



Colorado Department
of Public Health
and Environment

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT
Health Facilities and Emergency Medical Services Division

6 CCR 1011-1

STANDARDS FOR HOSPITALS AND HEALTH FACILITIES
(PROMULGATED BY THE STATE BOARD OF HEALTH)

CHAPTER II
General Licensure Standards

Last amended 08/17/11, effective 09/30/11

Health Facilities Regulation Division

STANDARDS FOR HOSPITALS AND HEALTH FACILITIES

CHAPTER II - GENERAL LICENSURE STANDARDS

6 CCR 1011-1 Chap 02

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

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

Division Director

Colorado Department of Public Health and Environment

Health Facilities Division

4300 Cherry Creek Drive South

Denver, Colorado 80222-1530

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

Division Director

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PART 1 - GENERAL BUILDING AND FIRE SAFETY PROVISIONS

1.100 SUBMISSION OF CONSTRUCTION PLANS/DOCUMENTS AND COMPLETION OF THE PLAN REVIEW PROCESS

1.200 USE OF ANTIFREEZE IN SPRINKLER SYSTEMS

1.100 SUBMISSION OF CONSTRUCTION PLANS/DOCUMENTS AND COMPLETION OF THE PLAN REVIEW PROCESS

1.101 STATUTORY AUTHORITY AND APPLICABILITY

- (1) Authority to establish minimum standards through regulation and to administer and enforce such regulations is provided by Sections 25-1.5-103 and 25-3-101, C.R.S., et seq.
- (2) This Subpart 1.100 applies to all licensed facilities subject to plan review in accordance with requirements established in the respective chapter under 6 CCR 1011-1, associated with each type of health care entity. It is the responsibility of the health facility to ensure that any construction project complies with the applicable local, state, and federal standards and codes.

1.102 DEFINITIONS. Reserved.

1.103 SUBMISSION OF CONSTRUCTION PLANS/DOCUMENTS. Materials submitted for review shall be in the format and/or on forms prescribed by the department. The following construction plans/documents for all facilities subject to plan review shall be submitted to the department prior to the start of construction:

- (1) A written description of the type and size of patient/resident service or services to be provided in the area subject to the plan review.
- (2) Scale drawings showing the proposed general location, boundaries, approaches to and physical features of the site, other buildings on the site, means of water supply, sewage disposal, and other utilities to the site, and other services, as applicable, to ensure the review is accurate and complete. The drawings shall also show the proposed layout of each floor of the facility with each room labeled as to its use and dimensions, and a general cross section of the structure indicating type of construction.
- (3) Specifications indicating electrical, mechanical and other features not shown on drawings.

1.104 COMPLETION OF THE PLAN REVIEW PROCESS

- (1) For the purposes of this Section 1.104, the plan review process consists of the following steps:
 - (a) submittal of construction plans/documents by the facility.
 - (b) preliminary review by the department of the health care entity submittals and written notification of preliminary review findings.¹

¹ Preliminary review findings will vary based on the type of construction or remodel being reviewed and may include that insufficient information was submitted to make conclusive findings. When sufficient information is submitted, findings for new construction, for example, will establish whether the construction type, occupancy separations, smoke barriers meet Life Safety Code requirements. For a kitchen hood and duct work remodel, on the other hand, findings will establish whether the system is properly designed, routed, and accessible.

- (c) completion of the project by the health care entity.
 - (d) final review/inspection by the Department of the completed project.
 - (e) department approval of the project indicating that the facility is in compliance and no additional changes need to be made.
- (2) The steps outlined in Section 1.104 (1)(c) through 1.104 (1)(e) shall be completed:

- (a) for those facilities that submit construction plans on or after May 1, 2010, within 24 months after the issuance of the preliminary review findings by the department, unless extensions are obtained pursuant to Section 1.104 (3).
- (b) for those facilities that submit construction plans prior to May 1, 2010, within 24 months after the issuance of the preliminary review findings by the department or by May 1, 2012, whichever is later, unless extensions are obtained pursuant to Section 1.104 (3).

(3) Extensions

- (a) Notwithstanding Section 1.104 (2), the facility may obtain a one-month extension for the completion of the plan review process beyond the 24-month period.
 - (i) The facility may obtain a one-month extension by submitting a written request, in the form required by the Department, no later than 10 working days prior to the 24-month completion due date.
 - (ii) The facility is only eligible for a single one-month extension.
- (b) If the plan review process is not completed within the 24-month period established in Section 1.104 (2), or 25-month period if the one-month extension was obtained, the applicant may obtain a 6-month extension, as long as the applicant has commenced project construction and construction is ongoing.
 - (i) The facility may obtain a six-month extension by submitting an extension fee of \$500 and a written request, in the form required by the Department, no later than 10 working days prior to the completion due date.
 - (ii) The facility is eligible for multiple six-month extensions.
 - (iii) Extension fees are non-refundable.
- (4) Failure to complete the plan review process within the 24-month period established in Section 1.104 (2) or within the timeframes authorized by the extensions shall result in the plan review process being administratively closed. After an administrative closure, the applicant may activate a new plan review by resubmitting the construction plans/documents along with the corresponding plan review fee.

1.200 USE OF ANTIFREEZE IN SPRINKLER SYSTEMS

1.201 STATUTORY AUTHORITY AND APPLICABILITY

- (1) Authority to establish minimum standards through regulation and to administer and enforce such regulations is provided by Sections 25-1.5-103 and 25-3-101, C.R.S., et seq.
- (2) This Subpart 1.200 applies to all licensed facilities that provide services upon their licensed premises, except for certain community clinics.

1.202 DEFINITIONS

- (1) "Acute care facility" means an ambulatory surgical center, birth center, community clinic and emergency center, community clinic with an anesthetizing location, community clinic with sleeping rooms for stays over 24 hours, chiropractic center/hospital, convalescent center,

dialysis treatment clinic, hospital (including a general hospital, psychiatric hospital, maternity hospital, and rehabilitation center), and hospital unit.

- (2) "Dwelling unit" means one or more rooms arranged for the use of one or more individuals living together as in a single housekeeping unit normally having cooking, living, sanitary and sleeping facilities. For the purposes of this Subpart 1.200, dwelling unit includes apartments, sleeping rooms in nursing homes and similar living units.
- (3) "Residential facility" means an assisted living residence, acute treatment unit, community residential home for persons with developmental disabilities, intermediate care facility for persons with developmental disabilities, nursing home or residential hospice.
- (4) "System riser" means the aboveground horizontal or vertical pipe between the water supply and the mains (cross or feed) that contains a control valve (either directly or within its supply pipe) and a waterflow alarm device.

1.203 PROTECTION AGAINST COMBUSTIBLE ANTIFREEZE - RESIDENTIAL FACILITIES

- (1) On or after September 15, 2010, residential facilities shall not permit antifreeze within the dwelling unit portions of sprinkler systems:
 - (a) in facilities that apply for initial licensure; except that such facilities with a sprinkler system with an onsite water supply shall not be permitted to use antifreeze in any portion of that sprinkler system.
 - (b) in new construction, additions of previously uninspected or unlicensed square footage under the license to an existing occupancy, and relocations in whole or in part of another physical plant. This requirement applies to construction for which the application for a building permit from the local authority having jurisdiction is dated between September 15, 2010 and December 31, 2010.
- (2) On or after January 1, 2011, existing residential facilities shall not permit antifreeze within the dwelling unit portions of sprinkler systems in additions of previously uninspected or unlicensed square footage under the license and relocations in whole or in part to another physical plant. This requirement applies to construction for which the complete submission of construction plans and documents for plan review in accordance with 6 CCR 1011-1, Part 1, Section 1.103 was received by the Department on or after January 1, 2011.

1.204 PROTECTION AGAINST COMBUSTIBLE ANTIFREEZE - ACUTE CARE FACILITIES

- (1) On or after January 1, 2011, acute care facilities shall not permit antifreeze within the patient sleeping room, patient use area, and egress corridor portions of sprinkler systems:
 - (a) in facilities that apply for initial licensure;
 - (b) for existing facilities, in additions of previously uninspected or unlicensed square footage under the license and relocations in whole or in part to another physical plant. This requirement applies to construction for which the complete submission of construction plans and documents for plan review in accordance with 6 CCR 1011-1, Part 1, Section 1.103 was received by the Department on or after January 1, 2011.

Part 2 Licensure Process

2.1 Statutory Authority and Applicability

- 2.1.1 The statutory authority for the promulgation of these rules is set forth in sections 25-1.5-103 and 25-3-101, *et seq.*, C.R.S.
- 2.1.2 A health care entity licensed by the Department shall comply with all applicable federal and state statutes and regulations including this Chapter II. In the event of a discrepancy between the Department's regulations, the more specific standards shall apply.

2.2 Definitions

For purposes of this Part 2, the following definitions shall apply:

- 2.2.1 "Business Entity" means any organization or enterprise and includes, but is not limited to, a sole proprietor, an association, corporation, business trust, joint venture, limited liability company, limited liability partnership, partnership or syndicate.
- 2.2.2 "Campus" means the physical area immediately adjacent to the health care entity'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 health care entity's campus.
- 2.2.3 "Controlling Interest" means the operational direction or management of a health care entity including, but not limited to, the authority, express or reserved, to change the corporate identity of the applicant; the authority to appoint members of the board of directors, board of trustees, or other applicable governing body of the health care entity; the ability to control any of the assets or other property of the health care entity or to dissolve or sell the health care entity.
- 2.2.4 "Deficiency" means a failure to fully comply with any statutory and/or regulatory requirements applicable to a licensed health facility.
- 2.2.5 "Department" means the Colorado Department of Public Health and Environment.
- 2.2.6 "Direct Ownership" means the possession of stock, equity in capital or any interest greater than 5 percent of the health care entity.
- 2.2.7 "Health Care Entity" means a health care facility or agency that is required to obtain a license from the Department pursuant to section 25-3-101, C.R.S. Unless otherwise indicated, the term "health care entity" is synonymous with the terms "health facility" or "facility" as used elsewhere in 6 CCR 1011-1, Standards for Hospitals and Health Facilities.
- 2.2.8 "Indirect Ownership" means any ownership interest in an entity that has an ownership interest in the applicant, including an ownership interest in any entity that has an indirect ownership interest in the applicant.
- 2.2.9 "Licensee" means the person, business entity or agency that is granted a license or certificate of compliance to operate a health care entity and that bears legal responsibility for compliance with all applicable federal and state statutes and regulations.
- 2.2.10 "Management Company" means the person, business entity or agency that is paid by the licensee and has a contractual agreement with the licensee to manage the day-to-day operation of the health care entity on behalf of the licensee.
- 2.2.11 "Review" means any type of administrative oversight by the Department including, but not limited to, examination of documents, desk audit, complaint investigation or on-site inspection.

2.3 License Required

2.3.1 No person or business entity shall establish, maintain or operate a health care entity without first having obtained a license therefore or, in the case of governmental facilities, a certificate of compliance from the Department. For purposes of these rules, the holder of a certificate of compliance shall be considered a licensee.

(A) Any person or business entity operating a health care entity shall not provide services in areas subject to plan review except as approved by the Department.

(B) Any person or business entity operating a health care entity who does not have a provisional, conditional or regular license from the Department is guilty of a misdemeanor and, upon conviction thereof, shall be punished by a fine of not less than fifty dollars (\$50), nor more than five hundred dollars (\$500). Each day of operation shall be considered a separate offense.

(C) No health care entity shall create the impression that it is a licensed entity at any location unless it meets the legal definition of the health care entity that it purports to be.

2.3.2 A separate license shall be required for each physical location or campus of a health care entity, except as otherwise specified in Chapter IV, General Hospitals and Chapter XXVI, Home Care Agencies.

2.3.3 Each health care entity offering services that are regulated by more than one chapter of 6 CCR 1011-1, Standards for Hospitals and Health Facilities, shall obtain a separate license for each category of services that requires a state license.

(A) If any licensed health care entity offers services within the same building or on the same campus as another licensee, the care facilities of one licensee shall be separately identifiable from the care facilities of any other licensee.

(1) Care facilities shall include, but not be limited to, patient/resident bed wings, diagnostic, procedure and operating rooms.

