



Colorado Department
of Public Health
and Environment

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

6 CCR 1011-1, Chapter II

**STATE BOARD OF HEALTH
GENERAL LICENSURE STANDARDS
(Last Amended March 20, 2002, effective April 30, 2002)**

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CHAPTER II
GENERAL LICENSURE STANDARDS

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

Division Director
Colorado Department of Public Health And Environment
Health Facilities Division
4300 Cherry Creek Drive South
Denver, Colorado 80222-1530
Main Switchboard:
(303) 692-2000

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

Division Director
Colorado Department of Public Health And Environment
Health Facilities Division
4300 Cherry Creek Drive South
Denver, Colorado 8022-1530
Main switchboard:
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Certified copies of material shall be provided by the division, at cost, upon request. Additionally, any material that has been incorporated by reference after July 1, 1994 may be examined in any state publications depository library. Copies of the incorporated materials have been sent to the state publications depository and distribution center, and are available for interlibrary loan.

Part 1 - REVIEW OF BUILDING PLANS AND SPECIFICATIONS

1.1 SUBMISSION OF BUILDING PLANS. Plans and drawings for all facilities to be built, added to, or altered that are presently or may be licensed by the Department shall be submitted to the department for review in the following sequence prior to the start of construction:

1.1.1 A written program describing the objectives of the sponsoring organization, and the type and size of service or services to be provided in the proposed facility.

1.1.2 Preliminary 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. The preliminary drawings shall also show the proposed layout of each floor of the facility with each room labeled as to its use, and a general cross section of the structure indicating type of construction.

1.1.3 Outline specifications indicating important electrical, mechanical and other features not shown on drawings.

1.1.4 Final working drawings and specifications. These must be approved before construction is begun.

1.2 COMPLIANCE RESPONSIBILITY. It is the responsibility of the health facility to insure that any construction project complies with the applicable standards and codes.

1.3 Materials submitted for review shall be in the format and/or on forms prescribed by the department.

Part 2 - APPLICATION FOR LICENSE

2.1 LICENSE REQUIRED. No person or entity shall establish, maintain, or operate a health facility 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.

2.2 BED CAPACITY. Each license shall state the maximum bed capacity for which it is issued. No person shall admit a patient or resident to a health facility if such admission would exceed the facility's licensed capacity. If the facility has the physical and staff capacity to meet an extra patient's or resident's needs, the Department may allow admission above the licensed capacity for a period up to one month if the patient or resident requires immediate admission and there is no convenient alternative source of admission, as determined by the Department.

2.3 APPLICATION. Any person or entity that opens, conducts, or maintains a health facility shall obtain a license or certificate of compliance as required in the regulations before accepting patients or residents for care or treatment. Each facility providing such care or treatment shall obtain a separate license. Each facility located upon a separate physical location shall obtain a separate license, except that facilities so located but which provide services as part of a single licensed facility type, taking into consideration boards of directors or applicable governing boards, medical staffs, administration, by-laws and articles of incorporation or governing documents, and are located within reasonable geographic proximity as determined by the Department; based upon such factors as, but not limited to, geographical barriers, usual and customary service areas, political boundaries,

and standard metropolitan statistical areas, may operate under a single license. The burden of proving this exception shall be upon the applicant or facility. Applicants shall state on the application, the services provided and the locations of the services that are subject to the Department's authority to license and inspect health facilities.

2.3.1 Initial or renewal application shall be made on forms prescribed by and available from the Department. No license shall be issued until the applicant conforms to all applicable statutes and regulations.

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

2.3.3 By-laws and Articles of Incorporation or Partnership Agreement, as appropriate, shall accompany the initial application.

2.3.4 The license fee established by law for operation of a health facility shall accompany the application.

2.3.5 An application for an initial license shall include the following information, updated as required by 2.4:

- (1) The name, address, and respective ownership
 - (a) The operator of the health facility, including administrators and management contractors;
 - (b) Any person who, directly or indirectly, owns or controls five percent or more of the applicant;
 - (c) Any person who, directly or indirectly, owns or controls five percent or more of the land on which the services are provided;
 - (d) Any person who, directly or indirectly, owns or controls a five percent or more interest in the building in which the facility is located;
 - (e) Any person who, directly or indirectly, owns five percent or more of any mortgage, note, deed of trust, or other obligation secured in whole or in part by the facility or any of the property or assets thereof;
 - (f) Any person who, directly or indirectly, has any interest as lessor or lessee in any lease or sublease of the land on which or the building in which the facility is located;

