital's license application. The campus is considered one licensed facility at one location as opposed to off-campus locations or facilities subject to a separate license.

(13) "Licensed independent practitioner" means an individual permitted by law and the facility to independently diagnose, initiate, alter or terminate health care treatment within the scope of his or

her license.

(14) "Medication monitoring" is a service provided under the supervision of a licensed physician or advanced nurse practitioner to evaluate, prescribe or administer and monitor a patient's use of psychotropic medications including anti-Parkinsonian medications.

(15) "Off-campus location" means a facility whose operations are directly owned by the hospital and under the same governing body that is not located on the hospital's campus, but which provides services that are organizationally and functionally integrated with the hospital which the hospital chooses to list under its hospital license, and is either:

(a) a distinct part unit providing rehabilitation or psychiatric services in existence prior to January 1, 2011; or

(b) an outpatient facility providing preventive, diagnostic and/or treatment services that is not regulated by a Chapter of 6 CCR 1011-1,Standards for Hospitals and Health Facilities.

(16) "Patient care unit" means a designated area of the hospital that provides a bedroom or a grouping of bedrooms with respective supporting facilities and services to meet the care and clinical management needs of inpatients; and that is thereby planned, organized, operated, and maintained to function as a separate and distinct unit.

(17) "Pharmacist" means a person licensed by the Colorado State Board of Pharmacy as a pharmacist.

(18) "Plan review" means the review by the Department, or its designee, of new construction or remodeling plans to ensure compliance by the facility with the National Fire Protection Association (NFPA) Life Safety Code and with this Chapter IV. Plan review consists of the examination of new construction or remodeling plans and onsite inspections, where warranted. In reference to the National Fire Protection Association requirements, the Department is the authority having jurisdiction for state licensure.

(19) "Public cord blood bank" means a public cord blood bank that has obtained all applicable federal and state licenses, certifications and registrations and is accredited as a public cord blood bank by an accrediting entity recognized or otherwise approved by the Secretary of Health and Human Services under the Public Health Service Act, as such Act may be amended. (42 U.S.C. Section 274k)

(20) "Recreational therapy" is the use of treatment, education and recreation to help psychiatric patients develop and use leisure in ways that enhance their health, functional abilities, independence and quality of life.

(21) "Relative Analgesia" means a state of sedation and partial block of pain perception produced in a patient by the inhalation of concentrations of nitrous oxide insufficient to produce loss of consciousness; i.e., conscious sedation.

(22) "Respiratory care" means that service which is organized to provide facilities, equipment, and personnel who are qualified by training, experience and ability to treat conditions caused by deficiencies or abnormalities associated with respiration.

(23) "Surgical recovery room" means designated room(s) designed, equipped, staffed, and operated to provide close, individual surveillance of patients recovering from acute affects of anesthesia, surgery, and diagnostic procedures.

(24) "Utensil" means any implement used in the storage, preparation, transportation, or service of food.

(25) "Voluntary cord blood donor" means a pregnant woman who has delivered or will deliver a newborn baby and/or such other individual(s) as may be identified by the hospital as required to consent to the voluntary donation of neonatal blood remaining in the placenta and/or the umbilical cord after separation from the newborn baby and who has provided timely informed written consent in accordance with standards established by the hospital pursuant to the provisions of Section 20.152 (1)(d).

Part 3. DEPARTMENT OVERSIGHT

3.100 APPLICATION FEES

3.101 SUBMITTAL OF FEES. Fees shall be submitted to the Department as specified below.

(1) Initial License (when such initial licensure is not a change of ownership). A license applicant shall submit a nonrefundable fee with an application for licensure as follows:

(a) See table below.

Number of Beds	Fee
1 - 25 beds	$8,000
26 - 50 beds	$10,000
51 - 100 beds	$12,500
101 + beds	Base: $9,800
.	Per bed: $50
.	Cap: $20,000

(b) Notwithstanding the provisions of Section 3.101 (1)(a), the initial fee for facilities to be licensed as general hospitals but certified as long term hospitals pursuant to 42 CFR 482 et seq. shall submit: a base fee of $5,700 and a per bed fee of $50. The initial licensure fee for long term hospitals shall not exceed $10,500.

(2) Renewal License. A license applicant shall submit a nonrefundable fee with an application for licensure as shown in the following table. The renewal fee shall not exceed $8,000.

Number of Beds	Fee
1 - 50 beds	Base: $900
.	Per bed: $ 12
51 - 150 beds	Base: $1,400
.	Per bed: $12
151 + beds	Base: $2,000
.	Per bed: $12

(3) Change of Ownership. A license applicant shall submit a nonrefundable fee of $2,500 with an application for licensure.

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

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

shall assess the fee based on the anticipated costs of monitoring compliance with the conditional license. 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.

(6) Other Regulatory Functions. If a facility requests an onsite inspection for a regulatory oversight function other than those listed in Sections 3.101 (1) through (3) and Section 4.101 Plan Review, the Department may conduct such onsite inspection upon notification to the facility of the fee in advance and payment thereof. The fee shall be calculated solely on the basis of the cost of conducting such survey. A detailed justification of the basis of the fee shall be provided to the facility upon request.

(7) Off-Campus Locations

(a) Addition, Annual Renewal and Termination of Off- Campus Locations. A licensee shall submit a nonrefundable fee of:

(i) $1,000 for the addition of each location to the list of off-campus locations under the license, except that critical access hospitals shall submit a nonrefundable fee of $500.

(ii) $500 for the annual renewal of each off-campus location listed under the license.

(iii) $360 for the removal of each location from the list of off-campus locations under the license.

3.200 INCREASE IN LICENSED CAPACITY

3.201 Each licensee shall comply with the requirements of 6 CCR 1011-1, Chapter II, section 2.10.5 regarding written notification of changes affecting the licensee's operation or information, except that the procedure regarding a proposed increase in licensed capacity set forth in Chapter II, section 2.10.5(A)(1) shall be as follows:

(1) Subject to subpart (a), if a licensee notifies the Department in writing at least thirty (30) calendar days in advance of an increase in licensed capacity, an amended license shall be issued upon payment of the appropriate fee. Upon request by the Department, the licensee shall meet with a Department representative prior to implementation to discuss the proposed changes.

(a) If a licensee requesting an increase in licensed capacity has, within 12 months prior to giving notice thereof, been subject to conditions imposed upon its license pursuant to § 2.9.4 or been subject to a plan of correction pursuant to § 2.11.3(B), the licensee shall submit to the Department satisfactory evidence that the noted condition(s) have been met or the plan of correction implemented, as applicable, in connection with the notice of increased capacity.

Part 4. FIRE SAFETY AND PHYSICAL PLANT STANDARDS

4.101 PLAN REVIEW AND PLAN REVIEW FEES.

Both plan review and plan review fees are required as listed below in sections (A) and (B). Fees are nonrefundable and shall be submitted prior to the Department initiating a plan review for a facility.

4.101A. Plan Review Procedure

Due to the expansive and complex nature of many hospital projects, the items delineated below

shall be applied in conjunction with 6 CCR, 1011-1, Chapter II, Part 1 Submission of Construction Plans/Documents and Completion of the Plan Review Process.

(1) Package Assessment

(a) Upon receipt of a request for plan review, the Department shall assess the package to determine if it is complete; the construction documents are in the correct format; if the plan review is required; and if the appropriate plan review fee is included.

(b) If the plan review packet meets the criteria in subsection (1)(a), the Department shall, within fourteen (14) calendar days of determining the submittal package is complete, provide the primary contact for the project (as indicated in the project submittal) a written or electronic communication good faith estimate of when it will issue the written preliminary review findings.

(2) Preliminary Review

(a) Upon receipt of the Department's written preliminary review findings, the hospital may agree with them and revise its construction documents to include the Department's review findings, or challenge the preliminary findings as provided for in paragraph (5)(a) of this section 4.101A.

(b) The issuance of written preliminary review findings triggers the 24 month period for completion of the project.

(3) Deferred Submittals and/or Change Orders

(a) The hospital shall submit deferred submittals or change orders related to Life Safety Code or adopted Department standards to the Department for review.

(b) Within fourteen (14) calendar days of receipt of a complete change order package as defined by the Department, the Department shall provide the facility a written good faith estimate of when it will issue written comments/approvals regarding such change order. If the Department requires an extension, it shall notify the facility within seven (7) calendar days.

(c) If the Department determines that any further design consideration is needed for code compliance, it shall provide the primary contact for the project with written findings to that effect. The hospital shall have thirty (30) calendar days from the date of such findings to submit all required documentation to the Department regarding the corrections.

(4) Final Inspection

(a) Prior to requesting a final inspection, the hospital shall provide the Department with local building, zoning and fire department approvals; the certificate of occupancy reflecting the proposed use; and a statement (in the format prescribed by the Department) that the hospital is ready for a final life safety code inspection.

(i) The Department may accept a temporary certificate of occupancy and schedule a final inspection upon receipt of a statement from the issuing entity that outlines the conditions preventing issuance of a final certificate of occupancy, and a determination by the Department that the final certificate of occupancy has been delayed for reasons that do not impact

life safety or other regulatory issues.

(b) The Department shall conduct the final review/inspection of the completed project within thirty (30) calendar days of receiving all the required documentation specified in subsection (4)(a).

(5) Dispute Resolution

(a) Within 30 days of issuance of written findings from the Department regarding plan review, a project's primary contact may challenge the Department's written findings. Such challenge shall consist of a written request for a meeting (to be conducted in person, telephonically or electronically) with the assigned inspector and Life Safety Code Manager or designee to discuss the findings and attempt to reach an agreement. Such request shall outline the issue being challenged, the facility's position on the issue, and the code basis for its position. Such meeting shall occur within a reasonable timeframe. If, after meeting with the assigned inspector, the hospital continues to object to the plan review findings and an agreement has not been achieved, it may pursue the options in paragraph (i) and/or paragraph (ii) as set forth below.

(I) Request review by the Plan Review Technical Advisory Panel (PRTAP) for consideration regarding interpretation of the applicable regulatory requirements. This review shall be scheduled no later than 14 calendar days following submission of such request unless a quorum cannot be convened, in which case the meeting shall be convened at the earliest practicable time.

(A) The panel shall consist of no more than seven members, four of whom shall be qualified by experience and/or education regarding Life Safety Code or other building requirements and not be employed by the Department.

(B) Members shall be appointed by the Division Director who shall consider the recommendations of professional organizations such as the American Institute of Architects (AIA), the Colorado Association of Healthcare Engineers and Directors (CAHED) or other relevant professional organizations;

(C) Members may have a designated/appointed alternative who may serve when the appointed member has a conflict ofinterest in the matter before the panel.

(D) A quorum of the panel shall be no less than three members, of which at least two shall not be Department employees.

(E) The panel shall determine the process and procedures for the rendering of recommendations to the Division Director or designee.

(F) The Division Director or designee shall consider the recommendations of the panel and issue an agency action within ten (10) calendar days.

(ii) Submit a waiver request consistent with 6 CCR 1011-1, Chapter II, Part 4.

(b) Appeal of the Department's action shall be made pursuant to the State Administrative Procedure Act, Section 24-4-101, et seq., C.R.S.

4.101B. PLAN REVIEW FEES

(1) Initial licensure Applicable to applications for an initial license, when such initial license is not a change of ownership. This includes new facility construction and existing structures. The requirement for plan review and the fee applies to initial license applications submitted on or after January 1, 2008. Fee : See table below.

Square Footage	Cost per square foot	Explanatory Note
0-35,000 sq ft	$0.37	This is the cost for the first 35,000 sq ft of any plan submitted.
35,001-200,000	$0.03	This cost is applicable to the additional square footage over 35,000 and up to 200,000 sq ft.
200,001+	$0.01	This cost is applicable to the additional square footage over 200,000 sq ft.

(2) Additions and Relocations

(a) Applicable to additions of previously uninspected or unlicensed square footage under the license to an existing occupancy, the addition of an off-campus location, and relocations of a currently licensed facility in whole or in part to another physical plant, except as exempted in Section 4.101(2)(b), below. The requirement for plan review and the fee applies to construction for which the application for the building permit from the local authority having jurisdiction is dated on or after January 1, 2008. However, facilities for which the application for the building permit from the local authority having jurisdiction is dated prior to January 1, 2008 may request a partial plan review. The partial plan review is subject to a ten (10) to twenty-five (25) percent reduction of the fee, as determined by the Department, dependent on the phase of facility construction; except that the fee shall not be below the minimum fee established by this subsection. Fee : See table below. Minimum fee: $2,000.

Square Footage	Cost per square foot	Explanatory Note
0-35,000	$0.37	This is the cost for the first 35,000 sq ft of any plan submitted.
35,001-200,000	$0.03	This cost is applicable to the additional square footage over 35,000 and up to 200,000 sq ft.
200,001+	$0.01	This cost is applicable to the additional square footage over 200,000 sq ft.

(b) An off-campus location in operation prior to January 1, 2011 is not subject to the plan review required under Section 4.101 (2) (a), if it is added:

(i) to the license of a hospital licensed prior to January 1, 2011;

(ii) through the renewal licensure application process; and

(iii) at the first licensure renewal that occurs on or after April 1, 2011.

(3) Remodeling – General and Phased

(a) Remodeling - General. Applicable to relocation, removal or installation of walls resulting in 50% or more of a smoke compartment being reconfigured. The cost per square footage listed in the table below is to be assessed for the entire smoke compartment(s) being reconfigured. The requirement for plan review and the fee applies to construction for which the application for the building permit from the local authority having jurisdiction is dated on or after January 1, 2008. Fee : See table below. Minimum fee: $2,000.

Square Footage	Cost per square foot	Explanatory note
0-35,000	$0.25	This is cost for the first 35,000 sq ft of any plan submitted.
35,001-200,000	$0.03	This cost is applicable to the additional square footage over 35,000 and up to 200,000 sq ft.
200,001+	$0.01	This cost is applicable to the additional square footage over 200,000 sq ft.

(b) Remodeling - Phased. Applicable to projects whereby one area is remodeled and occupied by personnel vacated from another area within the licensed facility and such vacated space is subsequently remodeled. In addition to the general remodeling fee established in subsection (3)(a), the facility shall also submit a fee of $2,500 per separate area being remodeled and occupied; with the exception of critical access hospitals, for which the fee shall be $750 per separate area. Prior to being occupied, the remodeled area is subject to inspection for compliance with the LSC requirements in effect at the time of the construction plan submittal. In order to be considered a phased project all aspects of the entire project (all phases) must be submitted at the inception of the project. Phases submitted at a later date will be considered separate projects and will be subject to the plan review requirements and fees applicable at that later date.

(4) Remodeling – Egress Components. Applicable to the relocation, removal, or addition of any egress component, including but not limited to corridors, stairwells, exit enclosures, or points of refuge. (Widening of an egress component is not relocation.) The requirement for plan review and the fee applies to construction for which the application for the building permit from the local authority having jurisdiction is dated on or after January 1,

2008. Fee : $2,000. However, if these renovations are part of the smoke compartment reconfiguration subject to the fee listed in Section 4.101 (3), the fee in this Section 1.101 (4) shall not apply.

(5) Remodeling – Specific Systems. Applicable to significant modifications to the following systems: fire sprinkler, fire alarm, medical gas, kitchen exhaust/suppression system, and essential electrical system. The requirement for plan review and the fee applies to significant modifications where construction is initiated on or after July 1, 2008. For the purposes of this Section 4.101 (5), construction of significant modifications is deemed initiated when there is an alteration associated with the remodeling to an existing structure that results in a physical change. Fee : $2,000 for up to four smoke compartments, plus $500 for each additional compartment. However, if these renovations are part of the smoke compartment reconfiguration subject to the fee listed in Section 4.101 (3), the fee in this Section 4.101 (5) shall not apply. Significant modifications include:

(a) Fire sprinkler: 100 or more sprinklers. Notwithstanding the other provisions in this Section 2.203 (5), the extension of a sprinkler system involving the installation of 25 to 99 sprinkler heads for an area previously unsprinklered is subject to a partial plan review consisting of the review of the remodeling plans and a fee of $500.

