

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

STANDARDS FOR HOSPITALS AND HEALTH FACILITIES CHAPTER 4 - GENERAL HOSPITALS

6 CCR 1011-1 Chapter 4

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

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Part 1. STATUTORY AUTHORITY AND APPLICABILITY

- 1.1 The statutory authority for the promulgation of these regulations is set forth in Sections 25-1.5-103 and 25-3-101, et seq., C.R.S.
- 1.2 Applicability
 - (A) All hospitals shall meet applicable federal, state, and local laws and regulations, including but not limited to:

- (1) 6 CCR 1011-1, Chapter 2, except as noted below:
 - (a) Notwithstanding 6 CCR 1011-1, Chapter 2, Part 2.2.2, hospital services or departments provided for under this Chapter 4 shall not require a separate license if they are on the hospital campus.
 - (b) Services that are subject to separate licensure including, but not limited to, ambulatory surgical centers, assisted living residences, hospices, hospital units, home care agencies, nursing care facilities, and dialysis treatment centers, shall not be considered part of the hospital campus.
- (2) This Chapter 4, except as noted below:
 - (a) Facilities that are federally certified or are undergoing federal certification under 42 CFR 482, et seq., as long term care hospitals shall meet the requirements of this chapter, except that they shall not be required to have an emergency department, perinatal services, or anesthesia services.
 - (b) Facilities that have twenty-five (25) inpatient beds or fewer 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.
- (3) 6 CCR 1010-2, Colorado Retail Food Establishment Regulations, except as noted below:
 - (a) These regulations apply only to a retail operation of a hospital that stores, prepares, or packages food for human consumption or serves or otherwise prepares food for human consumption to consumers.
 - (b) These regulations shall not apply to hospital patient feeding operations.
- (B) Contracted services shall meet the standards established herein.

Part 2. DEFINITIONS

- 2.1 “Auxiliary personnel” means any licensed practical nurse, certified nurse assistant, or Emergency Medical Services provider working under the supervision of an individual authorized by law to do so.
- 2.2 “Campus” means the physical areas immediately adjacent to the hospital’s main building(s), other areas and structures that are not strictly contiguous to the main building(s) but are located within 250 yards of the main building(s), and any other areas determined by the Department, on an individual case basis, to be part of the hospital’s campus.
- 2.3 “Care plan” means a plan of care, treatment, and services designed to meet the needs of the patient.
- 2.4 “Critical care unit” means a designated area of the hospital providing specialized facilities and services to care for patients who require continuing, acute observation and concentrated, highly proficient care.

- 2.5 “Department” means the Department of Public Health and Environment.
- 2.6 “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.
- 2.7 “Emergency Medical Services provider” means an individual who holds a valid emergency medical service provider certificate or license issued by the Department and includes Emergency Medical Technician, Advanced Emergency Medical Technician, Emergency Medical Technician Intermediate, and Paramedic. An Emergency Medical Services Provider is referred to in this chapter 4 as an EMS provider.
- 2.8 “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.
- 2.9 “General hospital” means a health facility that, under an organized medical staff, offers and provides inpatient services, emergency medical and emergency surgical care, continuous nursing services, and necessary ancillary services, to individuals for the diagnosis or treatment of injury, illness, pregnancy, or disability, twenty-four (24) hours per day, seven (7) days per week.
- (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 (24) 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 hospital that are not on the hospital campus may be incorporated under the license.
- 2.10 “Governing body” means the board of trustees, directors, or other body in whom the ultimate authority and responsibility for the conduct of the hospital is vested.
- 2.11 “Inpatient 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.
- 2.12 “Investigational drug” means a new drug or biological drug that is used in a clinical investigation. 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.
- 2.13 “Licensed independent practitioner” means an individual permitted by law and the hospital to independently diagnose, initiate, alter, or terminate health care treatment within the scope of their license.

- 2.14 “Medical Staff” means the organized body that is responsible for the quality of medical care provided to patients by the hospital. The medical staff must be composed of doctors of medicine or osteopathy. The medical staff may also include other categories of physicians and non-physician practitioners who are determined to be eligible for appointment by the governing body.
- 2.15 “Off-Campus Location” means a facility that meets all of the following criteria:
- (A) Whose operations are directly or indirectly owned or controlled by, in whole or in part, or affiliated with a hospital, regardless of whether the operations are under the same governing body as the hospital;
 - (B) That is located more than two hundred fifty (250) yards from the hospital’s main campus;
 - (C) That provides services that are organizationally and functionally integrated with the hospital;
 - (D) That is an outpatient facility providing preventative, diagnostic, treatment, or emergency services; and
 - (E) That is not otherwise subject to regulation under 6 CCR 1011-1.
- 2.16 “Pharmacist” means a person licensed by the Colorado State Board of Pharmacy as a pharmacist.
- 2.17 “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.
- 2.18 “Specialty hospital” means a hospital that:
- (A) Limits admission according to age, type of disease, or medical condition;
 - (B) Does not maintain a dedicated emergency department; and
 - (C) Is not otherwise eligible for licensure under 6 CCR 1011-1.
- 2.19 “Surgical recovery room” means designated room(s) designed, equipped, staffed, and operated to provide close, individual surveillance of patients recovering from acute effects of anesthesia, surgery, and diagnostic procedures.
- 2.20 “Telehealth” means a mode of delivery of health care services through HIPAA-compliant telecommunications systems, including information, electronic, and communication technologies, remote monitoring technologies, and store-and-forward transfers, to facilitate the assessment, diagnosis, consultation, treatment, education, care management, or self-management of a person’s health care.
- 2.21 “Utensil” means any implement used in the storage, preparation, transportation, or service of food.

Part 3. DEPARTMENT OVERSIGHT

- 3.1 Application Fees
- (A) Initial License (when such initial licensure is not a change of ownership)

- (1) A license applicant shall submit a nonrefundable fee with an application for licensure as follows:

Number of Inpatient Beds	Fee
1 - 25 beds	\$8,360.40
26 - 50 beds	\$10,450.50
51 - 100 beds	\$13,063.14
101 + beds	Base: \$10,241.50
	Per bed: \$52.25
	Cap: \$20,901.02

- (a) The initial fee for facilities to be licensed as general hospitals, but certified as long term care hospitals pursuant to 42 CFR 482 et seq., shall be as follows: a base fee of \$5,956.78 and a per inpatient bed fee of \$52.25. The initial licensure fee for long-term care hospitals shall not exceed \$10,973.03.

(B) Renewal License

- (1) A license applicant shall submit an application for licensure with a nonrefundable fee as shown in the following table. The total renewal fee shall not exceed \$8,360.40.
- (2) A license applicant that is accredited by an accrediting organization recognized by the Centers for Medicare and Medicaid Services as having deeming authority may be eligible for a ten (10) percent discount off the base renewal license fee. In order to be eligible for this discount, the license applicant shall submit copies of its most recent recertification survey(s), and any plan(s) of correction with the most recent letter of accreditation showing the license applicant has full accreditation status in addition to a completed renewal application.

Number of Inpatient Beds	Fee	Fee with Deeming Discount
1 - 50 beds	Base: \$940.54 Per bed: \$12.54	Base: \$846.49 Per bed: \$12.54
51 - 150 beds	Base: 1,463.07 Per bed: \$12.54	Base: \$1,316.76 Per bed: \$12.54
151+ beds	Base: \$2,090.10 Per bed: \$12.54 Cap: \$8,360.40	Base: \$1,881.09 Per bed: \$12.54 Cap: \$8,360.40

(C) Change of Ownership

- (1) A license applicant shall submit a nonrefundable fee of \$2,612.62 with an application for licensure.

(D) Provisional License

- (1) A license applicant may be issued a provisional license upon submittal of a nonrefundable fee of \$2,612.62.
- (2) If a provisional license is issued, the provisional license fee shall be paid in addition to the initial license fee.

(E) Conditional License

- (1) A license applicant that is issued a conditional license by the Department shall submit a nonrefundable fee ranging from ten (10) to twenty-five (25) percent of its applicable renewal fee.
- (2) The Department shall determine and assess the fee based on the anticipated costs of monitoring compliance with the conditional license.
- (3) Conditional license fees shall be paid in accordance with the requirements of 6 CCR 1011-1, Chapter 2, Part 2.8.3.

(F) Other Regulatory Functions

- (1) If a license applicant requests an onsite inspection for a regulatory oversight function other than those listed in Parts 3.1(A)-(E), the Department may conduct such onsite inspection upon notification to the hospital of the fee in advance and payment thereof.
- (2) The fee shall be calculated solely based on the cost of conducting such survey. A detailed justification of the basis of the fee shall be provided to the license applicant upon request.

(G) Off-Campus Locations

- (1) A license applicant shall submit a nonrefundable fee, as set forth below, for the requested license action.
 - (a) Addition of Location: \$1,045.05 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 \$522.52.
 - (b) Annual Renewal: \$522.52 for the annual renewal of each off-campus location listed under the license.
 - (i) \$470.28 for the annual renewal of each off-campus location that is accredited by an accrediting organization recognized by the Centers for Medicare and Medicaid Services as having deeming authority. In order to be eligible for this discount, the license applicant shall submit copies of its most recent recertification survey(s), and any plan(s) of correction with the most recent letter of accreditation showing the license applicant has full accreditation status in addition to a completed renewal application.
 - (c) Removal of Location: \$376.22 for the removal of each location from the list of off-campus locations under the license.

3.2 Increase in Licensed Capacity

(A) Planned increase in licensed capacity

- (1) Each hospital shall comply with the requirements of 6 CCR 1011-1, Chapter 2, Part 2.9.6, regarding the written notification of changes affecting the licensee's operation or information.

- (2) In addition to (A)(1) above, a hospital that wishes to increase its licensed capacity shall follow the following process:
 - (a) If a hospital notifies the Department, in writing, at least thirty (30) days prior to an increase in licensed capacity, an amended license shall be issued upon payment of the appropriate fee.
 - (b) If requested by the Department, the hospital shall meet with a Department representative prior to implementation to discuss the proposed changes.
 - (c) If a hospital requesting an increase in licensed capacity has been subject to conditions imposed upon its license, pursuant to 6 CCR 1011-1, Chapter 2, Part 2.8.3, or been subject to a plan of correction pursuant to 6 CCR 1011-1, Chapter 2, Part 2.10.4(B), within the past twelve (12) months, the hospital shall submit to the Department evidence that the noted condition(s) have been met, or the plan of correction implemented, when providing the notice of increased capacity.
- (B) Temporary increase in licensed capacity
 - (1) A hospital seeking a temporary increase in licensed capacity shall follow the requirements of 6 CCR 1011-1, Chapter 2, Part 2.8.2(B).

Part 4. GENERAL BUILDING AND FIRE SAFETY PROVISIONS

- 4.1 Any construction or renovation of a hospital initiated on or after July 1, 2020, shall comply with 6 CCR 1011-1, Chapter 2, Part 3, General Building and Fire Safety Provisions, with the following additions:
 - (A) For purposes of compliance with FGI standards at 2.1-3.4.4.3 regarding observation of all patient care stations from the nurse stations. The hospital must be able to directly observe the patient's head and chest either from any point within the nurse station without the need to exit into adjoining spaces or through the use of a closed circuit camera/monitor systems station(s).

