

1 Chapter II – General Licensure Standards

2 Part 1 – ~~REVIEW OF BUILDING PLANS AND SPECIFICATIONS SUBMISSION OF CONSTRUCTION~~  
3 ~~PLANS/DOCUMENTS AND COMPLETION OF THE PLAN REVIEW PROCESS~~

4 1.101 STATUTORY AUTHORITY AND APPLICABILITY

5 (1) AUTHORITY TO ESTABLISH MINIMUM STANDARDS THROUGH REGULATION AND TO ADMINISTER AND ENFORCE  
6 SUCH REGULATIONS IS PROVIDED BY SECTION 25-1.5-103 AND 25-3-101, C.R.S., ET. SEQ.

7 (2) THIS PART 1 APPLIES TO ALL LICENSED FACILITIES SUBJECT TO PLAN REVIEW. ~~1.2 COMPLIANCE~~  
8 ~~RESPONSIBILITY.~~ It is the responsibility of the health facility to ~~insure~~ ENSURE that any construction  
9 project complies with the applicable LOCAL, STATE, AND FEDERAL standards and codes.

10 1.102 ~~4.4 SUBMISSION OF BUILDING PLANS CONSTRUCTION PLANS AND DOCUMENTS. 4.3~~  
11 Materials submitted for review shall be in the format and/or on forms prescribed by the department.  
12 ~~Plans and drawings~~ THE FOLLOWING CONSTRUCTION PLANS AND DOCUMENTS for all facilities to be built,  
13 added to, or altered that are presently or may be licensed by the Department shall be submitted to the  
14 Department for review ~~in the following sequence prior to the start of construction:~~

15 (1) ~~4.1.1 A written program describing the objectives of the sponsoring organization, and~~ DESCRIPTION OF  
16 the type and size of service or services to be provided ~~in the proposed facility~~ BY THE PHYSICAL PLANT  
17 SUBJECT TO THE PLAN REVIEW.

18 (2) ~~4.1.2 Preliminary~~ SCALE drawings showing the proposed general location, boundaries, approaches to  
19 and physical features of the site, other buildings on the site, means of water supply, sewage disposal,  
20 and other utilities to the site. The ~~preliminary~~ drawings shall also show the proposed layout of each floor  
21 of the facility with each room labeled as to its use AND DIMENSIONS, and a general cross section of the  
22 structure indicating type of construction.

23 (3) ~~4.1.3~~ Outline specifications indicating ~~important~~ SIGNIFICANT electrical, mechanical and other features  
24 not shown on drawings.

25 ~~4.1.4 Final working drawings and specifications. These must be approved before construction is~~  
26 ~~begun.~~

27 1.103 COMPLETION OF THE PLAN REVIEW PROCESS. COMPLETION OF PLAN REVIEW IS EVIDENCED BY  
28 DEPARTMENT APPROVAL INDICATING THAT THE FACILITY IS IN COMPLIANCE AND NO ADDITIONAL CONSTRUCTION  
29 CHANGES NEED TO BE MADE.

30 (1) AFTER THE RECEIPT OF THE CONSTRUCTION PLANS/DOCUMENTS AND FEES, THE DEPARTMENT SHALL CONDUCT  
31 A PRELIMINARY REVIEW OF THE CONSTRUCTION PLANS/DOCUMENTS AND ISSUE WRITTEN NOTIFICATION TO THE  
32 APPLICANT OF EITHER THE FINDINGS OF SUCH REVIEW OR NOTIFICATION THAT THE SUBMITTALS WERE  
33 INSUFFICIENT TO ESTABLISH SUCH FINDINGS. THE PLAN REVIEW PROCESS SHALL BE COMPLETED WITHIN 24  
34 MONTHS OF THE DATE THE DEPARTMENT ISSUES SUCH WRITTEN NOTIFICATION. *{Explanatory note:*  
35 *Department findings for the preliminary review will vary based on the type of construction or remodel*  
36 *being reviewed. For new construction, for example, findings will establish whether the construction*  
37 *type, occupancy separations, smoke barriers meet Life Safety Code requirements. For a kitchen hood*  
38 *and duct work remodel, on the other hand, findings will establish whether the system is properly*  
39 *designed, routed, and accessible.}*

40 (2) EXTENSIONS

41 (a) THE FACILITY MAY OBTAIN A ONE-MONTH EXTENSION FOR THE COMPLETION OF THE PLAN REVIEW  
42 PROCESS.