(b) Fire alarm: any modification to the fire alarm system that involves the replacement of the main fire alarm control unit (panel).

(c) Medical gas: modifications that affect 50% or more of a smoke compartment.

(d) Kitchen exhaust/suppression system: replacement of the suppression or hood exhaust/duct system.

(e) Essential electrical system: replacement or addition of a generator or transfer switch.

4.102 COMPLIANCE WITH THE LIFE SAFETY CODE

(1) Facilities shall be compliant with the National Fire Protection Association (NFPA) 101, Life Safety Code (2000). This section incorporates by reference the NFPA 101, Life Safety Code (2000). Such incorporation by reference, as provided for in 6 CCR 1011-1, Chapter II, excludes later amendments to or editions of referenced material.

(a) Facilities licensed on or before September 30, 2003 shall meet Chapter 19, Existing Health Care Occupancies, NFPA 101 (2000).

(b) Facilities licensed on or after October 1, 2003 or portions of facilities that undergo remodeling on or after October 1, 2003 shall meet Chapter 18, New Health Care Occupancies, NFPA 101 (2000). In addition, if the remodel represents a modification of more than 50 percent, or more than 4,500 square feet of the smoke compartment, the entire smoke compartment shall be renovated to meet Chapter 18, New Health Care Occupancies, NFPA 101 (2000).

(c) An off-campus location in operation prior to January 1, 2011 may meet either the existing or the new occupancy Life Safety Code requirements, if it is added to the hospital license at the first renewal licensure that occurs on or after April 1, 2011.

(d) Notwithstanding 6 CCR 1011-1, Chapter II, Part 2.3.5(A), an off-campus location that contains an anesthetizing location shall have an intact, two-hour fire rated separation wall, floor or

ceiling assembly under the following circumstances:

(I) For each applicant seeking an initial license on or after January 1, 2011, except for a health care entity that has submitted building plans to the Department and obtained a building permit prior to January 1, 2011,from the local authority having jurisdiction.

(ii) For each licensee that submits building plans to the Department or obtains a building permit on or after January 1, 2011, for relocations in whole or in part to another physical structure.

(iii) For each licensee that submits building plans to the Department or obtains a building permit on or after January 1, 2011, to add previously un-inspected or unlicensed square footage to an existing license. For the purposes of compliance with this section, the two-hour fire rated separation shall be around either the entire perimeter of the added square footage or the entire perimeter of the facility.

(iv) For each licensee that creates a new anesthetizing location on or after January 1, 2011, within an existing off-campus location.

4.103 COMPLIANCE WITH AIA GUIDELINES

(1) The publication "Guidelines for Design and Construction for Health Care Facilities," (2006 Edition), American Institute of Architects (AIA) may be used by the Department in resolving building, health and safety issues for construction initiated or systems installed on or after March 2, 2010. The AIA guidelines are hereby incorporated by reference. Such incorporation by reference, as provided for in 6 CCR 1011-1, Chapter II, excludes later amendments to or editions of referenced material.

Part 5. FACILITY OPERATIONS

5.100 Central Medical Surgical Supply Services

5.200 Housekeeping Services

5.300 Maintenance Services

5.400 Waste Disposal Services

5.500 Linen and Laundry

5.100 CENTRAL MEDICAL-SURGICAL SUPPLY SERVICES

5.101 ORGANIZATION AND STAFFING

(1) All hospitals shall provide central medical-surgical supply services with facilities for processing, sterilizing, storing, and dispensing supplies and equipment for all departments/services of the hospital.

(2) The central medical-surgical supply services shall be organized as a service under the immediate supervision of a person who is competent in management, asepsis, supply processing, and control methods.

(3) Sufficient supporting personnel shall be assigned to the service and properly trained in central medical-surgical supply services.

5.102 PROGRAMMATIC FUNCTIONS

(1) Continuous supervision shall be maintained throughout receiving, cleaning, processing, sterilizing, and storing. A combination of controls or indicators shall be used to determine THE effectiveness of the sterilization process. Bacteriological methods shall be used to evaluate the effectiveness of sterilization, by at least monthly cultures with records maintained.

(2) Written policies and procedures shall be established for all functions of central medical-surgical supply services. Such written procedures shall include, but not be limited to, obtaining, cleaning, processing, sterilizing, storing and issuing supplies. These policies and procedures shall be periodically reviewed by the Infection Control Committee, as applicable.

(3) Policies shall be established to provide supervision and training programs for all personnel involved in central medical-surgical supply operations and services.

(4) Water used for sterile solutions shall be distilled and sterilized in flasks which are resistant to heat, chemical, and electrical action.

(5) Dry heat and special chemical methods are available and acceptable for sterilization of materials which would be damaged by pressurized steam.

5.103 EQUIPMENT

(1) Pressurized steam sterilizers, or equivalent, and water stills, of approved type and necessary capacity for adequate sterilization, shall be provided and maintained. Pressurized steam sterilizers shall be installed and provided with arecording thermometer that indicates temperature in discharge line of the sterilizer.

5.104 FACILITIES

(1) This service shall be separated physically from other areas of the hospital and shall include areas designated for the following: 1) Receiving; 2) Cleaning and processing; 3) Sterilizing; 4) Storing clean and sterile supplies; 5) Storing bulk supplies and equipment.

(2) A two-compartment sink, with counter or drainboard and knee-or-wrist action valves, shall be provided in the cleaning area.

(3) Adequate cabinets, cupboards, and other suitable equipment shall be provided for the processing of materials and for the storage of equipment and supplies in a clean and orderly manner.

(4) Pressurized steam sterilizers shall be installed and provided with indirect waste connections. Vents used for sterilizers that emit steam exhaust shall be installed in such a manner as to avoid recirculation.

(5) Ventilation

(a) Ventilation to this area may be supplied from the general ventilation system, if properly filtered.

(b) The flow of air should be from the clean areas toward the exhaust in the soiled area. In the case of new hospital construction or the modification of a hospital facility, the flow of air shall be from the clean areas toward the exhaust in the soiled area.

(c) Exhausts shall be installed over sterilizers to prevent condensation on walls and ceilings.

5.200 HOUSEKEEPING SERVICES

5.201 ORGANIZATION AND STAFFING

(1) Each hospital shall establish organized housekeeping services. The hospital environment shall be clean and sanitary.

(2) The services shall be under the supervision of a person competent in environmental sanitation and management.

5.202 PROGRAMMATIC FUNCTIONS

(1) Written policies and procedures shall be established and implemented for cleaning the physical plant and equipment. The policies and procedures shall be designed to prevent and control infection. At minimum, the policies and procedures shall address: cleaning schedules, cleaning methods, the proper use and storage of cleaning supplies, hand washing, and the supervision and training of housekeeping personnel. These policies and procedures shall be periodically reviewed by the Infection Control Committee, as applicable.

(2) Dry dusting and sweeping are prohibited.

(3) All personnel shall wash their hands thoroughly after handling waste products.

(4) Accumulated waste material shall be removed at least daily.

5.203 EQUIPMENT AND SUPPLIES

(1) Suitable equipment and supplies shall be provided for cleaning of all surfaces. Such equipment shall be maintained in a safe, sanitary condition.

(2) Selection of germicides shall be under the supervision of competent individual(s).

(3) Solutions, cleaning compounds, and hazardous substances shall be labeled properly and stored in safe places. Paper towels, tissues, and other supplies shall be stored in a manner to prevent their contamination prior to use.

4) All external rubbish and refuse containers shall be impervious and tightly covered.

(5) Carts used to transport rubbish and refuse shall be constructed of impervious materials, shall be enclosed, and shall be used solely for this purpose.

5.204 FACILITIES. Reserved.

5.300 MAINTENANCE SERVICES

5.301 ORGANIZATION AND STAFFING

(1) The hospital shall provide facility maintenance services which shall be responsible for the upkeep of the hospital's grounds, physical plant, equipment and furnishings. The grounds, physical plant, equipment and furnishings shall be hazard free and in good repair.

(2) The building and mechanical programs shall be under the direction of a qualified person informed in the operations of the facility and in the building structures, their component parts and facilities.

(3) Only properly trained responsible personnel shall be allowed to apply insecticides and rodentcides.

5.302 PROGRAMMATIC FUNCTIONS

(1) The hospital shall implement written policies and procedures to keep the entire facility in good repair and to provide for the safety, welfare, and comfort of the occupants of the building(s).

(2) Physical Plant Maintenance

(a) Inspections and maintenance shall be conducted, in accordance with written maintenance schedules, of physical plant systems including but not limited to the electrical system, emergency power generators, water supply, and ventilation.

(b) Records shall be maintained showing the date of maintenance and action taken to correct any deficiencies.

(3) Equipment Maintenance

(a) Inspections and preventive maintenance shall be conducted in accordance with written maintenance schedules of equipment, including equipment used for direct patient care, to ensure that it is in good working order. Preventive maintenance includes, but is not limited to, routine inspections, cleaning, testing and calibrating in accordance with manufacturer's instructions or if there are not manufacturers' instructions, as specified by the hospital's written policies and procedures.

(b) Records shall be maintained showing the date of maintenance and action taken to correct any deficiencies.

(4) Insect, Pest, and Rodent Control

(a) The facility shall develop and implement written policies and procedures for the effective control and eradication of insects, pests, and rodents.

(b) Pesticides shall not be stored in patient or food areas and shall be kept under lock.

5.303 EQUIPMENT. Reserved.

5.304 FACILITIES

(1) Screens or other effective methods shall be provided on all exterior openings and the structure so maintained as to prevent entry of rats or mice through cracks in foundations, holes in walls, around service pipes, etc.

5.400 WASTE DISPOSAL SERVICES

5.401 ORGANIZATION AND STAFFING

(1) The hospital shall provide for the safe disposal of all types of waste products.

(2) Infectious waste disposal shall be directed by a person qualified by education, training, or experience in the principles of infectious waste management.

5.402 PROGRAMMATIC FUNCTIONS

(1) The hospital shall implement written policies and procedures to ensure the safe disposal of waste products. The policies and procedures shall address:

(a) sewage. All sewage shall be discharged into a public sewer system.

(b) garbage and refuse. All garbage and refuse, not treated as sewage, shall be collected in and stored in covered containers and shall be removed from the hospital premises as frequently as necessary to prevent nuisance or health hazards or incinerated once a day.

(c) infectious waste. Infectious waste shall be handled and disposed of in accordance with the requirements of C.R.S. 25-15-401, et seq.

(d) biological non-infectious waste.

(2) Refuse or garbage shall not be burned on the premises except in an incinerator. Incinerators shall comply with federal, state and local air pollution regulations.

5.403 EQUIPMENT

(1) Incinerators shall be so constructed as to prevent insect and rodent breeding and harborage.

(2) A sufficient number of sound water-tight containers with tight fitting lids, to hold all refuse that accumulates between collections, shall be provided. Lids must be kept on the containers. Garbage containers shall be cleaned each time emptied. (Single service container liners are recommended).

5.404 FACILITIES

(1) No exposed sewer line shall be located directly above working, storing, or eating surfaces in kitchens, dining rooms, pantries, or food storage rooms, or where medical or surgical supplies are prepared, processed, or stored.

(2) Racks or stands for garbage containers shall be kept in good repair. A paved storage area for the containers should be provided.

5.500 LINEN AND LAUNDRY SERVICES

5.501 ORGANIZATION AND STAFFING

(1) The hospital shall provide linen and laundry services. There shall be proper laundering of washable goods and a sufficient supply of clean linen.

(2) Linen and laundry services shall be under the supervision of a person qualified by education, training or experience.

5.502 PROGRAMMATIC FUNCTIONS

(1) There shall be written policies and procedures for the collection, processing, distribution and storage of linen. These policies and procedures shall be reviewed periodically by the infection control committee, as applicable.

(2) Clean linen shall be stored and distributed to the point of use in a way that minimizes microbial contamination from surface contact or airborne particles.

(3) Soiled linen shall be collected at the point of use and transported to the soiled linen holding room in a manner that minimizes microbial dissemination.

(4) Laundering shall be conducted in accordance with manufacturers' instructions regarding the washing

machine and the cleaning agent used.

5.503 EQUIPMENT

(1) The hospital shall use only commercial laundry equipment to process hospital linen and laundry.

5.504 FACILITIES

(1) Laundry Area. Handwashing facilities and a toilet should be available in the laundry area. The general air movement shall be from the cleanest areas to the most contaminated areas. A minimum ventilation rate of ten room volumes of outside air per hour with no recirculation is recommended for the laundry proper. Laundry exhaust should be carried to a point above the roof or 50 feet away from any window and shall not discharge near any fresh air inlet.

(2) Soiled Linen Storage and Sorting Area

(a) If a laundry is not provided in the hospital, a soiled linen storage room shall be provided.

(b) Soiled linen storage room shall be enclosed, designed and used solely for that purpose, and provided with exhaust ventilation direct to the outside. Recirculation of air from this room shall not be permitted. The room shall have negative pressures relative to adjacent areas. Eight room volumes of outside air per hour is recommended for the sorting area. In the case of new hospital construction, or modification of an existing hospital facility, the room shall also be mechanically ventilated to the outside air.

(3) Clean Linen Storage

(a) A clean linen storage and sewing room shall be provided separate from the laundry room.

(b) Clean linen stored on patient care units shall be in closets, shelves, conveyances, or rooms used only for clean linen storage.

Part 6. GOVERNANCE AND LEADERSHIP

6.100 GOVERNING BOARD

6.101 ORGANIZATION & STAFFING

(1) The governing board shall be organized formally with written constitution or articles of incorporation and by-laws, have meetings at regularly stated intervals, but at least quarterly, and maintain records of these meetings.

(2) The governing board shall appoint an administrative officer who is qualified by training and experience in hospital administration and delegate to him or her the executive authority and responsibility for the administration of the hospital.

(3) The governing board shall appoint the medical staff. Appointments shall be made following consideration of the recommendations by the medical staff. The governing board shall establish formal liaison with; and approve the by-laws, rules, and regulations of the medical staff.

(4) The governing board shall provide professional and ancillary personnel in sufficient numbers, types and qualifications necessary to protect the health, welfare and safety of patients commensurate with the scope and type of services provided.

6.102 PROGRAMMATIC FUNCTIONS. The governing board shall:

(1) provide services and hospital departments necessary for the welfare and safety of patients. The scope of care and services shall be defined in writing.

(2) be responsible for all the functions performed within the hospital.

(3) ensure that each facility service/department provides, at minimum, 12 hours of training annually regarding the direct patient care and services provided by the service/department.

(4) adopt a written emergency management plan.

(a) at minimum, the plan shall address the following emergency situations:

(i) loss of heat or air conditioning.

(ii) unanticipated interruption of utilities, including water, gas, and electricity either within the facility or within a local widespread area.

(iii) fire, explosion, or other physical damage to the hospital.

(iv) local and widespread weather emergencies or natural disasters endemic to the region.

(v) pandemics or other situations where the community's need for services exceeds the availability of beds and services regularly offered by the hospital. The hospital response for emergency epidemics shall be directed by 6 CCR 1009-5, Regulation 2 – Preparations by General or Critical Access Hospitals for an Emergency Epidemic.

(b) at minimum, the plan shall address the following components of the facility response:

(i) the responsibilities of those involved in the emergency management activities within the facility, including authority to activate the plan.

(ii) patient triage, care, and discharge.

(iii) staff education and training.