Part 5. HOSPITAL OPERATIONS

5.1 Materials Management Services

- (A) All hospitals shall provide materials management services with facilities for receiving, processing, storing, and dispensing supplies and equipment for all departments/services of the hospital.
- (B) Materials management services shall be overseen by a person who is competent in materials management, supply processing, and control methods to ensure integrity of the system is maintained throughout receiving, cleaning, processing, storing, and issuing supplies.
- (C) Sufficient supporting personnel shall be assigned to the service and be properly trained in materials management services.
- (D) Written policies and procedures shall be established for all functions of the materials management services.

- (E) At a minimum, the policies and procedures shall address: obtaining, cleaning, processing, storing, and issuing supplies, and the training and supervision of personnel.

5.2 Environmental Services

- (A) Each hospital shall establish organized environmental services, to ensure the hospital environment is clean and sanitary.
- (B) Environmental services shall be overseen by a person competent in environmental sanitation and management.
- (C) Written policies and procedures shall be established and implemented for cleaning the physical plant and equipment.
- (D) The policies and procedures shall be designed to prevent and control infection. At a minimum, the policies and procedures shall address:
 - (1) Cleaning schedules,
 - (2) Cleaning methods,
 - (3) The proper use and storage of cleaning supplies,
 - (4) Hand washing, and
 - (5) The supervision and training of environmental services personnel.
- (E) Dry dusting and sweeping are prohibited.
- (F) Suitable equipment and supplies shall be provided for cleaning of all surfaces. Such equipment shall be maintained in a safe, sanitary condition.
- (G) Carts used to transport rubbish and refuse shall be constructed of impervious materials, shall be enclosed, and shall only be used for this purpose.

5.3 Facility Services

- (A) The grounds, physical plant, equipment, and furnishings shall be hazard free and in good repair.
- (B) The hospital shall provide facility maintenance services, which shall be responsible for the upkeep of the hospital's grounds, physical plant, equipment, and furnishings.
- (C) The building and mechanical programs shall be overseen by a qualified person informed in the operations of the hospital and in the building structures, their component parts, and facilities.
- (D) The hospital shall implement written policies and procedures to keep the entire hospital in good repair and to provide for the safety, welfare, and comfort of the occupants of the building(s).
- (E) Physical Plant Maintenance

- (1) Inspections and maintenance shall be conducted of physical plant systems including, but not limited to, the electrical system, emergency power generators, water supply, and ventilation.
 - (2) Inspection and maintenance shall be conducted in accordance with written maintenance schedules.
 - (3) Records shall be maintained showing the date of inspection and maintenance and action taken to correct any deficiencies.
- (F) Equipment Maintenance
 - (1) Inspections and preventive maintenance shall be conducted of equipment, including equipment used for direct patient care, to ensure that it is in good working order.
 - (2) Preventive maintenance shall be conducted in accordance with written maintenance schedules.
 - (3) Preventive maintenance includes, but is not limited to: routine inspections, cleaning, testing, and calibrating in accordance with manufacturers' instructions, or if there are not manufacturers' instructions, as specified by the hospital's written policies and procedures.
 - (4) A hospital may, under certain conditions, use equipment maintenance activities and frequencies that differ from those recommended by the manufacturer. Hospitals that choose to employ alternate maintenance activities and/or schedules must develop, implement, and maintain a documented alternate equipment maintenance program to minimize risks to patients and others in the hospital associated with the use of hospital or medical equipment.
- (G) Records shall be maintained showing the date of maintenance and action taken to correct any deficiencies.
- (H) Insect, Pest, and Rodent Control
 - (1) The hospital shall develop and implement written policies and procedures for the effective control and eradication of insects, pests, and rodents.
 - (2) Pesticides shall not be stored in patient or food areas and shall be kept under lock.
 - (3) Only properly trained, responsible personnel shall be allowed to apply insecticides and rodenticides.

5.4 Waste Disposal Services

- (A) The hospital shall provide for the safe disposal of all types of waste products.
- (B) Infectious waste disposal shall be overseen by a person qualified by education, training, competencies, and/or experience in the principles of infectious waste management.
- (C) All personnel shall wash their hands thoroughly after handling waste products.

- (D) The hospital shall develop and implement written policies and procedures to ensure the safe disposal of waste products.
- (E) The policies and procedures shall address, at a minimum, the following:
 - (1) The discharge of all sewage into a public sewer system;
 - (2) Garbage and refuse;
 - (a) All garbage and refuse, not treated as sewage, shall be collected and stored in covered containers.
 - (b) All garbage and refuse shall be removed from the hospital premises as frequently as necessary to prevent nuisance or health hazards.
 - (3) Infectious waste; and
 - (a) Infectious waste shall be handled and disposed of in accordance with the requirements of Section 25-15-401, et. seq., C.R.S.
 - (4) Biological non-infectious waste.
- (F) In-facility refuse containers shall be kept clean, and single-service liners shall be used when appropriate to the container.
- (G) Each hospital shall have a sufficient number of watertight containers with tight fitting lids, to hold all refuse that accumulates between collections.
- (H) Containers used for storing or holding refuse waiting for collection must be enclosed.
- (I) Accumulated waste material shall be removed from the building at least daily.
- (J) All external rubbish and refuse containers shall be impervious and tightly covered.

5.5 Linen and Laundry Services

- (A) The hospital shall provide linen and laundry services, directly or by contract, to ensure the proper laundering of washable goods and a sufficient supply of clean linen.
- (B) Linen and laundry services shall be overseen by a person qualified by education, training, competencies, and/or experience.
- (C) The hospital shall develop and implement policies and procedures for the collection, processing, distribution, and storage of linen.
- (D) 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.
- (E) 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.
- (F) Laundering shall be conducted in accordance with manufacturers' instructions regarding the washing machine and the cleaning agent used.
- (G) Only commercial laundry equipment shall be used to process hospital linen and laundry.

Part 6. GOVERNANCE AND LEADERSHIP

6.1 Governing Body

- (A) Each hospital shall have a governing body that is legally responsible for the conduct of the hospital.
- (B) Organization and responsibilities of the governing body
 - (1) The governing body shall:
 - (a) Be formally organized with a written constitution or articles of incorporation and bylaws.
 - (b) Hold meetings at regularly stated intervals, but at least quarterly, and maintain records of these meetings.
 - (c) Appoint an administrative officer who is qualified by education, training, competency, and experience in hospital administration, and delegate to them the executive authority and responsibility for the administration of the hospital. The administrative officer shall:
 - (i) Act as the liaison between the governing body and the medical staff.
 - (ii) Develop and implement a written organizational plan defining the authority, responsibility, and functions of each category of personnel.
 - (iii) Develop written policies and procedures for employee and medical staff use.
 - (iv) Ensure policies and procedures are reviewed and, if necessary, updated every three (3) years, or more often as appropriate.
 - (2) The governing body shall be responsible for all the functions performed within the hospital through the approval and implementation of written policies and procedures.
 - (3) With respect to patient care and services provided, the governing body shall:
 - (a) Provide services and hospital departments necessary for the welfare and safety of patients.
 - (b) Ensure that the patients receive care in a safe setting, including providing the equipment, supplies, and facilities necessary for the welfare and safety of patients.
 - (c) Ensure that each hospital department or service has written organizational policies and procedures that identify the scope of care and services provided, the lines of authority and accountability, and the qualifications of the personnel performing the services.
 - (d) Ensure services are provided in accordance with current standards of practice.

- (e) Ensure hospital policies and procedures are available to employees at all times.
 - (f) Ensure that each service or department provides, at minimum, twelve (12) hours of training annually regarding the direct patient care and services provided by the service or department.
 - (g) Provide professional staff and auxiliary personnel in sufficient numbers, types, and qualifications necessary to protect the health, safety, and welfare of patients commensurate with the scope and type of services provided.
 - (h) Ensure that services performed under a contract are provided in a safe and effective manner.
 - (i) Ensure there is medical staff coverage twenty-four (24) hours per day, seven (7) days per week.
- (4) With respect to the oversight of off-campus locations, the governing body shall 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 health information management system that is integrated with that of the hospital campus.
 - (e) Has onsite supervision of services that is appropriate to the scope of services offered and 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, so patients know they are entering the hospital and will be billed accordingly.
 - (h) Has exterior building signage containing the main hospital's name, but does not have an emergency department in conformance with Part 21 of this chapter, Emergency Services, and that the off-campus location:
 - (i) posts signage on or near the front entrance indicating the 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; and

- (iii) staff trained to respond to acute care emergencies and emergency transfer protocols, as appropriate to their responsibilities.
- (5) With respect to the oversight of the Medical Staff, the governing body shall:
 - (a) Determine which categories of practitioners are eligible candidates for appointment to the medical staff.
 - (b) Appoint members to the medical staff after consideration of medical staff recommendations.
 - (c) Approve medical staff bylaws and other medical staff policies and procedures.
 - (d) Consult directly with the appointed or elected medical staff leader or their designee.
 - (e) Ensure any disciplinary action that results in a suspension, revocation, or limitation of the privileges of a member of the medical staff is reported to the appropriate licensing or certification authority.

6.2 Medical Staff

- (A) All hospitals shall have an organized medical staff that is responsible for the quality of medical care provided to patients by the hospital.
- (B) Organization and responsibilities of the medical staff
 - (1) The medical staff shall:
 - (a) Be organized in a manner approved by the governing body.
 - (b) Adopt written bylaws, which address at a minimum:
 - (i) Application and appointment to the medical staff;
 - (ii) Privileges and duties of each category of medical staff member, in accordance with the requirements of Section 25-3-103.5, C.R.S.;
 - (iii) Professional conduct in the hospital;
 - (iv) Discipline of medical staff members;
 - (v) The right to appeal medical staff decisions;
 - (vi) Attendance requirements for medical staff meetings; and
 - (vii) The formation of committees.
 - (c) Ensure the governing body approves the bylaws.
 - (d) Appoint or elect a physician from the organized medical staff as the medical staff leader.

- (e) Meet regularly and maintain written records of these meetings.
- (2) The Medical Staff shall be responsible for the following:
 - (1) Exercising oversight of all medical staff members or licensed independent practitioners in the hospital through processes such as peer review and making recommendations concerning privileging and re-privileging.
 - (2) Ensuring all persons admitted as patients to a hospital shall have the benefit of continuing daily care of a medical staff member or a licensed independent practitioner.
 - (3) Developing and implementing policies and procedures for coordinating and designating responsibility when more than one member of the medical staff or licensed independent practitioner is treating a patient.