2.3.4 Each health care entity that is federally certified shall have a state license for each category of services for which it is certified, if such a license category exists.

2.3.5 Two-Hour Fire Separation Required Between Occupancies

(A) An intact, two-hour fire rated separation wall, floor or ceiling assembly between the facility and all adjoining occupancy areas shall be required under the following circumstances unless the health care entity meets the criteria for one of the alternatives or exclusions outlined in paragraphs (B) and (C) below:

(1) For each applicant seeking an initial license on or after July 1, 2010, except for a health care entity that has submitted building plans to the Department and obtained a building permit prior to July 1, 2010 from the local authority having jurisdiction.

(2) For each licensee who obtains a building permit on or after July 1, 2010 for relocations in whole or in part to another physical structure.

(3) For each licensee who obtains a building permit on or after July 1, 2010 to add previously un-inspected or unlicensed square footage to an existing license. For the purposes of compliance with this section, the two-hour fire rated separation

shall be around either the entire perimeter of the added square footage or the entire perimeter of the facility.

(B) Alternatives

Where there are adjoining occupancies by licensed health care entities and all are directly owned by one of the licensees or share the same governing body, the following alternatives to section 2.3.5(A) shall be acceptable.

- (1) Install a one-hour rated separation wall, floor or ceiling assembly between each occupancy if all occupancies are board and care, ambulatory care, or business occupancy. This alternative shall not apply to health care occupancies.
- (2) Have no separation wall, floor, or ceiling assembly between the adjoining occupancies on the condition that all adjoining occupancies shall meet the standards applicable to the most stringent occupancy requirements and the citing of a life safety code deficiency in one occupancy shall result in the citing of such deficiency for all adjoining licensed occupancies.

(C) Exclusions

- (1) A health care entity that does not provide services on its licensed physical premises.

2.3.6 Each health care entity applying for initial licensure shall submit a distinctive license name that does not mislead or confuse the public regarding the type of health services to be provided. The entity name need not include the services to be provided. If, however, those services are included in the name, that inclusion shall not mislead or confuse the public. Duplication of an existing name is prohibited except between health care entities that are affiliated through ownership or controlling interest.

- (A) Each health care entity shall be identified by this distinctive name on stationery, billing materials and exterior signage that clearly identifies the licensed entity. Exterior signage shall conform to the applicable local zoning requirements.

2.4 Initial License Application Procedure

2.4.1 Any person or entity seeking a license to operate a health care entity shall initially notify the Department by submitting a letter of intent upon such form and in such manner as prescribed by the Department. Such notification shall include the proposed name, location, license category, services and date of opening of said entity. Upon receipt of the letter of intent, the Department will provide the applicant with the appropriate application.

2.4.2 The applicant shall provide the Department with a complete application including all information and attachments specified in the application form and any additional information requested by the Department. The appropriate non-refundable fee(s) for the license category requested shall be submitted with the application, unless previously tendered in connection with a plan review. Applications shall be submitted at least ninety (90) calendar days before the anticipated start-up date.

2.4.3 Each applicant shall provide the following information:

- (A) The legal name of the entity and all other names used by it to provide health care services. The applicant has a continuing duty to notify the Department of all name changes at least thirty (30) calendar days prior to the effective date of the change.

- (B) Contact information for the entity including mailing address, telephone and facsimile numbers, e-mail address and, if applicable, website address.
- (C) The identity of all persons and business entities with a controlling interest in the health care entity, including administrators, directors, managers and management contractors.
 - (1) A non-profit corporation shall list the governing body and officers.
 - (2) A for-profit corporation shall list the names of the officers and stockholders who directly or indirectly own or control five percent or more of the shares of the corporation.
 - (3) A sole proprietor shall include proof of lawful presence in the United States in compliance with section 24-76.5-103(4), C.R.S.
- (D) The name, address and business telephone number of every person identified in section 2.4.3(C) and the individual designated by the applicant as the chief executive officer of the entity.
 - (1) If the addresses and telephone numbers provided above are the same as the contact information for the entity itself, the applicant shall also provide an alternate address and telephone number for at least one individual for use in the event of an emergency or closure of the health care entity.
- (E) Proof of professional liability insurance obtained and held in the name of the license applicant as required by the Colorado Health Care Availability Act, section 13-64-301, *et seq.*, C.R.S., with the Department identified as a certificate holder. Such coverage shall be maintained for the duration of the license term and the Department shall be notified of any change in the amount, type or provider of professional liability insurance coverage during the license term.
- (F) Articles of incorporation, articles of organization, partnership agreement, or other organizing documents required by the Secretary of State to conduct business in Colorado; and by-laws or equivalent documents that govern the rights, duties and capital contributions of the business entity.
- (G) The address of the physical location that is to constitute the entity, and the name(s) of the owner(s) of each structure on the campus where licensed services are provided if different than those identified in paragraph (C) of this section.
- (H) A map for each floor of the health care entity's buildings indicating room layout, services to be provided in each of the rooms, and the proposed physical extent of the license within each building. If multiple buildings are involved, a map of the campus shall also be submitted that indicates which floor and which buildings are occupied as part of the license. Maps shall be submitted in the format prescribed by the Department.
- (I) A copy of any management agreement pertaining to operation of the entity that sets forth the financial and administrative responsibilities of each party.
- (J) If an applicant leases one or more building(s) to operate as a licensed health care entity, a copy of the lease shall be filed with the license application and show clearly in its context which party to the agreement is to be held responsible for the physical condition of the property.

(K) A statement signed and dated contemporaneous with the application stating whether, within the previous ten years, one or more individuals or entities identified in response to sections 2.4.3(C) and (D) has a controlling or ownership interest in any type of health facility and has been the subject of, or a party to, one of more of the following events, regardless of whether action has been stayed in a judicial appeal or otherwise settled between the parties.

- (1) Been convicted of a felony under the laws of any state or of the United States. A guilty verdict, a plea of guilty or a plea of nolo contendere (no contest) accepted by the court is considered a conviction,
- (2) A disciplinary action imposed upon the applicant by an agency in another jurisdiction that registers or licenses health facilities including, but not limited to, a citation, sanction, probation, civil penalty, or a denial, suspension, revocation, or modification of a license or registration whether it is imposed by consent decree, order, or other decision, for any cause other than failure to pay a license fee by the due date,
- (3) Limitation, revocation or suspension by any state board, municipality, federal or state agency of any health care related license,
- (4) The refusal to grant or renew a license for operation of a health care entity, contract for participation or certification for Medicaid, Medicare, or other public health or social services payment program, or
- (5) A civil judgment or criminal conviction resulting from conduct or an offense in the operation, management or ownership of a health facility related to patient or resident care or fraud in public health or social service payment program. A guilty verdict, a plea of guilty or a plea of nolo contendere (no contest) accepted by the court is considered a conviction.

(L) Any statement regarding the information requested in paragraph (K) shall include the following, if applicable:

- (1) If the event is an action by a governmental agency (as described above) the name of the agency, its jurisdiction, the case name, and the docket, proceeding or case number by which the event is designated, and a copy of the consent decree, order or decision.
- (2) If the event is a felony conviction, the court, its jurisdiction, the case name, the case number, a description of the matter or a copy of the indictment or charges, and any plea or verdict entered by the court.
- (3) If the event concerns a civil action or arbitration proceeding, the court or arbiter, the jurisdiction, the case name, the case number, a description of the matter or a copy of the complaint, and a copy of the verdict, the court or arbitration decision.

2.4.4 Each application shall be signed under penalty of perjury by an authorized corporate officer, general partner, or sole proprietor of the applicant as appropriate.

2.4.5 Failure of the applicant to accurately answer or report any of the information requested by the Department shall be considered good cause to deny the license application. The Department shall have the discretion, based upon the information received in response to section 2.4.3 (K), to request additional information from the applicant beyond the specified ten-year time frame.

2.4.6 The Department shall conduct a preliminary assessment of the application and notify the applicant of any application defects.

(A) The applicant shall respond within fourteen (14) calendar days to written notice of any application defect.

2.4.7 A license application shall be considered abandoned if the applicant fails to address all application defects within the timeframes established by the Department and may result in administrative closure of the application process.

(A) After an administrative closure, the applicant may file a new license application along with the corresponding initial license fee.

2.5 Provisional License

2.5.1 Where a health care entity fails to fully conform to the applicable statutes and regulations but the Department determines the entity is making a substantial good faith attempt to comply, the Department may refuse to issue an initial license and instead grant the applicant a provisional license upon payment of the non-refundable provisional license fee.

2.5.2 A provisional license shall be valid for ninety (90) days.

2.5.3 Except for Assisted Living Residences, a second provisional license may be issued if the Department determines that substantial progress continues to be made and it is likely compliance can be achieved by the date of expiration of the second provisional license.

2.5.4 The second provisional license shall be issued for the same duration as the first upon payment of a second non-refundable provisional license fee.

2.5.5 During the term of the provisional license, the Department shall conduct any review it deems necessary to determine if the applicant meets the requirements for a regular license.

2.5.6 If the Department determines, prior to expiration of the provisional license, that the applicant has achieved reasonable compliance, it shall issue a regular license upon payment of the applicable initial license fee. The regular license shall be valid for one year from the date of issuance, unless otherwise acted upon pursuant to section 2.9.3 of this chapter.

2.6 Renewal License Application Procedure

2.6.1 Except for those renewal applicants described in subsection (A) below, a licensee seeking renewal shall provide the Department with a license application, signed under penalty of perjury by an authorized corporate officer, general partner, or sole proprietor of the applicant as appropriate, and the appropriate fee at least sixty (60) calendar days prior to the expiration of the existing license. Renewal applications shall contain the information required in section 2.4.3 of this Chapter unless the information has been previously submitted and no changes have been made to the information currently held by the Department.

(A) In order to comply with Colorado Division of Insurance Rule 2-1-1, a licensee that has an insurance policy with any portion of self-insured retention or alternate form of security shall submit its license application and fee to the Department at least ninety (90) calendar days prior to the expiration of the existing license.

2.6.2 Failure to submit a completed renewal application to the Department thirty (30) calendar days prior to expiration of the existing license shall result in assessment of a late fee in an amount equal to the applicable renewal fee including any bed fees or operating/procedure room fees.

2.6.3 Failure of the licensee to accurately answer or report any of the information requested by the Department shall be considered good cause to deny the license renewal application.

2.6.4 The Department shall conduct a preliminary assessment of the renewal application and notify the licensee of any application defects.

(A) The applicant shall respond within fourteen (14) calendar days to written notice of any application defect.

2.7 Change of Ownership

2.7.1 When a currently licensed health care entity anticipates a change of ownership, the current licensee shall notify the Department within the specified time frame and the prospective new licensee shall submit an initial license application along with the requisite fees and documentation within the same time frame. The time frame for submittal of such notification and documentation shall be least ninety (90) calendar days before a change of ownership involving any health care entity except those specifically enumerated in subsection (A) below.

(A) Notification and documentation regarding the change of ownership of an assisted living residence; facility for persons with developmental disabilities; outpatient mental health care facility, including but not limited to a community mental health center or clinic; and any extended care facility or hospice with sixteen (16) or fewer inpatient beds, including but not limited to nursing homes or rehabilitation facilities, shall be submitted to the Department at least thirty (30) calendar days before the change of ownership.

2.7.2 The Department shall consider any of the following circumstances to constitute a change of ownership.

(A) Partnerships: Dissolution of the partnership and conversion thereof into any other entity or the substitution of one or more of the partners.

(1) Change of ownership does not include dissolution of the partnership to form a corporation with the same persons retaining the same shares of ownership in the new corporation. For purposes of this subsection, "substitution" means any arrangement whereby a person other than the original partner can participate in the management or administration of the partnership business or affairs.

(B) Sole proprietors: Transfer of title to the business, whether or not title to real property is transferred to another person.

(1) Change of ownership does not include forming a corporation from the sole proprietorship with the proprietor as the sole shareholder.

(C) Corporations: Consolidation of two or more corporations resulting in the creation of a new corporate entity; formation of a corporation from a partnership or a sole proprietorship except as provided in subsections (A)(1) and (B)(1) above; or the transfer, purchase or sale of shares in the corporation such that it changes at least 75 percent of the direct or indirect ownership of the corporation.