- (2) The applicant's legal name and any other names under which it does business;
- (3) The following information, depending on the type of business entity applying:
 - (a) If a partnership, the name, address, ownership share (expressed as a percentage), and legal status (general or limited) of each partner;
 - (b) If a corporation, the address and ownership share of each shareholder who directly or indirectly owns or controls five percent or more of the shares of the corporation, and the name, address, and corporate title of each officer and director. In addition, the applicant shall file with the Department copies of all documents of incorporation filed with the Colorado Secretary of State;
 - (c) If a sole proprietorship or any other form of business entity, the name, address, title, and ownership share (expressed as a percentage) of each person with a financial interest therein, and the name, address, and title of every person who controls, directs, or operates the business entity;
 - (d) If the applicant is the lessee of the health facility, it shall furnish the information required in (a) through (c) for itself and the lessor. It shall also submit a copy of the relevant lease.
 - (e) for purposes of these regulations, "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.
- (4) Each applicant shall furnish to the Department a signed statement at the time of application describing and dating every known proceeding in the United States within five years of the date of the application, in which the applicant, or any of its present shareholders owning an interest of five percent or more, officers, directors, partners, or other controlling or managing persons, was involved, the result of which was a limitation upon or a suspension, revocation, or refusal to grant or renew a health facility license, certification for Medicaid or Medicare or other public health or social services payment program, or contract for participation in Medicaid or Medicare.
 - (a) For purposes of these regulations, reportable proceedings include final agency action, whether or not such action has been stayed in a judicial appeal.
 - (b) For purposes of these regulations, "known proceedings" means proceedings of which the applicant knew or reasonably should have known.

(c) For purposes of these regulations, "controlling or managing person" means a person or organization that exercises operational or managerial control over or who directly or indirectly conducts day-to-day operation of the entire facility.

(5) Each applicant shall furnish a signed statement to the Department at the time of application, describing every known civil and criminal proceeding within five years of the date of the application in which the applicant or any of its present shareholders owning an interest of five percent or more, officers, directors, partners, or other controlling or managing persons, has sustained a civil judgment, or criminal conviction, or in which a guilty plea or nolo contendere plea has been accepted, involving conduct or an offense in the operation, management, or ownership of a health facility related to patient or resident care or fraud in a public health or social services payment program.

(6) Each applicant shall furnish to the Department the information required in sections (3) through (5) with respect to any management company with which it contracts for management services for the facility.

2.4 CURRENT INFORMATION REQUIRED. Each licensee shall keep current all information required in sections 2.3.5(1) through (6) and shall report changes in the required information to the Department within thirty (30) days of the occurrence or of the date upon which the licensee reasonably should have known of the occurrence.

2.5 FITNESS INVESTIGATION. Upon receipt of a completed application for new license, renewal of license, or modification or change of licensure, the Department shall review the applicant's fitness (as defined in this subsection) and shall determine by on-site inspection or other appropriate investigation the applicant's compliance with applicable statutes and regulations.

2.5.1 The Department shall not approve an application for a new, renewed, modified, or changed license unless it has conducted an investigation of the fitness of the applicant. In determining fitness, the Department shall consider the following:

- (1) Whether the applicant has legal capacity demonstrated by such documents as articles of incorporation to provide the services for which the license is sought;
- (2) Whether the financial resources and sources of revenue for the specific facility of the applicant appear adequate to provide staff, services, and the physical environment sufficient to comply with state law and regulations;
- (3) Whether the applicant, its incorporators, officers, directors, partners, owners or shareholders who, directly or indirectly, own or control five percent or more of the applicant, and any controlling or managing persons, including any management company or individual manager that manages the applicant, have the competence to establish, maintain, or operate a

health facility. In so determining, the Department may consider other pertinent evidence of competence and shall consider the following:

- (a) Compliance with all applicable standards, such as state licensing and federal Medicare and Medicaid certification standards;
- (b) Health facility-related civil judgments, criminal convictions, or guilty or nolo contendere pleas, as specified in 2.3.5(5);
- (c) Adverse action, as specified in 2.3.5(4); and
- (d) Whether any person described in 2.5.1(3) has violated any provisions of state health law or the Department's health and licensure regulations in any health facility within five years prior to the date of application.

2.6 LICENSEE NAME. Each health facility applying for a license shall be designated by a distinctive name and identified or held out to the public by one of the health facility categories requiring licensure. Each facility, regardless of the number of locations, when such locations conform to section 2.3 of these regulations, shall be identified by this distinctive name, using clearly visible signage at the location and on stationery and billing materials that identify the licensed facility name. In the case of common support services shared by more than one licensee, the name of the legal owner of the health facility licensees so supported shall be used to identify the service. Any facility shall notify the Department of any proposed name change. If the Department determines that such change would create confusion or misrepresentation to the public regarding the type of licensed facility or services it can provide or regarding the fitness of the licensee to conduct and maintain such facility, it may disapprove such name change.

2.7 MEETING LICENSURE DEFINITIONS. No facility shall create the impression that it is a health facility at any location unless it meets the legal definition of the facility which it purports to be and is so licensed by the Department, or is part of a licensed health facility and conforms to the provisions of sections 2.3 and 2.6 of these regulations.