Part 7. EMERGENCY PREPAREDNESS

7.1 Emergency Management Plan

- (A) Each hospital shall develop and implement a comprehensive emergency management plan that meets the requirements of this part, utilizing an all-hazards approach. The plan shall take into consideration preparedness for natural emergencies, man-made emergencies, facility emergencies, bioterrorism event, pandemic influenza, or an outbreak by a novel and highly infectious agent or biological toxin, that may include, but are not limited to:
 - (1) care-related emergencies;
 - (2) equipment and power failures;
 - (3) interruptions in communications, including cyber-attacks;
 - (4) loss of a portion or all of a facility; and
 - (5) interruptions in the normal supply of essentials, such as water and food.
- (B) The emergency management plan shall address, at a minimum, the following:
 - (1) The plan shall be:
 - (a) specific to the hospital;
 - (b) relevant to the geographic area;
 - (c) readily put into action, twenty-four (24) hours a day, seven (7) days a week; and
 - (d) reviewed and revised periodically.
 - (2) the plan shall identify:
 - (a) who is responsible for each aspect of the plan; and

- (b) essential and key personnel responding to a disaster.
 - (3) The plan shall include:
 - (a) a staff education and training component;
 - (b) a process for testing each aspect of the plan at least every two (2) years or as determined by changes in the availability of hospital resources; and
 - (c) a component for debriefing and evaluation after each disaster, incident, or drill.
- 7.2 Each hospital shall comply with the requirements of 6 CCR 1009-5, Regulation 2 – Preparations by General or Critical Access Hospitals for an Emergency Epidemic.

Part 8. QUALITY MANAGEMENT PROGRAM

- 8.1 Each hospital shall comply with the requirements of 6 CCR 1011-1, Chapter 2, Part 4.1.
- 8.2 If a hospital is part of a hospital system consisting of multiple hospitals using a system governing body that is legally responsible for the conduct of two (2) or more hospitals, the system governing body may have a unified Quality Management Program (QMP) provided the QMP does the following:
- (A) Takes into account each hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital; and
 - (B) Establishes and implements policies and procedures to ensure the needs and concerns of each hospital, regardless of practice or location, are given due consideration, and that the unified QMP has mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed.
- 8.3 The system governing body is accountable for ensuring that each of its hospitals meet all of the requirements of this section.

Part 9. PERSONNEL

- 9.1 Each department or service of the hospital shall be directed by a person qualified by appropriate education, training, competencies, and experience.
- (A) A physician director of a department or service shall be a member of the hospital's medical staff.
 - (B) A physician director shall ensure that the quality of services provided by the medical staff of the department or service are monitored and evaluated.
- 9.2 Each department shall have a sufficient number of medical staff, nursing staff, and other auxiliary personnel, qualified by education, training, competencies, and experience, in each department or service to properly operate the department or service.
- 9.3 Hospital staff shall be licensed, certified, or registered in accordance with applicable state laws and regulations, and shall provide services within their scope of practice and, as appropriate, in accordance with credentialing.

- (A) Hospitals that utilize emergency medical service (EMS) providers, pursuant to Section 25-3.5-207, C.R.S., shall, in collaboration with its medical staff, establish operating policies and procedures that ensure EMS providers perform tasks and procedures, and administer medications within their scope of practice, as set forth in 6 CCR 1015-3, Chapter Two – Rules pertaining to EMS practice and medical director oversight.
- 9.4 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, policies, procedures, and the techniques involved to safeguard the welfare of patients.
 - (A) Prior to delivering patient care independently, new personnel shall receive orientation regarding the patient care environment and relevant policies and procedures.
- 9.5 The hospital shall maintain position descriptions that clearly state the qualifications and expected duties of the position for all categories of personnel.
- 9.6 The hospital shall maintain personnel records on each member of the hospital staff, to include employment application, verification of licensure, certification, or registration, and competencies.
 - (A) The hospital shall maintain procedures to ensure that staff for whom state and/or federal licenses, registrations, or certificates are required have a current license, registration, or certificate.
- 9.7 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.
- 9.8 The hospital shall ensure access to up-to-date reference materials for the professional staff.

Part 10. HEALTH INFORMATION MANAGEMENT

- 10.1 Each hospital shall comply with the requirements of 6 CCR 1011-1, Chapter 2, Part 6, regarding patient access to medical records.
- 10.2 A complete and accurate medical record shall be maintained on each inpatient and outpatient evaluated or treated in any part or location of the hospital from the time of initiation of services through discharge.
- 10.3 A registered record administrator or other trained medical record practitioner shall be responsible for the administration and functions of the health information management service.
- 10.4 There shall be a sufficient number of regular full-time and part-time employees so that health information management services may be provided as needed.
- 10.5 Medical records shall be stored in a manner to:
 - (A) Provide protection from loss, damage, and unauthorized use;
 - (B) Preserve the confidentiality of health information; and
 - (C) Allow for the prompt retrieval of records.
- 10.6 Medical records shall be preserved as original records, in a manner determined by the hospital:
 - (A) For minors, for the period of minority plus ten (10) years (i.e., until the patient is age 28) or ten (10) years after the most recent patient usage, whichever is later.

- (B) For adults, for ten (10) years after the most recent patient care usage of the medical record.
- 10.7 After the required time of record preservation, records may be destroyed at the discretion of the hospital in accordance with the hospital's record retention policy. Hospitals shall establish procedures for notification to patients whose records are to be destroyed prior to the destruction of such records.
- 10.8 If a hospital ceases operation, the hospital shall make provision for the secure, safe storage, and prompt retrieval of all medical records for the period specified in Part 10.6 above.
 - (A) A hospital that ceases operation shall comply with the provisions of 6 CCR 1011-1, Chapter 2, Part 2.14.4.
- 10.9 All orders for diagnostic procedures, treatments, and medications shall be signed by the physician or other licensed independent practitioner and entered into the medical record. The prompt completion of a medical record shall be the responsibility of the attending physician or other licensed independent practitioner. Authentication may be by written signature, identifiable initials, or computer key.
- 10.10 The medical record shall contain information necessary to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services.
- 10.11 All medical records shall include, at a minimum, the following:
 - (A) Admitting diagnosis, history, and physical examination completed no more than thirty (30) days prior to admission of the patient 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.
 - (B) Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient.
 - (C) Documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and/or anesthesia.
 - (D) Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by federal or state law, if applicable, to require written patient consent.
 - (E) All practitioners' orders, nursing notes, reports of treatment, medication records, radiology and laboratory reports, vital signs, and other information necessary to monitor the patient's condition.
 - (F) Discharge summary with outcome of hospitalization, disposition of case, and provisions for follow-up care.
 - (G) Final diagnosis with completion of medical records within (thirty) 30 days following discharge.
- 10.12 The following hospital records shall be maintained:
 - (A) Daily census,

- (B) Admissions and discharge report,
- (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, and
- (H) Register of outpatient and emergency room admissions and visits.

Part 11. INFECTION PREVENTION AND CONTROL AND ANTIBIOTIC STEWARDSHIP PROGRAMS

11.1 Infection Prevention and Control Program

- (A) The hospital shall have an infection prevention and control program responsible for the prevention, control, and investigation of infections and communicable diseases.
- (B) The infection prevention and control program shall reflect the scope and complexity of the services provided by the hospital.

11.2 Infection Prevention and Control Committee

- (A) There shall be a multi-disciplinary infection prevention and control committee charged with:
 - (1) Developing and implementing policies and procedures regarding prevention, surveillance, and control of healthcare acquired infections and infectious diseases.
 - (2) Making findings and recommendations to prevent and control healthcare acquired infections and infectious diseases.
 - (3) Reviewing the policies and procedures of the following services periodically, but no less than every three (3) years: anesthesia, critical care, dietary, environmental, linen and laundry, materials management, pediatric, perinatal, respiratory, and surgical and recovery.
- (B) The committee shall make findings and recommendations available promptly to the infection control officer for action.
- (C) The committee shall meet at least once every quarter and maintain minutes of the meetings.
- (D) The policies and procedures shall be based on nationally recognized guidelines and best practices for infection prevention and control. The policies shall address, at a minimum, the following:
 - (1) Maintenance of a sanitary hospital environment;

- (2) Development and implementation of infection prevention and control measures related to hospital personnel, staff, and volunteers;
 - (3) Mitigation of risks associated with patient infections present upon admission;
 - (4) Mitigation of risks contributing to healthcare associated infections, including, but not limited to, isolation procedures;
 - (5) Monitoring compliance with all policies, procedures, protocols, and other infection control program requirements;
 - (6) Program evaluation and revision on an annual basis or as necessary;
 - (7) Coordination with other federal, state, and local agencies, as necessary;
 - (8) Complying with reportable disease requirements, as found at Section 25-3-601, C.R.S., et seq.;
 - (9) Implementation of infection prevention and control measures during hospital renovations; and
 - (10) Training and education of hospital personnel, staff, and personnel providing contracted services in the hospital on the practical applications of infection prevention and control guidelines, policies, and procedures.
- (E) A hospital with twenty-five (25) beds or fewer that is not part of a multi-hospital system may choose not to have an infection prevention and control committee. If a hospital chooses not to have an infection prevention and control committee, the infection prevention and control officer is responsible for ensuring all requirements of this Part 11 are met.

11.3 Infection Prevention and Control Officer

- (A) The hospital shall have an infection prevention and control officer or officers, qualified through education, training, competencies, experience, and/or certification.
- (B) The infection prevention and control officer(s) shall implement the policies and procedures and the recommendations of the infection control committee.
- (C) The infection prevention and control officer(s) shall coordinate with the Administrative Officer, Elected Medical Staff Leader, and Senior Nurse Executive to implement corrective action plans, as necessary.

11.4 Infection Prevention and Control Policies and Procedures Regarding Equipment and Instruments

- (A) The Infection Prevention and Control Committee shall develop and implement policies and procedures regarding equipment and instrument cleaning, disinfecting, sterilizing, reprocessing, and storage.
- (B) The policies and procedures shall be based on nationally recognized guidelines, such as those promulgated by the Centers for Disease Control and Prevention (CDC), the Association for Professionals in Infection Control and Epidemiology (APIC), The Society for Healthcare Epidemiology of America (SHEA), the Association of periOperative Registered Nurses (AORN), and/or the association for the Advancement of Medical Instrumentation (AAMI).

- (C) Manufacturers' instructions shall be followed for the cleaning, disinfecting, and sterilizing of all reusable equipment and instruments.

11.5 Antibiotic Stewardship Program

- (A) The hospital shall have an antibiotic stewardship program responsible for the optimization of antibiotic use through stewardship.
- (B) The program shall be overseen by an individual who is qualified through education, training, competencies, and/or experience in infectious diseases and/or antibiotic stewardship.
- (C) The program shall involve coordination among all components of the hospital responsible for antibiotic use and resistance, including, but not limited to, the infection prevention and control program, the quality management program, the medical staff, nursing services, and pharmacy services.
- (D) The program shall document the evidence-based use of antibiotics in all departments and services of the hospital and any improvements in proper antibiotic use.
- (E) The program shall adhere to nationally recognized guidelines and best practices for improving antibiotic use.
- (F) The program shall reflect the scope and complexity of the hospital services provided.
- (G) Hospital personnel and staff, as identified by hospital policy, shall be trained on the practical applications of antibiotic stewardship guidelines, policies, and procedures.