(D) Management contracts, leases or other arrangements: Any action that results in the current licensee retaining no control of the operation or management of the entity.

(E) Limited Liability Companies: The transfer of 50 percent or more of the ownership interest in the company or the termination or dissolution of the company and the conversion thereof into any other entity accompanied by changes in the principals with ownership interest.

- (1) Change of ownership does not include transfers of ownership interest between existing members if the transaction does not involve the acquisition of ownership interest by a new member. For the purposes of this subsection, "member" means a person or entity with an ownership interest in the limited liability company.

2.7.3 The existing licensee shall be responsible for correcting all rule violations and deficiencies in any current plan of correction before the change of ownership becomes effective. In the event that such corrections cannot be accomplished in the time frame specified, the prospective licensee shall be responsible for all uncorrected rule violations and deficiencies including any current plan of correction submitted by the previous licensee unless the prospective licensee submits a revised plan of correction, approved by the Department, before the change of ownership becomes effective.

2.7.4 If the Department issues a license to the new owner, the previous owner shall return its license to the Department within five (5) calendar days of the new owner's receipt of its license.

2.8 Fitness Review Process

2.8.1 The Department shall review the applicant's fitness to conduct or maintain a licensed operation. The Department shall determine by on-site inspection or other appropriate investigation the applicant's compliance with applicable statutes and regulations. The Department shall consider the information contained in an entity's application and may request access to and consider other information including, but not limited to, the following:

- (A) Whether the applicant has legal status to provide the services for which the license is sought as conferred by articles of incorporation, statute or other governmental declaration.
- (B) Whether the applicant's financial resources and sources of revenue appear adequate to provide staff, services, and the physical environment sufficient to comply with the applicable state statutes and regulations; including, if warranted, review of an applicant's credit report,
- (C) The applicant's previous compliance history,
- (D) Review of the applicant's policies and procedures,
- (E) Review of the applicant's quality improvement plans, other quality improvement documentation as may be appropriate, and accreditation reports,
- (F) Physical inspection of the entity,
- (G) Credentials of staff,
- (H) Interviews with staff, and
- (J) Other documents deemed appropriate by the Department.

2.9 Issuance of License

2.9.1 No license shall be issued until the applicant conforms to all applicable statutes and regulations.

2.9.2 Each license shall contain the name of the health care entity, license category, term of license, holder of license and the licensed capacity. Each Dialysis Treatment Clinic and Ambulatory Surgical Center shall be licensed for its maximum operational capacity as determined by the

Department. Except as specified below, no person shall admit a patient or resident to a health care entity if such admission would exceed the entity's licensed capacity.

- (A) If the entity has the physical space and staff capacity to meet the needs of an additional patient or resident, the Department may, upon request, allow admission above the licensed capacity for no longer than one month if the patient or resident requires immediate admission and the Department determines that there is no convenient alternative source of admission.
- (B) In the event of a health emergency involving multiple ill or injured persons, hospitals and other licensed facilities providing essential emergent or continued care may admit patients or residents that exceed their maximum bed capacity for a period of no more than 14 consecutive days, as long as the facility remains in compliance with its life safety code, patient staffing requirements, and existing emergency/disaster plan. One extension for no more than an additional 14 consecutive days may be requested based upon extenuating circumstances.
 - (1) Any facility implementing the emergency bed increase shall provide the Department with verbal notice at the time of implementation and a written report within 14 calendar days after implementation explaining the emergent situation and the actions taken by the facility.

2.9.3 A license issued by the Department may be revoked, suspended, annulled, limited, or modified at any time during the license term because of a licensee's failure to comply with any of the applicable statutes or regulations, or to make the reports required by section 25-3-104, C.R.S. Unless consented to by the applicant, a limitation imposed prior to issuance of an initial or renewal license shall be treated as a denial. A modification of an existing license during its term, unless consented to by the licensee, shall be treated as a revocation.

2.9.4 The Department may impose conditions upon a license prior to issuing an initial or renewal license or during an existing license term. If the Department imposes conditions on a license, the licensee shall immediately comply with all conditions until and unless said conditions are overturned or stayed on appeal.

(A) If conditions are imposed at the same time as an initial or renewal license, the applicant shall pay the applicable initial or renewal license fee plus the conditional fee. If conditions are imposed during the license term, the licensee shall pay the conditional fee and the conditions shall run concurrently with the existing license term. If the conditions are renewed in whole or in part for the next license term, the licensee shall pay the applicable renewal fee along with the conditional fee in effect at the time of renewal.

(B) If the Department imposes conditions of continuing duration that require only minimal administrative oversight, it may waive the conditional fee after the licensee has complied with the conditions for a full license term.

2.9.5 If a licensee holds a conditional license, it shall post a clearly legible copy of the license conditions in a conspicuous public place in the health care entity.

2.9.6 Each license or certificate of compliance issued by the Department shall become void when the licensee fails to timely renew the license, ceases operation, or there is final agency action suspending or revoking the license. The license shall be returned to the Department within ten (10) calendar days of the event that invalidated it.

2.9.7 Each health care entity that surrenders its license or certificate shall accomplish the following with regard to any individual records that the entity is legally obligated to maintain:

- (A) Ten (10) calendar days prior to closure, inform the Department in writing of the specific plan for storage and retrieval of individual records,
- (B) Within ten (10) calendar days of closure, inform all patients, residents, consumers or authorized representatives thereof, in writing how and where to obtain their individual records; and
- (C) Provide secure storage for any remaining patient, resident or consumer records.

2.10 Continuing Obligations of Licensee

- 2.10.1 Each licensee shall have and maintain electronic business communication tools, including, but not limited to, a facsimile machine, internet access and a valid e-mail address. The licensee shall use these tools to receive and submit information, as required by the Department.
- 2.10.2 The license shall be displayed in a conspicuous place readily visible to patients, residents or clients who enter at the address that appears on the license. The license is only valid while in the possession of the licensee to whom it is issued and shall not be subject to sale, assignment or other transfer, voluntary or involuntary, nor shall a license be valid for any premises other than those for which it was originally issued.
- 2.10.3 The licensee shall provide, upon request, access to such individual patient, resident, client or consumer records as the Department requires for the performance of its regulatory oversight responsibilities.
 - (A) A licensee shall provide, upon request, access to or copies of reports and information required by the Department including, but not limited to, staffing reports, census data, statistical information, and such other records as the Department requires for the performance of its regulatory oversight responsibilities.
 - (B) The Department shall not release to any unauthorized person any information defined as confidential under state law.
- 2.10.4 Where a licensed health care entity is subject to inspection, certification, or review by other agencies, accrediting organizations, or inspecting companies, the licensee shall provide and/or release to the Department, upon request, any correspondence, reports or recommendations concerning the licensee that were prepared by such organizations.
- 2.10.5 Each licensee shall notify the Department in writing of any change in the information required by section 2.4.3 of this Chapter from what was contained in the last submitted license application. Except for the operational changes that require Department approval as set forth in subsection (A) below or the changes requiring advance notice as set forth in subsection (B), the licensee shall notify the Department of all changes in information as soon as practicable, but no later than thirty (30) calendar days after the change becomes effective.
 - (A) Except as otherwise provided in 6 CCR 1011-1 Chapter IV, Part 3.200, the following changes to the operation of the licensed health care entity shall not be implemented without prior approval from the Department. A licensee shall, at least thirty (30) calendar days in advance, submit a written request to the Department regarding any of these proposed changes.
 - (1) Increase in licensed capacity.

- (a) If a licensee requests an increase in licensed capacity that is approved by the Department, an amended license shall be issued upon payment of the appropriate fee.
 - (b) The Department has the discretion to deny a requested increase in licensed capacity if it determines that the increase poses a potential risk to the health, safety or welfare of the health care entity's patients, clients or residents based upon the entity's compliance history, life safety code requirements, or because the entity is unable to meet the required health and environmental criteria for the increased capacity.
- (2) Change in a management company or proposed use of a management agreement not previously disclosed in section 2.4.3.
 - (3) Change in license category or classification.
- (B) The following changes shall not be implemented by a health care entity without notification to the Department at least thirty (30) calendar days in advance of the proposed change. The appropriate fee shall accompany notification.
- (1) Decrease in licensed capacity.
 - (2) Change of legal name and/or license name used by the entity to provide services. License name changes shall conform to the requirements set forth in section 2.3.6 of this Chapter.

2.11 Department Oversight

- 2.11.1 The Department and any duly authorized representatives thereof shall have the right to enter upon and into the premises of any licensee or applicant for a license in order to determine the state of compliance with the law and regulations, and shall initially identify themselves to the person in charge of the health care entity at the time.
- (A) In accordance with section 25-1.5-103, C.R.S., routine unannounced onsite inspections shall be made only between the hours of 7 a.m. and 7 p.m.
- 2.11.2 If the Department has information about an applicant or licensee or its employees or managers that has been acquired in the context of a Department review, and provides such information to any state or federal agency that may have a statutory or regulatory interest in the entity or its employees, the Department shall also forward to the other agency any responses it has received from the licensee or applicant to the matter under review, if applicable.
- 2.11.3 The Department may use the following measures to ensure a licensee's full compliance with the applicable statutory and regulatory criteria.
- (A) **Unscheduled or unannounced reviews.**

The Department may conduct an unscheduled or unannounced review of a current licensee based upon, but not limited to, the following criteria:
 - (1) Routine compliance inspection,
 - (2) Reasonable cause to question the applicant's continued fitness to conduct or maintain licensed operations,

- (3) A complaint alleging non-compliance with license requirements,
- (4) Discovery of previously undisclosed information regarding a licensee or any of its owners, officers, managers or other employees if such information affects or has the potential to affect the licensee's provision of care, or
- (5) The omission of relevant information from documents requested by the Department or indication of false information submitted to the Department.

(B) Plan of Correction

After any Departmental review, the Department may request a plan of correction from a licensee or require a licensee's compliance with a Department directed plan of correction.

- (1) The plan of correction shall be in the format prescribed by the Department and include, but not be limited to, the following:
 - (a) A description of how the licensee will correct each identified deficiency,
 - (b) A description of how the licensee will monitor the corrective action to ensure each deficiency is remedied and will not recur, and
 - (c) A timeline with the expected implementation and completion date. The completion date is the date that the entity deems it can achieve compliance.
 - (i) The implementation date shall be no longer than thirty (30) calendar days from the date of the mailing of the deficiency to the licensee, unless otherwise required or approved by the Department.
- (2) A completed plan of correction shall be:
 - (a) Signed by the licensee's director, administrator or manager, and
 - (b) Submitted to the Department within ten (10) calendar days after the date of the Department's written notice of deficiencies.
 - (i) If an extension of time is needed to complete the plan of correction, the licensee shall request an extension in writing from the Department prior to the plan of correction due date. The Department may grant an extension of time.
- (3) The Department has discretion to approve, impose, modify or reject a plan of correction.
 - (a) If the plan of correction is accepted, the Department shall notify the entity by issuing a written notice of acceptance.
 - (b) If the plan of correction is unacceptable, the Department shall notify the licensee in writing, and the licensee shall re-submit the changes within the timeframe prescribed by the Department.
 - (c) If the licensee fails to comply with the requirements or deadlines for submission of a plan or fails to submit requested changes to the plan, the

Department may reject the plan of correction and impose disciplinary sanctions as set forth below.

- (d) If the licensee fails to implement the actions agreed to by the correction date in the approved plan of correction, the Department may impose disciplinary sanctions as set forth below.

2.12 Enforcement and Disciplinary Sanctions

License Denials

2.12.1 The Department may deny an application for an initial or renewal license for reasons including, but not limited to, the following:

- (A) The applicant has not fully complied with all local, state and federal laws and regulations applicable to that license category or classification,
- (B) The application or accompanying documents contain a false statement of material fact,
- (C) The applicant fails to respond in a timely manner to Departmental requests for additional information,
- (D) The applicant refuses any part of an on-site or off-site inspection,
- (E) The applicant fails to comply with or successfully complete an acceptable plan of correction,
- (F) The results of the fitness review and/or background check reveal issues that have harmed or have the potential to harm the health or safety of the individual(s) served,
- (G) The applicant has failed to cooperate with the investigation of any local, state or federal regulatory body, or
- (H) The applicant is not in compliance with regulatory requirements or has a documented pattern of non-compliance that has harmed or has the potential to harm the health or safety of the individual(s) served.