2.8 DISPLAY AND USE OF LICENSE. The license must be displayed in a conspicuous public place. Each license or certificate of compliance shall be valid only in the hands of the person 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 originally issued.

2.9 NOTICE OF CHANGES. At least thirty (30) days in advance of any of the following changes the holder of a license or certificate of compliance shall notify the Department and the new applicant shall file an application for a new license or certificate of compliance:

2.9.1 Change of Ownership

(1) In the case of a partnership, transfer of ownership shall include dissolution of the partnership and conversion thereof into any other entity or the substitution or attempted substitution of one or more of the partners. But 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 partner can participate in the management or administration of the partnership business or affairs.

(2) Transfer of ownership of a sole proprietorship (any business owned by a single individual) shall include transfer of title to the business, whether or not title to real property is transferred to another person. But change of ownership does not include forming a corporation from the sole proprietorship with the proprietor as the sole shareholder.

(3) Transfer of ownership of a corporation shall not, in itself, include transfer of corporate stock or merger of one or more corporations with the licensee surviving. Transfer of ownership of a corporation shall include consolidation of two or more corporations resulting in the creation of a new corporate entity, and except as provided in subsections (1) and (2) formation of a corporation from a partnership or a sole proprietorship.

(4) Transfer of ownership of a licensee shall include a management contract, lease or any other arrangement where the current licensee retains no control of the operation or management of the facility or where the licensee is paid by the manager or lessee.

2.9.2 Change in name or address of the health facility;

2.9.3 Increase or decrease in licensed bed capacity; or

2.9.4 Change in licensure category.

2.10 PROVISIONAL LICENSE. If a facility fails to conform to the requirements of the law and regulations, the Department may refuse to issue a license but may issue a provisional license to allow the facility to comply with licensing requirements, if the applicant or licensee is making a substantial good faith attempt to comply with such requirements and requires such time to effect compliance.

2.10.1 The provisional license shall be valid for ninety (90) days.

2.10.2 The provisional license may be renewed once, if the applicant demonstrates to the Department that it has made further substantial progress toward compliance and can effect compliance within the following ninety (90) days.

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2.10.3 The applicant shall pay the provisional license fee established by law.

2.10.4 Before determining whether to issue a permanent license to a provisionally licensed facility, the Department shall conduct a survey or such other investigation it deems necessary and shall find that the facility meets the requirements for licensure.

2.11 LICENSE TERM. Each license or certificate of compliance issued for the operation of a health facility shall expire after a period not longer than one year from the date issued unless earlier suspended or revoked, as provided by law and these licensure regulations or unless voluntarily surrendered by the licensee.

2.12 LICENSE RENEWAL APPLICATION. Each application for renewal of a license shall be submitted not less than sixty (60) days prior to expiration of the license and shall conform to all requirements in these regulations for applications for initial licenses except for the filing of duplicate information not amended during the applicable period. The applicant's failure to file timely its renewal application shall result in expiration of the current license on its last effective date. In such cases, the late renewal application shall in all respects be treated as an application for a new license.

2.13 INFORMATION REQUIREMENTS. Licensees shall provide upon request access to such patient or resident medical records as the Department shall reasonably require for the performance of its licensure and grievance functions. Licensees 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 business records as the Department shall reasonably require for the performance of its licensure and grievance functions. The Department shall not release to any unauthorized person any information defined as confidential under state law.

2.14 SURRENDER OF LICENSE. The holder of each license or certificate of compliance issued by the Department shall surrender the license or certificate immediately upon suspension, revocation, refusal to renew, or discontinuance of the operation of the health facility.

2.15 SUMMARY LICENSE SUSPENSION. Notwithstanding any 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. The summary suspension of any license shall be by order of the Executive Director of the Department or his authorized designee and shall comply with the requirements of C.R.S., 24-4-104, as amended. For purposes of this chapter, deliberate and willful conduct may be shown by either the existence of a pattern or practice of repeated, identical or similar violations or by intentional conduct.

2.16 FITNESS REVIEW. At any time upon reasonable cause, the Department may investigate an applicant's fitness to maintain or operate an facility and take appropriate action.

2.17 INFORMATION PROVIDED TO OTHER AGENCIES. If the Department has information about an applicant or licensee or its employees or managers gathered in the context of a department investigation and provides such information to any state or federal agency that is investigating the applicant or licensee, the Department shall also forward to such other agency any responses the licensee or applicant has made to allegations or charges that are contained in the information provided to such other agency.

2.18 DEPARTMENT INSPECTION. 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 determined the state of compliance with the law and regulations, and shall initially identify themselves to the person in charge of the facility at the time.

2.19 HOURS OF INSPECTION. The Department shall perform its routine unannounced on-site surveys between 7:00 A.M. and 7:00 P.M.