11.6 Unified Infection Prevention and Control and Antibiotic Stewardship Programs for Multi-Hospital Systems

- (A) If a hospital is part of a hospital system consisting of multiple hospitals using a system governing body that is legally responsible for the conduct of two or more hospitals, the system governing body may have unified infection control and antibiotic stewardship programs, provided the unified programs do the following:
 - (1) Take into account each hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital.
 - (2) Establish and implement policies and procedures to ensure the needs of each hospital, regardless of practice or location, are given due consideration, and that the programs have mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed; and
 - (3) Ensure a qualified individual(s) with expertise in infection prevention and control and in antibiotic stewardship has been designated at the hospital as responsible for:
 - (a) communicating with the unified infection prevention and control and antibiotic stewardship programs,
 - (b) implementing and maintaining the policies and procedures directed by the unified infection prevention and control and antibiotic stewardship programs, and

- (c) providing education and training on the practical applications of infection prevention and control and antibiotic stewardship to hospital staff.

Part 12. PATIENT RIGHTS.

The hospital shall comply with 6 CCR 1011-1, Chapter 2, Part 7, Client Rights.

Part 13. GENERAL PATIENT CARE SERVICES

- 13.1 The hospital shall provide inpatient and outpatient care services. Services shall be provided in accordance with nationally-recognized standards of practice, hospital policy and procedure, medical orders, and the established care plan.
- 13.2 Admissions
 - (A) Each patient admitted to the hospital shall have a visible means of identification placed on their person.
 - (1) 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. Exceptions may be made in the event of federally, state, or locally-declared.
 - (C) Except in emergent situations, patients shall only be accepted for care and services when the hospital can meet their identified and reasonably anticipated care, treatment, and service needs.
- 13.3 Written policies and procedures shall be developed and implemented by each department/ or service that provides direct patient care. These policies shall address, at a minimum, the following:
 - (A) Procedures for medical emergencies, which address the following requirements.
 - (1) Resuscitation services shall be available throughout the hospital.
 - (2) The medical staff shall develop and implement a policy and procedure outlining the scope of services provided to patients receiving services who develop emergency medical conditions.
 - (3) The hospital shall be organized and equipped to meet the needs of patients receiving services who develop emergency medical conditions.
 - (a) The following shall be readily available at all times in areas where care is provided:
 - (i) oxygen;
 - (ii) suction;
 - (iii) portable emergency equipment, supplies, and medications; and

- (iv) compatible supplies and equipment for immediate intravenous therapy.
 - (4) The hospital shall ensure all medical staff, nursing staff, and auxiliary personnel are trained to provide emergency services commensurate with the hospital's scope of services, and in accordance with nationally-recognized standards of care.
 - (5) The medical staff shall conduct ongoing assessments of the emergency medical services provided to patients receiving services, as part of the hospital's quality management program, established in Part 8, Quality Management Program.
 - (B) Coordination of care across multiple services or departments, as applicable.
 - (C) Transfer of inpatients to a higher level of care when their needs exceed the hospital's scope of services.
- 13.4 The hospital shall provide the necessary equipment, supplies, and medications commensurate with the scope of services.
- 13.5 Patient Assessment
- (A) Patient assessments shall document patient needs, capabilities, limitations, and goals. Qualified staff shall:
 - (1) Conduct an initial assessment of the patient's physical and psychological status; and
 - (2) Conduct an assessment or screening upon each initial contact with therapy, social, nursing, and dietary services, and at regular intervals thereafter.
- 13.6 Patient Care Planning
- (A) A care plan shall be prepared for each patient, and be reviewed and revised as needed. Care plans shall:
 - (1) Contain goals, both short-term and long-term as applicable, and timeframes for meeting such goals;
 - (2) Be in writing, and kept current;
 - (3) Be updated when there is a change in the patient's condition;
 - (4) Be individualized and designed to meet the patient's needs;
 - (5) Demonstrate patient-centered coordination when the patient is receiving services from multiple departments or services; and
 - (6) 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 care plan shall be easily identifiable and accessible within the medical record.

13.7 Orders

- (A) Medications and treatments shall be given only on the order of a physician or licensed independent practitioner.
- (B) Except as specified in subparagraph (E) below, 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.
- (C) 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 policies of the organized medical staff.
- (D) For all medications not specifically prescribed as to time or number of doses, the medical staff, in conjunction with the pharmacy service, shall establish stop orders for these medications.
- (E) All verbal orders shall be authenticated by a physician or responsible individual who has the authority to issue verbal orders in accordance with hospital and medical staff policies or bylaws. The policies or bylaws shall require that:
 - (1) Authentication of a verbal order occurs within forty-eight (48) hours after the time the order is made unless a read-back and verify process pursuant to paragraph (2) of this subsection (E) is used. The individual receiving a verbal order shall record in writing the date and time of the verbal order, and sign the verbal order in accordance with hospital policies or medical staff bylaws.
 - (2) A hospital policy may provide for a read-back and verify process for verbal orders. A read-back and verify process shall require that the individual receiving the order record it in writing and immediately read back the order to the physician or responsible individual, who shall immediately verify that the read-back order is correct. The individual receiving the verbal order shall record in writing that the order was read back and verified. If the read-back and verify process is followed, the verbal order shall be authenticated within 30 days after the date of the patient's discharge.
 - (3) Verbal orders shall be used infrequently. Nothing in this section shall be interpreted to encourage the more frequent use of verbal orders by the medical staff at a hospital.

13.8 Telehealth Services

- (A) The hospital may provide telehealth services to patients receiving services.
- (B) All telehealth services must meet the standards herein and be provided commensurate with the patient's needs.
- (C) The hospital shall develop and implement policies and procedures governing the use of telehealth. These policies shall be based on nationally-recognized guidelines and standards of practice and address, at a minimum, the following:
 - (1) Procedures for documenting all telehealth consultations within the patient's medical record.

- (2) Procedures for ensuring telehealth providers are authorized and qualified to offer services to the patient.
- (3) Training for hospital staff regarding the use of telehealth platforms and technology.

13.9 Discharge Planning

- (A) The hospital shall develop a discharge plan for each inpatient.
- (B) The hospital shall develop and implement policies and procedures regarding discharge planning. These policies shall be based on nationally-recognized guidelines and standards of practice and address, at a minimum, the following:
 - (1) The discharge planning process;
 - (2) The development of the discharge and evaluation plan, which shall be completed under the supervision of a registered nurse, social worker, or other appropriately qualified personnel;
 - (3) The qualifications of the staff responsible for implementing discharge planning;
 - (4) Initiation of discharge planning in a timely manner to allow for the arrangement of post-hospital care, as needed, and to avoid unnecessary delays in discharge;
 - (5) Regular re-evaluation of the patient's condition to identify changes that require modification of the discharge plan;
 - (6) The hospital's compliance with Section 25-1-128, C.R.S., regarding patient designation of a caregiver who will provide aftercare following patient discharge; and
 - (7) Evaluation of the discharge planning process periodically for effectiveness.
- (C) The discharge plan shall:
 - (1) Include an evaluation of the post-hospital care needs of the patient and the availability of corresponding services, taking into consideration the patient's access to those services;
 - (2) Identify the role of the hospital staff, patient, patient's family, or designated representative in initiating and implementing the discharge planning process; and
 - (3) Be discussed with the patient or designated representative prior to leaving the hospital.
- (D) For a patient with a discharge plan indicating the need for post-hospital health care services, the hospital shall:
 - (1) 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.
 - (2) 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.

- (3) Ensure that the receiving health care provider and, as applicable, the patient's primary care physician or licensed independent practitioner 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.
 - (a) Documentation shall also include contact information for the attending physician or licensed independent practitioner.
 - (b) The hospital must provide all necessary medical information pertaining to the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences, at the time of discharge, to the appropriate post-hospital care service providers and suppliers, facilities, agencies, and other outpatient service providers and practitioners responsible for the patient's follow-up or ancillary care.
- (E) For a patient with a discharge plan who is not transferred to another facility, the hospital shall provide the patient with:
 - (1) A contact to call in case the patient has questions after discharge.
 - (2) Written instructions about self-care, follow up care, modified diet, medications, and signs and symptoms to be reported to the practitioner, if applicable.
- (F) The hospital shall prepare a discharge summary to facilitate continuity of care that is signed by the attending physician or licensed independent practitioner and includes the following:
 - (1) Reason for admission;
 - (2) Significant findings;
 - (3) Procedures and treatment provided;
 - (4) Patient's discharge condition;
 - (5) Patient and family instructions;
 - (6) A medication list indicating new, changed, or discontinued; and
 - (7) A list of outstanding medical issues and pending tests at the time of discharge that require follow-up.

Part 14. NURSING SERVICES

- 14.1 There shall be a nursing department formally organized to provide complete, effective care to each patient.
- 14.2 Nursing services shall be directed by a registered nurse qualified by education, training, competencies, and experience to direct effective nursing care. For purposes of this chapter, this individual is referred to as the Senior Nurse Executive.

- 14.3 The Senior Nurse Executive shall be responsible for ensuring that all nursing staff have the qualifications, competencies, and experience necessary to deliver the care assigned in accordance with professional standards of practice and hospital policy and procedure.
- 14.4 Nursing Services Policies and Procedures
- (A) The service shall develop and implement policies and procedures that establish the standards for performance of safe nursing care.
 - (B) The policies and procedures shall be based on nationally-recognized practice guidelines and data-driven measures.
 - (C) The policies and procedures shall be reviewed periodically and revised as necessary, no less than every three (3) years.
- 14.5 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 hospital policy and professional standards of practice.
- 14.6 Nurse Staffing Plans
- (A) Master Nurse Staffing Plan
 - (1) There shall be a master nurse staffing plan, which provides for continuous registered nurse coverage, for distribution of nursing and auxiliary personnel, and for forecasting future needs.
 - (2) The master nurse staffing plan must be based on the different types of patients cared for on each inpatient care unit and in the emergency department, the skill mix, specialized qualifications, and level of competency necessary for nursing staff to ensure that the hospital is staffed to meet the safety and healthcare needs of patients.
 - (3) The master nurse staffing plan shall specify how each patient is provided access to care from a registered nurse, when applicable.
 - (4) Once the master nurse staffing plan has been initiated, ongoing staffing effectiveness shall be reviewed and documented through the nurse staffing oversight process.
 - (5) The master nurse staffing plan must be reviewed periodically, and revised as necessary, no less than every three (3) years.
 - (B) Inpatient Care Unit and Emergency Department Plans
 - (1) Each open inpatient care unit and emergency department within the hospital shall have a twenty-four (24) hour nurse staffing plan.
 - (C) The master nurse staffing plan, inpatient care unit plans, and emergency department plans shall be made available to and reviewed with each individual member of the nursing staff annually. The hospital shall maintain documentation of the annual plan reviews.