2.12.2 If the Department denies an application for an initial or renewal license, it shall provide the applicant with a written notice explaining the basis for the denial and affording the applicant or licensee the opportunity to respond and comply with all licensing requirements within the specified timeframe.

2.12.3 Appeals of licensure denials shall be conducted in accordance with the State Administrative Procedure Act, section 24-4-101, *et seq.* C.R.S.

Revocation or suspension of a license

2.12.4 The Department may revoke or suspend an existing license for good cause including, but not limited to, circumstances in which an owner, officer, director, manager, administrator or other employee of the licensee:

- (A) Fails or refuses to comply with the statutory and/or regulatory requirements applicable to that license type,

- (B) Makes a false statement of material fact about individuals served by the licensee, its staff, capacity, or other operational components verbally or in any public document or in a matter under investigation by the Department or another governmental entity,
- (C) Prevents, interferes with, or attempts to impede in any way the work of a representative or agent of the Department in investigating or enforcing the applicable statutes or regulations,
- (D) Falsely advertises or in any way misrepresents the licensee's ability to care for the individuals served based on its license type or status,
- (E) Fails to provide reports and documents required by regulation or statute in a timely and complete fashion,
- (F) Fails to comply with or complete a plan of correction in the time or manner specified, or
- (G) Falsifies records or documents.

2.12.5 If the Department revokes or suspends a license, it shall provide the licensee with a notice explaining the basis for the action. The notice shall also inform the licensee of its right to appeal and the procedure for appealing the action.

2.12.6 Appeals of Department revocations or suspensions shall be conducted in accordance with the State Administrative Procedure Act, section 24-4-101, *et seq.*, C.R.S.

Summary suspension of a license

2.12.7 Notwithstanding other remedies available under state law, the Department may summarily suspend a license pending proceedings for revocation or refusal to renew a license in cases of deliberate or willful violation of applicable statutes and regulations or where the public health, safety or welfare imperatively requires emergency action.

2.12.8 For purposes of this section, a deliberate and willful violation may be shown by intentional conduct or by a pattern or practice of repeated, identical or similar violations.

2.12.9 Summary suspension of any license shall be by order of the executive director of the Department or authorized designee and shall comply with the requirements of section 24-4-104, C.R.S.

2.12.10 Appeals of summary suspensions shall be conducted in accordance with the State Administrative Procedure Act, section 24-4-101, *et seq.*, C.R.S.

2.13 License Fees

Unless explicitly set forth elsewhere in 6 CCR 1011-1 or statute, the following non-refundable fees shall apply and be submitted to the Department with the corresponding application or notification. More than one fee may apply depending upon the circumstances.

Initial license	\$360.
Renewal license	\$360.
Conditional license	\$1,500.
First provisional license	\$1,000.
Second provisional license	\$1,000.
Change of ownership	\$360.

Change in licensed capacity	\$360.
Change of name	\$ 75.
Renewal application late fee	Equal to the applicable renewal license fee including bed fees or operating/procedure room fees.

PART 3. QUALITY MANAGEMENT

3.1 **QUALITY MANAGEMENT PROGRAM.** Every licensed or certified facility, except personal care boarding homes of nineteen beds or fewer and except, community residential homes for persons with developmental disabilities shall establish a quality management program appropriate to the size and type of facility that evaluates the quality of patient or resident care and safety, and that complies with this part 3.

3.1.1 Within 90 days of the effective date of this regulation for facilities licensed on the effective date of this regulation and within 90 days of the issuance of a license to a new facility, every facility defined in section 3.1 shall submit to the Department for its approval a plan for a quality management system that includes the following elements:

- (1) a general description of the types of cases, problems, or risks to be reviewed and criteria for identifying potential risks, including without limitation any incidents that may be required by Department regulations to be reported to the Department;
- (2) identification of the personnel or committees responsible for coordinating quality management activities and the means of reporting to the administrator or governing body of the facility.
- (3) a description of the method for systematically reporting information to a person designated by the facility within a prescribed time;
- (4) a description of the method for investigating and analyzing the frequency and causes of individual problems and patterns of problems;
- (5) a description of the methods for taking corrective action to address the problems, including prevention and minimizing problems or risks;
- (6) a description of the method for the follow-up of corrective action to determine the effectiveness of such action;
- (7) a description of the method for coordinating all pertinent case, problem, or risk review information with other applicable quality assurance and/or risk management activities, such as procedures for granting staff or clinical privileges; review of patient or resident care; review of staff or employee conduct; the patient grievance system; and education and training programs;
- (8) documentation of required quality management activities, including cases, problems, or risks identified for review; findings of investigations; and any actions taken to address problems or risks; and

(9) a schedule for plan implementation not to exceed 90 days after the date the facility receives written notice of the Department's approval of the plan.

3.1.2 If upon review of the facility's plan, the Department finds that it does not meet the requirements of these regulations, the Department shall return it to the facility along with the specific reasons for disapproval and establish a reasonable date for resubmittal of a revised plan meeting the requirements of these regulations.

3.1.3 In lieu of requiring the submission of an entire plan for a quality management program as required under section 3.1.1, the Department may accept documented evidence of compliance with any or all applicable standards of the Joint Commission on Accreditation of Health Care Organizations, Medicare conditions of participation, or other acceptable standards regarding risk management and quality assurance functions. The Department may accept submission of all or part of a plan or appropriate documentation regarding any or all elements required in section 3.1.1.

3.1.4 Any facility that makes a permanent and substantive change in its quality management plan shall submit a description of the change to the Department prior to implementation. The Department shall notify the facility if it determines that such change does not meet the requirements of these regulations along with the specific reasons therefor.

3.1.5 The Department may audit the quality management program to determine its compliance with the approved plan.

(1) If the Department determines that an investigation of any incident or patient or resident outcome is necessary, it may, unless otherwise prohibited by law, investigate and review relevant documents to determine actions taken by the facility.

(2) This section shall be effective June 1, 1988.

3.2 OCCURRENCE REPORTING. Notwithstanding any other reporting required by state law or regulation, each health care entity licensed pursuant to 25-1.5-103 shall report to the Department the occurrences specified at 25-1-124 (2) C.R.S.

3.2.1 The following occurrences shall be reported to the department in the format required by the Department by the next business day after the occurrence or the health care entity becomes aware of the occurrence:

(1) Any occurrence that results in the death of a patient or resident of the health care entity and is required to be reported to the coroner pursuant to section 30-10-606, C.R.S., as arising from an unexplained cause or under suspicious circumstances;

(2) Any occurrence that results in any of the following serious injuries to a patient or resident:

(a) Brain or spinal cord injuries;

(b) Life-threatening complications of anesthesia or life-threatening transfusion errors or reactions;

(c) Second or third degree burns involving twenty percent or more the body surface area of an adult patient or resident or fifteen percent or more of the body surface area of a child patient or resident;

- (3) Any time that a resident or patient of the health care entity cannot be located following a search of the health care entity, the health care entity grounds, and the area surrounding the health care entity and there are circumstances that place the resident's health, safety, or welfare at risk or, regardless of whether such circumstances exist, the patient or resident has been missing for eight hours;
- (4) Any occurrence involving physical, sexual, or verbal abuse of a patient or resident, as described in sections 18-3-202, 18-3-203, 18-3-204, 18-3-206, 18-3-402, 18-3-403, 18-3-404, or 18-3-405, C.R.S., by another patient or resident, an employee of the health care entity or a visitor to the health care entity;
- (5) Any occurrence involving neglect of a patient or resident, as described in section 26-3.1-101 (4)(b) C.R.S.;
- (6) Any occurrence involving misappropriation of a patient's or resident's property. For purposes of this paragraph, "misappropriation of a patient's or resident's property" means a pattern of or deliberately misplacing, exploiting, or wrongfully using, either temporarily or permanently, a patient's or resident's belongings or money without the patient's or resident's consent;
- (7) Any occurrence in which drugs intended for use by patients or residents are diverted to use by other persons; and
- (8) Any occurrence involving the malfunction or intentional or accidental misuse of patient or resident care equipment that occurs during treatment or diagnosis of a patient or resident and that significantly adversely affects or if not averted would have significantly adversely affected a patient or resident of the health care entity.

3.2.2 Any reports submitted shall be strictly confidential in accordance with and pursuant to 25-1-124 (4),(5), and (6) C.R.S.

3.2.3 (not used)

3.2.4 The department may request further oral reports or a written report of the occurrence if it determines a report is necessary for the department's further investigation.

3.2.5 Every health care entity shall have a policy that defines the deaths reportable to the local county coroner under 30-10-606(1), C.R.S. (1977) and that is consistent with the local coroner's reporting policy.

3.2.6 Every health care entity shall have a policy for requiring its employees to report occurrences to it.

3.2.7 No health care entity or officer or employee thereof shall discharge or in any manner discriminate or retaliate against any patient or resident of a health care entity, relative or sponsor thereof, employee of the health care entity, or any other person because such person, relative, legal representative, sponsor, or employee has made in good faith or is about to make in good faith, a report pursuant to this section 3.2 or has provided in good faith or is about to provide in good faith evidence in any proceeding or investigation relating to any occurrence required to be reported by a health care entity.

3.2.9 The department shall investigate all reports made to it under this part, and make a summary report.

- (1) Such report shall include: (a) a summary of finding(s) including the department's conclusion(s); (b) whether any violation of licensing standards was noted or whether a deficiency notice was issued; (c) whether the health care entity acted appropriately in response to the occurrence, and (d) if the investigation was not conducted on site, how the investigation was conducted.
- (2) A summary report shall not identify a patient, resident or health care professional.
- (3) In response to an inquiry, the department may confirm that it has obtained a report concerning the occurrence and that an investigation is pending.
- (4) Prior to releasing a summary report that identifies a health care entity, the department shall notify the health care entity and provide to it a copy of the summary report. The health care entity shall be allowed seven days to review, comment, and verify such information. If immediate release of information is necessary and the department cannot provide at least prior oral notice to the health care entity identified, it shall provide notice as soon as reasonably possible and shall explain why it could not provide prior notice.

3.2.10 Nothing in this part 3 shall be construed to limit or modify any statutory or common law right, privilege, confidentiality or immunity.

3.2.11 Nothing in this part shall affect a person's access to his or her medical record as provided in section 25-1-801, nor shall it affect the right of a family member or any other person to obtain medical record information upon the consent of the patient or his/her authorized representative.

Part 4. WAIVER OF REGULATIONS FOR HEALTH CARE ENTITIES

4.101 Statutory Authority, Applicability and Scope

- (1) This Part 4 is promulgated by the State Board of Health pursuant to Section 25-1-108(l)(c), C.R.S., in accordance with the general licensing authority of the Department as set forth in Section 25-1.5-103, C.R.S.
- (2) This Part 4 applies to health facilities licensed by the Department and establishes procedures with respect to waiver of regulations relating to state licensing and federal certification of health facilities.
- (3) Nothing contained in these provisions abrogates the Applicant's obligation to meet minimum requirements under local safety, fire, electrical, building, zoning, and similar codes.
- (4) Nothing herein shall be deemed to authorize a waiver of any statutory requirement under state or federal law, except to the extent permitted therein.
- (5) It is the policy of the State Board of Health and the Department that every licensed health care entity complies in all respects with applicable regulations. Upon application to the Department, a waiver may be granted in accordance with this Part 4, generally for a limited term. Absent the existence of a current waiver issued pursuant to this part, health care entities are expected to comply at all times with all applicable regulations.

4.102 Definitions For This Part 4

- (1) "Applicant" means a current health care entity licensee, or an applicant for federal certification or for an initial license to operate a health care entity in the state of Colorado.

- (2) "Board" means the State Board of Health.
- (3) "Department" means the Colorado Department of Public Health and Environment.
- (4) "Health Care Entity" means a health facility or agency licensed pursuant to Sections 25-1.5-103 and 25-3-102, C.R.S., and/or certified pursuant to federal regulations to participate in a federally funded health care program.
- (5) "Regulation(s)" means:
 - (a) Any state regulation promulgated by the Board relating to standards for operation or licensure of a health care entity, or
 - (b) Any federal regulation pertaining to certification of a care entity, but only when final authority for waiver of such federal regulation is vested in the Department. "Regulation(s)" includes the terms "standard(s)" and "rule(s)."