(iv) coordination with the external entities involved in the implementation of the plan, which at minimum, shall include the local fire department and emergency management office.

(v) evacuation and relocation plans.

(c) The facility shall conduct a training exercise of an emergency scenario at least once annually.

(5) ensure that the patients receive care in a safe setting.

(6) ensure that each off-campus location:

(a) has an administrator that reports to an identified administrator of the hospital campus.

(b) operates under the applicable policies and procedures of the hospital campus, as well as specific policies and procedures that address the services provided at the off-campus location.

(c) provides care and services by qualified personnel in accordance with recognized standards of practice.

(d) has a medical records system that is integrated with that of the hospital campus.

(e) has onsite supervision of services that are appropriate to the scope and services offered and that supervisory staff are available to furnish assistance and direction during the performance of a procedure if needed.

(f) has professional staff who has clinical privileges at the hospital campus.

(g) is held out to the public as part of the hospital such that patients know they are entering the hospital and will be billed accordingly.

(h) that has exterior building signage containing the main hospital's name but does not have an emergency department in conformance with Part 18, Emergency Services:

(i) posts signage, on or near the front entrance, indicating: hours of operation, services provided, and instructions to call 911 in an emergency when the location is closed.

(ii) has a staff member onsite during operating hours with current certification in first aid and CPR. Off-campus location staff shall be trained to respond to acute care emergencies and emergency transfer protocols, as appropriate to their responsibilities.

(7) ensure that each hospital department or service shall have written organizational policies and procedures that identify the scope of the services to be provided, the lines of authority and accountability and the qualifications of the personnel performing the services. Services shall be provided in accordance with current standards of practice. Such policies and procedures shall be available to employees at all times.

(8) approve and implement a credentialing process for medical staff appointments, both employees and contractual staff.

(9) implement a quality improvement program in which each department or service participates. The quality improvement program shall:

(a) collect data to monitor core services.

(b) evaluate core services according to nationally recognized standards of care.

(c) identify patterns and trends of concern.

(d) recommend, implement and monitor corrective actions in response to identified concerns. Such corrective actions shall include, but not be limited to, establishing acceptable clinical competence and credentials as well as requiring ongoing professional education.

(e) conduct an annual evaluation for the prior year's quality improvement activities.

6.103 EQUIPMENT AND SUPPLIES

(1) The governing board shall provide equipment and supplies necessary for the welfare and safety of patients.

6.104 FACILITIES

(1) The governing board shall provide facilities necessary for the welfare and safety of patients.

6.200 ADMINISTRATIVE OFFICER

6.201 ORGANIZATION AND STAFFING

(1) The facility shall have an administrative officer who shall be responsible for the onsite administration of the hospital and shall maintain liaison between the governing board and the medical staff.

(2) The hospital shall be organized formally to carry out its responsibilities. The administrative officer shall be responsible for developing and implementing a written plan of organization defining the authority, responsibility, and functions of each category of personnel.

6.202 PROGRAMMATIC FUNCTIONS

(1) The administrative officer shall be responsible for the development written policies and procedures for employee and medical staff use. Policies and procedures shall be reviewed and, if necessary, updated every three years or more often as appropriate.

6.203 EQUIPMENT AND SUPPLIES. Reserved.

6.204 FACILITIES. Reserved.

6.300 MEDICAL STAFF

6.301 ORGANIZATION AND STAFFING

(1) All hospitals shall have an organized medical staff with written rules, regulations, and by-laws. The by-laws shall make provision for application, appointment, privileges, discipline, control, right of appeal, attendance at medical staff meetings, committees, and professional conduct in the hospital.

(2) A physician from the organized medical staff shall be appointed or elected as chief of staff.

(3) The medical staff shall meet regularly and maintain written records of these meetings.

6.302 PROGRAMMATIC FUNCTIONS

(1) There shall be a medical committee composed of physicians to review systematically the work of the medical staff with respect to quality of medical care.

(2) Medical records shall include final diagnosis with completion of medical records within 30 days following discharge.

(3) The admitting diagnosis, history, and physical examination shall be completed no more than thirty (30) days prior to admission or within twenty-four (24) hours after the patient's admission to the hospital. If the examination was completed prior to admission, an admission status examination of the patient shall be completed and documented in the medical record within twenty-four (24)

hours after admission.

(4) All persons admitted as patients to a hospital shall have benefit of continuing daily care of a medical staff member or a licensed independent practitioner. Policies and procedures shall be developed and implemented for coordinating and designating responsibility when more than one member of the medical staff or licensed independent practitioner is treating a patient.

6.303 EQUIPMENT AND SUPPLIES. Reserved.

6.304 FACILITIES. Reserved.

Part 7. PERSONNEL

7.100

7.101 ORGANIZATION AND STAFFING

(1) Each department or service of the hospital shall be under the direction of a person qualified by training, experience, and ability to direct the department or service.

(a) The physician director of a department or service shall be a member of the facility's medical staff. A physician director shall ensure that the quality of services provided by the medical staff of the department or service is monitored and evaluated.

(2) There shall be sufficient personnel qualified by education and experience in each department or service to properly operate the department or service.

(3) Facility staff shall be licensed or registered in accordance with applicable state laws and regulation s and shall provide services within their scope of practice and, as appropriate, in accordance with credentialing.

(4) All persons assigned to the direct care of or service to patients shall be prepared through formal education, as applicable, and on-the-job training in the principles, the policies, the procedures, and the techniques involved so that the welfare of patients will be safeguarded.

7.102 PROGRAMMATIC FUNCTIONS

(1) There shall be personnel records on each person of the hospital staff including employment application and verification of licensure, competencies and credentials for medical and professional staff.

(2) All personnel shall have a pre-employment physical examination and such interim examinations as may be required by the hospital administration or the health service physician.

(3) There shall be library services available to meet the needs of the medical staff and other professional personnel.

(4) Prior to delivering patient care independently, new personnel shall receive orientation regarding the patient care environment and relevant policies and procedures.

7.103 EQUIPMENT AND SUPPLIES. Reserved.

7.104 FACILITIES. Reserved.

Part 8. MEDICAL RECORDS DEPARTMENT

8.100

8.101 ORGANIZATION AND STAFFING

(1) A complete and accurate medical record shall be maintained on every patient from the time of admission through discharge. In addition, complete and accurate medical records shall be maintained for patients receiving emergency and outpatient services.

(2) A registered record administrator or other trained medical record practitioner shall be responsible for the administration and functions of the medical record department.

(3) There shall be a sufficient number of regular full-time and part-time employees so that medical record services may be provided as needed.

8.102 PROGRAMMATIC FUNCTIONS

(1) Medical records shall be stored in a manner so as to:

(a) provide protection from loss, damage, and unauthorized use.

(b) preserve the confidentiality of health information.

(2) Medical records shall be preserved as original records, on microfilm or electronically:

(a) for minors, for the period of minority plus 10 years (i.e., until the patient is age 28) or 10 years after the most recent patient usage, whichever is later.

(b) for adults, for 10 years after the most recent patient care usage of the medical record.

(3) After the required time of record preservation, records may be destroyed at the discretion of the facility. Facilities shall establish procedures for notification to patients whose records are to be destroyed prior to the destruction of such records.

(4) If a facility ceases operation, the facility shall make provision for secure, safe storage, and prompt retrieval of all medical records for the period specified in 8.102 (2). The hospital shall publicize in a widely circulated newspaper(s) in the facility's service area a notice indicating where medical records can be retrieved.

(5) All orders for diagnostic procedures, treatments, and medications shall be signed by the physician or other licensed practitioner as authorized by law submitting them and entered in the medical record in ink or type; as a facsimile; or by electronic means. The prompt completion of a medical record shall be the responsibility of the attending physician or other practitioner authorized by law. Authentication may be by written signature, identifiable initials or computer key.

(6) The content of patient records shall be as follows.

(a) All patient records shall facilitate the continuity of care and include the following:

(i) Adequate identification - sociological data (including hospital number assigned to patient.)

(ii) Chief complaint and present illness.

(iii) History of disease or injury.

(iv) Past, family, and personal history.

(v) Physical examination reports.

(vi) Reports of any special examinations, including clinical and pathological laboratory findings. Original copies of all pathology test results shall be posted in the patient's medical record, to include reports of tests referred to another laboratory.

(vii) A written report of the findings and evaluation of each diagnostic imaging examination signed by the physician or other practitioner authorized by law responsible for the procedure, as applicable.

(viii) Reports of consultations by consulting physicians, when applicable.

(ix) Treatment and progress notes signed by the attending physician or other practitioner authorized by law.

(x) Findings of clinical or other staff involved in the care of the patient.

(xi) Progress notes, assessments, and plans of care.

(xii) All medications administered including the name, strength, dosage, mode of administration of the medication; date, time, and signature of the person administering.

(xiii) Signed informed consent forms.

(xiv) Final diagnosis, secondary diagnosis, complications.

(xv) Disposition of the case and instructions for follow-up care.

(xvi) Autopsy, if any.

(xvii) As applicable, rehabilitation services treatment records, progress notes of the rehabilitation therapist, and results of special tests and measurements.

(b) Inpatient records shall include the following:

(i) Date and time of admission and discharge.

(ii) Admission diagnosis.

(iii) Discharge plan and discharge summary, with outcome of hospitalization. If the patient is discharged in less than 24 hours, the discharge summary and plan may be included in the physician’s progress notes.

(c) Records of all patients undergoing surgery shall include the following:

(i) History, physical, special examinations, and diagnosis recorded prior to operation.

(ii) Anesthesia record, including post-anesthetic condition signed by the anesthetist, anesthesiologist, surgeon or licensed practitioner authorized by law to sign the record.

(iii) Complete description of operative procedures and findings including the provisional

diagnosis prior to the operative procedure, and post-operative diagnosis recorded and signed by the attending surgeon promptly following the operation.

(iv) The pathologist's report on all tissues removed at the operation.

(d) Records of all obstetric patients shall include the following:

(i) Record of previous obstetric history and pre-natal care including blood serology, and RH factor determination.

(ii) Admission obstetrical examination report describing conditions of mother and fetus.

(iii) Complete description of progress of labor and delivery, including reasons for induction and operative procedures.

(iv) Records of anesthesia, analgesia, and medications given in the course of labor and delivery.

(v) Records of fetal heart rate and vital signs.

(vi) Signed report of consultants when such services have been obtained.

(vii) Names of assistants present during delivery.

(viii) Progress notes including descriptions of involution of uterus, type of lochia, condition of breast and nipples, and report of condition of infant following delivery.

(e) Records of newborn infants shall be maintained as separate records and shall contain the following:

(i) Date and time of birth, birth weight and length, period of gestation, sex.

(ii) Parents' names and addresses.

(iii) Type of identification placed on infant in delivery room.

(iv) Description of complications of pregnancy or delivery including premature rupture of membranes; condition at birth including color, quality of cry, method and duration of resuscitation.

(v) Record of prophylactic instillation into each eye at delivery.

(vi) Results of newborn screening required by law and regulation.

(vii) Report of initial physical examination, including any abnormalities, signed by the attending physician.

(viii) Progress notes including temperature, weight, and feeding charts; number, consistency, and color of stools; condition of eyes and umbilical cord; condition and color of skin; and motor behavior.

(f) Records of all psychiatric patients shall include, as appropriate, the:

(i) admitting diagnosis, diagnoses of intercurrent diseases, and substantiated psychiatric diagnoses.

(ii) reason for admission or readmission.

(iii) history of findings and treatment.

(iv) social services records, including but not limited to, the patient's social history, strengths and deficits.

(v) patient’s legal status concerning voluntary or involuntary commitment.

(vi) documentation of the use of restraint or seclusion, where applicable.

(vii) Nursing notes, updated every shift.

(7) The following hospital records shall be maintained:

(a) Daily census.

(b) Admissions and discharges analysis record.

(c) Chronological register of all deliveries including live and stillbirths.

(d) Register of all surgeries performed (entered daily).

(e) Diagnostic index.

(f) Physician index.

(g) Death register.

(h) Register of out-patient and emergency room admissions and visits.

8.103 EQUIPMENT AND SUPPLIES

(1) Each facility shall provide adequate supplies and equipment for the safe storage and prompt retrieval of medical records.

8.104 FACILITIES

(1) Each hospital shall provide a medical record room or other suitable medical record facilities.

(2) In the case of new hospital construction or modification of an existing hospital facility the hospital shall have a medical record department with administrative responsibility for medical records and the following shall apply:

(a) Each hospital shall provide a medical record department and other medical record facilities with supplies and equipment for medical record functions and services. This department shall include:

(i) Active Record Storage Area.

(ii) Record Review and Dictating Room for physicians.

(iii) Work area for sorting, recording, typing, filing and other assigned medical record functions shall be separate from the record review and dictating room. Consideration should be given to isolation of noisy equipment. Accommodations

should be provided for conducting medical record business with hospital paramedical personnel or public individuals for legitimate access to medical records.

(iv) Medical record storage area within the department.

(v) Inactive medical record storage area. (May be omitted if microfilming used.) Medical record department shall be located in an area of the hospital that is convenient to most of the professional staff.

(b) Security measures shall be maintained by mechanical means in the absence of medical record supervision, to preserve confidentiality and to provide protection from loss, damage and unauthorized use of the medical records.

Part 9. INFECTION CONTROL SERVICES

9.100

9.101 ORGANIZATION AND STAFFING

(1) The facility shall have an infection control program responsible for reducing the risk of acquiring and transmitting nosocomial infections and infectious diseases in the facility.

(2) There shall be a multi-disciplinary infection control committee charged with:

(a) developing written policies and procedures regarding prevention, surveillance and control of nosocomial infections and infectious diseases.

(b) making findings and recommendations to prevent and control nosocomial infections and infectious diseases.

(3) Infection control officer(s) shall implement the policies and procedures and the recommendations of the infection control committee.

9.102 PROGRAMMATIC FUNCTIONS

(1) There shall be written policies and procedures regarding infection control consistent with the following guidelines of the Centers for Disease Control and Prevention (CDC): Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings, 2007 and Guidelines for Environmental Infection Control in Health-Care Facilities, 2003. Policies and procedures shall include, but not be limited to:

(a) the admission and isolation of patients with specific infectious diseases;

(b) the control of routine use of antibiotics and adrenocorticosteroids;

(c) the inservice education programs on the control of nosocomial and infectious diseases, including but not limited to universal precautions;

(d) standards for sterilization of equipment used for direct patient care;

(e) standards for cleaning and disinfecting all areas of the hospital;

(f) standards for linen and laundry services;

(g) the implementation of infection control measures during hospital renovations;

(h) the reporting of diseases as required by laws and regulations pertaining to disease control.

(2) The committee shall make findings and recommendations available promptly to the infection control officer for action.

(3) The committee shall meet at least monthly and maintain minutes of the meetings.

9.103 EQUIPMENT AND SUPPLIES. Reserved.

9.104 FACILITIES

(1) Rooms used for isolation of patients with infectious diseases should be: 1) Equipped with private toilet facilities; 2) Provided with an air supply and exhaust system that neither recirculates nor redistributes air from a central air system; 3) Designed to provide a negative or positive pressure in relation to adjacent areas.

In the case of new hospital construction, or modification of an existing hospital facility isolation room(s) shall be provided on the basis of one for each thirty (30) beds or major fraction thereof, if the hospital does not have a separate contagious disease unit. Each isolation room shall have:

(a) Handwashing facilities as required in Part 11, General Patient Care Services.

(b) Separate toilet room with bath or shower

(c) Mechanical ventilation shall be provided at the rate of six air changes per hour with no recirculation. Supply air shall be filtered using 80% efficient filters. Rooms to be of negative pressure relative to adjacent areas.