- (D) When updates are made to the master nurse staffing plan, inpatient care unit plan, or emergency department plan, the updates shall be made available to each member of the nursing staff.
- 14.7 The authority and responsibility of each nurse and auxiliary personnel shall be clearly-defined in written policies. Auxiliary personnel shall only be assigned duties for which they are qualified, and shall be under the supervision of a registered nurse.
- 14.8 At least one (1) registered nurse and one (1) auxiliary personnel shall be on duty at all times in each open inpatient unit and in the emergency department. Additional staffing needs shall be determined by the hospital's master nurse staffing plan.
- 14.9 One (1) registered nurse qualified by education, training, competencies, and experience, shall be designated in charge of each open inpatient care unit and the emergency department, and that individual shall be delegated the authority and responsibility for the nursing services on that unit. Additional registered nurses or other auxiliary personnel shall be available.
- 14.10 Nurse Staffing Oversight Process
 - (A) Each hospital shall establish and maintain a nurse staffing oversight process.
 - (B) The nurse staffing oversight process shall, at a minimum:
 - (1) Develop the master nurse staffing plan, including a specific plan for each inpatient care unit and emergency department; and
 - (2) Describe the process for addressing concerns brought forth by staff.
 - (C) The nurse staffing oversight process shall have at least 50% or greater participation by clinical staff nurses, in addition to auxiliary personnel and nurse management.
 - (D) The hospital shall develop, document, and implement a nurse staffing oversight charter or guideline that shall address, at a minimum, the following:
 - (1) The process for how complaints and feedback from hospital staff related to nurse staffing are received and processed;
 - (2) How decisions are made; and
 - (3) How the staffing plans will be monitored, evaluated, and modified over time.
 - (E) The nurse staffing oversight process documentation shall be made available to hospital nursing staff.
 - (F) If the results of the review and the written report indicate that the current master nurse staffing plan has not resulted in adequate staffing, and/or the healthcare needs of the patients are not met, the staffing plan shall be modified through the nurse staffing oversight process.
 - (G) Report Requirements
 - (1) A written report shall be made to the hospital's governing body, which maintains the responsibility to protect the health, safety, and welfare of patients, commensurate with the scope and types of services provided at the hospital, either directly or through the Senior Nurse Executive.

- (2) The purpose of the report is to ensure the hospital is adequately staffed, and the healthcare needs of patients are met. The following factors, at a minimum, shall be addressed in the report:
 - (a) Current best practices, taking into consideration community standards, and benchmarking or evidence-based metrics, as applicable;
 - (b) Patient census;
 - (c) Patient acuity or workload;
 - (d) Churn (admissions/discharges/transfers);
 - (e) Skill mix;
 - (f) RN education;
 - (h) Patient outcomes; and
 - (i) Workforce metrics and staff feedback.
- (3) The report shall be issued to the governing body for approval following each review of the staffing plan.

Part 15. PHARMACY SERVICES

- 15.1 The pharmacy service 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.
- 15.2 The pharmacy service shall be under the direct supervision of a pharmacist licensed to practice pharmacy in the State of Colorado.
- 15.3 Availability of Pharmacy Services
 - (A) The pharmacy services shall develop and implement policies and procedures ensuring convenient and prompt twenty-four (24) hour availability of drugs for administration to patients.
 - (B) Emergency pharmacy services shall be available twenty-four (24) hours per day, seven (7) days per week.
 - (C) If a pharmacist is not available on site on a twenty-four (24)-hour basis, a pharmacist shall be available on-call within thirty (30) minutes.
- 15.4 A pharmacist shall be responsible for compounding, preparing, labeling, transferring between containers, and dispensing drugs, including direct supervision of qualified personnel performing such tasks.
- 15.5 Pharmacy and Therapeutic Committee
 - (A) 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, minimization of drug errors, and other matters relating to drugs in hospitals.

- 15.6 Pharmacies shall be registered by the Colorado State Board of Pharmacy and have a current Drug Enforcement Administration registration.
- 15.7 The pharmacy shall maintain a current formulary of approved drugs and biologicals.
 - (A) The hospital shall maintain an adequate stock of the medications listed in the formulary.
 - (B) The hospital shall be responsible for the quality, quantity, and sources of supply of all medications.
 - (C) Medication stocks shall not contain outdated, unusable, or mislabeled products.
 - (D) The hospital shall have processes to approve and procure medications that are not on the hospital's formulary.
- 15.8 Current records shall be maintained that account for the receipt, distribution, disposition, and destruction of drugs and biologicals.
- 15.9 The receipt, distribution, administration, and disposition of controlled substances shall be readily traceable.
 - (A) Mechanisms shall be implemented to ensure the security of the drugs and to prevent and detect the diversion of controlled substances and other drugs that may be abused or illegally sold.
 - (B) When diversion is detected, appropriate corrective measures shall be implemented in accordance with hospital policy and procedure.
- 15.10 The hospital shall alert appropriate staff to remove any drugs or biologicals subject to a recall or discontinuation for safety reasons.
- 15.11 All drugs and biologicals shall be kept in a secure area to prevent unauthorized access. All controlled drugs shall be kept in a locked secure area.
- 15.12 Drugs and biologicals shall be stored under the proper conditions of sanitation, temperature, light, moisture, ventilation, and segregation, to maintain therapeutic integrity.
- 15.13 Pharmacy Policies and Procedures
 - (A) The pharmacy service shall develop and implement policies and procedures, based on nationally-recognized guidelines and standards of practice that address, at a minimum, the following:
 - (1) After-hours access, including the following requirements:
 - (a) If the pharmacy is not open twenty-four (24) hours, seven (7) days per week, the hospital shall have a policy and procedure regarding after-hour access to medications.
 - (b) The policy and procedure shall specify the personnel permitted access to the medication storage area(s).
 - (c) There shall be accountability for all doses of medications removed when the pharmacist is not present.

- (2) The disposal of unused medications.
- (3) The safe and appropriate procurement, storage, preparation, dispensing, use, tracking and control, and disposal of medications and medication delivery devices throughout the hospital.
- (4) Periodic inspection of the medication storage area.

15.14 Medication Administration

- (A) Prior to administration, medications shall be checked for integrity and to ensure the medication has not expired.
- (B) Prior to administration, the following shall be verified: patient, time, medication, dosage, route of administration, and indication.
- (C) The hospital shall develop and implement policies and procedures, based on nationally-recognized guidelines addressing, at a minimum, the following:
 - (1) The review of patient drug profiles.
 - (2) Medication monitoring.
 - (3) The safe administration of drugs and biologicals. Specifically, only appropriately-trained individuals who are authorized by law and the hospital shall administer medications.
 - (4) 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.
 - (5) Identification and reporting of adverse reactions, interactions, and medication errors.
 - (6) Self-administration of medication, including but not 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 physician or licensed independent practitioner.
 - (7) Use of the patient's own medications. Drugs and biologicals brought into the hospital by the patient may be administered only if the medication can be accurately identified by the pharmacy, secured, and pursuant to an order from the attending physician or licensed independent practitioner.
 - (8) Medications brought into the hospital by practitioners to be administered to patients.
 - (9) The review of medication orders by a pharmacist for appropriateness.

- 15.18** The hospital shall ensure up-to-date resources are 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.

15.19 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:
 - (1) When there is written approval of an Institutional Review Board (IRB), established in accordance with federal law and regulation; and
 - (2) Under the supervision of a member of the medical staff and administered in accordance with an IRB approved protocol.

15.20 Compounding Medications

- (A) All compounding of medications used or dispensed by the hospital shall be performed consistent with standards of safe practice applicable to both sterile and non-sterile compounding.
- (B) The hospital shall develop and implement policies and procedures to ensure the safe development and storage of compounded medications and/or admixtures.

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

15.22 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 16. LABORATORY SERVICES

16.1 Clinical Pathology

- (A) Clinical pathology services shall be made available as required by the needs of the medical staff. Emergency laboratory services shall be available twenty-four (24) hours per day, seven (7) days per week.
- (B) The laboratory shall be under the supervision of a physician certified in clinical pathology, either on a full-time, part-time, or consulting basis. This individual shall provide, at a minimum, monthly consultative visits.
- (C) There shall be a sufficient number of clinical laboratory technologists, qualified by education, training, competencies, and experience, to promptly and proficiently perform the laboratory tests and examinations required of them.
- (D) All clinical pathology services shall be ordered by a physician or a licensed independent practitioner.
- (E) Clinical pathology services shall comply with the requirements set forth in the Clinical Laboratory Improvement Amendments (CLIA).
- (F) A manual outlining all procedures performed in the laboratory shall be complete and readily available for reference.
- (G) The conditions and procedures for referring specimens to another laboratory shall be in writing and available in the laboratory.

- (H) Procedures for the adequate precautions for discarding specimens shall be in use, including sterilization, incineration, or both.
- (I) A record system shall be established which ensures that specimens are adequately identified, properly processed, and permanently recorded.
- (J) Duplicate copies of all reports shall be kept in the laboratory in a manner, which permits ready identification and accessibility for two (2) years.
- (K) All equipment shall be in good working order, be routinely checked and be precise in terms of calibration.
- (L) 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.
- (M) Vacuum breakers must be present on sinks where specimens are handled or discarded to ensure that the water supply is not contaminated.

16.2 Blood Banking

- (A) The hospital shall provide for the procurement, storage, and transfusion of blood as needed for routine and emergency cases.
- (B) Standards of the American Association of Blood Banks shall be used; or the hospital shall substitute alternate standards, which are safe and adequate for the collection and administration of blood and blood products, and are based on nationally-recognized guidelines and standards of practice.
- (C) Blood and blood products shall only be administered upon order of a physician or other licensed independent practitioner.
- (D) Before administering a blood transfusion, the following shall be authenticated by the individual administering the transfusion and one other individual (or an automated, electronic identification system, such as bar coding): 1) patient; 2) patient's blood specimen; 3) type, crossmatch, and expiration date of donor blood.
- (E) Records must be kept which show the complete receipt and disposition of blood.
- (F) Each unit of blood typed and cross-matched for transfusion must be adequately identified.
- (G) The hospital shall develop and implement policies and procedures to ensure the safe storage and transfusion of blood products.
- (H) Refrigerators used to store blood shall have a recording thermometer and an adequate alarm system. The refrigerator shall be on the emergency power source.

Part 17. DIAGNOSTIC AND THERAPEUTIC IMAGING SERVICES

- 17.1** The hospital shall have radiological imaging, including Computed Tomography (CT), available on campus, at all times. The hospital may provide other diagnostic or therapeutic imaging services either on campus or made available off-site.

- (A) The hospital shall develop a policy to be implemented in the event radiology equipment, including CT, is unavailable.
 - (B) The policy shall include procedures for notification of EMS providers and agencies and any other impacted facilities or providers.
- 17.2 Imaging services shall be directed by a qualified physician.
- 17.3 Radiology services shall be under the supervision of a qualified, full-time or consulting radiologist
- 17.4 Radiological services involving the use of machines that produce ionizing radiation or the use of radioactive materials for diagnostic or therapeutic purposes shall comply with 6 CCR 1007-1, Rules and Regulations Pertaining to Radiation Control.
- 17.5 The scope and complexity of radiological services maintained or made available must be specified in writing, and demonstrate how the hospital meets the needs of its patients.
- 17.6 The hospital must develop and implement policies and procedures that:
 - (A) Provide safety for affected patients and hospital personnel;
 - (B) Are based on nationally recognized guidelines, such as those promulgated by the American Medical Association, American College of Radiology, and the American Society of Radiologic Technologists;
 - (C) Comply with all applicable federal and state laws and regulations governing radiological services; and
 - (D) Are reviewed periodically and updated as needed, no less than every three (3) years.
- 17.7 The policies and procedures shall address, at a minimum, the following:
 - (A) Application of the fundamental principle of As Low as Reasonably Achievable to ionizing radiation services.
 - (B) Ensuring procedures are routinely performed in a safe manner, utilizing parameters and specifications that are appropriate to the ordered study or procedure.
 - (C) Ensuring protocols are designed to minimize the amount of radiation while maximizing the yield and producing diagnostically acceptable image quality.
 - (D) Identification of patients at high-risk for adverse events for whom a procedure may be contraindicated (e.g. pregnant women, individuals with known allergies to contrast agents, individuals with implanted devices).
 - (E) Management of patients with infectious diseases, critical care patients, and patients who experience medical emergencies.
 - (F) Training required by personnel permitted to enter areas where radiologic services are provided.
 - (G) Training and, as applicable, qualifications required for personnel who perform diagnostic imaging studies or therapeutic procedures utilizing radiologic services equipment.