- 1 (i) THE FACILITY MAY OBTAIN A ONE-MONTH EXTENSION BY SUBMITTING A WRITTEN REQUEST, IN  
2 THE FORM REQUIRED BY THE DEPARTMENT, NO LATER THAN 10 WORKING DAYS PRIOR TO THE  
3 24-MONTH COMPLETION DUE DATE.
- 4 (ii) THE FACILITY IS ONLY ELIGIBLE FOR A SINGLE ONE-MONTH EXTENSION.
- 5 (b) IF THE PLAN REVIEW PROCESS IS NOT COMPLETED WITHIN THE 24-MONTH PERIOD, OR 25-MONTH  
6 PERIOD IF THE ONE-MONTH EXTENSION WAS OBTAINED, THE APPLICANT MAY OBTAIN A 6-MONTH  
7 EXTENSION.
- 8 (i) THE FACILITY MAY OBTAIN A SIX-MONTH EXTENSION BY SUBMITTING AN EXTENSION FEE OF  
9 \$500 AND A WRITTEN REQUEST, IN THE FORM REQUIRED BY THE DEPARTMENT, NO LATER  
10 THAN 10 WORKING DAYS PRIOR TO THE COMPLETION DUE DATE.
- 11 (ii) THE FACILITY IS ELIGIBLE FOR MULTIPLE SIX-MONTH EXTENSIONS.
- 12 (iii) EXTENSION FEES ARE NON-REFUNDABLE.
- 13 (iv) IF THE APPLICANT OBTAINS A 6-MONTH EXTENSION, THE FACILITY SHALL MEET THE LICENSURE  
14 REGULATIONS IN EFFECT AT THE TIME OF THE FINAL INSPECTION.
- 15 (3) FAILURE TO COMPLETE THE PLAN REVIEW PROCESS WITHIN THE 24-MONTH PERIOD OR WITHIN THE TIMEFRAMES  
16 AUTHORIZED BY THE EXTENSIONS SHALL RESULT IN THE PLAN REVIEW PROCESS BEING ADMINISTRATIVELY  
17 CLOSED. AFTER AN ADMINISTRATIVE CLOSURE, THE APPLICANT MAY ACTIVATE **A NEW** PLAN REVIEW PROCESS BY  
18 **RESUBMITTING** THE CONSTRUCTION PLANS/DOCUMENTS ALONG WITH THE CORRESPONDING PLAN REVIEW FEE.

1 **Part 2. APPLICATION FOR LICENSE**

2 ~~2.1 LICENSE REQUIRED. No person or entity shall establish, maintain, or operate a health facility without~~  
3 ~~first having obtained a license therefor or, in the case of governmental facilities, a certificate of~~  
4 ~~compliance from the Department. For purposes of these rules, the holder of a certificate of compliance~~  
5 ~~shall be considered a licensee.~~

6 ~~2.2 BED CAPACITY. Each license shall state the maximum bed capacity for which it is issued. No person~~  
7 ~~shall admit a patient or resident to a health facility if such admission would exceed the facility's licensed~~  
8 ~~capacity. If the facility has the physical and staff capacity to meet an extra patient's or resident's needs,~~  
9 ~~the Department may allow admission above the licensed capacity for a period up to one month if the~~  
10 ~~patient or resident requires immediate admission and there is no convenient alternative source of~~  
11 ~~admission, as determined by the Department.~~

12 ~~2.3 APPLICATION. Any person or entity that opens, conducts, or maintains a health facility shall obtain a~~  
13 ~~license or certificate of compliance as required in the regulations before accepting patients or residents~~  
14 ~~for care or treatment. Each facility providing such care or treatment shall obtain a separate license.~~  
15 ~~Each facility located upon a separate physical location shall obtain a separate license, except that~~  
16 ~~facilities so located but which provide services as part of a single licensed facility type, taking into~~  
17 ~~consideration boards of directors or applicable governing boards, medical staffs, administration, by-laws~~  
18 ~~and articles of incorporation or governing documents, and are located within reasonable geographic~~  
19 ~~proximity as determined by the Department; based upon such factors as, but not limited to,~~  
20 ~~geographical barriers, usual and customary service areas, political boundaries, and standard~~  
21 ~~metropolitan statistical areas, may operate under a single license. The burden of proving this exception~~  
22 ~~shall be upon the applicant or facility. Applicants shall state on the application, the services provided~~  
23 ~~and the locations of the services that are subject to the Department's authority to license and inspect~~  
24 ~~health facilities.~~