(d) An anteroom with lavatory should be provided (One anteroom may serve more than one isolation room.)

Part 10. PATIENT RIGHTS. The facility shall be in compliance with 6 CCR 1011-1, Chapter II, Part 6.

Part 11. GENERAL PATIENT CARE SERVICES

11.100

11.101 ORGANIZATION AND STAFFING

(1) The facility shall provide inpatient and outpatient care services. Services shall be provided in accordance with recognized standards of practice, facility policy and procedure, medical orders, and the established plan of care.

11.102 PROGRAMMATIC FUNCTIONS

(1) Admissions

(a) Each patient admitted to the hospital shall have a visible means of identification placed on his or her person.

(i) Notwithstanding Section 11.102 (1)(a), the hospital may use other means of identification, in accordance with documented policies and procedures, if visible means of identification placed on the patient compromises medical or personal

safety.

(b) No patient shall be admitted for inpatient care to any room or area other than one regularly designated as a patient bedroom. There shall be no more patients admitted to a patient bedroom than the number for which the room is designed and equipped. State-declared emergencies are exceptions.

(c) Except in emergent situations, patients shall only be accepted for care and services when the facility can meet their identified and reasonably anticipated care, treatment, and service needs.

(2) Policies and Procedures. Written policies and procedures shall be developed and implemented by each department/service that provides direct patient care including, but not limited to:

(a) procedures for medical emergencies. Resuscitation services shall be available throughout the hospital.

(b) coordination of care across multiple services/departments, as applicable.

(3) Patient Assessment and Care Plan

(a) Patient assessments shall document patient needs, capabilities, limitations and goals. Qualified staff shall:

(i) conduct an initial assessment of the patient's physical and psychological status.

(ii) conduct an assessment or screening upon each initial contact with therapy, social, nursing, and dietary services and at regular intervals thereafter.

(4) Patient Care Planning

(a) A care plan shall be prepared for each patient, reviewed and revised as needed. Care plans shall:

(i) contain goals, both short-term and long-term as applicable, and timeframes for meeting such goals.

(ii) be in writing and maintained current.

(iii) be individualized and designed to meet the patient's needs.

(iv) demonstrate patient-centered coordination when the patient is receiving services from multiple departments/services.

(v) address the pain management needs of the patient.

(b) Staff shall evaluate the patient's progress based on the goals established in the care plan.

(c) The complete plan of care shall be easily identifiable and accessible within the medical record.

(5) Orders

(a) Medications and treatments shall be given only on the order of a physician or other practitioner authorized by law.

(b) Verbal orders. Verbal orders shall be:

(i) received by members of the appropriate discipline as specified by law and approved by the medical staff, nursing services, and the governing board. Orders shall be documented.

(ii) transferred to the medical record by a member of the specific discipline responsible for implementing the order.

(iii) authenticated within 48 hours.

(c) Orders shall be written and shall include the date, time, practitioner giving the order, and specifications of the order. For medications, the name, strength, dosage, frequency and route of administration shall be indicated.

(d) Orders prescribing high-risk drugs, i.e., narcotics, sedatives, anticoagulants, antibiotics, etc., shall include a time limit. Such time limit shall be agreed upon by the medical staff and shall be so recorded in the rules and regulations of the organized medical staff.

(e) Medical staff in conjunction with the pharmacist shall establish standard stop orders for all medications not specifically prescribed as to time or number of doses.

(6) Discharge Planning

(a) The facility shall develop a discharge plan for each inpatient. Discharge planning shall be initiated early in the care, service or treatment process.

(b) The facility shall develop and implement policies and procedures regarding discharge planning. At minimum, the policy and procedure shall address:

(i) the discharge planning process.

(ii) the qualifications of the staff responsible for implementing discharge planning.

(iii) initiation of discharge planning in a timely manner to allow for the arrangement of post-hospital care, as needed.

(iv) evaluation of the discharge planning process periodically for effectiveness.

(c) The discharge plan shall:

(i) include an evaluation of the post-hospital care needs of the patient and the availability of corresponding services.

(ii) identify the role of the facility staff, patient, patient's family or designated representative in initiating and implementing the discharge planning process.

(iii) be discussed with the patient or designated representative prior to leaving the facility.

(d) For a patient with a discharge plan indicating the need for a post-hospital health care service, the facility shall:

(i) inform the patient of the patient's freedom to choose among providers of post-hospital care as well as the choices available under the applicable health insurance coverage.

(ii) provide a comprehensive list of relevant, licensed post-hospital care providers in the geographic area requested. The information regarding post-hospital providers shall be presented in a manner that does not unduly direct patients to use a provider when such direction results in monetary or other benefits and considerations to the hospital or hospital personnel.

(iii) ensure that the receiving health care provider and, as applicable, the patient's primary care physician receive written documentation of the patient's discharge diagnosis, continuing care orders, current medications prior to discharge and the patient's discharge or transfer instructions. Documentation shall also include contact information for the attending licensed independent practitioner. The admission and discharge summaries shall be forwarded to the receiving health care provider within 30 days of discharge, upon request by the receiving health care provider.

(e) For a patient with a discharge plan who is not transferred to another facility, the facility shall provide the patient with:

(i) a contact to call in case the patient has questions after discharge.

(ii) written instructions about self-care, follow up care, modified diet, and medications, signs and symptoms to be reported to the practitioner, if relevant.

(f) The facility shall prepare a discharge summary to facilitate continuity of care that is signed by the attending physician and includes the following:

(i) reason for admission.

(ii) significant findings.

(iii) procedures and treatment provided.

(iv) patient's discharge condition.

(v) patient and family instructions.

(vi) a medication list indicating new, changed, or discontinued.

(vii) a list of outstanding medical issues and pending tests at the time of discharge that require follow-up.

11.103 EQUIPMENT/FURNITURE AND SUPPLIES

(1) All equipment used for patient care services shall be used in accordance with current standards practice, documented policies and procedures of care, as well as manufacturer's instructions.

(2) The following shall be readily available at all times: 1) Oxygen; 2) Suction; 3) Portable emergency equipment, supplies and medications; 4) Compatible supplies and equipment for immediate intravenous therapy.

(3) Patient bedrooms shall be equipped with movable furniture and equipment with the following for each patient: 1) Adjustable, washable bed with side rails; 2) Cabinet or bedside table; 3) Overbed table; 4) Complete personal care equipment that is sanitized or disposable including water carafe, mouth wash cups, emesis basin, wash basin, bedpan and urinal (when necessary).

11.104 FACILITIES

(1) Patient Rooms

(a) There shall be provisions for private and multiple bedrooms to meet the needs of patients and programs of the hospital. There shall be no more than four beds per patient bedroom. There should be no more than approximately 40 patient beds in a patient care unit.

(b) Each one-bed room shall contain a minimum floor area of 100 square feet. Each multiple-bed room shall contain a minimum floor area of 80 square feet per bed. This minimum floor area, may include built-ins not exceeding four feet in height.

(c) Privacy shall be provided for each patient in a multiple-bed room by the installation of approved cubicle curtains or partitions.

(d) Each patient bedroom shall have a minimum window area equal to 1/8 of the floor area. The ground level shall be maintained at or below the window sill for a distance of at least 8 feet measured perpendicular to the window. Privacy for the patient and control of light shall be provided at each window.

(e) Each patient bedroom shall have direct entry from a corridor. In the case of new hospital construction, or modification of an existing hospital facility, the door to each patient room may be no more than 120 feet from the nursing station or from the clean or soiled holding rooms.

(f) Artificial light shall be provided and include: 1) General illumination; 2) Other sources of sufficient illumination for reading, observations, examinations, and treatments; 3) Night light controlled at the door of the bedroom; 4) Quiet operating switches (not required in existing buildings.)

(g) A lavatory complete with mixing faucet, blade controls, soap and sanitary hand drying accommodations shall be provided in each patient bedroom, except that the lavatory may be installed within the toilet room in private bedrooms.

(h) Toilet facilities shall be provided immediately adjacent to private or multiple-bed rooms in the ratio of one facility for not more than four patient beds and shall include: 1) Toilet with bedpan flushing equipment; 2) Incombustible waste paper receptacle, either seamless or with removable impervious liner; 3) Approved grab bars convenient for the safety of patients; 4) Nurse-call signal system. In new construction the door to the toilet shall be at least 2'8" in width and shall not swing into the toilet room unless provided with rescue hardware. Recommend 3'0" door.

(i) Each patient shall be provided with separate closet space or locker. In the case of new hospital construction or modification of an existing hospital facility, the closet space or locker must open into the patient room.

(j) Each patient shall be furnished with a nurse-call signal system that registers a signal from the patient, at the corridor bedroom door, at the patient care control center (nurses station), and in service areas of the patient care unit. A duplex unit may be used for 2 patients in multi-bed rooms, but a light should be provided to indicate the patient placing the call.

(2) Service Areas

(a) The following service areas shall be provided and located conveniently for patient care: 1) Patient care control center (nurses station) accommodating a nurse call signal system

from patients, a communication system with other hospital departments, and the outside; 2) Medical record recording facilities; 3) Medicine preparation area; 4) Clean holding area: 5) Soiled holding area; 6) Janitor's closet; 7) Stretcher and wheelchair storage area, 8) Nourishment station shall be provided in the case of new hospital construction, or modification of an existing hospital facility; 9) Clinical examination and treatment room: 10) Bathing facilities.

(b) The patient care control center (nurses station)** shall be adequately designed and equipped.

(c) The medication preparation area** shall be equipped with: 1) Cabinets with suitable locking devices to protect drugs stored therein; 2) Refrigerator equipped with thermometer and used exclusively for pharmaceutical storage; 3) Counter work space; 4) Sink with approved handwashing facilities; 5) Antidote, incompatibility, and metri-apothecary conversion charts. Only medications, equipment, and supplies for their preparation and administration shall be stored in the medication preparation area. Test reagents, general disinfectants, cleaning agents, and other similar products shall not be stored in the medication area.

** Other approved facilities for patient services may be substituted to meet the requirements specified in 19.13 through 19.18

(3) Linen and Laundry

(a) (Not required in hospitals of 25 beds or less if the CSR is conveniently located on the same floor). The clean supply holding room*** shall be equipped with: 1) Suitable counter sink with mixing faucet, blade controls, soap, and sanitary band drying facility; 2) Waste container with cover (foot controlled recommended), and impervious, disposable liner; 3) Cupboards or carts for supplies. In the case of new hospital construction, or modification of an existing hospital facility, 4) Mechanical fresh air supply to maintain positive pressure; and 5) Nurse call utility station must also be provided.

(b) There shall be a separate closed area in the clean supply holding room, on a cart, or in a separate closet for clean linen supplies.***

(c) (Not required in hospitals of 25 beds or less if there is a CSR, and a soiled linen holding room or soiled linen chute conveniently located on the same floor). The soiled holding room*** shall be equipped with: 1) Suitable counter sink with mixing faucet, blade controls, soap, and sanitary hand-drying facility. In the case of new hospital construction, or modification of an existing hospital facility the sink must be 2-compartment. 2) Waste container with cover (foot controlled recommended) and impervious, disposable liner; 3) Soiled linen cart or hamper with impervious liner; 4) Accommodations and provisions for enclosed soiled articles; 5) Space for short-time holding of specimens awaiting delivery to laboratory; 6) Adequate shelf and counter space; and in the case of new hospital construction, or modification of an existing hospital facility, 7) Nurse call utility station; 8) A clinical flushing sink; and 9) Continuous mechanical exhaust ventilation to the outside.

(4) The janitor's closet*** shall be equipped with: 1) Sink, preferably a floor receptor, with mixing faucets; 2) Hook strip for mop handles from which soiled mopheads have been removed; 3) Shelving for cleaning materials; 4) Approved handwashing facilities, in the case of new hospital construction, or modification of an existing hospital facility, the handwashing facility must be separate if a floor receptor is used; 5) Waste receptacle with impervious liner.

The floor area should be adequate to store mop buckets on a roller carriage, wet and dry vacuum machine, and floor scrubbing machine.

(5) In new construction, recessed storage space or rooms shall be provided for extra equipment, stretchers, and wheelchairs.

(6) In new construction, the nourishment station shall contain a sink equipped for handwashing, equipment for serving nourishments between scheduled meals, refrigerator, and storage cabinets. Ice for patient service and treatment shall be provided only by ice maker - dispenser units.

*** Other approved facilities for patient services may be substituted to meet the requirements specified in 19.13 through 19.18.

(7) Patient bathing facilities shall be provided in the ratio of one tub or shower for each ten patients. Approved grab bars, and in the case of new hospital construction, or modification of an existing hospital facility, a nurse call, shall be installed at each tub or shower convenient for the safety of patients using the tub or shower. The room shall be sufficiently large to provide space for wheelchair movement and provision for privacy. In the case of new hospital construction or modification of an existing hospital facility, on each patient floor at least one shower shall be provided which will accommodate a wheelchair.

There should be toilet and lavatory facilities in the bathroom with mixing faucet, blade controls, soap, and sanitary hand-drying accommodations.

(8) Toilet facilities shall be provided for personnel on each patient care unit.

Part 12. NURSING SERVICES

12.100

12.101 ORGANIZATION AND STAFFING

(1) There shall be a nursing department. The nursing department shall be organized formally to provide complete, effective care to each patient.

(2) The nursing service department shall be under the direction of a registered nurse qualified by education and experience to direct effective nursing care.

(3) There shall be a master plan of nurse staffing for providing continuous registered nurse coverage, for distribution of nursing personnel, for replacement of nursing personnel, and for forecasting future needs. The nursing care required by different types of patients shall be the major consideration in determining the number, quality, and category of nursing personnel that are needed in any given situation.

(4) The authority and responsibility of each nurse and nursing personnel shall be defined clearly in written policies. Licensed practical nurses and auxiliary nursing personnel shall be assigned only those duties for which they are qualified and shall be under the supervision of a registered nurse.

(5) At least one registered nurse shall be on duty at all times in each patient care unit. One registered nurse shall be designated in charge and shall be delegated the authority and responsibility for the nursing services on that patient care unit. Additional registered nurses, licensed practical nurses, or other auxiliary personnel shall be available.

(6) The director of nursing shall be responsible for ensuring that all nursing staff have the qualifications, skills and experience necessary to deliver the care assigned in accordance with professional standards of practice and facility policy and procedure.

12.102 PROGRAMMATIC FUNCTIONS

(1) There shall be written nursing procedures that establish the standards of performance for safe, effective nursing care of patients. These procedures shall be reviewed periodically and revised as necessary.

(2) Nursing staff shall conduct initial and ongoing assessments and screenings of the patient's physical, cognitive, behavioral, emotional and psychosocial status in sufficient scope and detail to meet the needs of the patient, according to facility policy and professional standards of practice.

12.103 EQUIPMENT. Reserved.

12.104 FACILITIES. Reserved.

Part 13. PHARMACEUTICAL SERVICES

13.100

13.101 ORGANIZATION AND STAFFING

(1) The pharmaceutical services of the hospital shall be organized and maintained primarily for the benefit of the hospital patients, and shall be operated in accordance with federal and state laws and regulations.

(2) The pharmacy service shall be under the direct supervision of a pharmacist licensed to practice pharmacy in the State of Colorado.

(3) Provision shall be made for convenient and prompt 24-hour availability of drugs for administration to patients. Emergency pharmacy services shall be available 24 hours per day. If a pharmacist is not available on site on a 24-hour basis, a pharmacist shall be available on-call within 30 minutes.

(4) A pharmacist shall be responsible for compounding, preparing, labeling, transferring between containers, and dispensing drugs, including direct supervision of qualified personnel performing such tasks.