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.

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(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 3.1.4 shall be effective June 1, 1988.

3.2 Reporting. Notwithstanding any other reporting required by state law or regulation, each health facility 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 by telephone by the next business day after the occurrence or the facility becomes aware of the occurrence:

(1) Any occurrence that results in the death of a patient or resident of the facility and is required to be reported to the coroner pursuant to section 3-10-606, 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 facility cannot be located following a search of the facility, the facility grounds, and the area surrounding the facility 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 section 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 facility or a visitor to the facility;

(5) Any occurrence involving neglect of a patient or resident, as described in section 26-3.1-101 (4)(b) C.R.S.;

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(6) Any occurrence involving misappropriation of a patient=s or resident=s property. For purposes of this paragraph (f), "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 facility.

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 facility 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 facility shall have a policy for requiring its employees to report occurrences to it.

3.2.7 No health facility or officer or employee thereof shall discharge or in any manner discriminate or retaliate against any patient or resident of a facility, relative or sponsor thereof, employee of the facility, 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 facility.

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 facility 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 facility, the department shall notify the facility and provide to it a copy of the summary report. The facility 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 facility 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 FACILITIES

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(1)(c), C.R.S., in accordance with the general licensing authority of the Department as set forth in Section 25-1-107(1)(I)(I), 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 facility 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, facilities are expected to comply at all times with all applicable regulations.

4.102 Definitions For This Part 4

- (1) “Applicant” means a current health facility licensee, or an applicant for federal certification or for an initial license to operate a health facility 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) “Facility” means a health facility licensed pursuant to Sections 25-1-107 (1)(I)(I) 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 Facility, or
 - (b) Any federal regulation pertaining to certification of a Facility, 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 Facility;
 - (c) A description of the programs or services offered by the Facility that are anticipated to be affected by the waiver;
 - (d) A description of the number of residents or patients in the Facility 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 Facility'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 Facility 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 Facility;
 - (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 Facility 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 Facility 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 notice of the application and a meaningful description of the substance of the waiver request at all public entrances to the Facility, as well as in at least one area commonly used by patients or residents, such as a waiting room, lounge, or dining room. The notice must reflect the date of posting, and indicate that an application for a waiver has been made and that a copy of the waiver application shall be provided by the Facility 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 Facility 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 Facility'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 Facility 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 Facility, as defined in Section 2.9.1 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 Facility 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 Facility, and
 - (ii) Granting the requested waiver would not adversely affect the health and safety of the Facility'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's records include such diagnostic documentation as X-rays and EKG's. Patient records do not include doctor's 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 FACILITY RECORDS.

5.2.1 Except as hereinafter provided, patient records in the custody of health facilities required to be certified under section 25-1-107(1)(I),(II) or licensed under Part 1 of Article 3 of Title 25 of the C.R.S. 1973 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 The discharged patient or representative 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 his designated representative to inspect the patient's medical or psychological data pursuant to section 24-72-204(3)(1), C.R.S. 1973.

5.4.2 Nothing in this Part 5 shall be construed as to limit a right to inspect patient records which is otherwise granted by state statute to the patient or his designated representative.

5.4.3 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 to a parent, guardian, or person other than the minor or his designated representative.

5.4.4 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 GRIEVANCE MECHANISM AND FACILITY'S OBLIGATIONS TO THE PATIENT

6.1 APPLICABILITY

(This section is applicable to general hospitals, psychiatric hospitals, rehabilitation hospitals, chiropractic centers, maternity hospitals and related facilities having in excess of fifty beds except for nursing facilities conducted by or for the adherents of any well-recognized church or religious denominations for the purpose of providing for the care and treatment of the sick who depend exclusively upon spiritual means through prayer for healing in the practice of the religion of such church or denomination, nursing care facilities, and intermediate health care facilities which are subject to the provisions of C.R.S. 1973 25-1-120 as amended.)

6.2 PLAN SUBMISSION

Each facility meeting the above applicability clause shall submit to the Health Facilities Division, Colorado Department of Public Health And Environment, for approval, a plan for a grievance mechanism and a policy statement with respect to the obligations of the facility to patients using the facilities of such facility.

6.3 DEFINITIONS

6.3.1 Admission: The acceptance of a person as a patient and for whom a record of treatment is instituted, whether on an inpatient or outpatient basis.

6.3.2 Grievance Mechanism: The established procedure whereby complaints by patients may be initiated and resolved.

6.3.3 Patient: 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 next of kin or legal guardian, if possible.

6.3.4 Patient Representative: The person or persons designated by each facility to function as the primary contact to receive complaints from patients regarding facility services.

6.3.5 Chief Executive Officer: The person appointed by the governing body who is responsible for the continuous management of the facility. The chief executive officer shall authorize an individual to act for him in an absence which would preclude fulfillment of the regulations in a timely manner.