- (H) Establishment and maintenance of safety precautions against radiation hazards, including, but not limited to:
 - (1) Clear and easily recognizable signage identifying hazardous radiation areas,
 - (2) Limitations on access to areas containing radiologic services equipment,
 - (3) Appropriate use of shielding, and
 - (4) Identification and use of appropriate containers to be used for various radioactive materials, if applicable, when stored, in transport between locations within the hospital, in use, and during or after disposal.
 - (I) Ensuring periodic inspections of radiology equipment are conducted, current, and that problems identified are corrected in a timely manner. Equipment must be inspected in accordance with manufacturer's instructions and Federal and State laws, regulations, and guidelines.
 - (J) Periodic checks for amount of radiation exposure for diagnostic imaging service personnel as well as other hospital employees who may be regularly exposed to radiation.
- 17.8 Diagnostic or therapeutic imaging services shall be ordered by a physician or other licensed independent practitioner. 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.
- 17.9 The performance of radiologic studies must be done on campus or at a facility off the hospital's campus when resources are not available on campus.
- 17.10 The interpretation of radiologic studies may be performed remotely by a teleradiology practitioner, in a timely fashion.

Part 18. NUCLEAR MEDICINE SERVICES

- 18.1 The hospital may provide nuclear medicine services. If a hospital provides nuclear medicine services, the services must meet the needs of the patients in accordance with acceptable standards of practice.
- (A) Nuclear medicine services must be ordered only by practitioners whose scope of federal or state licensure and defined staff privileges allow such referrals.
 - (B) The governing body and medical staff may also authorize practitioners who do not have hospital clinical privileges to order such studies or procedures, as permitted under state law.
- 18.2 Nuclear medicine services shall be directed by under the direction of a physician qualified in nuclear medicine.
- 18.3 The qualifications, training, functions, and responsibilities of the nuclear medicine personnel must be specified by the physician director and approved by the medical staff.
- 18.4 Nuclear medicine services, including the preparation, labeling, use, transportation, storage, and disposal of radioactive materials shall comply with 6 CCR 1007-1, Rules and Regulations Pertaining to Radiation Control.

- 18.5 There shall be written policies and procedures for all services offered, based on nationally-recognized guidelines and standards of practice that address, at a minimum, the following:
- (A) The qualifications necessary to prepare and/or oversee in-house radiopharmaceuticals, if applicable.
 - (B) Steps to take in the event of an adverse reaction.
 - (C) Protection from non-therapeutic radiation exposure for patients and visitors while in the hospital.
 - (D) Information to be provided to patients who receive nuclear medicine therapy and still have radioactive particles in their bodies regarding how to prevent and/or minimize radiation exposure of others.
- 18.6 The hospital must maintain signed and dated reports of nuclear medicine interpretations, consultations, and procedures, and maintain copies of all nuclear medicine reports as part of the patient's medical record in accordance with Part 10 of this Chapter.
- 18.7 The hospital must maintain records of the receipt and distribution of radiopharmaceuticals.

Part 19. DIETARY SERVICES

- 19.1 There hospital shall have an organized food dietary service that is 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.
- 19.2 Dietary services shall be directed by a person qualified by education, training, competencies, and experience.
- 19.3 A registered dietitian shall be responsible, on a full-time, part-time, or consultant basis, 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.
- 19.4 If 24-hour dietary services are not provided, other means of providing adequate nourishment for patients shall be made available.
- 19.5 Dietary services shall be integrated, as necessary, with other departments and services of the hospital, including but not limited to, infection prevention and control and pharmacy.
- 19.6 The nutritional needs of the patients shall be met in accordance with recognized dietary standards and in accordance with orders of the physician or licensed independent practitioners responsible for the care of the patient, a registered dietitian, or a qualified nutrition professional as authorized by the medical staff and in accordance with state law governing dietitians and nutrition professionals.
- 19.7 The hospital shall develop and implement policies and procedures based on nationally-recognized guidelines and standards of practice that address, at a minimum, the following:
- (A) The triggers and processes for conducting a nutritional risk screening or assessment of clinically relevant malnutrition, and the integration of therapeutic interventions into the patient's care plan.

- (B) 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 Prevention and Control Committee. Food served to patients in isolation because of infectious diseases shall be served with disposable utensils.
 - (C) Food condition, preparation, handling, and storage, in accordance with nationally-recognized guidelines.
 - (D) Methods to ensure hygienic practices, addressing, at a minimum, the following concepts: staff hygiene, food-contact surfaces, dietary services equipment, utensils, warewashing, clean environment, storage, and waste disposal.
- 19.8 Therapeutic diets and nourishments shall be served as prescribed by the attending licensed independent practitioner, registered dietitian, or qualified nutrition professional. A current diet manual approved by the dietitian shall be available to all medical, nursing, and food service personnel for fulfilling dietary prescriptions.
- 19.9 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, if applicable, reasonable menu adjustments made.

PART 20. ANESTHESIA SERVICES

- 20.1 The hospital shall provide anesthesia services commensurate with the scope of services provided by the hospital.
- 20.2 Administration of Anesthesia
- (A) General or regional anesthesia shall be administered only by the following individuals:
 - (1) A physician qualified by education, training, competencies, and experience in providing anesthesia;
 - (2) A certified registered nurse anesthetist; or
 - (3) An appropriately qualified anesthesiologist assistant, under the supervision of an anesthesiologist.
 - (B) In the case of dental treatment, dentists may administer local and inhalation anesthetics.
- 20.3 Patients recovering from anesthesia shall remain under continuous care of a registered nurse.
- (A) 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.
- 20.4 There shall be equipment and facilities for the administration of anesthesia that is commensurate with the clinical procedures and programs conducted within the hospital.
- 20.5 The hospital shall develop and implement policies and procedures regarding the cleaning and sterilization of anesthesia equipment. These policies shall be based on nationally-recognized guidelines and be reviewed by the Infection Prevention and Control Committee.

- 20.6 The hospital shall develop and implement policies and procedures regarding the delivery of anesthesia services. The policies shall be based on nationally-recognized guidelines and standards of practice and shall address, at a minimum, the following:
- (A) Patient consent,
 - (B) Infection control practices,
 - (C) Safety practices in all anesthetizing areas,
 - (D) Protocol for supportive life functions,
 - (E) Reporting requirements,
 - (F) Documentation Requirements, and
 - (G) Equipment requirements, as well as the monitoring, inspection, testing, and maintenance of anesthesia equipment.

Part 21. EMERGENCY SERVICES

- 21.1 All General Hospitals shall maintain a dedicated emergency department and shall follow the standards in Part 21.3 below.
- 21.2 Licensed Rehabilitation Hospitals, Psychiatric Hospitals, Hospital Units, Long-Term Care Hospitals, as defined at 42 U.S.C. 1395x(ccc), and Specialty Hospitals, as defined at Part 2.18 above, shall not be required to maintain a dedicated emergency department and shall follow the standards in Part 21.4 below. If the hospital chooses to maintain a dedicated emergency department, it shall follow the standards in Part 21.3 below.
- 21.3 Dedicated Emergency Department
- (A) Organization
 - (1) The emergency department shall be formally organized as a department or service directed by a qualified member of the medical staff.
 - (2) The emergency department shall provide emergency services twenty-four (24) hours a day, including providing immediate lifesaving intervention, resuscitation, and stabilization.
 - (3) The entrance to the emergency department shall be clearly marked and separate from the main hospital entrance.
 - (4) The hospital shall integrate its emergency department with other hospital departments, as needed, to ensure the hospital can immediately make available the full extent of its patient resources to assess and render appropriate care.
 - (5) Patients shall be discharged from the emergency department only upon a physician or licensed independent practitioner's recorded authorization, including instructions given to the patient for follow-up care.
 - (6) The emergency department shall be conveniently located with respect to radiological and laboratory services. The emergency department shall be separate and removed from surgical and obstetrical suites.

- (7) If provided, operating rooms located within the emergency department shall meet the requirements specified in Part 24, Surgical and Recovery Services.
- (B) Personnel
 - (1) A physician or licensed independent practitioner must be available at all times to the emergency department to direct care.
 - (2) Nurse staffing shall be provided in accordance with the requirements of Part 14 of this chapter, Nursing Services.
 - (3) The hospital shall ensure the availability of additional personnel during an unexpected influx of patients.
 - (4) A roster of on-call medical staff members must be available in the emergency department.
- (C) Scope of Services
 - (1) The hospital shall develop policies and procedures outlining the scope of services provided in the emergency department, including, but not limited to the following:
 - (a) Procedures for immediately addressing and treating any incidents of overdose or accidental poisoning.
 - (2) Services rendered shall be based on nationally-recognized guidelines, procedure manuals, and reference materials.
 - (3) The hospital shall transfer patients to a higher level of care when their needs exceed the hospital's scope of services.
- (D) Minimum Services
 - (1) The hospital shall provide the necessary resources, including instruments, equipment, and personnel, in accordance with acceptable standards of practice, and shall ensure resources are immediately available to meet the needs of presenting patients.
 - (2) The hospital shall provide the necessary resources to address, at a minimum, the following types of emergencies for both adult and pediatric patients: airway, cardiac, circulatory, neurologic, obstetric, orthopedic, pulmonary, and psychiatric.

21.4 Hospitals without a Dedicated Emergency Department

- (A) Signage indicating that the hospital does not have an emergency department shall be posted at all public entrances.
- (B) The hospital shall have the ability to provide basic life saving measures to patients, staff, and visitors, and shall have written policies for the appraisal of emergencies, initial treatment, and transfer when appropriate.