4.103 Application Procedure

- (1) General Waiver applications shall be submitted to the Department on the form and in the manner required by the Department.
 - (a) Only one Regulation per waiver application will be considered.
 - (b) The Applicant shall provide the Department such information and documentation as the Department may require to validate the conditions under which the waiver is being sought.
 - (c) The application must include the Applicant's name and specify the Regulation that is the subject of the application, identified by its citation.
 - (d) The application must be signed by an authorized representative of the Applicant, who shall be the primary contact person for the Department and the individual responsible for ensuring that accurate and complete information is provided to the Department.
- (2) At a minimum, each waiver application shall include the following:
 - (a) A copy of the notice required to be posted pursuant to Section 4.103(4);
 - (b) If the waiver application pertains to building requirements, schematic drawings of the areas affected and a description of the effect of the requested waiver on the total health care entity;
 - (c) A description of the programs or services offered by the health care entity that are anticipated to be affected by the waiver;
 - (d) A description of the number of residents or patients in the health care entity and the level of care they require;
 - (e) A description of the nature and extent of the Applicant's efforts to comply with the Regulation;
 - (f) An explanation of the Applicant's proposed alternative(s) to meet the intent of the Regulation that is the subject of the waiver application;

- (g) An explanation of why granting the waiver would not adversely affect the health, safety or welfare of the health care entity's residents or patients;
- (h) If the waiver is being sought for state Regulation, a description of how any applicable federal Regulation similar to the state Regulation for which the waiver is sought (if any) is being met.

(3) A waiver application shall address the following matters, to the extent applicable or relevant:

- (a) Staffing considerations, such as staff/resident or patient ratios, staffing patterns, scope of staff training, and cost of extra or alternate staffing;
- (b) The location and number of ambulatory and non-ambulatory residents or patients;
- (c) The decision-making capacity of the residents or patients;
- (d) Recommendations of attending physicians and other care-givers;
- (e) The extent and duration of the disruption of normal use of resident or patient areas to bring the health care entity into compliance with the Regulation;
- (f) Life safety code factors, including but not limited to:
 - (i) The availability and adequacy of areas safe from fire and smoke to hold residents or patients during a fire emergency;
 - (ii) Smoking regulations;
 - (iii) Fire emergency plan;
 - (iv) The availability, extent and types of automatic fire detection and fire extinguishment systems provided in the health care entity;
 - (v) The ability to promptly notify, and availability of, the fire department;
- (g) Financial factors, including but not limited to:
 - (i) The estimated cost of complying with the Regulation, including capital expenditures and any other associated costs, such as moving residents or patients;
 - (ii) How application of the Regulation would create a demonstrated financial hardship on the health care entity that would jeopardize its ability to deliver necessary health care services to residents or patients;
 - (iii) The availability of financing to implement the Regulation, including financing costs, repayment requirements, if any, and any financing or operating restrictions that may impede delivery of health care to residents or patients; and
 - (iv) The potential increase in the cost of care to residents or patients as a result of implementation of the Regulation.

- (h) Why waiver of the Regulation is necessary for specific health care entity programs to meet specific patient or resident needs, and why other patient or resident needs are not thereby jeopardized.

(4) *Notice and Opportunity to Comment on Application*

- (a) No later than the date of submitting the waiver application to the Department, the applicant shall post written notice of the application for thirty (30) days at all public entrances to the health care entity, as well as in at least one area commonly used by patients or residents, such as a waiting room, lounge, or dining room. Applicants that do not provide services on their own licensed premises, such as home care agencies and hospices, shall instead provide such written notice directly to patients. The notice shall be dated and include that an application for a waiver has been made, a meaningful description of the substance of the waiver, and that a copy of the waiver shall be provided by the health care entity upon request.
- (b) The notice must also indicate that any person interested in commenting on the waiver application may forward written comments directly to the Department at the following address:

CDPHE - HFD, A2 - Waiver Program

4300 Cherry Creek Drive South

Denver, CO 80246.

- (c) The notice must specify that written comments from interested persons must be submitted to the Department within thirty (30) calendar days of the date the notice is posted by the Applicant, and that persons wishing to be notified of the Department's action on the waiver application may submit to the Department at the above address a written request for notification and a self-addressed stamped envelope.

4.104 Department Action Regarding Waiver Application

- (1) *General*. Upon an Applicant's submission of a completed waiver application to the Department, a waiver of a particular Regulation with respect to a health care entity may be granted in accordance with this Part 4.

(2) *Decision on Waiver Application*

- (a) In acting on a waiver application, the Department shall consider:
 - (i) The information submitted by the Applicant;
 - (ii) The information timely submitted by interested persons, pursuant to Section 4.103 (4); and
 - (iii) Whether granting the waiver would adversely affect the health safety or welfare of the health care entity's residents or patients.
- (b) In making its determination, the Department may also consider any other information it deems relevant, including but not limited to occurrence and complaint

investigation reports, and licensure or certification survey reports and findings related to the health care entity and/or the operator or owner thereof.

(c) The Department shall act on a waiver application within ninety (90) calendar days of receipt of the completed application. An application shall not be deemed complete until such time as the Applicant has provided all information and documentation requested by the Department.

(3) *Terms and conditions of the waiver*. The Department may specify terms and conditions under which any waiver is granted, which terms and conditions must be met in order for the waiver to remain effective.

4.105 Termination, Expiration and Revocation of Waiver

(1) *General*. The term for which each waiver granted will remain effective shall be specified at the time of issuance.

(a) The term of any waiver shall not exceed any time limit set forth in applicable state or federal law.

(b) At any time, upon reasonable cause, the Department may review any existing waiver to ensure that the terms and conditions of the waiver are being observed, and/or that the continued existence of the waiver is otherwise appropriate.

(c) Within thirty (30) calendar days of the termination, expiration or revocation of a waiver, the Applicant shall submit to the Department an attestation, in the form required by the Department, of compliance with the Regulation to which the waiver pertained.

(2) *Termination*

(a) *Change of Ownership*. A waiver shall automatically terminate upon a change of ownership of the health care entity, as defined in Section 2.7 of Part 2, Chapter II of these Regulations. However, to prevent such automatic termination, the prospective new owner may submit a waiver application to the Department prior to the effective date of the change of ownership. Provided the Department receives the new application by this date, the waiver will be deemed to remain effective until such time as the Department acts on the application.

(3) *Expiration*

(a) Except as otherwise provided in this Part 4, no waiver shall be granted for a term that exceeds one year from the date of issuance.

(b) A waiver with a term in excess of one year may be granted for Regulations pertaining to state building or fire safety Regulations, or in other specific cases where it is determined a longer term is appropriate.

(c) If an Applicant wishes to maintain a waiver beyond the stated term, it must submit a new waiver application to the Department not less than ninety (90) calendar days prior to the expiration of the current term of the waiver.

(4) *Revocation*

- (a) Notwithstanding anything in this Part 4 to the contrary, the Department may revoke a waiver if it determines that:
 - (i) The waiver's continuation jeopardizes the health, safety, or welfare of residents or patients;
 - (ii) The Applicant has provided false or misleading information in the waiver application;
 - (iii) The Applicant has failed to comply with the terms and conditions of the waiver;
 - (iv) The conditions under which a waiver was granted no longer exist or have changed materially; or
 - (v) A change in a federal or state law or Regulation prohibits, or is inconsistent with, the continuation of the waiver.
- (b) Notice of the revocation of a waiver shall be provided to the Applicant in accordance with the Colorado Administrative Procedures Act, Section 24-4-101 et seq., C.R.S.

4.106 Waiver of Building and Fire Safety Regulations for Skilled and Intermediate Health Facilities

- (1) Notwithstanding anything in this Part 4 to the contrary, an application for waiver of building or fire safety Regulations promulgated by the Board that is submitted with respect to a health care entity that is a skilled or intermediate health care facility shall be reviewed and acted upon in accordance with this Section 4.106. To the extent they do not conflict with the express provisions of this Section 4.106, the remaining provisions of this Part 4 shall also apply to this type of waiver application.
- (2) A waiver application described in Section 4.106(1) shall be submitted to the Department and notice thereof shall be posted in accordance with Section 4.103. The application must address those matters set forth in Section 4.103(2) and Sections 4.103(3) (f) and (g). Other matters described in Section 4.103(3) may also be addressed, as appropriate.
- (3) The Department shall review the application in accordance with Section 4.104(2), and shall make a recommendation to the Board within ninety (90) calendar days of receipt of the complete application as to whether or not the requested waiver should be granted.
 - (a) The Department may recommend granting a waiver only upon finding that:
 - (i) Rigid application of the Regulation would result in demonstrated financial hardship to the health care entity, and
 - (ii) Granting the requested waiver would not adversely affect the health and safety of the health care entity's residents or patients.
 - (b) The Department's recommendation shall include the term of the waiver and any terms and conditions for issuance thereof.
- (4) The Department's recommendation to the Board on any waiver application subject to this Section 4.106 shall be in writing and shall include the following:

- (a) A statement of the Department's recommendation, including the required findings described in Section 4.106(3)(a) and a general statement of the basis for the recommendation; and
 - (b) A list of the documents and other information reviewed by the Department in preparing its recommendation, which documents shall be made available to the Board for review upon request.
- (5) The Board shall review and act upon the Department's recommendation at its next regularly scheduled meeting, or as soon as reasonably possible thereafter. The Department shall provide the Applicant notice of the Board's action, and if the waiver is approved, shall issue the waiver in accordance with the direction of the Board.
- (6) The Department shall be responsible for monitoring any waiver approved by the Board pursuant to this Section 4.106 and, at the Board's request, shall provide periodic reports to the Board concerning the status thereof. Such waivers shall be subject to the provisions of Section 4.105 concerning termination, expiration and revocation; provided, however, that the Department's action to revoke a waiver pursuant to Section 4.105(4)(a) shall be subject to the Board's prior approval.

4.107 Appeal Rights

- (1) An Applicant may appeal the decision of the Department or the Board regarding a waiver application or revocation as provided in the Colorado Administrative Procedures Act, Section 24-4-101 et seq., C.R.S.

Part 5. ACCESS TO PATIENT MEDICAL RECORDS

5.0 It is the intent of the legislature and these regulations that persons who have been treated by health care facilities or individual providers have access to their medical records in order to take more complete responsibility for their own health and to improve their communication with health care providers.

5.1 DEFINITIONS

- 5.1.1 **PATIENT** - A patient is any individual admitted to or treated in a health facility defined in 5.2 or treated by any of the providers defined in 5.3.
- 5.1.2 **PATIENT RECORD** - A patient record is a documentation of services pertaining to medical and health care that are performed at the direction of a physician or other licensed health care provider on behalf of the patient by physicians/dentists, nurses, technicians and other health care personnel. Patient records include such diagnostic documentation as X-rays and EKG's. Patient records do not include doctors' office notes, which are the notes by-a physician of observations about the patient made while the patient is in a non-hospital setting and maintained in the physician's office
- 5.1.3 **ATTENDING HEALTH CARE PROVIDER** - An attending health care provider is the physician currently or most recently responsible for coordinating the patient's care in a facility, or in the case of outpatient services, is the custodian of the record of the outpatient service. If the attending health care provider is deceased or unavailable, the current custodian of the record shall designate a substitute attending health care provider for purposes of compliance with these regulations.
- 5.1.4 **DESIGNATED REPRESENTATIVE** - A designated representative of a patient or attending health care provider is a person so authorized in writing or by court order to act on

behalf of the patient or attending health care provider. In the case of a deceased patient, the personal representative or, if none has been appointed, heirs shall be deemed to be designated representatives of the patient.

5.2 HEALTH CARE ENTITY RECORDS

5.2.1 Except as hereinafter provided, patient records in the custody of health care entities required to be certified under Section 25-1.5-103 (1)(II) or licensed under Part 1 of Article 3 of Title 25 of the C.R.S. shall be available to a patient or his/her designated representative through the attending health care provider or his/her designated representative at reasonable times and upon reasonable notice.