25 ~~2.3.1 Initial or renewal application shall be made on forms prescribed by and available from the~~  
26 ~~Department. No license shall be issued until the applicant conforms to all applicable statutes~~  
27 ~~and regulations.~~

28 ~~2.3.2 Each application shall be signed under penalty of perjury by an authorized corporate officer,~~  
29 ~~general partner, or sole proprietor of the applicant, as appropriate.~~

30 ~~2.3.3 By laws and Articles of Incorporation or Partnership Agreement, as appropriate, shall~~  
31 ~~accompany the initial application.~~

32 ~~2.3.4 The license fee established by law for operation of a health facility shall accompany the~~  
33 ~~application.~~

34 ~~2.3.5 An application for an initial license shall include the following information, updates as required~~  
35 ~~by 2.4:~~

36 ~~(1) The name, address, and respective ownership~~

37 ~~(a) The operator of the health facility, including administrators and management~~  
38 ~~contractors;~~

39 ~~(b) Any person who, directly or indirectly, owns or controls five percent or more of~~  
40 ~~the applicant;~~

41 ~~(c) Any person who, directly or indirectly, owns or controls five percent or more of~~  
42 ~~the land on which the services are provided;~~

43 ~~(d) Any person who, directly or indirectly, owns or controls a five percent or more~~  
44 ~~interest in the building in which the facility is located;~~

- 1 (e) — Any person who, directly or indirectly, owns five percent or more of any  
2 mortgage, note, deed of trust, or other obligation secured in whole or in part by  
3 the facility or any of the property or assets thereof;
- 4 (f) — Any person who, directly or indirectly, has any interest as lessor or lessee in  
5 any lease or sublease of the land on which or the building in which the facility is  
6 located;
- 7 (2) — The applicant's legal name and any other names under which it does business;
- 8 (3) — The following information, depending on the type of business entity applying:
- 9 (a) — If a partnership, the name, address, ownership share (expressed as a  
10 percentage), and legal status (general or limited) of each partner;
- 11 (b) — If a corporation, the address and ownership share of each shareholder who  
12 directly or indirectly owns or controls five percent or more of the shares of the  
13 corporation, and the name, address, and corporate title of each officer and  
14 director. In addition, the applicant shall file with the Department copies of all  
15 documents of incorporation filed with the Colorado Secretary of State;
- 16 (c) — If a sole proprietorship or any other form of business entity, the name, address,  
17 title, and ownership share (expressed as a percentage) of each person with a  
18 financial interest therein, and the name, address, and title of every person who  
19 controls, directs, or operates the business entity;
- 20 (d) — If the applicant is the lessee of the health facility, it shall furnish the information  
21 required in (a) through (c) for itself and the lessor. It shall also submit a copy of  
22 the relevant lease.
- 23 (e) — For purposes of these regulations, "indirect" ownership means any ownership  
24 interest in an entity that has an ownership interest in the applicant, including an  
25 ownership interest in any entity that has an indirect ownership interest in the  
26 applicant.
- 27 (4) — Each applicant shall furnish to the Department a signed statement at the time of  
28 application describing and dating every known proceeding in the United States within  
29 five years of the date of the application, in which the applicant, or any of its present  
30 shareholders owning an interest of five percent or more, officers, directors, partners, or  
31 other controlling or managing persons, was involved, the result of which was a limitation  
32 upon or a suspension, revocation, or refusal to grant or renew a health facility license,  
33 certification for Medicaid or Medicare or other public health or social services payment  
34 program, or contract for participation in Medicaid or Medicare.
- 35 (a) — For purposes of these regulations, reportable proceedings include final agency  
36 action, whether or not such action has been stayed in a judicial appeal.
- 37 (b) — For purposes of these regulations, "known proceedings" means proceedings of  
38 which the applicant know or reasonably should have known.
- 39 (c) — For purposes of these regulations, "controlling or managing person" means a  
40 person or organization that exercises operational or managerial control over or  
41 who directly or indirectly conducts day-to-day operation of the entire facility.
- 42 (5) — Each applicant shall furnish a signed statement to the Department at the time of  
43 application, describing every known civil and criminal proceeding within five years of the  
44 date of the application in which the applicant or any of its present shareholders owning  
45 an interest of five percent or more, officers, directors, partners, or other controlling or

1 managing persons, has sustained a civil judgment, or criminal conviction, or in which a  
2 guilty plea or nolo contendere plea has been accepted, involving conduct or an offense  
3 in the operation, management, or ownership of a health facility related to patient or  
4 resident care or fraud in a public health or social services payment program.