Part 22. OUTPATIENT SERVICES

- 22.1 The hospital shall provide outpatient services that meet the needs of patients, in accordance with acceptable standards of practice.
- 22.2 Outpatient services must be appropriately organized and integrated with inpatient services. There shall be one or more individuals designated the responsibility for oversight of the outpatient services.
- 22.3 Nursing Services
- (A) Outpatient nursing services shall be under the supervision of a registered nurse qualified by education, training, competencies, and experience.
 - (B) Each outpatient service shall have a sufficient number of qualified medical staff, nursing staff, and auxiliary personnel, based on the scope and complexity of the outpatient services offered.
 - (C) The Nurse Staffing Plan requirements in Part 14 of this chapter shall not apply to the hospital's outpatient services.
- 22.4 The hospital shall develop and implement policies and procedures, based on nationally-recognized guidelines and standards of care that address, at a minimum, the following:
- (A) Admissions and discharge of patients,
 - (B) Physician responsibility,
 - (C) Staffing, and
 - (D) Individual patient care, and equipment and supplies.
- 22.5 Outpatient services must be ordered by a physician or licensed independent practitioner who is:
- (A) Responsible for the care of the patient;
 - (B) Licensed in the state where they provide care to the patient;
 - (C) Acting within their scope of practice under state law; and
 - (D) Authorized in accordance with state law and policies adopted by the medical staff and approved by the governing body to order the applicable outpatient services.
- 22.6 Each outpatient service shall provide the following, in physically separated areas:
- (A) Adequate waiting room;
 - (B) Public toilet facilities;
 - (C) Public phone;
 - (D) Drinking fountain;
 - (E) Patient preparation area, with adjacent toilet room, handwashing, and provision for storing patient's clothing;

- (F) Provisions within the patient preparation area for medication storage and preparation; and
- (G) Recovery room equipped as specified in Part 24, Surgical and Recovery Services.

Part 23. PERINATAL SERVICES

23.1 The hospital shall provide emergent labor and delivery services in accordance with federal law. The hospital may provide non-emergent perinatal care services. If provided, the following standards shall apply.

23.2 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 (100) beds or fewer located in a rural area may have a physician director who is qualified by education, training, competencies, and experience to direct the scope of care provided.
- (B) The director of neonate services shall be a physician who is board eligible or certified in pediatrics. However, an acute care hospital with one hundred (100) beds or fewer located in a rural area may have a physician director who is qualified by education, training, competencies, 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 thirty (30) minutes of being summoned.

23.3 Nursing Services

- (A) Labor, delivery, neonate, and postpartum nursing care shall be supervised by a registered nurse qualified by education, training, competencies, and experience.
- (B) A registered nurse qualified by education, training, competencies, and experience in delivery room nursing shall be present as a circulating nurse during each delivery.
- (C) Additional registered and licensed practical nurses or auxiliary personnel shall be available as necessary.
- (D) 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.
- (E) A registered nurse shall supervise the nursing care of neonates. A registered nurse shall be in attendance in the nursery at all times that neonates are present.

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

23.5 The hospital shall have obstetrical and neonatal specialists, as appropriate to the hospital's scope of services.

23.6 The hospital shall develop and implement admission and transfer criteria for perinatal services that reflect the hospital's scope of services.

23.7 Labor and Delivery

- (A) The hospital shall develop and implement policies and procedures, based on nationally-recognized guidelines and standards of care that address, at a minimum, the following:
 - (1) Receipt of prenatal records for admissions, other than emergency admissions.
 - (2) Management of labor, including but not limited to the monitoring of the well-being of the mother and the fetus.
 - (3) Cesarean Sections, including the following:
 - (a) The capability of performing a Cesarean section within thirty (30) minutes of the decision to perform such a delivery method.
 - (b) Vaginal birth after a Cesarean section.
 - (4) Use of analgesic and anesthetic agents for pain management and the responsibilities of persons who administer it. This policy shall be developed in consultation with the anesthesia service.
 - (5) Postpartum assessments and care of the obstetrical patient and the neonate.
 - (6) Identification and management of high risk obstetrical patients including protocols for consultations and for the transfer of patients whose needs exceed the hospital's scope of services to a facility capable of providing the appropriate level of care. The transfer is a joint responsibility of the sending and receiving facilities.
 - (7) Protocols for visitors during labor and delivery.
 - (8) Miscarriages and stillbirths.
 - (9) Any policies and procedures required by federal or state law.
 - (10) Infection prevention and control. These policies shall be reviewed by the infection prevention and control committee and shall include the following:
 - (a) Obstetric patients shall be separated from other patients, with the exception of non-infectious gynecological patients.
 - (b) A protocol to be followed for obstetric patients and neonates with suspected or confirmed communicable disease.
 - (c) Isolation of communicable disease cases, based on nationally-recognized perinatal standards of practice. If a neonate is isolated with their mother, both shall be isolated in a private room.
- (B) There shall be an appropriately credentialed staff member present at every delivery who has been trained according to nationally recognized standards in neonatal resuscitation.

23.8 Neonate Care

- (A) Identification shall be placed securely on each neonate before removal from the delivery room.

- (B) Neonate screening shall be conducted in accordance with 5 CCR 1005-4, Newborn Screening and Second Newborn Screening and 6 CCR 1009-6, Newborn Hearing Screening.
- (C) Security measures shall be instituted to safeguard newborns neonates against access by unauthorized persons.
- (D) The hospital shall develop and implement policies and procedures based on nationally-recognized guidelines and standards of practice, that address, at a minimum, the following:
 - (1) Stabilization of neonates after birth, including stabilization of high-risk neonates.
 - (2) Monitoring of neonates, including the following requirements:
 - (a) Examination of neonates at least once per day until discharge.
 - (b) A physical examination performed by an appropriately credentialed licensed independent practitioner prior to discharge of the neonate.
 - (3) Care of high-risk neonates, including protocols for consultations and for the transfer of neonates whose needs exceed the hospital's scope of services 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.
 - (4) Parent and sibling visitation of neonates.
 - (5) Admission and care of neonates born outside of the hospital.

23.9 Discharge Planning

- (A) As part of the discharge planning process, the hospital shall assess the educational needs of the parent(s) and provide, or arrange for, education in self-care and neonate care, as appropriate.

Part 24. SURGICAL AND RECOVERY SERVICES

- 24.1** The hospital shall provide emergency surgical care commensurate with the scope and types of services provided at the hospital. The hospital may provide other surgical services.
- 24.2** Surgical and recovery services shall be directed by a physician qualified by education, training, competencies, and experience.
- 24.3** The nursing service of the surgical suite shall be supervised by a registered nurse qualified by education, training, competencies, and experience to direct operating room nursing services.
- 24.4** A registered nurse qualified by education, training, competencies, and experience in operating room nursing shall be present as a circulating nurse during operative procedures.
- 24.5 Staffing**
 - (A) At least one (1) registered nurse shall be on duty at all times in the surgical recovery room when patients are present.

- (1) Nurses shall have been instructed in the care of post-anesthetic and post-surgical patients and shall have no other duties during the time they care for such patients.
 - (B) Additional registered nurses and auxiliary personnel shall be available.
 - (C) 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.
- 24.6 Surgical Privileges
 - (A) Surgical services shall maintain a roster of practitioners specifying the surgical privileges of each practitioner.
 - (B) Surgical privileges shall be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner.
 - (C) Surgical privileges shall be reviewed and updated at least every two (2) years.
- 24.7 The hospital shall develop and implement policies and procedures related to surgical and recovery services. The policies and procedures shall be based on nationally-recognized guidelines and standards of care. These policies shall address, at a minimum, the following:
 - (A) Admission of patients, personnel, and visitors;
 - (B) Authority and responsibilities of nursing personnel;
 - (C) Admission and length of stay of patients in the surgical recovery room;
 - (D) Infection prevention and control policies, including, but not limited to, the cleaning and sterilization of surgical supplies and equipment. This policy shall be reviewed by the Infection Prevention and Control Committee;
 - (E) Documentation requirements, including, but not limited to, informed consent for surgical procedures, when applicable; and
 - (F) Surgical smoke evacuation, in compliance with the requirements of Section 25-3-120, C.R.S.
- 24.8 The hospital shall maintain minimum life support and resuscitative equipment in the surgical suites. The minimum equipment maintained shall be based on nationally-recognized guidelines and standards of practice and be commensurate with the scope of services offered by the hospital.

Part 25. CRITICAL CARE SERVICES

- 25.1 The hospital may provide critical care services in a critical care unit. If provided, the following standards shall apply.
- 25.2 Critical care services shall be directed by under the direction of a physician qualified by education, training, competencies, and experience.

25.3 Nurse Staffing

- (A) The nursing service shall be supervised by a registered nurse qualified by education, training, competencies, and experience.
- (B) At least one (1) registered nurse and one (1) auxiliary personnel shall be on duty at all times to give direct patient care.
- (C) Additional nursing and auxiliary personnel shall be available, consistent with the nursing care required by the different types of patients, and the nurse staffing plan requirements of Part 14, Nursing Services.

25.4 The hospital shall develop and implement policies and procedures related to critical care services. The policies and procedures shall be based on nationally-recognized guidelines and standards of practice. These policies shall address, at a minimum, the following:

- (A) Criteria for admission, transfer in and out, and discharge of patients from the service;
- (B) Physician responsibility;
- (C) Staffing;
- (D) Procedures for individual patient care; and
- (E) Equipment and supplies, including cleaning and sterilization of equipment. This specific policy shall be reviewed by the Infection Prevention and Control Committee.

Part 26. RESPIRATORY CARE SERVICES

26.1 The hospital may provide respiratory care services. If provided, the following standards shall apply.

26.2 Respiratory care services shall be directed by a physician qualified by education, training, competencies, and experience.

26.3 Personnel

- (A) Respiratory care services shall be administered only by persons qualified by education, training, competencies, and experience and ability in respiratory therapy.
- (B) There shall be adequate numbers of respiratory therapists, respiratory therapy technicians, and other personnel qualified by education, training, competencies, and experience to respond to the respiratory care needs of the patients.
- (C) Personnel qualified to perform specific procedures, and the amount of supervision required for personnel to carry out specific procedures, must be designated in writing.

26.4 Services must only be provided under the orders of a qualified physician or licensed independent practitioner who is responsible for the care of the patient, acting within their scope of practice, and who is authorized by the hospital's medical staff to order the services in accordance with hospital policies and procedures.

26.5 The equipment and facilities provided for respiratory care services shall be commensurate with the clinical procedures and programs of the hospital.

- 26.6 The hospital shall develop policies and procedures related to the cleaning and sterilization of respiratory care equipment. This policy shall be reviewed by the Infection Prevention and Control Committee.

Part 27. REHABILITATION SERVICES

- 27.1 The hospital may provide rehabilitation services. If provided, the following standards shall apply.

(A) For purposes of this Part 27, rehabilitation services include physical therapy, occupational therapy, audiology, speech pathology, and other rehabilitative therapies.

- 27.2 Rehabilitation services shall be performed under the supervision of qualified practitioners.

- 27.3 The hospital may provide a rehabilitation service under either a single-service or a multi-service rehabilitation department.

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

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

- 27.6 Rehabilitation services shall be delivered in accordance with orders issued by the attending physician or licensed independent practitioner or provided within the scope of practice and hospital policy for the delivery of care provided by the therapist.

- 27.7 The hospital shall develop and implement written policies and procedures governing the management and care of patients. These policies shall be based on nationally-recognized guidelines and standards of care. The policies and procedures shall address, at a minimum, the following:

- (A) Initial patient evaluation and regular assessments.
- (B) Care plans that describe the patient's: functional limitations; measurable short and long term goals; and type, amount, frequency, and duration of services.
- (C) The procedures for 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 hospital shall specify how orders from outside sources will be managed.
- (E) Cleaning, disinfecting, and sterilization (if applicable) of equipment and supplies after use.