13.102 PROGRAMMATIC FUNCTIONS

(1) Pharmacy and Therapeutic Committee. There shall be a hospital pharmacy and therapeutic committee to assist in the formulation of broad professional policies regarding the evaluation, selection, procurement, distribution, use, safety procedures, and other matters relating to drugs in hospitals.

(2) Compliance with External Standards. Pharmacies shall:

(a) be registered by the Colorado State Board of Pharmacy.

(b) have a current Drug Enforcement Administration registration.

(3) Inventory. The facility shall develop and implement policies and procedures regarding:

(a) stocking of medications. The pharmacy shall maintain a current formulary of approved drugs and biologicals. The facility shall maintain an adequate stock of the medications listed in the formulary. The facility shall be responsible for the quality, quantity and sources of supply of all medications. Drug stocks shall not contain outdated, unusable, or mislabeled products.

(b) pharmaceutical service transactions. Current records shall be maintained that account for the receipt, distribution, disposition, and destruction of drugs and biologicals.

(c) controlled substances and other drugs subject to abuse and illegal distribution. The receipt, distribution, administration, and disposition of controlled substances shall be readily

traceable. Mechanisms shall be implemented to ensure the security of the drugs and prevent and detect the diversion of controlled substances and other drugs that may be abused or illegally sold. When diversion is detected, appropriate corrective measures shall be implemented.

(d) after-hours access. If the pharmacy is not open 24 hours, 7 days per week, the facility shall have a policy and procedure regarding after-hour access. The policy and procedure shall specify the personnel permitted access to the drug storage area(s). There shall be accountability for all doses of drugs removed when the pharmacist is not present.

(e) recall and drug discontinuation management. The facility shall alert appropriate staff to remove any drugs or biologicals subject to a recall or discontinuation for safety reasons.

(f) disposal of unused prepared medications.

(g) periodic inspection of the medication storage area.

(4) Storage. The facility shall develop and implement policies and procedures regarding:

(a) the prevention of unauthorized access to drugs and biologicals. All drugs and biologicals shall be kept in a secure area. All controlled drugs shall be kept in a locked secure area.

(b) maintenance of therapeutic integrity. Drugs and biologicals shall be stored under the proper conditions of sanitation, temperature, light, moisture, ventilation, and segregation.

(5) Medication Administration. Medications shall be identified with at least the name, strength, and dosage. Prior to administration, the name, strength, dosage, frequency and route of administration on the patient order shall be checked. The facility shall develop and implement policies and procedures regarding:

(a) the review of patient drug profiles.

(b) safe administration of drugs and biologicals. Only persons who are authorized by law and the facility and are appropriately trained shall administer medications.

(c) monitoring and documenting the effects of medication, including but not limited to, the process for monitoring the first dose of a medication that has been identified as one with the potential for serious adverse reactions.

(d) identification and reporting of adverse reactions, interactions, and medication errors.

(e) self-administration. Policies and procedures shall include, but not be limited to, storage and documentation of the self-administered drugs. Patients shall only be permitted to self-administer medications pursuant to an order from a licensed independent practitioner.

(f) use of the patient's own medications. Drugs and biologicals brought into the facility by the patient may be administered only if the medication can be accurately identified by the pharmacy, secured, and pursuant to an order from an the attending licensed independent practitioner.

(g) medications brought into the facility by practitioners to be administered to patients.

(h) the review of medication orders by a pharmacist for appropriateness.

(6) Information Resources. Up-to-date resources shall be made readily available to professional staff

regarding the appropriate use of drugs and biologicals, including but not limited to: therapeutic use, potential adverse effects, dosage, and routes of administration.

(7) Investigational Drugs

(a) If investigational drugs are used, policies and procedures shall be developed and implemented for their safe and proper use.

(b) Investigational drugs shall be used only:

(i) when there is written approval of an Institutional Review Board (IRB), established in accordance with federal law and regulation.

(ii) under the supervision of a member of the medical staff and administered in accordance with an IRB approved protocol.

13.103 EQUIPMENT

(1) A refrigerator with thermometer and freezing compartment shall be provided for the proper storage of thermolabile products.

(2) The facility shall have a Laminar flow or other class 100 environment for preparing intravenous admixtures.

13.104 FACILITIES

(1) Facilities shall be provided for the adequate storage, preparation, and dispensing of drugs with security, proper lighting, temperature control, moisture, ventilation, and sanitation facilities

Part 14. LABORATORY SERVICES

14.100 CLINICAL PATHOLOGY

14.101 ORGANIZATION AND STAFFING

(1) Clinical pathology services shall be made available as required by the needs of the medical staff. Emergency laboratory services shall be made available whenever needed.

(2) The laboratory shall be under the supervision of a physician, certified in clinical pathology, either on a full-time, part-time, or consulting basis. The pathologist shall provide, at a minimum, monthly consultative visits.

(3) There shall be a sufficient number of clinical laboratory technologists, qualified by training and experience, to promptly and proficiently perform the laboratory tests and examinations required of them.

14.102 PROGRAMMATIC FUNCTIONS

(1) All clinical pathology services shall be ordered by a physician or a person authorized by law to use the results of such findings.

(2) Clinical pathology services shall comply with the requirements set forth in the Clinical Laboratory Improvement Amendments (CLIA).

(3) Policies and Procedures

(a) A manual outlining all procedures performed in the laboratory shall be complete and readily available for reference.

(b) The conditions and procedures for referring specimens to another laboratory be in writing and available in the laboratory.

(c) Procedures for the adequate precautions for discarding specimens shall be in use -- sterilization, incineration, or both.

(4) Records

(a) A record system shall be established which ensures that specimens are adequately identified, properly processed, and permanently recorded.

(b) Duplicate copies of all reports shall be kept in the laboratory in a manner which permits ready identification and accessibility for two years.

14.103 EQUIPMENT AND SUPPLIES

(1) All equipment shall be in good working order, be routinely checked and be precise in terms of calibration.

(2) If tests are performed in the specialties of mycobacteriology, mycology, and/or virology, the laboratory shall be equipped with a microbiological safety cabinet, with an adequately filtered exhaust system.

(3) Vacuum breakers must be present on sinks where specimens are handled or discarded to ensure that the water supply is not contaminated.

14.104 FACILITIES. Reserved.

14.200 BLOOD BANKING

14.201 ORGANIZATION AND STAFFING

(1) The hospital shall provide for the procurement, storage, and transfusion of blood as needed for routine and emergency cases.

14.202 PROGRAMMATIC FUNCTIONS

(1) Standards of the American Association of Blood Banks shall be used; or the administrative staff of the hospital must substitute, in writing, alternate standards which are safe and adequate for the collection and administration of blood and blood products.

(2) Blood and blood products shall only be administered upon order of a physician or other practitioner authorized by law.

(3) Before administering a blood transfusion, the following shall be identified accurately and verified by a registered nurse and a licensed health care professional acting within his or her standard of practice: 1) Patient; 2) Patient's blood specimen; 3) Type, crossmatch, and expiration date of donor blood.

(4) Records must be kept which show the complete receipt and disposition of blood.

(5) Each unit of blood typed and cross-matched for transfusion must be adequately identified by an

attached tag which cannot be removed from the unit accidentally.

14.203 EQUIPMENT AND SUPPLIES

(1) Equipment shall be available which ensures safe storage and transfusion of blood.

(2) Refrigerators used to store blood overnight shall have a recording thermometer and an adequate alarm system. The refrigerator shall be on the emergency power source.

14.204 FACILITIES

(1) Facilities shall be available to ensure safe storage and transfusion of blood.

Part 15. DIAGNOSTIC IMAGING SERVICES

15.100

15.101 ORGANIZATION AND STAFFING

(1) The hospital shall provide diagnostic radiology services in accordance with the scope of care established pursuant to Section 6.102 (1). Radiological imaging shall be available at all times. The hospital may provide other diagnostic imaging services, such as ultrasound and magnetic resonance imaging.

(2) Imaging services shall be under the direction of a qualified physician. Radiology services shall be under the supervision of a full-time or consulting radiologist whose professional competence has been determined by the organized medical staff.

15.102 PROGRAMMATIC FUNCTIONS

(1) Radiological services involving the use of machines that produce ionizing radiation or the use of radioactive materials for diagnostic purposes shall be in compliance with 6 CCR 1007-1, Rules and Regulations Pertaining to Radiation Control.

(2) The hospital shall be responsible for the formulation, implementation and periodic review of written policies and procedures governing the services offered and in addition include the management of patients with infectious diseases, critical care patients, and patients who experience medical emergencies.

(3) Diagnostic imaging services shall be ordered by a physician or other practitioner authorized by law. The order shall include the name of the patient, the name of the ordering individual, and the radiological procedure ordered. Services shall be provided in accordance with the order.

15.103 EQUIPMENT AND SUPPLIES. Reserved.

15.104 FACILITIES

(1) The facilities used to provide diagnostic imaging services shall have adequate space, storage (including storage for radiological images), lighting and ventilation.

Part 16. DIETARY SERVICES

16.100

16.101 ORGANIZATION AND STAFFING

(1) There shall be an organized food service planned, equipped, and staffed to serve adequate meals to patients. Food prepared outside the hospital shall be from sources that comply with these regulations and other applicable laws and regulations.

(2) A person qualified by training and experience in food service shall direct the dietary services.

(3) A registered dietitian shall be responsible for the nutritional aspects of care, including but not limited to, the evaluation of the nutritional status and needs of patients, the review of modified and special diets for nutritional adequacy, and patient counseling.

(4) If 24-hour dietary services are not provided, other means of providing adequate nourishment for patients shall be made available.

(5) The facility's dietary services shall be integrated, as necessary, with other departments and services of the facility, including but not limited to, infection control and pharmacy.

16.102 PROGRAMMATIC FUNCTIONS

(1) Patient Care

(a) The nutritional needs of the patients shall be met in accordance with recognized dietary standards and in accordance with orders of the licensed independent practitioners responsible for the care of the patient.

(b) The facility shall develop and implement policies and procedures regarding:

(i) the triggers and processes for conducting: nutritional risk screening; assessment of clinically relevant malnutrition; and the integration of therapeutic interventions into the patient's care plan.

(ii) infection control methods for the provision of services to patients in isolation. These policies and procedures shall be developed in conjunction with and reviewed periodically by the Infection Control Committee. Food served to patients in isolation, because of infectious diseases, shall be in disposable utensils or in utensils that shall be sterilized.

(c) Therapeutic diets and nourishments shall be served as prescribed by the attending licensed independent practitioner. A current diet manual shall be available to medical staff and personnel for fulfilling dietary prescriptions.

(d) Menus shall be varied to meet patient needs. Food allergies and intolerances, personal tastes, desires, cultural patterns and religious beliefs of patients shall be considered and reasonable menu adjustments made.

(2) Food: Condition, Preparation/Handling, Storage

(a) Condition

(i) Food shall be in sound condition, free from spoilage, misbranding, or contamination, and shall be safe for human consumption.

(ii) All food served shall be from approved sources. An approved source is a source that is inspected by and in compliance with the standards of a local, state, and/or federal agency responsible for the oversight of the production, processing, and/or preparation of food.

(iii) Poisonous and toxic materials shall be used only in such ways that they will neither contaminate food nor be hazardous to employees.

(b) Preparation and Handling

(i) Food shall be palatable and prepared using methods that conserve nutritive value, flavor, and appearance.

(ii) Unwrapped food on display for service shall be protected against contamination by sneeze guards and other devices.

(iii) Food being conveyed shall be covered, completely wrapped or packaged to protect from contamination.

(iv) Potentially perishable foods shall be maintained at a temperature of 41°F (5°C). or below, or 135°F (57°C). or above.

(v) Convenient and suitable utensils, including self-service, such as forks, knives, tongs, and spoons shall be used to handle food at all points where food is prepared and served.

(c) Storage

(i) Containers of food shall be stored above the floor on clean racks, dollies, or other clean surfaces to protect them from contamination.

(ii) Stored foods shall be clearly identifiable and dated, as appropriate.

(iii) Poisonous and toxic materials shall be labeled and stored separately from food.

(iv) Food shall not be placed under: sewer lines; water lines that are not protected to intercept potential drips, including leaking automatic fire protection sprinkler heads; or lines on which water has condensed.

(3) Hygienic Practices. The facility's dietary services shall be operated in a manner that prevents foodborne illness.

(a) Staff Hygiene

(i) Employees shall wash their hands thoroughly in a hand washing facility before starting work and as often as may be necessary to remove soil and contamination. Each employee shall wash his hands before resuming work after visiting the toilet room. Handwashing shall not be conducted in kitchen sinks used for cleaning kitchenware or as part of food preparation; instead, separate handwashing facilities shall be used.

(ii) All dietary employees shall wear hair nets, head-bands, caps, or other effective hair restraints. Beards and mustaches that are not closely cropped shall be covered.

(iii) Employees shall not use tobacco in any form while engaged in food preparation, service, or equipment washing areas.

(iv) No person, while infected with a disease in a communicable form which can be transmitted by foods or who is afflicted by a boil, or an infected wound, shall work in a food service setting in any capacity in which there is a likelihood of such

person contaminating food or food contact surfaces with pathogenic organisms or transmitting diseases to other persons.

(b) Food-contact surfaces, dietary services equipment, and utensils shall be:

(i) non-toxic, smooth, made of impervious materials, free of open seams, not readily corrosible, and free of difficult-to-clean internal corners and crevices.

(ii) clean to sight and touch, except when current or recent usage precludes it.

(iii) cleaned and disinfected in a manner and at intervals that are in accordance with recognized standards and the facility's written policies and procedures. Food contact surfaces shall be cleaned and disinfected using methods and agents approved as safe for food contact surface application and either at intervals not to exceed four hours when the surface is in continuous use, or if not in continuous use, after final use each work day.

(c) Warewashing

(i) Utensils shall be pre-rinsed or pre-scraped, and when necessary pre-soaked to remove gross particles and soil.

(ii) Manual Warewashing. Sinks shall be cleaned and disinfected before use. A thermometer shall be readily available and frequently used to monitor temperatures. The temperature of the wash solution shall be not less than 110°F (43°C) unless a different temperature is specified on the cleaning agent manufacturer's label instructions. Ware shall be rinsed free of detergent and abrasive with clean water, disinfected and air-dried. Disinfection shall be conducted in accordance with one of the following methods:

(A) Immersion for at least 1 minute in a clean solution containing a minimum of 50 parts per million (mg/L) and no more than 200 parts per million (mg/L) of available chlorine as hypochlorite and having a temperature of at least 75°F (24°C); or

(B) Immersion for at least 1 minute in a clean solution containing at least 12.5 parts per million of available iodine, having a pH range not higher than 5.0, unless otherwise certified to be effective by the manufacturer, and at a temperature of at least 75°F (24°C); or

(C) Immersion in a clean solution containing a quarternary ammonia product or any other chemical sanitizing agent allowed under Sanitizers, 21 CFR Section 178.1010.

(iii) Mechanical Warewashing. Commercial ware washing machines shall be used. Machines shall be operated in accordance with manufacturers' instructions.

(iv) Utility ware, pots, pans, and similar utensils shall be cleaned in an area separated from the dishwashing operation.

(v) Separate drainboards shall be used for soiled utensils prior to washing and for clean utensils following disinfecting.

(d) Clean Environment

(i) The walls, ceiling and floors of all areas where food is stored, prepared or served shall be kept clean and in good repair.

(ii) All non-food contact surfaces of equipment, including transport vehicles, shall be cleaned as often as necessary to keep the equipment free from the accumulation of dust, dirt, food particles, and other debris.

(iii) Dietary services areas and loading docks shall be protected from and free of vermin.

(e) Storage. Utensils and dietary services equipment shall be cleaned and disinfected prior to storage.

(i) Cleaned and disinfected utensils and dietary services equipment shall be handled in a way that protects them from contamination.