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

8 ~~2.4 — CURRENT INFORMATION REQUIRED. Each licensee shall keep current all information required in~~  
9 ~~sections 2.3.5(1) through (6) and shall report changes in the required information to the Department~~  
10 ~~within thirty (30) days of the occurrence or of the date upon which the licensee reasonably should have~~  
11 ~~known of the occurrence.~~

12 ~~2.5 — FITNESS INVESTIGATION. Upon receipt of a completed application for new license, renewal of~~  
13 ~~license, or modification or change of licensure, the Department shall review the applicant's fitness (as~~  
14 ~~defined in this subsection) and shall determine by on-site inspection or other appropriate investigation~~  
15 ~~the applicant's compliance with applicable statutes and regulations.~~

16 ~~2.5.1 — The Department shall not approve an application for a new, renewed, modified, or changed~~  
17 ~~license unless it has conducted an investigation of the fitness of the applicant. In determining~~  
18 ~~fitness, the Department shall consider the following:~~

19 (1) — ~~Whether the applicant has legal capacity demonstrated by such documents as articles~~  
20 ~~of incorporation to provide the services for which the license is sought;~~

21 (2) — ~~Whether the financial resources and sources of revenue for the specific facility of the~~  
22 ~~applicant appear adequate to provide staff, services, and the physical environment~~  
23 ~~sufficient to comply with state law and regulations;~~

24 (3) — ~~Whether the applicant, its incorporators, officers, directors, partners, owners or~~  
25 ~~shareholders who, directly or indirectly, own or control five percent or more of the~~  
26 ~~applicant, and any controlling or managing persons, including any management~~  
27 ~~company or individual manager that manages the applicant, have the competence to~~  
28 ~~establish, maintain, or operate a health facility. In so determining, the Department may~~  
29 ~~consider other pertinent evidence of competence and shall consider the following:~~

30 (a) — ~~Compliance with all applicable standards such as state licensing and federal~~  
31 ~~Medicare and Medicaid certification standards;~~

32 (b) — ~~Health facility related civil judgements, criminal convictions, or guilty or nolo~~  
33 ~~contendere pleas, as specified in 2.3.5(5);~~

34 (c) — ~~Adverse action, as specified in 2.3.5(4); and~~

35 (d) — ~~Whether any person described in 2.5.1(3) has violated any provisions of state~~  
36 ~~health law or the Department's health and licensure regulations in any health~~  
37 ~~facility within five years prior to the date of application.~~

38 ~~2.6 — LICENSEE NAME. Each health facility applying for a license shall be designated by a distinctive name~~  
39 ~~and identified or held out to the public by one of the health facility categories requiring licensure. Each~~  
40 ~~facility, regardless of the number of locations, when such locations conform to section 2.3 of these~~  
41 ~~regulations, shall be identified by this distinctive name, using clearly visible signage at the location and~~  
42 ~~on stationery and billing materials that identify the licensed facility name. In the case of common support~~  
43 ~~services shared by more than one licensee, the name of the legal owner of the health facility licensees~~  
44 ~~so supported shall be used to identify the service. Any facility shall notify the Department of any~~  
45 ~~proposed name change. If the Department determines that such change would create confusion or~~  
46 ~~misrepresentation to the public regarding the type of licensed facility or services it can provide or~~

1 regarding the fitness of the licensee to conduct and maintain such facility, it may disapprove such name  
2 change.

3 ~~2.7 MEETING LICENSURE DEFINITIONS. No facility shall create the impression that it is a health facility at~~  
4 ~~any location unless it meets the legal definition of the health facility which it purports to be and is so~~  
5 ~~licensed by the Department, or is part of a licensed health facility and conforms to the provisions of~~  
6 ~~sections 2.3 and 2.6 of these regulations.~~

7 ~~2.8 DISPLAY AND USE OF LICENSE. The license must be displayed in a conspicuous public place. Each~~  
8 ~~license or certificate of compliance shall be valid only in the hands of the person to whom it is issued~~  
9 ~~and shall not be subject to sale, assignment or other transfer, voluntary or involuntary, nor shall a~~  
10 ~~license be valid for any premises other than those for which originally issued.~~

11 ~~2.9 NOTICE OF CHANGES. At least thirty (30) days in advance of any of the following changes the holder~~  
12 ~~of a license or certificate of compliance shall notify the Department and the new applicant shall file an~~  
13 ~~application for a new license or certificate of compliance:~~