5.2.2 Inpatient Records

5.2.2.1 While an inpatient in a facility described in 5.2.1, a person may inspect his/her patient record within a reasonable time, which should normally not exceed 24 hours of request (excluding weekends and holidays). The patient or designated representative shall sign and date the request. The attending health care provider or his/her designated representative shall acknowledge in writing the patient's or representative's request. After inspection, the patient or designated representative shall sign and date the patient record to acknowledge inspection.

5.2.2.2 The patient or designated representative shall not be charged for inspection.

5.2.2.3 If the attending health care provider feels that any portion of the patient record pertaining to psychiatric or psychological problems or any doctor's notes would have a significant negative psychological impact upon the patient, the attending health care provider shall so indicate on his/her acknowledgment of the patient's or representative's request to inspect the patient record. The attending health care provider or his/her designated representative shall so inform the patient or representative within a reasonable time, normally not to exceed 24 hours, excluding holidays and weekends. The facility shall permit inspection of the remaining portions of the patient record. The portion of the patient record pertaining to psychiatric or psychological problems or doctor's notes may then be withheld from the patient or representative until completion of the treatment program, if in the opinion of an independent third party who is a licensed physician practicing psychiatry, the portion of the record would have a significant negative psychological impact upon the patient. The Department of Public Health and Environment, upon request of either the patient or the attending health care provider, shall identify an independent third party psychiatrist to review the record and render a final decision.

If the record or a portion thereof pertaining to psychiatric or psychological problems or doctor's note having a significant negative psychological impact is withheld from the patient, a summary thereof prepared by the attending health care provider may be available following termination of the treatment program, upon written, signed and dated request by the patient or his/her designated representative, without the necessity of further consultation with an independent third party.

5.2.2.4 A statement setting forth the requirements of 5.2 of these regulations, the facility's procedures for obtaining records, and the right to appeal grievances regarding access to records to the Department of Public Health and Environment shall be posted in conspicuous public places on the premises and made available to each patient upon admission to the facility.

5.2.3 Discharged Inpatient Record

- 5.2.3.1 A discharged inpatient or his/her designated representative may inspect or obtain a copy of his/her record after submitting a signed and dated request to the facility. The attending health care provider or his/her designated representative shall acknowledge in writing the patient's or representative's request. After inspection, the patient or designated representative shall sign and date the record to acknowledge inspection.
- 5.2.3.2 The facility shall make a copy of the record available or make the record available for inspection within a reasonable time, from the date of the signed request, normally not to exceed ten days, excluding weekends and holidays, unless the attending health care provider or designated representative is unavailable to acknowledge the request, in which case the facility shall so inform the patient and provide the patient record as soon as possible.
- 5.2.3.3 Discharged patients or their representatives shall not be charged for inspection of patient records.
- 5.2.3.4 Unless otherwise prohibited by law, a representative of the patient, other than a "personal representative" as defined in the Federal Health Insurance Portability and Accountability Act (HIPAA) § 164.502(g), with the patient's written authorization, shall pay for the reasonable cost of obtaining a copy of the patient's record, which shall be \$16.50 for the first ten or fewer pages, \$.75 per page for pages 11-40, and \$.50 per page for every additional page.

The discharged patient or personal representative (as defined under HIPAA § 164.502(g)) shall pay for the reasonable cost of obtaining a copy of his/her patient record, not to exceed \$14.00 for the first ten or fewer pages, \$.50 per page for pages 11-40, and \$.33 per page for every additional page. Actual postage or shipping costs and applicable sales tax, if any, also may be charged. The per-page fee for records copied from microfilm shall be \$1.50 per page. No fees shall be charged by a health care provider of patient records for requests for medical records received from another health care provider or to an individual regulated pursuant to Section 25-1-802(1) solely for the purpose of providing continuing medical care to a patient.

For one or more specific classes of records or services, institutions may charge additional sums upon presenting a justification therefor acceptable to the Department.

- 5.2.3.5 If the patient or the patient's designated representative so approves, the facility may supply a written interpretation by the attending health care provider or his/her designated representative of records, such as X-rays, which cannot be reproduced without special equipment. If the requestor prefers to obtain a copy of such records, he/she must pay the actual cost of such reproduction.
- 5.2.3.6 If the attending health care provider feels that any portion of the patient record pertaining to psychiatric or psychological problems or any doctor's notes would have a significant negative psychological impact upon the patient, the attending health care provider shall so indicate on his/her acknowledgment of the patient's or representative's request to inspect or obtain a copy of the patient's record. The attending health care provider or his/her designated representative shall so inform the patient or representative within a reasonable time of the date of the request, normally not to exceed five days, excluding weekends and holidays. The facility shall permit inspection or provide a copy of the remaining portion of the

record within that time. The portion of the patient record pertaining to psychiatric or psychological problems may then be withheld from the patient or representative until completion of the treatment program if, in the opinion of an independent third party who is a licensed physician practicing psychiatry, the portion of the patient record would have a significant negative psychological impact upon the patient. The Department of Public Health and Environment, upon request of either the patient or the attending health care provider, shall identify an independent third party psychiatrist to review the record and render a final decision.

If the patient record or a portion thereof pertaining to psychiatric or psychological problems or doctor's note having a significant negative psychological impact is withheld from the patient, a summary thereof prepared by the attending health care provider may be available following termination of the treatment program, upon written, signed and dated request by the patient or his/her designated representative, without the necessity of further consultation with an independent third party.

5.2.4 Nothing in this section shall apply to any nursing facility conducted by or for the adherents of any well-recognized church or religious denomination for the purpose of providing facilities for the care and treatment of the sick who depend exclusively upon spiritual means through prayer for healing and the practice of the religion of such church or denomination.

5.2.5 Facilities licensed by the Department of Public Health and Environment shall submit to the Department a copy of their policy and procedure to comply with this regulation and all forms used to implement it, and shall promptly submit to the Department any future amendments to such policies and procedures.

5.2.6 EMERGENCY ROOM RECORDS. Patient records in the custody of emergency rooms of facilities described in 5.2.1 shall be available to patients or their designated representatives as provided in 5.2.

5.2.7 If any changes/corrections, deletions, or other modifications are made to any portion of a patient record, the person must note in the record the date, time, nature, reason, correction, deletion, or other modification, his/her name and the name of a witness, to the change, correction, deletion or other modification.

5.4 EFFECT OF THIS PART 5 ON SIMILAR RIGHTS OF A PATIENT

5.4.1 Nothing in this Part 5 shall be construed so as to limit the right of a patient or the patient's designated representative to inspect patient records, including the patient's medical or psychological data pursuant to section 24-72-204 (3) (a)(I), C.R.S.

5.4.2 Nothing in this Part 5 shall be construed to require a person responsible for the diagnosis or treatment of venereal diseases or addiction to or use of drugs in the case of minors, pursuant to sections 25-4-402 (4) and 13-22-102, C.R.S. 1973, to release patient records of such diagnosis or treatment to a parent, guardian, or person other than the minor of his designated representative.

5.4.3 Nothing in this Part 5 shall be construed to waive the responsibility of a custodian of medical records in facilities to maintain confidentiality of those records in its possession.

PART 6. PATIENT RIGHTS

6.100 PATIENT RIGHTS

6.200 PATIENT GRIEVANCE MECHANISM

6.100 PATIENT RIGHTS

6.101 STATUTORY AUTHORITY AND APPLICABILITY

- (1) Authority to establish minimum standards through regulation and to administer and enforce such regulations is provided by Sections 25-1.5-103 and 25-3-101, et. seq.
- (2) Applicability . Subpart 6.100 applies to ambulatory surgical centers, birth centers, chiropractic centers and hospitals, community clinics, community clinics with emergency centers, convalescent centers, dialysis treatment clinics, hospitals and hospital units.

6.102 DEFINITIONS

- (1) "Abuse" means the willful infliction of injury, unreasonable confinement, intimidation, or punishment, with resulting physical harm, pain, or mental anguish.
- (2) "Admission" means the acceptance of a person as a patient whether on an inpatient or outpatient basis.
- (3) "Informed consent" means:
 - (a) an explanation of the nature and purpose of the recommended treatment or procedure in layman's terms and in a form of communication understood by the patient, or the patient's-designated representative;
 - (b) an explanation of the risks and benefits of a treatment or procedure, the probability of success, mortality risks, and serious side effects;
 - (c) an explanation of the alternatives with the risks and benefits of these alternatives;
 - (d) an explanation of the risks and benefits if no treatment is pursued;
 - (e) an explanation of the recuperative period which includes a discussion of anticipated problems; and
 - (f) an explanation that the patient, or the patient's designated representative, is free to withdraw his or her consent and to discontinue participation in the treatment regimen.
- (4) "Department" means the Colorado Department of Public Health and Environment, unless the context dictates otherwise.
- (5) "Licensed independent practitioner" means an individual permitted by law and the facility to independently diagnose, initiate, alter or terminate health care treatment within the scope of his or her license.
- (6) "Financial interest" means direct or indirect ownership of 5 percent or more of the capital, stock or property.
- (7) "Neglect" means the failure to provide goods and services necessary to attain and maintain physical and mental well-being.

- (8) "Patient" means a person accepted on either an inpatient or outpatient basis. Where a patient is incompetent or unable to act on his or her own behalf, such interest devolves on the patient designated representative or next of kin, if possible.
- (9) "Patient designated representative" is a person authorized to act on behalf of the patient by state law, by court order or in writing in accordance with the policies and procedures of the facility.
- (10) "Restraint" means a physical, mechanical or chemical restraint that immobilizes or reduces the ability of the patient to move his or her arms, legs, head or body freely. Methods typically used for medical-surgical care shall not be considered restraints, such as: the use of bandages and orthopedically prescribed devices, the use of a required device to limit mobility during a medical procedure, or the use of a drug when it is part of a standard treatment or dosage for the patient's condition. For the purposes of this definition, physical restraints used for fall prevention (including but not limited to raised bed rails) shall not be considered methods typically used for medical surgical care.

6.103 DEPARTMENT OVERSIGHT. This Section 6.103 applies only to health care entities having in excess of fifty (50) beds. The Department shall approve the patient rights policy of applicable health care entities prior to issuance of an initial or renewal license in accordance with Section 25-1-121, C.R.S. The facility shall submit the policy in the manner prescribed by the Department.

6.104 PATIENT RIGHTS POLICY

- (1) The health care entity shall develop and implement a policy regarding patient rights. The policy shall ensure that each patient or, where appropriate, patient designated representative has the right to:
 - (a) participate in all decisions involving the patient's care or treatment;
 - (b) be informed about whether the health care entity is participating in teaching programs, and to provide informed consent prior to being included in any clinical trials relating to the patient's care.
 - (c) refuse any drug, test, procedure, or treatment and to be informed of risks and benefits of this action;
 - (d) to care and treatment, in compliance with state statute, that is respectful, recognizes a person's dignity, cultural values and religious beliefs, and provides for personal privacy to the extent possible during the course of treatment;
 - (e) know the names, professional status, and experience of the staff that are providing care or treatment to the patient;
 - (f) receive, upon request:
 - (i) prior to initiation of care or treatment, the estimated average charge to the patient for non-emergent care. This includes reasonable assistance with determining the charges which may include deductibles and co-payments that would not be covered by a third-party payer based on the coverage information supplied by the patient or patient designated representative. In discharging its responsibility hereunder, a health care entity may provide the estimated charge for an average patient with a similar diagnosis and inform the patient or the patient designated

representative that there are variables that may alter the estimated charge.