(ii) Spoons, knives, and forks shall be touched only by their handles. Cups, glasses, bowls, plates, and similar items shall be handled without contact with inside surfaces or surfaces that contact the user's mouth.

(iii) Cleaned and disinfected utensils and dietary services equipment shall be stored 6 inches above the floor in a clean, dry location in a way that protects them from contamination by splash, dust, and other means.

(iv) Utensils and dietary services equipment shall not be placed under: sewer lines; water lines that are not protected to intercept potential drips, including leaking automatic fire protection sprinkler heads; or lines on which water has condensed.

(v) Utensils shall be air-dried before being stored or shall be stored in a self-draining position.

(vi) Glasses and cups shall be stored inverted. Other stored utensils shall be covered or inverted, wherever practical. Facilities for the storage of knives, forks and spoons shall be designed and used to present the handle to the staff or user. Unless tableware is pre-wrapped, holders for knives, forks and spoons at self-service locations shall protect these articles from contamination and present the handle of the utensil to the consumer.

(f) Waste Disposal

(i) Garbage and refuse located in the dietary services area shall be placed in impervious containers equipped with tightly fitting covers when filled or stored, or not in continuous use.

16.103 EQUIPMENT AND SUPPLIES

(1) Adequate equipment shall be provided for efficient preparation of meals.

(2) A minimum of two units of refrigeration shall be provided to protect foods kept on hand. Refrigerators and storerooms used for perishable foods shall be equipped with reliable thermometers.

(3) Walk-in refrigerators and freezers shall have inside lighting and inside lock releases, or an audiovisual signal system as a suitable safety device.

(4) Equipment on tables or counters, unless readily movable, shall be installed so as to facilitate cleaning and safety.

(5) Floor-mounted equipment, unless readily movable shall be sealed to the floor to prevent liquids or debris from settling under the equipment. Lubricated bearings and gears shall be constructed so that lubricants cannot get into the food.

(6) Food waste grinders shall be installed in compliance with applicable laws and regulations and manufacturer's instructions.

16.104 FACILITIES

(1) Adequate space shall be provided to allow for fixed and movable equipment and employee functions for receiving and storage, refrigeration, food preparation, and dishwashing.

(2) Clean, well-ventilated food storerooms shall be provided.

(3) Facilities and systems for storage of silverware shall be designed and maintained to prevent contamination.

(4) Areas for preparing food and storing and cleaning utensils shall be adequately lighted.

(5) Rooms for preparing and serving food and warewashing shall be well ventilated. Filters shall be readily removable for cleaning or replacement.

(6) Adequate, clean toilet facilities shall be provided.

(7) Separate handwashing facilities with soap and sanitary hand-drying accommodations shall be conveniently provided.

(8) Separate two-compartment sinks are required for manual washing operations, and they shall be of such length, width, and depth to permit complete immersion of equipment and utensils.

(9) In the case of new hospital construction, or modification of an existing hospital facility, the following shall apply:

(a) Cart washing space must be provided, preferably in the dishwashing area. Hot water and a floor drain must be provided in this area.

(b) A lounge, complete with lockers and toilet facilities for the dietary staff shall be provided near the kitchen.

(c) Dining area(s) must be provided for staff, visitors and patients.

(d) Warewashing Operations

(i) Commercial mechanical dishwashing equipment shall be physically separate from food preparation and service areas.

(ii) The dishwash room shall be arranged such that clean dishes are discharged from the dish machine onto a clean dish table outside the dishwash room.

(iii) On or after March 2, 2010, separate three-compartment sinks are required for manual washing operations, and they shall be of such length, width, and depth to permit complete immersion of equipment and utensils. Each sink compartment used in manual warewashing operations shall be supplied with hot and cold water under pressure through a mixing faucet.

Part 17. ANESTHESIA SERVICES

17.100

17.101 ORGANIZATION AND STAFFING

(1) The hospital shall provide anesthesia services commensurate with the services provided by the hospital.

(2) 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 case of dental treatment, dentists may administer local anesthetics.

17.102 PROGRAMMATIC FUNCTIONS

(1) Patients recovering from anesthesia shall remain under continuous care of a registered nurse. Nurses shall have been instructed in the care of post-anesthetic patients, shall have no other duties during the time they are caring for such patients and shall have facilities for immediate communication with the attending surgeon, anesthesiologist, or qualified substitute present in the hospital.

17.103 EQUIPMENT

(1) There shall be equipment for the administration of anesthesia that is commensurate with the clinical procedures and programs conducted within the hospital.

(2) Anesthesia equipment shall be cleaned properly and sterilized after each use excepting multi-use heat sensitive equipment may be disinfected using a process that is bactericidal, tuberculocidal and virucidal. Hypodermic needles, syringes, and allied equipment shall be sterilized, unless disposed of after use. Written procedures shall be developed for these processes.

17.104 FACILITIES

(1) There shall be facilities for the administration of anesthesia that are commensurate with the clinical procedures and programs conducted within the hospital.

(2) Areas used to care for post-anesthetic patients shall have facilities for immediate communication with the attending surgeon, anesthesiologist, or qualified substitute present in the hospital.

Part 18. EMERGENCY SERVICES

18.100

18.101 ORGANIZATION AND STAFFING

(1) Each general hospital shall be organized and equipped to provide emergency treatment at any hour to persons presenting or presented for this purpose. Such treatment shall be rendered in an area specifically designated for this service, and hereafter referred to as the “emergency department” .

(2) Each hospital shall have a well defined plan for the provision of emergency care. This plan shall relate to community need and the capability of the hospital. If the hospital elects to transfer patients, the referring hospital shall institute essential life saving measures and provide emergency procedures.

(3) The emergency department shall be organized formally as a department or service of the organized

medical staff.

(4) Provision shall be made for medical staff coverage at any hour.

(5) A registered nurse qualified by training and experience in emergency procedures shall be available at all times to supervise nursing care in the emergency unit. Nursing staff shall be available to cover average utilization. Provision shall be made for additional nursing personnel during unusual circumstances.

18.102 PROGRAMMATIC FUNCTIONS

(1) Emergency patient care shall be guided by written policies, and shall be supported by appropriate procedure manuals and reference material.

(2) Each patient shall be discharged from the emergency department only upon a physician's recorded authorization including instructions given to the patient for follow-up care.

(3) A poison control chart and the location and telephone number of the nearest poison control center shall be posted prominently in the emergency department.

18.103 EQUIPMENT AND SUPPLIES

(1) Equipment, supplies and drugs shall be provided commensurate with the scope of operation.

(2) The equipment and supplies shall include but not be limited to the administration of blood, plasma, plasma expanders, parenteral solutions; the administration of oxygen; tracheotomy; the control of bleeding; emergency splinting of fractures; and gastric lavage. X-Ray permeable stretchers intended for use as examining tables should be provided.

18.104 FACILITIES

(1) Emergency facilities should be conveniently located with respect to radiological and laboratory services. Emergency facilities shall be separate and removed from surgical and obstetrical suites and shall consist, as a minimum of the following:

(a) A well-marked ENTRANCE, separate from the main hospital entrance, at grade level and sheltered from the weather with provisions for ambulance and pedestrian service.

(b) A RECEPTION AND CONTROL AREA with visual control of the entrance, waiting room and treatment area. (Required for hospitals of 50 beds or more).*

(c) COMMUNICATIONS with appropriate nursing stations outside the emergency unit and connected to emergency power source.

(d) PUBLIC WAITING SPACE with toilet facilities, telephone, drinking fountain, stretcher and wheelchair storage.*

(e) EMERGENCY ROOM equipped with clinical sink and handwashing facilities.*

(f) NURSES STATION which may be combined with reception and control area, or it may be within the emergency room.*

(g) STORAGE FOR CLEAN SUPPLIES.*

* Required only in case of new hospital construction, or modification of an existing hospital facility.

(2) If provided, operating rooms located within the emergency unit shall meet the requirements specified in Part 21 surgical suite and recovery room(s).

(3) The following physically separated areas must be provided: 1) An adequate waiting room, 2) public toilet facilities, 3) public phone, 4) drinking fountain, 5) patient preparation area with adjacent toilet room, handwashing and provision for storing patient's clothing, 6) provisions within the patient preparation area for medication storage and preparation, 7) recovery room equipped as specified in Part 21, Section 11.

Part 19. OUTPATIENT SERVICES

19.100

19.101 ORGANIZATION AND STAFFING

(1) Hospitals shall provide outpatient services.

(2) There shall be specific written policies for admissions and discharge of patients, physician responsibility, staffing, and procedures for individual patient care, and equipment and supplies.

(3) The nursing service shall be under the supervision of a registered nurse qualified by training, experience and ability. There shall be such professional and non-professional personnel as required for efficient operation.

19.102 PROGRAMMATIC FUNCTIONS. Reserved.

19.103 EQUIPMENT AND SUPPLIES. Reserved.

19.104 FACILITIES

(1) The following physically separated areas shall be provided: 1) An adequate waiting room, 2) public toilet facilities, 3) public phone, 4) drinking fountain, 5) patient preparation area with adjacent toilet room, handwashing and provision for storing patient's clothing, 6) ' provisions within the patient preparation area for medication storage and preparation, 7) recovery room equipped as specified in Part 21, Surgical and Recovery Services.

Part 20. PERINATAL SERVICES

20.100 Labor, Delivery and Newborn Care

20.150 Public Umbilical Cord Blood Collection

20.100 LABOR, DELIVERY AND NEWBORN CARE

20.101 ORGANIZATION AND STAFFING

(1) The facility shall provide emergent labor and delivery services in accordance with federal law. The facility may provide non-emergent perinatal care services. If the facility provides non-emergent perinatal care services, the following standards shall apply.

(2) Physician Services

(a) The director of obstetrical services shall be a physician who is board eligible or certified in obstetrics. However, an acute care hospital with one hundred beds or less located in a rural area may have a physician director who is qualified by training and experience to

direct the scope of care provided.

(b) The director of newborn services shall be a physician who is board eligible or certified in pediatrics. However, an acute care hospital with one hundred beds or less located in a rural area may have a physician director who is qualified by training and experience to direct the scope of care provided.

(c) There shall be a physician with obstetrical privileges in the hospital or able to arrive within 30 minutes of being summoned.

(3) Nursing Services

(a) Labor, delivery and newborn nursing care shall be under the supervision of a registered nurse with training and experience in perinatal nursing.

(b) A registered nurse qualified by training and experience in delivery room nursing shall be present as a circulating nurse during each delivery. Additional registered and licensed practical nurses or auxiliary nursing personnel shall be available as necessary.

(c) Maternity patients shall be closely observed by a registered nurse during and after delivery until vital signs are established, shock and hemorrhage are not evidenced, and the patient is awake.

(d) A registered nurse shall supervise the nursing care of newborn infants. A nurse shall be in attendance in the nursery at all times that neonates are present.

(4) All deliveries shall be attended by an obstetrician, a physician with obstetrical privileges, or a certified nurse midwife, except in emergencies.

(5) The facility shall have obstetrical and neonatal specialists as appropriate to the scope of care provided.

20.102 PROGRAMMATIC FUNCTIONS

(1) The facility shall develop and implement admission and transfer criteria for perinatal services that reflect the scope of care provided by the facility.

(2) Labor and Delivery

(a) Policies and Procedures. The facility shall develop and implement policies and procedures regarding:

(i) receipt of prenatal records for admissions other than emergency admissions.

(ii) management of labor, including but not limited to the monitoring of the well being of the mother and the fetus. There shall be the capability of performing a Cesarean section within 30 minutes of the decision to perform such a delivery method.

(iii) use of analgesic and anesthetic agents for pain management and the responsibilities of persons who administer it developed in consultation with the anesthesia service.

(iv) vaginal birth after a Cesarean section.

(v) post partum assessments and care of the obstetrical patient and the newborn.

(vi) identification of high risk obstetrical patients and management of such patients including protocols for consultations and for the transfer of patients whose needs exceed the scope of care provided by the facility to a facility capable of providing the appropriate level of care. The transfer is a joint responsibility of the sending and receiving facilities.

(vii) protocols for visitors during labor and delivery.

(viii) miscarriages and stillbirths.

(b) There shall be a staff member present at every delivery who has been trained according to nationally recognized standards and credentialed by the facility in neonatal resuscitation.

(3) Newborn Care

(a) Identification shall be placed securely on each infant before removal from the delivery room.

(b) Newborn screening shall be conducted in accordance with 5 CCR 1005-4 Newborn Screening and Second Newborn Screening.

(c) Security measures shall be instituted to safeguard newborns against access by unauthorized persons.

(d) Policies and Procedures. The facility shall develop and implement policies and procedures regarding:

(i) stabilization of newborns after birth, including stabilization of high-risk newborns.

(ii) monitoring newborns. Infants shall be examined at least daily until discharge. An appropriately credentialed licensed independent practitioner shall perform a physical exam of the newborn prior to discharge.

(iii) care of high risk newborns, including protocols for consultations and for the transfer of neonates whose needs exceed the scope of care provided by the facility to a facility recognized for its capability to provide the appropriate higher level of care. The transfer is a joint responsibility of the sending and receiving facilities.

(iv) parent and sibling visitation of newborns.

(v) admission and care of neonates born outside of the facility.

(4) Discharge Planning. As part of the discharge planning process, the facility shall assess the educational needs of the mother and provide or arrange for education in self care and newborn care, as appropriate.

(5) Infection Control

(a) Obstetric patients shall be separated from other patients, with the exception of non-infectious gynecological patients.

(b) The facility shall develop and implement policies and procedures to maintain an environment that protects patients from infections, to include but not be limited to:

(i) a protocol to be followed for obstetric patients and newborns with suspected or confirmed communicable disease. Isolation of communicable disease cases shall

be conducted in accordance with written perinatal standards of practice. If an infant is isolated with his or her mother, both shall be isolated in a private room.

(ii) handwashing. At minimum, personnel shall cleanse their hands before and after handling each patient.

(iii) the flow of hospital staff between the perinatal care service and other services/departments of the hospital based on infection control criteria.

20.103 EQUIPMENT AND SUPPLIES

(1) Delivery Room. The following equipment and supplies shall be available for each delivery room:

(a) Infant warmer.

(b) Suction and resuscitation equipment for adults and infants.

(c) Supplies for spinal, epidural, and saddle-block anesthesia.

(d) Instruments and supplies for management of normal delivery and obstetric emergencies.

(e) Emergency drugs, solutions, and supplies.

(f) Infant identification.

(2) Nursery. Each nursery shall be equipped with the following:

(a) Easily cleaned bassinet for each infant.

(b) Storage space for the individual infant supplies in a compartment in the bassinet or on an individual table; however, infant supplies other than suction bulbs shall not be stored within the bassinet basket.

(c) Incubator or warmer.

(d) Infant emergency equipment and supplies essential to resuscitation.

(e) Diaper waste receptacles with foot controls and disposable impervious liners.

(f) Soiled linen waste receptacles with foot controls and disposable impervious liners.

(g) Accurate easily cleaned scales.

20.104 FACILITIES

(1) Labor and Delivery

(a) Physical arrangements shall separate obstetric patients from other patients, with the exception of non-infectious gynecological patients.

(b) The delivery suite and labor room(s) shall be located so as to minimize traffic to patients, visitors, and personnel from other areas of the hospital.

(c) The design of and equipment in labor room(s) shall meet the requirements for a private bedroom specified in Part 11, General Patient Care Services except that windows need

not be provided if mechanical ventilation is installed.

(d) There shall be a delivery room or operating room equipped for major obstetrical operative procedures, including caesarian section.