14 ~~2.9.1 Change of ownership.~~

15 ~~(1) In the case of a partnership, transfer of ownership shall include dissolution of the~~  
16 ~~partnership and conversion thereof into any other entity or the substitution or attempted~~  
17 ~~substitution of one or more of the partners. But change of ownership does not include~~  
18 ~~dissolution of the partnership to form a corporation with the same persons retaining the~~  
19 ~~same shares of ownership in the new corporation. For purposes of this subsection,~~  
20 ~~"substitution" means any arrangement whereby a partner can participate in the~~  
21 ~~management or administration of the partnership business or affairs.~~

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

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

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

36 ~~2.9.2 Change in name or address of the health facility;~~

37 ~~2.9.3 Increase or decrease in licensed bed capacity; or~~

38 ~~2.9.4 Change in licensure category.~~

39 ~~2.10 PROVISIONAL LICENSE. If an facility fails to conform to the requirements of the law and regulations,~~  
40 ~~the Department may refuse to issue a license but may issue a provisional license to allow the facility to~~  
41 ~~comply with licensing requirements, if the applicant or licensee is making a substantial good faith~~  
42 ~~attempt to comply with such requirements and requires such time to effect compliance.~~

43 ~~2.10.1 The provisional license shall be valid for ninety (90) days.~~

- 1           2.10.2 ~~The provisional license may be renewed once, if the applicant demonstrates to the Department~~  
2           ~~that it has made further substantial progress toward compliance and can effect compliance~~  
3           ~~within the following ninety (90) days.~~
- 4           2.10.3 ~~The applicant shall pay the provisional license fee established by law.~~
- 5           2.10.4 ~~Before determining whether to issue a permanent license to a provisionally licensed facility, the~~  
6           ~~Department shall conduct a survey or such other investigation it deems necessary and shall find~~  
7           ~~that the facility meets the requirements for licensure.~~
- 8   2.11 ~~LICENSE TERM. Each license or certificate of compliance issued for the operation of a health facility~~  
9   ~~shall expire after a period not longer than one year from the date issued unless earlier suspended or~~  
10 ~~revoked, as provided by law and these licensure regulations or unless voluntarily surrendered by the~~  
11 ~~licensee.~~
- 12 2.12 ~~LICENSE RENEWAL APPLICATION. Each application for renewal of a license shall be submitted not~~  
13 ~~less than sixty (60) days prior to expiration of the license and shall conform to all requirements in these~~  
14 ~~regulations for applications for initial licenses except for the filing of duplicate information not amended~~  
15 ~~during the applicable period. The applicant's failure to file timely its renewal application shall result in~~  
16 ~~expiration of the current license on its last effective date. In such cases, the late renewal application~~  
17 ~~shall in all respects be treated as an application for a new license.~~
- 18 2.13 ~~INFORMATION REQUIREMENTS. Licensees shall provide upon request access to such patient or~~  
19 ~~resident medical records as the Department shall reasonably require for the performance of its licensure~~  
20 ~~and grievance functions. Licensees shall provide upon request access to or copies of reports and~~  
21 ~~information required by the Department, including but not limited to, staffing reports, census data,~~  
22 ~~statistical information, and such business records as the Department shall reasonably require for the~~  
23 ~~performance of its licensure and grievance functions. The Department shall not release to any~~  
24 ~~unauthorized person any information defined as confidential under state law.~~
- 25 2.14 ~~SURRENDER OF LICENSE. The holder of each license or certificate of compliance issued by the~~  
26 ~~Department shall surrender the license or certificate immediately upon suspension, revocation, refusal~~  
27 ~~to renew, or discontinuance of the operation of the health facility.~~
- 28 2.15 ~~SUMMARY LICENSE SUSPENSION. Notwithstanding any other remedies available under state law,~~  
29 ~~the Department may summarily suspend a license pending proceedings for revocation of or refusal to~~  
30 ~~renew a license in cases of deliberate or willful violation of applicable statutes and regulations or where~~  
31 ~~the public health, safety, or welfare imperatively requires emergency action. The summary suspension~~  
32 ~~of any license shall be by order of the Executive Director of the Department or his authorized designee~~  
33 ~~and shall comply with the requirements of C.R.S., 24-4-104, as amended. For purposes of this chapter,~~  
34 ~~deliberate and willful conduct may be shown by either the existence of a pattern or practice of repeated,~~  
35 ~~identical or similar violations or by intentional conduct.~~
- 36 2.16 ~~FITNESS REVIEW. At any time upon reasonable cause, the Department may investigate an applicant's~~  
37 ~~fitness to maintain or operate a facility and take appropriate action.~~
- 38 2.17 ~~INFORMATION PROVIDED TO OTHER AGENCIES. If the Department has information about an~~  
39 ~~applicant or licensee or its employees or managers gathered in the context of a department~~  
40 ~~investigation and provides such information to any state or federal agency that is investigating the~~  
41 ~~applicant or licensee, the Department shall also forward to such other agency any responses the~~  
42 ~~licensee or applicant has made to allegations or charges that are contained in the information provided~~  
43 ~~to such other agency.~~
- 44 2.18 ~~DEPARTMENT INSPECTION. The Department and any duly authorized representatives thereof shall~~  
45 ~~have the right to enter upon and into the premises of any licensee or applicant for a license in order to~~  
46 ~~determine the state of compliance with the law and regulations, and shall initially identify themselves to~~  
47 ~~the person in charge of the facility at the time.~~