6.4 The patient grievance mechanism plan shall include but not be limited to the following:

6.4.1 A provision for a patient representative to serve as a liaison between the patient and the facility.

6.4.2 A description of the qualifications of the patient representative.

6.4.3 An outline of the job description of the patient representative.

6.4.4 A description of the amount of decision-making authority given to the patient representative.

6.4.5 A method by which each patient will be made aware of the patient representative program and how the representative of the program may be contacted.

6.4.6 Provision for informing patients that every effort will be made to translate the grievance procedure into the language of the patient if the patient does not understand or is unable to read English.

6.4.7 A means to inform the patient that the facility encourages patients to speak out and to present grievances without fear of retribution.

6.4.8 Provision for inclusion in new employee orientation programs of a briefing on the facility's grievance procedure and at least annually transmission of information to all staff members who have direct patient contact covering the grievance mechanism.

6.5 GRIEVANCE PROCEDURE

6.5.1 The facility grievance mechanism will be so designed as to provide for the submission of grievances by patients, orally and in writing, to the patient representative.

6.5.2 To insure prompt action, the grievance mechanism will provide that a grievance may be submitted to a staff member at any time, 24 hours per day, and that the grievance will be submitted to the patient representative by the next working day.

6.5.3 Complaints that cannot be resolved by the patient representative shall be referred to the facility chief executive officer or his designee immediately, but in any event no later than three days after the receipt of the report of the patient representative to the patient. The chief executive officer or his designee shall cause an additional investigation to be made and provide results of his investigation to the complainant within seven days.

6.5.4 If the complainant is dissatisfied with the report of the facility chief executive officer, the complainant shall be informed that the problem may be referred in writing to the Executive Director, Colorado Department of Public Health And Environment, by the patient representative if requested by complainant. The complainant shall also be notified by the patient representative that the complainant may refer the matter to the Executive Director as well.

6.5.5 Upon receipt of the complaint, the Colorado Department of Public Health And Environment shall, within seven days, notify the complainant and the facility that an investigation has been initiated and a report in writing will be made to the complainant and to the facility as to its findings and/or recommendations within fourteen days after notification.

6.6 POLICY STATEMENT

(A) In addition to any posting requirements under this part of the regulations, each facility shall make available, upon admission, a disclosure of its policy statement on patient rights pursuant to 25-1-121(4), C.R.S. and this part 6 of the regulations. The disclosure shall be made available

through the use of an appropriate communication medium and in a manner understood by the patient, or the patient's legal representative. 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.

6.6.1 The policy statement shall include, at least, the following explanations:

6.6.6.1 The physician's, dentist's, or podiatrist's duty to obtain informed consent.

(A) The explanation of the physician's, dentist's, or podiatrist's duty in the policy statement shall include at a minimum the following information:

(1) the right of the patient or the patient's legal representative to give informed consent for all treatment and procedures consistent with other state and federal statutes.

(B) For the purposes of this regulation, the term, "informed consent," shall include, but not be limited to, the following:

(1) an explanation of the recommended treatment or procedure in layman's terms and in a form of communication understood by the patient or the patient's legal representative;

(2) an explanation of the risks and benefits of a treatment or procedure; the probability of success, mortality risks, and serious side effects;

(3) an explanation of the alternatives with the risks and benefits of these alternatives;

(4) an explanation of the probable or likely consequences if no treatment is pursued;

(5) an explanation of the recuperative period which includes a discussion of anticipated problems and the anticipated length of the recuperative period;

(6) an explanation that the patient, or the patient's legal representative, is free to withdraw his or her consent and to discontinue participation in the treatment regimen; and

(7) an explanation to the patient, or patient's legal representative, if the patient's physician, dentist, or podiatrist is participating in teaching programs and/or in research, and experimental or educational projects relating to the patient's own case.

6.6.1.2 Admission procedures.

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(A) The explanation of admission procedures shall include disclosure to each patient or patient's legal representative, regarding the facility's policy statement on patient rights upon admission for care or treatment consistent with paragraph 6.6.(A).

(B) The policy statement providing the explanation of a patient's rights shall, in addition to patient rights in the other subsections of this part 6, include, but not be limited to, the following:

- (1) the right to participate in all decisions involving the patient's care or treatment consistent with other state and federal statutes;
- (2) the right to refuse any drug, test, procedure, or treatment consistent with other state and federal statutes; and to be informed of the probable or likely medical consequences of this action;
- (3) the right to be informed of the facility's rules and regulations as they apply to the patient;
- (4) the right to be informed of the facility's grievance procedure.

6.6.1.3 Staff identification (how different staff members are identified; i.e., uniforms, badges, etc.)

(A) The policy statement shall also inform the patient or the patient's legal representative of the right to know the names, professional status, and experience of the staff that are providing care or treatment to the patient.