(e) In case of new hospital construction, or modification of an existing hospital facility the following shall apply:

(i) In hospitals of 30 beds or less, one operating suite may be used for surgical or delivery procedures, providing there is a labor room equipped for emergency delivery adjacent and accessible to the suite and with a minimum area of 180 sq. ft., no dimension to be less than 12'0" except ceiling height. Ventilation of the emergency delivery room must be either a separate system from that in the operating suite, allowing recirculation in each area, or if connected to the same system as the operating suite, the system must provide 100% exhaust with no recirculation.

(ii) Sub-sterilizing room adjacent; to delivery room(s) will not be required unless major gynecological surgical procedures are performed in the delivery room.

(f) The requirements specified in Part 21, Surgical and Recovery Services, Section 21.104, with the exception of the requirements for the operating room shall be met.

(2) Nursery

(a) The nursery should be located in the labor and delivery patient care unit as close to the mothers as possible and away from the line of traffic of others than maternity services. The nursery(ies) shall be separated physically and functionally from other hospital services.

(b) A minimum of twenty-four (24) square feet per infant shall be provided within the nursery.

(c) A control area shall be provided to serve as a work space and nursery entry for security.

(d) A fixed view window shall be provided between nursery(ies) and control area or between two nursery(ies). Fixed view windows between the nurseries and corridor shall be wire glass set in steel frames. In the case of new hospital construction or modification of an existing hospital facility, the view windows shall be 1/4 inch thick welded wire glass set in steel frames. Curtains or drapes when used in nurseries shall be laundered frequently and maintained flame-retardant.

(e) All electrical outlets must have a common ground. One electrical outlet shall be provided for every two bassinets. Some of the outlets shall be connected to an emergency source of power. In the case of new hospital construction, or modification of an existing hospital facility fifty (50) percent of the outlets shall be connected to an emergency source of power. The use of adapters, extension cords, and junction boxes should be discouraged.

(f) The nursery(ies) shall be well lighted to permit optimal observation and for easy detection of jaundice or cyanosis. In the case of new hospital construction, or modification of an existing hospital facility, shadow-free illumination with at least 100 ft. candle intensity at the infants' level is required and is best provided by fluorescent lamps. A suggested fluorescent tube for illuminations is General Electric's fluorescent tubes F-40-CWX(deluxe cool white) or equal. Light fixtures should be provided with lenses to reduce glare. The number and exact location of fixtures cannot be recommended because ceiling height and windows influence the intensity of the illumination. Spot illumination can be provided

by a portable lamp containing two 15 watt fluorescent bulbs which, when held 12" from the infant, will produce about 100 ft. candle intensity of light.

(g) Wall surfaces shall be washable and non-glare. Acoustical ceiling tile is permissible if it is incombustible and washable.

(h) A minimum ventilation rate of 12 room volumes of out-door air per hour with no recirculation shall be provided by mechanical supply and exhaust air systems. Filters with a minimum efficiency of 90-99 percent in the retention of particles shall be provided. Positive air pressure relative to the air pressure of adjoining areas should be maintained. A temperature of 75-82° F. and a relative humidity of less than 50% is recommended. In the case of new hospital construction, or modification of an existing hospital facility, access openings in ducts for cleaning purposes shall be provided.

(i) Nursery facilities shall be available for the immediate isolation of all newborn infants who have or are suspected of having communicable disease. Such nursery facilities shall have a minimum of 30 square feet of space for each bassinet or incubator.

(j) The following shall be provided in each nursery:

(i) Lavatory with mixing faucet, knee, foot or automatically operated, soap and sanitary hand-drying accommodations.

(ii) Piped oxygen with outlets, one for every four bassinets.

(iii) In the case of new hospital construction, or modification of an existing hospital facility, a nurse call system shall be provided.

20.150 PUBLIC UMBILICAL CORD BLOOD COLLECTION

20.151 ORGANIZATION AND STAFFING. Reserved.

20.152 PROGRAMMATIC FUNCTIONS

(1) A hospital licensed under this Chapter that is certified by the Centers for Medicare and Medicaid Services may elect to participate in a public umbilical cord blood collection program. A hospital that so elects shall adopt policies, procedures, and best practice guidelines establishing:

(a) Standards for ensuring all such donations are transported to a public cord blood bank;

(b) Standards governing the collection, temporary storage and transport of public umbilical cord blood donations to a public cord blood bank. Such standards shall specify that collection, transport, processing and storage shall be accomplished at no cost to the donor(s);

(c) Person(s) required to provide written informed consent to the voluntary donation, collection, storage and use of an umbilical cord blood donation and a plan to address potential objections to donation;

(d) Standards governing how the hospital will obtain or work with the public cord blood bank to obtain timely informed written consent on a hospital-approved consent form for the voluntary donation, collection, storage and use of cord blood after providing adequate disclosure of information. As used in this paragraph "adequate disclosure of information" means standardized, objective information concerning cord blood unit donation, including full disclosure of risks involved, sufficient to allow an umbilical cord blood donor to make an informed decision as to whether to volunteer to participate the hospital’s umbilical cord

blood donation program. Such information shall be provided in a language understood by the donor(s);

(e) Standards ensuring that donation request, consent and collection procedures do not interfere with standard labor and delivery practices or otherwise endanger the safety of or health care provided to the mother and baby;

(f) Standards ensuring secure links are maintained between the medical records of donors and the banked cord blood unit. All such records shall be maintained in a confidential and secure manner that affords the full protection of all applicable laws; and;

(g) Standards governing how the hospital will advise the appropriate donor(s) of any abnormality discovered during testing in a manner that is appropriate in relation to the nature and severity of the abnormality.

(2) A participating hospital shall ensure that the public cord blood bank provides timely education and periodic in-service training regarding policies, procedures and best practice guidelines established in accordance with paragraph 20.152(1) to the hospital's authorized health care professionals who are or will be engaged in collecting, temporarily storing or transferring umbilical cord blood donations following the birth of a newborn baby.

(3) A participating hospital shall submit such statistical and other non-identifying information concerning voluntary participation in an umbilical cord blood collection program as may be required by the department.

20.153 EQUIPMENT AND SUPPLIES. Reserved.

20.154 FACILITIES. Reserved.

Part 21. SURGICAL AND RECOVERY SERVICES

21.100

21.101 ORGANIZATION AND STAFFING

(1) The hospital shall provide emergency surgical care in accordance with the scope of care established pursuant to Section 6.102 (1), and may provide other surgical services.

(2) The nursing service of the surgical suite shall be under the supervision of a registered nurse qualified by training and experience to direct operating room nursing.

(3) A registered nurse qualified by training and experience in operating room nursing shall be present as a circulating nurse during operative procedures.

(4) At least one registered nurse shall be on duty at all times in the surgical recovery room when patients are present. Nurses shall have been instructed in the care of post-anesthetic and post-surgical patients, shall have no other duties during the time they are caring for such patients. Additional registered and licensed practical nurses, and auxiliary nursing personnel shall be available. The nursing care required by different types of patients shall be the major consideration in determining the number, quality, and category of nursing personnel that are needed in any given situation.

21.102 PROGRAMMATIC FUNCTIONS

(1) Policies related to the surgical suite shall be written and available for staff use. Policies shall include the admission of patients, personnel, and visitors.

(2) Policies governing the authority and responsibilities of nursing personnel and the admission and length of stay of patients in the surgical recovery room shall be written.

21.103 EQUIPMENT

(1) Equipment in anesthetizing areas shall be constructed of metal or other electrically conductive material and equipped with rubber pads, leg tips, casters, or equivalent devices which are conductive.

(2) Only approved portable X-ray equipment shall be used in anesthetizing locations.

(3) At least one pressurized steam sterilizer or equivalent shall be installed in the sub-sterilizing room, and provided with indirect waste connections and recording thermometer that indicates temperature in discharge line of sterilizer. In the case of new hospital construction, or modification of an existing hospital facility pressurized steam sterilizer or equivalent, shall be installed in each sub-sterilizing facility, and provided with an indirect waste connection and a recording thermometer that indicates temperature in the discharge line of the sterilizer.

21.104 FACILITIES

(1) Signs identifying the surgical suite shall be posted at each entrance to the suite.

(2) Interior finishes in the surgical suite shall be smooth, unbroken, and shall facilitate and withstand frequent cleaning and disinfecting.

(3) The surgical suite shall be located so that traffic will not pass through the suite to any other part of the hospital and shall be separated physically from the delivery suite and emergency department. However, in hospitals of 30 beds or less, one operating suite may be used for surgical and delivery procedures, providing there is a labor room equipped for emergency delivery adjacent and accessible to the suite and with a minimum area of 180 sq. ft. See Section 9.3.1.

(4) Operating Room

(a) The surgical suite shall be provided with at least one operating room. There should be one operating room for each 50 beds or major fraction thereof up to and including 200 beds. Above 200 beds the number of operating rooms will be based on the expected average of daily operations.

(b) The operating room design, equipment, and functional layout should be commensurate to the surgical procedures performed.

(c) Each operating room should not be less than 18 feet in any one dimension.

(d) Operating room(s) shall be provided with an approved electrical nurse call system. In the case of new hospital construction, or modification of an existing hospital facility, this system must be to the operations and control station or nurses station where additional help is available.

(e) General and spot illumination shall be provided in each operating room.

(f) The ceiling height shall not be less than 9 feet in operating rooms.****

(g) Each operating room shall be provided with piped oxygen. Nitrous oxide and vacuum are recommended.

In addition to operating room(s) the following physically separated areas shall be provided within the suite. In the case of new hospital construction or modification of an existing hospital facility these areas shall be separated by doors and/or walls: 1) Sub-sterilizing facilities; 2) Scrubup area; 3) Cleanup room: 4) Instrument and supply storage; 5) Anesthesia storage; 6) Janitor's facilities: 7) Doctors' locker and dressing room; 8) Nurses' locker and dressing room; 9) Stretcher alcove. In the case of new hospital construction, or modification of an existing hospital facility, an anesthesia workroom must also be provided. Stretcher space must also be provided in the surgery suite.

**** Not required in existing buildings.

(5) The sub-sterilizing room shall be physically separated from but adjacent to the operating room for service to the room without passing through contaminated areas. In the case of new hospital construction, or modification of an existing hospital facility, sub-sterilizing facilities shall be located to serve each operating room conveniently. More than one sub-sterilizing facility shall be provided if a suite of operating rooms is not compactly arranged

(6) The scrubup area shall be adjacent to the operating room to permit immediate access to the room after scrubbing. Surgeon scrub sink(s) with knee or foot controls shall be installed in the scrubup area.

(7) A clinical sink with an integral fresh water trap seal, and a sink with wrist-blade or foot-action valves shall be installed in each cleanup room.

(8) Toilet, shower, and lavatory facilities shall be provided in the doctors' locker rooms and in the nurses' locker rooms.

(9) In the case of new hospital construction, or modification of an existing hospital facility, at least one anesthesia equipment workroom for the cleaning, testing and storage of anesthesia equipment shall be provided. It shall contain a work counter and sink. In hospitals of 30 beds or less, the anesthesia workroom may be combined with other spaces provided that the resulting plan will not compromise the best standards of safety and of medical and nursing practices.

(10) Ventilation

(a) Operating rooms shall be provided with a minimum ventilation rate of 8 room volumes of outdoor air per hour with no recirculation, except when not in use, by mechanical supply and exhaust air systems. In the case of new hospital construction or modification of an existing hospital facility, operating rooms shall be provided with a minimum ventilation rate of twenty-five room volumes of air per hour by mechanical supply and exhaust air systems. (a) Outdoor air intakes shall be located as far as practical but not less than 25 feet from the exhausts from any ventilating system, combustion equipment, medical-surgical vacuum system, or plumbing vent or areas which may collect noxious fumes. The bottom of outdoor air intakes shall be located as high as practical but not less than three feet above ground level, or if installed through the roof, 3 feet above the roof level. (b) All air supplied to sensitive areas such as operating and delivery rooms and nurseries shall be delivered at or near the ceiling of the area served.

(b) Filters shall be installed down draft from blower and provide a minimum efficiency of 90% of 1-5 micron size particles. In the case of new hospital construction, or modification of an existing hospital facility: 1) All ventilation or air conditioning systems serving surgery and delivery 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%. 2) Filter Bed No. 2 shall be downstream of the supply fan and air conditioning equipment and humidifying equipment. Filter Bed No. 2 shall have a minimum efficiency of 90% of 1-5 micron size particles. 3) Each filter bed serving sensitive areas shall have a manometer

installed across each filter bed.

(c) Exhaust outlets, at least two (2), shall be provided, not less than 4 inches above the floor. In the case of new hospital construction, or modification of an existing hospital facility, exhaust outlets, at least two (2), shall be provided in each operating room, not less than 4 inches above the floor.

(d) The entire surgical suite shall have a balanced air pressure. The surgical suite shall be maintained at a positive air pressure relative to the air pressures of adjacent areas within the hospital. In the case of new hospital construction, or modification of an existing hospital facility, operating rooms shall have a positive air pressure relative to the air pressures of adjacent rooms within the suite. The surgical suite shall be maintained at a positive air pressure relative to the air pressures of adjacent areas within the hospital.

(11) Surgical Recovery Room

(a) The design and equipment shall conform generally to the critical care unit. In the case of new hospital construction, or modification of an existing hospital facility, the surgical recovery room must provide for the visual observation of all patients, medicine dispensing facilities, charting facilities, clinical sink with a bedpan washer attachment, and storage space for supplies and equipment.

(b) The surgical recovery room(s) shall be located in the surgical suite or adjacent thereto.

(c) The surgical recovery room shall have facilities for immediate communications with the attending surgeon, anesthesiologist, or qualified substitute present in the hospital.

Part 22. CRITICAL CARE SERVICES

22.100

22.101 ORGANIZATION AND STAFFING

(1) The hospital may provide critical care services in a critical care unit. The following standards shall apply only if the hospital provides such services.

22.102 PROGRAMMATIC FUNCTIONS

(1) There shall be specific written policies for admission and discharge of patients, physician responsibility, staffing, and procedures for individual patient care.

(2) The nursing service shall be under the supervision of a registered nurse qualified by training, experience, and ability. At least a minimum of one registered nurse shall be on duty at all times to give direct patient care. Additional nursing personnel shall be available, consistent with the nursing care required by the different types of patients.

22.103 EQUIPMENT AND SUPPLIES

(1) There shall be written policies regarding equipment and supplies.

(2) The equipment shall include: 1) Variable height beds with safety sides; 2) Bedside cabinets; 3) Sphygnomannometers; 4) Resuscitation apparatus; 5) Additional equipment as oxygen tents, pacemaker, defibrillator, and electrocaridiography apparatus.

22.104 FACILITIES

(1) A system shall be established for calling selected emergency personnel to the unit.

(2) The critical unit shall have: 1) Intravenous rods installed in ceilings or walls, or attached to beds; 2) Piped oxygen; 3) Suction outlets; 4) Emergency signal system at each bed and nurses station, 5) In case of new hospital construction or modification of an existing hospital facility, an emergency call from unit to outside the unit where additional personnel are available shall be provided.

(3) The area shall be sufficient in size to allow movable equipment to be placed on either side of the bed(s) and provide-at least 80 square feet per bed in multiple bedrooms and 100 square feet in single bedrooms. Space for storage of commonly used equipment and supplies shall be provided. (Storage carts are recommended). A patient care control center (nurses station), medicine preparation area, clean and soiled holding areas, and janitor's closet conforming to the requirements of Part 11, General Patient Care Services, shall be provided in proximity to the bedrooms or within the enclosures. When more than one enclosure is provided within room, the size of these areas should be increased.

(4) A toilet complete with flushing attachments shall be provided in each room. In case of new hospital construction or modification of an existing hospital facility the door to the toilet room shall be 2'8" wide, 3'0" recommended.

(5) A lavatory complete with mixing faucet, blade controls, soap, and sanitary hand-drying accommodations shall be provided within each room.