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

- 27.9 There shall be appropriate facilities, equipment, and supplies to meet the rehabilitative care needs of patients.

Part 28. PEDIATRIC SERVICES

- 28.1 The hospital shall provide pediatric patient care commensurate with its identified scope of services.
- 28.2 Director of Pediatric Services
- (A) The director of pediatric services shall be a physician qualified by education, training, competencies, and experience.
 - (B) The director of pediatric services at a hospital that maintains a dedicated pediatric department shall be a physician who is board eligible or certified in pediatrics.
- 28.3 Pediatric Nursing Care
- (A) Pediatric nursing care shall be directed by a registered nurse qualified by education, training, competencies, and experience.
 - (B) All nursing personnel assigned to care for children shall be oriented to the special care of children.
- 28.4 The hospital shall have pediatric specialists as appropriate to the hospital's scope of services.
- 28.5 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.
- 28.6 The hospital shall develop and implement policies and procedures based on nationally-recognized guidelines and standards of practice, that address, at a minimum, the following:
- (A) Admission criteria for pediatric services that addresses the ages of patients served and reflects the hospital's scope of services.
 - (B) The transfer of pediatric patients whose needs exceed the hospital's scope of services 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. This policy shall be developed in coordination with the pharmacy service.
 - (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 hospital's pediatric population.
 - (I) Regular and routine cleaning of equipment in the pediatric area, including play equipment. This policy shall be reviewed by the Infection Prevention and Control Committee.

- (J) Security measures to prevent harm, kidnapping, or elopement.
- 28.7 The hospital shall have appropriate equipment and supplies for the pediatric services provided.
- 28.8 When a dedicated pediatric inpatient care unit is established it shall provide, at a minimum:
 - (a) Washable tables and chairs of various sizes; and
 - (b) Appropriate entertainment and educational materials.

Part 29. PSYCHIATRIC SERVICES

- 29.1 Hospitals may provide psychiatric services. If provided, the following standards shall apply.
 - (A) Hospitals that do not provide psychiatric or substance-use disorder services shall develop and implement a written plan for the referral of patients to treatment options.
 - (B) For purposes of this Part 29, 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.
- 29.2 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.
- 29.3 Nursing Services
 - (A) Psychiatric Nursing Director
 - (1) Psychiatric nursing care shall be directed by a registered nurse qualified by education, training, competencies, and experience to effectively direct psychiatric nursing, provide skilled nursing care and therapy, and evaluate the nursing care furnished.
 - (2) Education and Experience Requirements:
 - (a) The psychiatric nursing director shall have either a bachelor's degree in nursing and two (2) years of clinical experience in a psychiatric setting; or
 - (b) An associate's degree in nursing and five (5) years of experience in a psychiatric setting.
 - (3) Regardless of education and experience level, the psychiatric nursing director shall have at least one (1) year of nurse supervision experience as a registered nurse.
 - (B) Additional Nursing Personnel
 - (1) A registered nurse qualified by education, training, competencies, and experience to provide psychiatric care shall be available in the psychiatric unit twenty-four (24) hours per day, seven (7) days per week.

- (2) All nursing personnel assigned to care for specific populations, such as pediatric or geriatric patients, shall be qualified by education, training, competencies, and experience to provide care to that population.
- 29.4 Psychology services, if provided, shall be directed by a licensed psychologist, licensed psychiatrist, or licensed clinical social worker. There shall be sufficient psychology services to meet the needs of the patients in accordance with care plans.
- 29.5 Social services shall be directed by an individual with a master's degree in social work or an individual with a related master's degree and documented training, competencies, and experience to oversee the social services provided by the hospital.
 - (A) The hospital shall ensure there is social work staff available to provide psychological data for diagnosis and treatment, participate in discharge planning, and arrange for follow-up care, in order to meet the needs of the patients in accordance with care plans.
- 29.6 The hospital shall ensure there are qualified personnel available to provide therapeutic and recreational therapy programming designed to improve the patient's ability to adjust to social stress, physical demands, and daily living skills, in order to meet the needs of the patients in accordance with care plans.
- 29.7 The hospital shall ensure there are qualified clinical and supportive staff available to assess the needs of psychiatric patients, implement individualized active treatment care plans, and ensure a safe, therapeutic environment for patients and staff, in order to meet the needs of the patients in accordance with care plans.
- 29.8 The hospital shall provide annual training to direct care personnel on the following topics, at a minimum:
 - (A) Use of least-restrictive alternatives;
 - (B) Management of assaultive and self-destructive behaviors, including effective methods to de-escalate various states of agitation;
 - (1) This training shall also be provided to security personnel assigned to the service.
 - (C) Patient rights, in compliance with 6 CCR 1011-1, Chapter 2, Part 7; and
 - (D) Special needs of the patient population.
- 29.9 Patient Assessments
 - (A) Within four (4) hours of admission, an initial assessment for immediate safety needs shall be conducted by qualified personnel.
 - (B) Within eight (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 twenty-four (24) hours of admission for inpatients, or within three (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:
 - (1) Medical history and physical evaluation;

- (2) Psychiatric history;
- (3) A complete mental status exam, including but not limited a determination of the onset of the illness and circumstances leading to admission; and
- (4) Current attitudes, behavior, memory, and orientation.

29.10 Care Plan

- (A) The patient shall receive services in accordance with an individualized care plan that meets the needs of the patient.
- (B) The plan shall:
 - (1) Be initiated within twenty-four (24) hours after admission and updated as needed for inpatients, or within seven (7) days after initiating treatment for outpatients.
 - (2) Be developed by an interdisciplinary team and based on the psychiatric, medical, social behavior, and developmental aspects of the patient as identified through assessments.
 - (a) The interdisciplinary team shall complete the care plan within seventy-two (72) hours of admission and review the plan at least every seven (7) days for appropriateness for the first thirty (30) days, or more often if indicated by changes in the patient's condition.
 - (b) For inpatient stays longer than thirty (30) days, and up to twelve (12) months, subsequent care plan reviews shall be conducted at intervals specified by the patient's psychiatrist. Such intervals shall not exceed thirty (30) days.
 - (c) For inpatient stays longer than twelve (12) months, subsequent care plan reviews shall be conducted at intervals specified by the patient's psychiatrist. Such intervals shall not exceed three (3) months.
 - (3) 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.
 - (4) Reflect patient and family participation to the extent possible.
 - (5) Incorporate environmental modifications necessary to keep the patient from harming self or others, as applicable.

29.11 The hospital shall develop and implement policies and procedures, based on nationally-recognized guidelines and standards of practice that address, at a minimum, the following:

- (A) Restraint and seclusion consistent with state and federal law and regulation, including 6 CCR 1011-1, Chapter 2, Part 8, Protection of Persons from Involuntary Restraint or Seclusion. 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 policy shall include, at a minimum, protocols for:
 - (1) Systematic assessments and elimination of environmental risks, to include periodic checking of breakaway hardware;
 - (2) Summoning immediate assistance for staff and patients;
 - (3) Opening locked or barricaded doors in the event of an emergency, using methods that do not cause harm to patients; and
 - (4) Immediately addressing and treating any incidents of overdose or accidental poisoning.
- (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) The use of electroconvulsive therapy, consistent with Section 13-20-401, C.R.S., et seq., if applicable. This policy shall address the following:
 - (1) indications for use,
 - (2) informed consent,
 - (3) medical clearance,
 - (4) response to life- or limb-threatening emergencies, and
 - (5) the services and facilities necessary to provide treatment adequately and safely.
- (F) Medical detoxification and any other types of substance-use disorder treatment, if applicable.
- (G) Medication monitoring.
- (H) Visitors.
- (I) Confidentiality.
 - (1) This policy shall ensure that all information about psychiatric patients, whether oral or written, shall be kept confidential by all personnel, staff (including volunteers), and physicians or licensed independent practitioners at the hospital, and shall only be disclosed in accordance with state and federal law.

29.12 Discharge Planning

- (A) The service shall comply with the discharge planning requirements in Part 13, General Patient Care Services.
- (B) The patient's discharge plan shall include notations from each member of the patient's interdisciplinary team regarding continuity of care, as appropriate.
- (C) In evaluating the post hospital care needs, the hospital shall consider the patient's ability to comply with the medication regimen and to live independently.

29.13 Pediatric Psychiatric Services

- (A) Children, adolescent, and adult populations are shall not be commingled on inpatient care units.
 - (1) Children shall be classified as ages five (5) through twelve (12).
 - (2) Adolescents shall be classified as ages thirteen (13) through eighteen (18).
 - (3) The hospital shall develop and implement policies and procedures governing the decision-making process to place a patient of one age category (children/adolescent/adult) on a unit designed and operated for a different age category.
- (B) The hospital shall make appropriate education programs available to all school-age patients who will be hospitalized for over fourteen (14) days.
 - (1) These educational programs may be provided by either the local school district or by the hospital.
 - (2) If provided by the hospital, the educational program shall be approved by the Colorado Department of Education.
- (C) Hospitals shall develop and implement policies and procedures regarding the treatment of pediatric patients. These policies shall be based on nationally-recognized guidelines and standards of practice and shall address, at a minimum, the following:
 - (1) Training requirements for all personnel regarding the special needs of pediatric patients.
 - (2) Strategies regarding family involvement in the care of the patient.
 - (3) Provision of psychiatric, social, and recreation services in a manner that is appropriate for pediatric patients.
 - (4) Modifications to the policies developed and implemented pursuant to Part 29.11, as appropriate, to meet the needs of pediatric patients.
- (D) In addition to the assessment requirements in Part 29.9(C), an assessment of a pediatric patient shall also address the following:
 - (1) The impact of the patient's condition on the family and the family's impact on the patient;
 - (2) The patient's legal custody status;
 - (3) The patient's growth and development, including physical, emotional, cognitive, educational, nutritional, and social development; and
 - (4) The patient's play and daily activity needs.

Editor's Notes

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

History

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

Rule 33 eff. 01/30/2008.

Entire rule eff. 05/15/2008.

Rule 2.202 eff. 11/30/2008.

Entire rule eff. 03/02/2010.

Rules 1.102, 2.100, 3.101, 4.101, 4.102, 6.102 eff. 04/30/2010.

Rules 1.102(1)(a)(i), 2.100; 3.101(7), 3.200, 4.101-4.102 eff. 12/30/2010.

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

Rules 2.100(18), 3.101(6), 4, 5.102(1), 11.102(5), 11.104, 18.104(1), 19.104(1), 20.104(2) eff. 08/14/2013.

Rule 9.102(3) eff. 05/15/2014.

Rules 3.101(2), 3.101(7) eff. 08/14/2014.

Rule 3.101 eff. 07/01/2019.

Rules 1.101(1), 1.102(1)(a)(i), 3.201, 4.101, Part 10, 26.102(3)(a) eff. 01/14/2020.

Rule 3.101 eff. 07/01/2020.

Entire rule eff. 10/15/2021.