6.6.1.4 Privacy concerning medical treatment and care.

(A) The policy statement shall also inform the patient or the patient's legal representative of the right to care or treatment that is respectful, recognizes a person's dignity, and provides for personal privacy to the extent possible during the course of treatment.

6.6.1.5 Medical records will be maintained in confidence and in accordance with medical staff bylaws, rules and regulations. The right of patient access will be specified pursuant to 25-1-801, C.R.S., et. seq. and consistent with part 5 of this chapter II of the regulations.

6.6.1.6 Billing procedures.

(A) The patient, or the patient's legal representative, has the right to be informed upon request, prior to the initiation of care or treatment, that is non-emergent of the charge(s) for service(s) that is routine, usual, and customary; or the estimated charge(s) for service(s) based upon an average patient with a diagnosis similar to the tentative or preliminary admission diagnosis of the patient being admitted; and, based upon insurance information supplied by the patient, to be given

assistance on obtaining an estimate of any co-payment, deductible, or other charges that will not be covered by a third party payer and must be paid by the patient. The patient, or the patient's legal representative, has the right to be informed prior to the initiation of care or treatment, of the facility's general billing procedures. A facility may include a disclaimer with the disclosure of any charges. Such disclaimer may include further information on variables which may alter any disclosed charge. If charges to the patient are prohibited by law or by third party payer contract, then a disclaimer of no charge shall meet the requirements of this paragraph.

6.6.1.7 The facility shall provide information to the patient, or the patient's legal representative, if the facility or the patient's physician, dentist, or podiatrist is participating in teaching programs and/or in research, experimental, or educational projects relating to the patient's own case.

6.6.2 The policy statement, with respect to the obligations of the facility to patients, shall be conspicuously posted in a public place on the premises of the facility preferably in, but not limited to, the admissions area.

6.6.3 Each facility shall adhere to, treat, and provide services to patients in accordance with the provisions of the facility's policy statement.

6.7 The grievance plan and performance of the facility thereunder shall be approved by the Colorado Department of Public Health And Environment prior to certification of compliance or issuance or renewal of a license. The Department shall notify the facility as to the acceptance or rejection of its institutional plan within fourteen days of receipt. If unacceptable, the Department shall provide a detailed written statement of the reasons for the plan's unacceptability and suggested changes.

6.8 Each facility shall post notice, in a conspicuous place in the facility, of the existence of its internal grievance procedure. The notice shall also inform patients, or their legal representatives, that if still dissatisfied with physician, dental, or podiatric patient care services, excluding fee disputes, a complaint may be filed with the Colorado State Board of Medical Examiners, the State Board of Dental Examiners, and the Colorado Podiatry Board. Upon request, the facility shall provide the patient, or the patient's legal representative, with the address of the appropriate board and inform such person that these boards are prohibited from arbitrating or adjudicating fee disputes between licensees or between a licensee and any other party, pursuant to sections 12-36-104.5, 12-35-107.5, and 12-32-104.5, C.R.S.

(A) A facility may post such notice in a manner that is conducive to a positive customer relations approach as long as the above provisions are incorporated in a manner that is consistent with the intent of the regulation.

Part 7 - SINGLE USE DISPOSABLE MEDICAL DEVICES

CHAPTER II

7.1 APPLICABILITY. This section is applicable to all health facilities licensed by the Department.

7.2 BASIS AND PURPOSE. Statutory authority for adoption of these regulations is C.R.S. 1973, 25-1-107(1)(1)(I) and 25-1-108(1)(c)(I). The regulations are proposed to control the re-use of single use or disposable medical devices. Without such regulations, the public health safety may be jeopardized.

7.3 DEFINITIONS:

7.3.1 A medical device is "an instrument, apparatus, implement, machine, contrivance, implant, in-vitro reagent or other similar or related article intended for use in the diagnosis of disease or in the cure, mitigation, treatment or prevention of disease." Examples are cardiac pacemakers, glass clinical thermometers, catheters, cardiac guidewires, renal dialyzers, etc.

7.3.2 A single-use or disposable medical device is one labeled as such by the manufacturer, or one in which a caution is included in the accompanying literature or catalogue recommending one time only usage

7.3.3 Dialyzer Regeneration means the preparation for reuse of a single-use dialyzer in accordance with this Section 7 of Chapter II.

7.4 POLICY STATEMENT.

7.4.1 The re-use of medical devices labeled as single-use or disposable shall be prohibited with the following exceptions:

1. Dialyzers for the same patient.
2. Balloon-assist catheters (opening but not inserted).
3. Devices not requiring maintenance of sterility (irrigation and other patient devices).

7.4.2 Prior to re-use of any items except dialyzers list in 7.4.1 (reuse of which is subject to the provisions of 7.5, 7.6, 7.7), the facility shall submit the Department for approval written processing procedures which shall meet the following guidelines based on F.D.A. standards:

1. The device can be adequately cleaned prior to disinfection and reuse.
2. The physical characteristics of the device material will not be adversely affected by cleaning, disinfection, or re-use.