- (ii) the health care entity's general billing procedures.
 - (iii) an itemized bill that identifies treatment and services by date. The itemized bill shall enable patients to validate the charges for items and services provided and shall include contact information, including a telephone number for patient billing inquiries. The itemized bill shall be made available either within 10 business days of the request, or 30 days after discharge for inpatients, or 30 days after the service is rendered for outpatients – whichever is later.
- (g) give informed consent for all treatment and procedures. It is the responsibility of the licensed independent practitioner and other health professionals to obtain informed consent for procedures that they provide to the patient.
- (h) register complaints with the health care entity and the Department and to be informed of the procedures for registering complaints including contact information.
- (i) be free of abuse and neglect. To effectuate this patient right, the health care entity shall develop and implement policies and procedures to prevent, detect, investigate, and respond to incidents of abuse or neglect. Prevention includes, but is not limited to, adequate staffing to meet the needs of the patients, screening employees for records of abuse and neglect and protecting patients from abuse during investigation of allegations. Detection includes, but is not limited to, establishing a reporting system and training employees regarding identifying, reporting, and intervening in incidences of abuse and neglect. The health care entity shall investigate, in a timely manner, all allegations of abuse or neglect and implement corrective actions in accordance with such investigations.
- (j) be free of the inappropriate use of restraints. Inappropriate use includes improper application of a restraint or the usage of a restraint as a means of coercion, discipline, convenience, or retaliation by staff. A health care entity that does not use restraints shall include a written statement in their policies and procedures to that effect. A health care entity that does use restraints shall develop and implement policies and procedures regarding:
- (i) the provision of training on the use of restraints.
 - (ii) ongoing individual patient assessment to determine: when a medical condition or symptom indicates use of restraint to protect the patient or others from harm; the least restrictive intervention; and the discontinuation of the intervention at the earliest possible time.
 - (iii) documentation of the use of restraint in the patient's medical record.
- (k) except in emergent situations, patients shall only be accepted for care and services when the facility can meet their identified and reasonable anticipated care, treatment, and service needs.
- (l) care delivered by the health care entity in accordance with the needs of the patient.
- (m) confidentiality of medical records.

- (n) receive care in a safe setting.
 - (o) disclosure as to whether referrals to other providers are entities in which the health care entity has a financial interest.
 - (p) to formulate advance directives and have the health care entity comply with such directives, as applicable and in compliance with applicable state statute.
- (2) The health care entity shall disclose the policy regarding patient rights prior to treatment or upon admission, where possible. For any patient care or treatment course requiring multiple patient encounters, disclosure provided at the beginning of such care or treatment course shall meet the intent of the regulations.
- (3) Each health care entity shall post a clear and unambiguous notice in a public location in the health care entity specifying that complaints may be registered with the health care entity, the Department, and with the appropriate oversight board at the Department of Regulatory Agencies (DORA). Upon request, the health care entity shall provide the patient and any interested person with contact information for registering complaints.

6.200 Patient Grievance Mechanism

6.201 STATUTORY AUTHORITY AND APPLICABILITY

- (1) Authority to establish minimum standards through regulation and to administer and enforce such regulations is provided by Sections 25-1-121, 25-1.5-103 and 25-3-101, C.R.S., et. seq.
- (2) Applicability. Subpart 6.200 applies to the following health care entities having in excess of fifty (50) beds: birth centers, chiropractic centers and hospitals, community clinics with emergency centers, convalescent centers, hospitals and hospital units. This Subpart 6.200 does not apply to billing disputes other than those that pertain to the rights established in Chapter II, Subpart 6.100, Section 6.104 (1)(f).

6.202 DEFINITIONS

- (1) "Admission" means the acceptance of a person as a patient whether on an inpatient or outpatient basis.
- (2) "Administrative officer" means the person appointed by the governing body who is responsible for the day-to-day management of the health care entity.
- (3) "Patient" means a person accepted on either an inpatient or outpatient basis. Unless the context dictates otherwise, where a patient is incompetent or unable to act on his or her own behalf, such interest devolves on the next of kin or patient designated representative, if possible.
- (4) "Patient care advocate" means the person or persons designated by each health care entity to function as the primary contact to receive complaints from patients regarding health care entity services.
- (5) "Patient designated representative" is a person authorized to act on behalf of the patient by state law, by court order or in writing in accordance with the policies and procedures of the health care entity.

- (6) "Grievance mechanism" means the process whereby complaints by patients may be initiated and resolved by the health care entity.

6.203 DEPARTMENT OVERSIGHT. The department shall approve the patient grievance mechanism plan prior to issuance of an initial or renewal license. The health care entity shall submit the plan in the manner prescribed by the department.

6.204 PATIENT GRIEVANCE MECHANISM

- (1) Patient Grievance Mechanism Plan . The health care entity shall develop and implement a patient grievance mechanism plan that shall include but not be limited to the following:

- (a) a patient care advocate that serves as a liaison between the patient and the health care entity. The plan shall describe:

- (i) the qualifications, job description, and level of decision-making authority of the patient care advocate.
- (ii) how each patient will be made aware of the patient grievance mechanism and how the patient care advocate may be contacted.

- (b) Patient grievance procedure. The health care entity shall implement a grievance procedure with, at minimum, the following components:

- (i) the ability for patients to submit grievances 24 hours per day, either orally or in writing, to a health care entity staff member. If the grievance is submitted to a staff member other than the patient care advocate, the staff member shall submit the grievance to the patient care advocate by the next working day.

- (ii) The patient care advocate shall contact the patient within three (3) working days of receipt of the grievance to acknowledge receipt of such grievance.

- (iii) The patient care advocate shall investigate the grievance and respond to the patient in writing within fifteen (15) working days of the submittal of the grievance.

- (iv) If the patient is dissatisfied with the report of the patient care advocate, the patient shall be informed that upon request, the patient care advocate will either:

- (A) forward the grievance and the health care entity findings in writing to the department; or

- (B) forward the grievance to the administrative officer or such officer's designee.

- (v) Within ten (10) working days of receiving the forwarded grievance, the administrative officer or such officer's designee shall investigate the grievance and report findings in writing to the patient. If the patient is dissatisfied with the report of the administrative officer or such officer's designee, the patient shall be informed that upon request, the patient care advocate will refer the grievance and the health care entity findings

in writing to the department, and that the patient may register the grievance directly with the department.

- (c) A means to inform the patient regarding how to lodge a grievance and that the health care entity encourages patients to speak out and to present grievances without fear of retribution.
- (d) A requirement that new employees will be trained regarding the grievance mechanism plan and that all staff with direct patient contact will be briefed at least annually regarding the plan.
- (e) How patients will be informed that interpretation and translation needs are available regarding the grievance procedure for patients unable to understand or read English and how language assistance services will be provided.

PART 7. MEDICATIONS, MEDICAL DEVICES, AND MEDICAL SUPPLIES

7.100 USE OF REPROCESSED SINGLE USE MEDICAL DEVICES

7.101 STATUTORY AUTHORITY AND APPLICABILITY

- (1) Authority to establish minimum standards through regulation and to administer and enforce such regulations is provided in Sections 25-1.5-103 and 25-3-101, C.R.S.
- (2) This Subpart 7.100 applies to all health care entities; however, this part does not apply to dialyzer regeneration.

7.102 DEFINITIONS

- (1) "Health care entity" means a health facility or agency that is required to obtain a license from the Department pursuant to Sections 25-1.5-103 and 25-3-101, C.R.S.
- (2) "Reprocessed single use device" means a single use device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient.
- (3) "Reprocessor" means a medical device manufacturer who cleans, sterilizes and performance tests single use devices that have been previously used on a patient.
- (4) "Single use device" means a device intended for one use on a single patient during a single procedure.

7.103 USE OF REPROCESSED SINGLE USE DEVICES

- (1) A health care entity may use a reprocessed single use device:
 - (a) obtained from a reprocessor registered with the U.S. Food and Drug Administration (FDA) and in compliance with FDA regulations, including but not limited to, standards regarding the validation of infection control procedures and product integrity for the reprocessed single use device. The health care entity shall make available, upon department request, documentation evidencing reprocessor compliance with FDA regulations.
 - (b) for which the number of times the device has been subjected to reprocessing is tracked when such data is relevant to ensuring optimal product function.

7.200 DONATION OF UNUSED MEDICATIONS, MEDICAL DEVICES AND MEDICAL SUPPLIES

7.201 STATUTORY AUTHORITY AND APPLICABILITY

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

(2) APPLICABILITY

(a) This Subpart 7.200 applies to medications, medical devices and medical supplies donated by the patient, resident or his or her next of kin to the following health care entities: acute treatment units, assisted living residences, community mental health centers, community residential homes for persons with developmental disabilities, intermediate care facilities for the developmentally disabled, hospices, hospitals (including general hospitals, psychiatric hospitals, maternity hospitals and rehabilitation centers), hospital units and long term care facilities.

(b) Notwithstanding Section 7.201 (2)(a), this Subpart 7.200 does not apply to items donated:

(i) by the patient, resident, or his or her next of kin directly to a pharmacist employed or contracted by the health care entity subject to 3 CCR 719-1, Section 3.00.80.

(ii) the Cancer Drug Repository Program established pursuant to Section 25-35-101, et seq. C.R.S and 6 CCR 1015-10.

7.202 DEFINITIONS. For the purposes of this Subpart 7.200, the following definitions apply:

- (1) "Customized patient medication package" means a package prepared and dispensed by a pharmacist that contains two or more different drugs.
- (2) "Donor" means a patient, resident or a patient's or resident's next of kin who donates unused medications, medical devices or medical supplies.
- (3) "Health care entity" means a licensed acute treatment unit, assisted living residence, community mental health center, community residential home for the developmentally disabled, intermediate care facilities for the developmentally disabled, hospice, hospital (including a general hospital, maternity hospital, psychiatric hospital, or rehabilitation center), hospital unit or long term care facility.
- (4) "Medication" means a drug dispensed pursuant to an order to a patient or resident of the health care entity.
- (5) "Medical device" means an instrument, apparatus, implement, machine, contrivance, implant, or similar or related article that is required to be labeled pursuant to 21 CFR Part 801.
- (6) "Medical supply" means a consumable supply item that is disposable and not intended for reuse.
- (7) "Person legally authorized to dispense medications" means, in accordance with Section 12-22-121 (6)(a), C.R.S., a pharmacist or a practitioner authorized to prescribe medications.
- (8) "Pharmacist" means a pharmacist licensed in the State of Colorado.

(9) "Relief agency" means a nonprofit entity that has the express purpose of providing medications, medical devices, or medical supplies for relief victims who are in urgent need as a result of natural or other types of disasters.

(10) "Unused item" means an unused medication, medical device or medical supply.

7.203 ACCEPTING UNUSED ITEMS FROM DONORS

(1) Prior to accepting unused items, the health care entity shall have documented evidence that the patient, resident or his or her next of kin consented to the donation of the items. The health care entity shall maintain such documentation for two years after the unused item was donated.

(2) Items Eligible for Donation. As applicable, a health care entity shall only accept unused items that meet the following criteria:

(a) items intended for use within the health care entity by the patient or resident.

(b) medications packaged as follows:

(i) if liquid, the vial must be sealed and properly stored.

(ii) individually packaged and the packaging has not been damaged.

(iii) in the original, unopened, sealed and tamper-evident unit dose packaging.

(iv) with labelling that identifies: name and strength of the medication, and in the case of a single dose package, the total number of individual tablets or capsules per dose; the medication's expiration date; the identity of the manufacturer or distributor; and the manufacturer's or distributor's lot number.

(c) single use disposable devices packaged in the manufacturer's original sealed packaging.

(d) medications with an expiration date at least six months or more from the date of the donation.

(3) Items Not Eligible for Donation. A health care entity shall not accept medications that:

(a) were dispensed in a traditional brown or amber pill bottles.

(b) are controlled substances.

(c) require refrigeration, freezing, or special storage.

(d) require special registration with the manufacturer.

(e) are adulterated or misbranded, as determined by the health care entity.

(f) are dispensed in a customized patient medication package.

(g) are compounded drugs.

(h) are packaged by a pharmacist as split tablets or capsules.

- (4) Policies and Procedures. Health care entities that accept unused items shall develop and implement policies and procedures regarding:
- (a) Storage. Unused items shall be stored:
 - (i) in a manner that retains the items' medical efficacy as provided for by storage protocols approved by a licensed pharmacist. Such protocols shall be reviewed and approved by a licensed pharmacist at least every three years.
 - (ii) separately from non-donated unused items.
 - (b) Inventory control. The health care entity shall:
 - (i) develop processes for the prevention and detection of diversion of donated unused items that may be illegally sold. When diversion is detected, prompt appropriate corrective measures shall be implemented.
 - (ii) adequately dispose of unused donated items not transferred to a pharmacist or a relief agency.
 - (c) Transporting unused items. If the health care entity is responsible for transporting unused items, it shall do so in a manner that retains the item's medical efficacy.