(6) Two duplex convenience outlets shall be installed in proximity to the head of each bed. General lighting shall be uniform throughout the room and controlled by a dimmer. The electrical system shall be connected to the emergency power system. In the case of new hospital construction, or modification of an existing hospital facility, four duplex convenience outlets shall be installed in proximity to the head of each bed.

(7) A waiting room shall be provided. This may be shared with as adjacent patient care unit.

Part 23. RESPIRATORY CARE SERVICES

23.100

23.101 ORGANIZATION AND STAFFING

(1) The hospital may provide respiratory care services. The following standards shall apply only if the hospital provides such services.

(2) The respiratory care service should be under the direct supervision of a committee of the organized medical staff or a physician who has had special training in respiratory diseases and therapy.

23.102 PROGRAMMATIC FUNCTIONS

(1) Respiratory care services shall be administered only by persons qualified by training, experience, and ability in respiratory therapy.

23.103 EQUIPMENT AND SUPPLIES

(1) The equipment for respiratory care services shall be commensurate with the clinical procedures and programs of the hospital.

(2) Respiratory care equipment shall be cleaned properly and disinfected after each use in accordance with written procedures. The disinfection process shall be bactericidal, tuberculocidal, and

virucidal.

23.104 FACILITIES

(1) The facilities for respiratory care services shall be commensurate with the clinical procedures and programs of the hospital.

Part 24. REHABILITATION SERVICES

24.101 ORGANIZATION AND STAFFING

(1) The facility may provide rehabilitation services. The following standards apply only if the facility provides such services. Rehabilitation services include physical therapy, occupational therapy, audiology, speech pathology, and other rehabilitative therapies.

(2) Rehabilitation services shall be performed under the supervision of qualified practitioners.

(3) The facility may provide a rehabilitation service under either a single-service or a multi-service rehabilitation department.

(4) The director of single- or multi-service rehabilitation department shall have the necessary education, training and experience to direct the services provided by the department.

(5) There shall be a sufficient number of qualified supervisory staff to evaluate each patient, initiate the plan of treatment, and supervise supportive personnel.

24.102 PROGRAMMATIC FUNCTIONS

(1) Rehabilitation services shall be delivered in accordance with orders issued by the attending licensed independent practitioner or provided within the scope of practice and facility policy for the delivery of care provided by the therapist.

(2) The facility shall develop and implement written policies and procedures governing the management and care of patients. At minimum, the policies and procedures shall address:

(a) initial patient evaluation and regular assessments.

(b) care plans. Care plans shall describe the patient's: functional limitations; measurable short and long term goals; and type, amount, frequency and duration of services.

(c) ensuring that the patient's response to treatment is communicated to the attending licensed independent practitioner in a timely manner.

(d) If rehabilitation services are provided on an outpatient basis, the facility shall specify how orders from outside sources will be managed.

(3) Treatment and progress shall be documented, including progress toward long and short-term goals for each visit or session.

(4) Equipment shall be appropriately cleaned and disinfected after use.

24.103 EQUIPMENT AND SUPPLIES

(1) There shall be appropriate equipment and supplies to meet the rehabilitative care needs of patients.

24.104 FACILITIES

(1) There shall be adequate facilities, space and storage areas to meet the rehabilitative care needs of patients.

Part 25. PEDIATRIC SERVICES

25.100

25.101 ORGANIZATION AND STAFFING

(1) The hospital shall provide pediatric patient care in accordance with the scope of care established pursuant to Section 6.102 (1).

(2) The director of pediatric services shall be a physician qualified by experience and training to direct the scope of care provided. If the facility has a dedicated pediatric department, the department shall be under the direction of a physician who is board eligible or certified in pediatrics.

(3) Pediatric nursing care shall be under the direction of a registered nurse qualified by training, experience, and ability to direct effective pediatric nursing. All nursing personnel, assigned to care for children, shall be oriented to the special care of children.

(4) The facility shall have pediatric specialists as appropriate to the scope of care provided.

25.102 PROGRAMMATIC FUNCTIONS

(1) The hospital shall not admit children to patient bedrooms where accommodations are shared with adults, with the exception of acute care cases where the child and adult are related and the needs of the patients can be adequately addressed.

(2) The hospital shall develop and implement policies and procedures, as appropriate, regarding:

(a) admission criteria for pediatric services that addresses the ages of patients served and reflects the level of services offered by the facility.

(b) the transfer of pediatric patients whose needs exceed the scope of service provided by the facility to a facility capable of providing the appropriate level of care. The transfer is a joint responsibility of the sending and receiving facility.

(c) assessments based on the age and developmental stage of the patient.

(d) pediatric consultations.

(e) weight and/or length based drug administration and dosing, in coordination with pharmaceutical services.

(f) parent visitation, overnight stays, and respite care.

(g) child-proofing measures, such as the covering of electrical outlets, to prevent patient injury.

(h) organized play and educational activities appropriate to the facility's pediatric population.

(i) regular and routine cleaning of play equipment in the pediatric area, in accordance with infection control requirements.

(j) security measures to prevent harm, kidnapping or elopement.

25.103 EQUIPMENT AND SUPPLIES

(1) The facility shall have appropriate equipment and supplies for the pediatric services provided.

(2) When a pediatric patient care unit is established it shall provide:

(a) washable tables and chairs of various sizes.

(b) appropriate entertainment and educational materials.

25.104 FACILITIES

(1) The facility shall have separate pediatric patient care unit(s) when the number of pediatric beds is or exceeds 14 beds.

(2) When a pediatric patient care unit is established it shall provide:

(a) a playroom with washable tables and chairs of various sizes, storage for equipment and supplies, and appropriate entertainment materials.

(b) an examination and treatment room with equipment and supplies appropriate for the care of children.

(c) rooms designed and furnished to facilitate grouping patients according to condition and age groups.

(d) space with adequate facilities for safe storing and warming of food.

(3) Reasonable privacy, without limiting necessary observation, shall be available for adolescents.

Part 26. PSYCHIATRIC SERVICES

26.100

26.101 ORGANIZATION AND STAFFING

(1) General hospitals may provide psychiatric services; however, facilities that do not provide psychiatric or substance abuse services shall develop and implement a written plan for the referral of patients to treatment options. The following standards apply only if the facility provides psychiatric care. Psychiatric care includes, but is not limited to, the provision of the following as appropriate to the patient: psychiatric physician and nursing services, psychological services, social services, occupational therapy and recreational therapy.

(2) The director of psychiatric services shall be a physician who is board certified or has met the training and experience requirements for examination by the American Board of Psychiatry and Neurology or the American Osteopathy Board of Neurology and Psychiatry.

(3) Nursing Services

(a) Psychiatric nursing care shall be under the direction of a registered nurse qualified by training, experience, and ability to effectively direct psychiatric nursing, provide skilled nursing care and therapy, and evaluate the nursing care furnished. At minimum, such registered nurse shall have either a bachelor's degree in nursing and two years of clinical

experience in a psychiatric setting or an associate degree in nursing and five years of experience in a psychiatric setting. In addition, the psychiatric nursing director shall have at least one year of nurse supervision experience as a registered nurse.

(b) A registered nurse qualified by education and experience to provide psychiatric care shall be available in the psychiatric unit 24 hours per day, 7 days per week.

(c) All nursing personnel assigned to care for specific populations, such as pediatric or geriatric patients, shall be trained, have the necessary experience and maintain current competency. Unexpected emergency events that require the use of nurses that lack the necessary training, experience or competency are exceptions; such events shall be documented and, where possible, planned for in the future. Inexpert nursing personnel in such events shall be assigned to the lowest acuity situations possible.

(4) Psychology services, if provided, shall be under the direction of a licensed psychologist. There shall be sufficient psychology services to meet the needs of the patients.

(5) Social services shall be under the direction of an individual with a master's degree in social work or an individual with a related master's degree and documented training and experience to oversee the social services provided by the hospital. There shall be sufficient social work staff to provide psychosocial data for diagnosis and treatment, participate in discharge planning, and arrange for follow-up care.

(6) There shall be a sufficient number of qualified personnel to provide therapeutic and recreational therapy programming designed to improve the client’s ability to adjust to social stress, physical demands and daily living skills to meet the needs of the patients, in accordance with the care plan.

(7) There shall be a sufficient number of qualified clinical and supportive staff to assess the needs of psychiatric patients, implement individualized active treatment care plans, and ensure a safe therapeutic environment for patients and staff.

26.102 PROGRAMMATIC FUNCTIONS

(1) Patient Assessments

(a) Within 4 hours of admission, an initial assessment for immediate safety needs shall be conducted by qualified personnel.

(b) Within 8 hours of admission, a nursing assessment shall be conducted. Care shall be provided, as determined by the nursing assessment, to maintain the individual's safety and physical well-being.

(c) Within 24 hours of admission for inpatients and 3 days of initiating services for outpatients, a comprehensive psychiatric assessment shall be conducted by medical staff. The assessment shall include, but not be limited to: medical history and physical evaluation; psychiatric history; a complete mental status exam, including but not limited a determination of the onset of the illness and circumstances leading to admission; and current attitudes, behavior, memory, and orientation.

(2) Care Plan. The patient shall receive services in accordance with an individualized care plan that meets the needs of the patient. The plan shall:

(a) be initiated within 24 hours after admission and updated as needed for inpatients and within 7 days after initiating treatment for outpatients.

(b) be developed by an interdisciplinary team and based on the psychiatric, medical, social behavior and developmental aspects of the patient as identified through assessments. The interdisciplinary team shall complete the care plan within 72 hours of admission and review the plan at least every 7 days for appropriateness for the first 30 days, more often if indicated by changes in the patient's condition. For inpatient stays longer than 30 days and up to 12 months, subsequent care plan reviews shall be conducted at intervals specified by the patient's psychiatrist; however, such intervals shall not exceed 30 days. For inpatient stays longer than 12 months, subsequent care plan reviews shall be conducted at intervals specified by the patient's psychiatrist, however, such intervals shall not exceed 3 months.

(c) include short- and long-term goals with measurable outcomes, active treatment modalities to be used, and the responsibility of each member of the treatment team.

(d) reflect patient and family participation to the extent possible.

(e) as applicable, incorporate environmental modifications necessary to keep the patient from harming self or others.

(3) Policies and Procedures. The facility shall develop and implement policies and procedures regarding:

(a) restraint and seclusion consistent with state and federal law and regulation, including 6 CCR 1011-1, Chapter II, Part 8, Protection of Persons from Involuntary restraint. Medications shall only be used for treatment and stabilization, not for staff convenience.

(b) admissions and discharge compliant with involuntary commitment law and regulation.

(c) safety and security precautions for the prevention of suicide, assault, elopement, and patient injury at all hours. This shall include, but not be limited to protocols for:

(i) systematic assessments and elimination of environmental risks, to include periodic checking of breakaway hardware.

(ii) summoning immediate assistance for staff and patients.

(iii) opening locked or barricaded doors in the event of an emergency, using methods that do not cause harm to patients.

(d) behavior management techniques ranging from the least to most restrictive and when techniques that can result in harm to the patient are authorized.

(e) if applicable, the use of electroconvulsive therapy, consistent with Section 13-20-401, C.R.S., et seq. The facility shall have policies and procedures consistent with standard of practice that address the indications for use, informed consent, medical clearance, response to life- or limb-threatening emergencies, and the services and facilities necessary to provide treatment adequately and safely.

(f) if applicable, medical detoxification and any other types of substance abuse treatment.

(g) medication monitoring.

(h) visitors.

(4) Discharge Planning. In addition to the discharge planning requirements under Part 11, General Patient Care Services:

(a) the patient’s discharge plan shall include notations from each member of the patient’s interdisciplinary team regarding continuity of care, as appropriate.

(b) in evaluating the post hospital care needs, the facility shall consider the patient's ability to comply with the medication regimen and to live independently.

(5) Children and Adolescents

(a) Hospitals shall develop and implement policies and procedures to ensure that:

(i) children, adolescent and adult populations are not be commingled in ways that compromise patient safety.

(ii) school-age patients shall have educational exposure if they are to be hospitalized for over 14 days.

(6) Poison control information shall be readily available.

(7) Direct care and security personnel shall have annual inservice training on effective methods to de-escalate various states of agitation associated with emotional disturbed behaviors.

(8) Patient Confidentiality. The hospital shall develop policies and procedures to ensure that all information about psychiatric patients whether oral or written, shall be maintained confidential by all personnel, staff (including volunteers) and attending providers at the facility, and shall only be disclosed in accordance with state and federal law.

26.103 EQUIPMENT. Reserved.

26.104 FACILITIES

(1) When a psychiatric patient care unit is established, the unit shall be designed to maximize a home-like environment. The unit shall provide:

(a) a day-room or solarium.

(b) an area for dining.

(c) space for therapy and recreation with storage facilities for supplies.

(d) a conference and interview room.

(e) two or more seclusion rooms. A seclusion room shall:

(i) be designed to prevent patient hiding, escape, injury, or suicide.

(ii) not have electrical switches or receptacles.

(f) Storage for patient effects

(i) Each patient shall be provided with individual storage space which is readily accessible to patients at reasonable times, with systems in place to protect patient property against theft or loss.

(ii) A staff controlled, secured storage area shall be provided for patient's effects determined potentially harmful, such as cigarette lighters, nail files and patient

contraband.

(g) a system for summoning help in the event of an emergency.

(2) The physical plant and interior details shall be designed such that the capacity for self-injury is minimized.

(3) New construction

(a) For additions of previously uninspected or unlicensed square footage under the license and relocations in whole or in part to another physical plant for which the complete submission of construction plans and documents for plan review was received on or after July 1, 2011, the facility shall:

(I) In toilet and bathing facilities, grab bars shall be designed to prevent them from being used for hanging.

Part 27. NUCLEAR MEDICINE SERVICES

27.100

27.101 ORGANIZATION AND STAFFING

(1) The hospital may provide nuclear medicine services. The following standards shall apply only if the hospital provides such services.

(2) Nuclear medicine services shall be under the direction of a qualified physician.

27.102 PROGRAMMATIC FUNCTIONS

(1) Nuclear medicine services shall be in compliance with 6 CCR 1007-1, Rules and Regulations Pertaining to Radiation Control.

(2) There shall be written policies and procedures for all services offered which shall additionally include:

(a) steps to take in the event of an adverse reaction.

(b) protection from non-therapeutic radiation exposure for patients and visitors while in the hospital.

(c) information to be provided to patients who receive nuclear medicine therapy and still have radioactive particles in their bodies regarding how to prevent/minimize radiation exposure of others.

27.103 EQUIPMENT. Reserved.

27.104 FACILITIES. Reserved.

Editor's Notes

6 CCR 1011-1 has been divided into separate chapters for ease of use. Versions prior to 05/01/2009 and rule history are located in the main section, 6 CCR 1011-1. Prior versions can be accessed from the History link that appears above the text in 6 CCR 1011-1. To view versions effective on or after

05/01/2009, select the desired chapter, for example 6 CCR 1011-1 Chap IV or 6 CCR 1011-1 Chap XVIII.

History

Chapter IV Sections 7, 9.3, 10.34, 14.8, 19.3, 19.4, 19.5, 19.9, 23, 32 eff. 08/30/2007. Sections 14.9, 29.3 repealed eff. 08/30/2007.

Chapter IV Section 33 eff. 01/30/2008.

Chapter IV Part 1.102(1)(b)(ii); Part 2.100, Part 5.203(4), 5.502 (4), Part 6.102 (7-9); 6.202(1), 6.302(4), Part 7, 7.101, 7.102(4), Part 8.102(6)(a), (6)(f) – 8.102(7), Part 13.102(7), Part 20; Parts 25-26 eff. 06/30/2011.