3. The packaging material will allow effective penetration of the disinfecting agent and will prevent recontamination of the device under the storage conditions to which devices will be subjected.
4. If disinfecting process is effective.
5. If the treated device is used parenterally, the process will not evoke pyrogenic response.
6. The device, after gas or chemical disinfection, will not contain toxic residues.

7.5 DIALYZER REGENERATION.

7.5.1 Regeneration shall not be permitted on dialyzers used for hepatitis antigen positive patients.

7.5.2 Prior to individual dialyzer regeneration, each patient shall be provided by the physician with a presentation of possible complications and hazards and possible benefits of such regeneration. This shall be incorporated into the consent for dialysis form and shall become a part of the patient's dialysis record. Patients shall have access to the number of times their dialyzer has been reused.

7.5.3 No person shall be denied access to dialysis in the facility as a result of that patient's refusal to permit regeneration of his or her dialyzer. Refusal to permit regeneration shall be documented.

7.5.4 The facility shall document the qualifications of and the protocols for training personnel responsible for the regeneration process.

7.5.5 The facility shall provide training for all personnel in the protocols and procedures for regeneration at the time of employment and no less than annually.

7.5.6 The facility shall establish policies and procedures to ensure the safety of employees in regard to the use of disinfecting agents and procedures to deal with accidents and spillage of disinfectants.

7.6 QUALITY CONTROL FOR DIALYZER REGENERATION. Procedures shall be established and documented in the facility procedure manual which shall include but not be limited to:

7.6.1 Each dialyzer to be reused shall be indelibly and clearly labeled with the patient's name and other unique identifying information before the initial use.

7.6.2 At each subsequent use, the label shall be checked by two separate individuals, the dialysis staff member and the patient, if feasible.

7.6.3 The number of the uses shall be recorded both in a reuse record maintained for each dialyzer, and in the patient's permanent dialysis record.

7.6.4 Water used to formulate cleaning solution and to rinse dialyzers shall be passed through a reverse osmosis membrane, ultrafiltration membrane or a submicron filter (0.45 micron) which is appropriately maintained. This water shall contain less than 200 bacteria per ml, which shall be documented by bacteriologic sampling of the source water outlet in the reprocessing area monthly. Where such sampling reveals bacterial counts that periodically approach or exceed this limit, corrective measures and weekly sampling shall be accomplished. Results of such samples shall be recorded.

7.6.5 Disinfection shall be achieved with an effective agent, the addition of which to each dialyzer shall be documented and recorded. If formaldehyde is used as the disinfecting agent, a minimum concentration of 2% in both the blood and dialysate compartments, and minimum exposure time of 24 hours if required.

7.6.6 Disinfection shall be monitored epidemiologically of all febrile reactions during dialysis with new or used dialyzers and shall be documented in the patients record.

7.6.7 Blood and dialysate cultures shall be done on all patients during febrile reactions. Reports of cultures shall be recorded in the dialysis record.

7.6.8 Documentation and recording of the addition of effective disinfectant concentrations in the dialyzer to be reused shall be done.

7.6.9 Documentation and recording of effective disinfectant removal from each dialyzer immediately prior to reapplication shall be done. Validation tests of methodologic achievement shall be made monthly.

7.6.10 Removal of any other potentially toxic substances added as any part of the reprocessing procedure shall be documented and recorded by routine testing and/or validation studies as appropriate.

7.6.11 The effectiveness of the reprocessing procedure must be documented before each subsequent use of each dialyzer.

1. For hollow fiber dialyzers, a hollow fiber bundle volume (HFBV) of not less than 80% of the initial HFBV, measured at 0 ± 10 MM. of HG transmembrane pressure, shall be maintained.

2. For parallel plate or coil dialyzers, small molecular clearance tests shall be performed during or after each use, performance less than 90% of original capacity will not be permitted.

7.6.12 Blood leaks during use of both new and reprocessed dialyzers shall be documented and recorded. If the blood-leak rate of used dialyzers exceeds that of new dialyzers, each dialyzer must be pressure tested for possible blood compartment leak before reuse.

7.6.13 Dialyzers shall be discarded unless the following criteria are met at the time the dialyzer is to be used on the patient:

1. The dialyzer has no cracked or broken parts.
2. The dialyzer appears clear and free of dissolved or residual blood manifest by a brownish or pinkish tinge.
3. Headers are visibly free of all but small peripheral clots.

7.6.14 A clean storage space for disinfected dialyzers will be provided.

7.6.15 Where such committee exists, all quality control procedures shall be approved by the Infection Control Committee.

7.7 DIALYZER REGENERATION FACILITIES. A separate room shall be provided.

7.7.1 Unless the room is equipped with an appropriate flushing system, the room shall be equipped with a counter and counter sink.