7.204 TRANSFERRING UNUSED ITEMS FROM THE HEALTH CARE ENTITY

- 1) A health care entity may transfer unused items to pharmacists or nonprofit relief entities as authorized by Section 12-22-133 (2), C.R.S.
- (2) The health care entity shall maintain a record, to be retained for two years after the unused item was transferred from the health care entity, of the:
 - (a) name of the donor and the date the unused item was donated to the health care entity, as applicable.
 - (b) name or a brief description of the unused item.
 - (c) quantity of the unused item.
 - (d) date the unused item(s) was transferred from the health care entity, to whom it was transferred, and signed receipt by the recipient.
 - (e) manner that it transported the unused item and that such transportation retained the item's medical efficacy, as applicable.
- (3) Upon transfer from the health care entity, unused items shall not include in their labeling any identifying patient or resident information.

Part 8. PROTECTION OF PERSONS FROM INVOLUNTARY RESTRAINT

8.101 Statutory Authority and Applicability. This part is promulgated pursuant to Sections 26-20-106 and 26-20-108, C.R.S. This part applies to the use of involuntary restraint in all licensed health care facilities, except under the circumstances described:

- (1) for hospitals as provided for in Section 8.103 (l)(a); and

(2) for Medicare/Medicaid certified nursing homes as provided for in Section 8.103 (3).

8.102 Definitions

- (1) "Chemical restraint" means giving an individual medication involuntarily for the purpose of restraining that individual; except that "chemical restraint" does not include the involuntary administration of medication pursuant to Section 27-10-111 (4.5), C.R.S., or administration of medication for voluntary or life-saving medical procedures.
- (2) "Emergency" means a serious, probable, imminent threat of bodily harm to self or others where there is the present ability to effect such bodily harm.
- (3) "Mechanical restraint" means a physical device used to involuntarily restrict the movement of an individual or the movement or normal function of a portion of his or her body.
- (4) "Physical restraint" means the use of bodily, physical force to involuntarily limit an individual's freedom of movement; except that "physical restraint" does not include the holding of a child by one adult for the purposes of calming or comforting the child.
- (5) "Restraint" means any method or device used to involuntarily limit freedom of movement, including but not limited to bodily physical force, mechanical devices, or chemicals. "Restraint" includes a chemical restraint, a mechanical restraint, a physical restraint, and seclusion.
- (6) "Seclusion" means the placement of a person alone in a room from which egress is involuntarily prevented.

8.103 Exemptions

- (1) "Restraint" does not include:
 - (a) The use of any form of restraint in a licensed or certified hospital when such use:
 - (I) Is in the context of providing medical or dental services that are provided with the consent of the individual or the individual's guardian. For the purposes of this Section (1)(a) the term "medical services" means the provision of care in a hospital where the primary goal of treatment is treatment of a medical condition as opposed to treatment of a psychiatric disorder, and
 - (II) Is in compliance with industry standards adopted by a nationally recognized accrediting body or the conditions of participation adopted for federal Medicare and Medicaid programs;
 - (b) The use of protective devices or adaptive devices for providing physical support, prevention of injury, or voluntary or life-saving medical procedures;
 - (c) The holding of an individual for less than five minutes by a staff person for protection of the individual or other persons;
 - (d) Placement of an inpatient or resident in his or her room for the night;
 - (e) The use of time-out as may be defined by written policies, rules, or procedures of a facility; or

- (f) Restraints used while the facility is engaged in transporting a person from one facility or location to another facility or location when it is within the scope of that facility's powers and authority to effect such transportation.
- (2) " A facility, as defined in Section 27-10-102 (4.5), C.R.S., that is designated by the Executive Director of the Department of Human Services to provide treatment pursuant to Sections 27-10-105,27-10-106,27-10-107, or 27-10-109, C.R.S., to any mentally ill person, as defined in Section 27-10-102 (7), C.R.S., may use seclusion to restrain a mentally ill person when such seclusion is necessary to eliminate a continuous and serious disruption of the treatment environment.
- (3) If the use of restraint in skilled nursing and nursing care facilities licensed under state law is in accordance with the federal statutes and regulations governing the Medicare program set forth in 42 U.S.C. sec. 1395i-3(c) and 42 C.F.R. part 483, subpart B and the Medicaid program set forth in 42 U.S.C. sec. 1396r(c) and 42 C.F.R. part 483, subpart B and with chapter V, Long Term Care Facilities, there shall be a conclusive presumption that such use of restraint is in accordance with this Part 8.
- (4) If any provision of this Part 8 concerning the use of restraint conflicts with any provision concerning the use of restraint stated in Article 10.5 of Title 27, C.R.S., or any regulation adopted pursuant thereto, the provision of Article 10.5 of Title 27, C.R.S., or the regulation adopted pursuant thereto shall prevail.

8.104 Basis for use of restraint

- (1) A facility may only use restraint:
 - (a) In cases of emergency; and
 - (I) After the failure of less restrictive alternatives; or
 - (II) After a determination that such alternatives would be inappropriate or ineffective under the circumstances.
- (2) A facility that uses restraint pursuant to the provisions of subsection (1) of this; section shall use such restraint:
 - (a) For the purpose of preventing the continuation or renewal of an emergency;
 - (b) For the period of time necessary to accomplish its purpose; and
 - (c) In the case of physical restraint, using no more force than is necessary to limit the individual's freedom of movement.

8.105 Duties relating to use of restraint

- (1) Notwithstanding the following provisions - Section 8.103, subsections (1)(f), (2), (3)* and (4) and Section 8.104 - a facility that uses restraint shall ensure that:
 - (a) At least every fifteen minutes, staff shall monitor any individual held in mechanical restraints to assure that the individual is properly positioned, that the individual's blood circulation is not restricted, that the individual's airway is not obstructed, and that the individual's other physical needs are met;

- (b) No physical or mechanical restraint of an individual shall place excess pressure on the chest or back of that individual or inhibit or impede the individual's ability to breathe;
 - (c) During physical restraint of an individual, an agent or employee of the facility shall check to ensure that the breathing of the individual in such physical restraint is not compromised;
 - (d) A chemical restraint shall be given only on the order of a physician who has determined, either while present during the course of the emergency justifying the use of the chemical restraint or after telephone consultation with a registered nurse, certified physician assistant, or other authorized staff person who is present at the time and site of the emergency and who has participated in the evaluation of the individual, that such form of restraint is the least restrictive, most appropriate alternative available;
 - (e) An order for a chemical restraint, along with the reasons for its issuance, shall be recorded in writing at the time of its issuance;
 - (f) An order for a chemical restraint shall be signed at the time of its issuance by such physician if present at the time of the emergency;
 - (g) An order for a chemical restraint, if authorized by telephone, shall be transcribed and signed at the time of its issuance by an individual with the authority to accept telephone medication orders who is present at the time of the emergency;
 - (h) Staff trained in the administration of medication shall make notations in the record of the individual as to the effect of the chemical restraint and the individual's response to the chemical restraint.
- (2) For individuals in mechanical restraints, facility staff shall provide relief periods, except when the individual is sleeping, of at least ten minutes as often as every two hours, so long as relief from the mechanical restraint is determined to be safe. During such relief periods, the staff shall ensure proper positioning of the individual and provide movement of limbs, as necessary. In addition, during such relief periods, staff shall provide assistance for use of appropriate toileting methods, as necessary. The individual's dignity and safety shall be maintained during relief periods. Staff shall note in the record of the individual being restrained the relief periods granted.
- (3) Relief periods from seclusion shall be provided for reasonable access to toilet facilities.
- (4) An individual in physical restraint shall be released from such restraint within fifteen minutes after the initiation of physical restraint, except when precluded for safety reasons.

8.106 Staff training

- (1) All agencies shall ensure that staff utilizing restraint in facilities or programs are trained in the appropriate use of restraint.
- (2) All agencies shall ensure that staff are trained to explain, where possible, the use of restraint to the individual who is to be restrained and to the individual's family if appropriate.

8.107 Documentation requirements. Each facility shall ensure that an appropriate notation of the use of restraint is documented in the record of the individual restrained. Each facility shall document the following in the patient record:

- (1) type of restraint and length of time in the restraint;
- (2) identification of staff involved in the initiation and application of the restraint;
- (3) care provided while in the restraint, including monitoring conducted and relief periods granted; and
- (4) the effect of the restraint on the individual.

8.108 Review of the use of restraint. Each facility that allows for the use of restraint under this Part 8 shall ensure that a review process is established for the appropriate use of the restraints.

Part 9 Hospital-Acquired Infection Reporting

Section 1 - Statutory Authority and Applicability

9.1.1 The statutory authority for the promulgation of these rules is set forth in sections 25-1.5-103, 25-3-103 and 25-3-607, C.R.S.

9.1.2 Each hospital, hospital unit, ambulatory surgical center or outpatient dialysis treatment clinic that is licensed or certified by the Department shall comply with this Part 9.

Section 2 - Definitions

For purposes of this Part 9, the following definitions shall apply:

9.2.1 "Department" means the Department of Public Health and Environment.

9.2.2 "Health Facility" means a hospital, a hospital unit, an ambulatory surgical center or outpatient dialysis treatment clinic currently licensed or certified by the Department.

9.2.3 "Infection" means the invasion of the body by pathogenic microorganisms that reproduce and multiply, causing disease by local cellular injury, secretion of a toxin, or antigen-antibody reaction in the host.

Section 3 - General Provisions

9.3.1 Each health facility shall collect data on hospital-acquired infection rates for specific clinical procedures including, but not limited to:

- (A) Cardiac surgical site infections;
- (B) Orthopedic surgical site infections;
- (C) Abdominal surgical site infections; and
- (D) Central line-related bloodstream infections.

9.3.2 An individual who collects data on hospital-acquired infection rates shall take the test for the appropriate national certification for infection control and become certified within six (6) months after the individual becomes eligible to take the certification test.

- (A) Mandatory national certification requirements shall not apply to individuals collecting data on hospital-acquired infections in hospitals licensed for 50 beds or less, licensed ambulatory surgical centers, and certified dialysis treatment centers. Qualifications for these

individuals may be met through ongoing education, training, experience or certification as directed by the Department.

9.3.3 Each health facility shall develop a policy to ensure that each physician who performs one of the procedures listed in section 9.3.1 at that facility promptly reports to it any hospital-acquired infection that the physician diagnoses at a follow-up appointment with the patient.

Section 4 - Reporting

9.4.1 A health facility shall enroll in the National Health Safety Network (NHSN) and routinely submit its hospital-acquired infection data to NHSN in accordance with its requirements and procedures.

(A) If a health facility is a division or subsidiary of another entity that owns or operates other health facilities or related organizations, the data submissions required under this part shall be for the specific division or subsidiary and not for the other entity.

9.4.2 Each health facility shall authorize the department to have access to the health facility specific data contained in the NHSN database consistent with section 25-3-601, *et seq.*, C.R.S.

Section 5 - Plan of Correction

9.5.1 If a health facility fails to fully comply with the requirements of this Part 9, the Department may request a plan of correction from the facility or require the facility's compliance with a Department directed plan of correction.

9.5.2 Plans of correction shall conform to the requirements set forth in Part 2 of this Chapter.

Section 6 – Enforcement and Disciplinary Sanctions

9.6.1 If the Department determines that a health facility is out of compliance with any of the provisions of section 25-3-601, *et seq.*, C.R.S. or this Part 9, it may impose any of the following sanctions.

(A) Revocation of the health facility's license;

(B) Denial of the health facility's application for license renewal; or

(C) A civil penalty of up to \$1,000 per violation for each day the health facility is deemed to be out of compliance.

9.6.2 If the Department revokes a license or denies an application for a renewal license, it shall provide the applicant with a written notice explaining the basis for the revocation or denial and affording the applicant or licensee the opportunity to respond and comply with all licensing requirements within the specified timeframe.

9.6.3 Appeals of licensure revocations or denials shall be conducted in accordance with the State Administrative Procedure Act, section 24-4-101, *et seq.*, C.R.S.

Editor's Notes

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

History

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