7.7.2 The room shall have approved hand-washing facilities and storage cabinets.

7.7.3 The room shall be separated in clean and soiled areas. Regeneration dialyzers shall be maintained only in the clean area.

7.7.4 The room shall be ventilated with fresh air at a minimum rate of six air changes per hour or locally exhausted. Air shall not be recirculated through the ventilating system except at those times when processing is not taking place. If general exhaustion of the room is selected, as opposed to local exhaustion, the site of exhaustion must be, at a maximum, six inches from floor level. (NOTE: Formaldehyde gas is heavier than air.)

7.7.5 The rooms shall be lighted to a level of 50 foot candles at the work surfaces.

7.7.6 Storage space shall be provided for supplies and for regenerated dialyzers proportional to the number of patients in the unit.

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

- support,
- (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 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.
 - (b)
- (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 B Section 8.103, subsections (1)(f), (2), (3) and (4) and Section 8.104 B 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 - PATIENT RIGHTS

9.1 Any facility licensed by the department, unless exempted under section 9.4, shall make available, upon admission for care or treatment, a disclosure of its policy on patient rights. The disclosure shall be made available through the use of an appropriate communication medium, and in a manner understood by the patient, or the patient's legal representative. 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. A facility shall treat patients in accordance with the provisions of the patient rights statement.

9.2 The patient rights statement shall include but not be limited to the following:

- (a) the right to participate in all decisions involving the patient's care or treatment;
- (b) the right to know the names, professional status, and experience of the staff that are providing care or treatment to the patient;
- (c) the right to know if the facility is participating in teaching programs, research, and/or experimental programs;
- (d) the right to refuse any drug, test, procedure, or treatment;
- (e) the right to care or treatment that is respectful, recognizes a person's dignity, and provides for personal privacy to the extent possible during the course of treatment;
- (f) the right to be informed of the facility's rules and regulations as they apply to the patient; and
- (g) the right to be informed, upon request, prior to the initiation of care or treatment that is non-emergent, of the charge(s) for service(s) that is routine, usual, and customary; or the estimated charge(s) for service(s) based upon an average patient with a diagnosis similar to the tentative or preliminary admission diagnosis of the patient being admitted; and, based upon insurance information supplied by the patient, to be given assistance obtaining an estimate of any co-payment, deductible, or other charges that will not be covered by a third party payer and must be paid by the patient; and, the right to be informed prior to the initiation of care or treatment of the facility's general billing procedures. A facility may include a disclaimer with the disclosure of any charges. Such disclaimer may include further information on variables which may alter any disclosed charge. If charges to the patient are prohibited by law, or by third party payer contract, then a disclaimer of no charge shall meet the requirements of this paragraph;
- (h) the right to give informed consent for all treatment and procedures.
- (i) the right to be informed of the facility's grievance procedure.

9.3 For the purposes of this regulation, the term, "informed consent", shall include, but not be limited to, the following:

- (a) an explanation of the recommended treatment or procedure in layman's terms and in a form of communication understood by the patient, or the patient's legal 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 consequences if no treatment is pursued;
- (e) an explanation of the recuperative period which includes a discussion of anticipated problems and the anticipated length of the recuperative period; and
- (f) an explanation that the patient, or the patient's legal representative, is free to withdraw his or her consent and to discontinue participation in the treatment regimen.

9.4 APPLICABILITY. The provisions of 9.1 and 9.2 shall not apply to any facility currently covered under section 25-1-121 and the regulations promulgated pursuant to said section in Chapter II, Part 6 of the regulations. The provisions of 9.1 and 9.2 shall not apply to long term care facilities, personal care boarding homes, residential facilities for the developmentally disabled, and hospice that are regulated pursuant to section 25-1-120 and 6 CCR 1011-1, Chapter V, Chapter VIII, Part 5, and Chapter XXI respectively.

9.5 Each facility shall post notice, in a conspicuous place in the facility, of the existence of its internal grievance procedure. The notice shall also inform patients, or their legal representatives, that if still dissatisfied with physician, dental, or podiatric patient care services, excluding fee disputes, a complaint may be filed with the Colorado State Board of Medical Examiners, the State Board of Dental Examiners, and the Colorado Podiatry Board. Upon request, the facility shall provide the patient, or the patient's legal representative, with the address of the appropriate board and inform such person that these boards are prohibited from arbitrating or adjudicating fee disputes between licensees or between a licensee and any other party, pursuant to sections 12-36-104.5, 12-35-107.5, and 12-32-104.5, C.R.S.

- (A) A facility may post such notice in a manner that is conducive to a positive customer relations approach as long as the above provisions are incorporated in a manner that is consistent with the intent of the regulation.

CHAPTER II
LICENSURE

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