1 ~~2.19 HOURS OF INSPECTION. The Department shall perform its routine unannounced on-site surveys~~  
2 ~~between 7:00 A.M. and 7:00 P.M.~~

3 ~~2.20 LICENSURE FEES. Unless otherwise specified in either 6 CCR 1011-1 or the Colorado Revised~~  
4 ~~Statutes, fees shall be assessed as follows:~~

Initial license	\$360
Renewal license	\$360
Conditional license	\$360
Provisional license	\$360
Change of ownership	\$360
Change of facility name	\$360
Change of address	\$360
Change of beds	\$360

5 **THE CURRENT VERSION OF PART 2, SHOWN IN STRIKE-OUT ABOVE, IS BEING REPLACED IN ITS**  
6 **ENTIRETY BY THE FOLLOWING:**

7 **PART 2 – LICENSURE PROCESS**

8 **2.1 STATUTORY AUTHORITY AND APPLICABILITY**

9 2.1.1 THE STATUTORY AUTHORITY FOR THE PROMULGATION OF THESE RULES IS SET FORTH IN SECTIONS 25-1.5-103  
10 AND 25-3-101, *ET SEQ.*, C.R.S.

11 2.1.2 A HEALTH CARE ENTITY LICENSED BY THE DEPARTMENT SHALL COMPLY WITH ALL APPLICABLE FEDERAL AND  
12 STATE STATUTES AND REGULATIONS INCLUDING THIS CHAPTER II. IN THE EVENT OF A DISCREPANCY BETWEEN  
13 REGULATIONS, THE MORE SPECIFIC STANDARDS SHALL APPLY.

14 **2.2 DEFINITIONS**

15 FOR PURPOSES OF THIS CHAPTER, THE FOLLOWING DEFINITIONS SHALL APPLY:

16 2.2.1 “BUSINESS ENTITY MEANS ANY ORGANIZATION OR ENTERPRISE AND INCLUDES, BUT IS NOT LIMITED TO, A SOLE  
17 PROPRIETOR, AN ASSOCIATION, CORPORATION, BUSINESS TRUST, JOINT VENTURE, LIMITED LIABILITY COMPANY,  
18 LIMITED LIABILITY PARTNERSHIP, PARTNERSHIP OR SYNDICATE.

19 2.2.2 “CAMPUS” MEANS THE PHYSICAL AREA IMMEDIATELY ADJACENT TO THE HEALTH CARE ENTITY’S MAIN BUILDINGS,  
20 OTHER AREAS AND STRUCTURES THAT ARE NOT STRICTLY CONTIGUOUS TO THE MAIN BUILDINGS BUT ARE  
21 LOCATED WITHIN A WALKING DISTANCE OF 250 YARDS OF THE MAIN BUILDINGS, WITHOUT CROSSING MORE THAN  
22 TWO LANES OF TRAFFIC. THE DEFINITION OF CAMPUS SHALL ALSO INCLUDE ANY OTHER AREAS DETERMINED BY  
23 THE DEPARTMENT, ON AN INDIVIDUAL CASE BASIS, TO BE PART OF THE HEALTH CARE ENTITY’S CAMPUS.

24 2.2.3 “CONTROLLING INTEREST” MEANS THE OPERATIONAL DIRECTION OR MANAGEMENT OF A HEALTH CARE ENTITY  
25 INCLUDING, BUT NOT LIMITED TO, THE AUTHORITY, EXPRESS OR RESERVED, TO CHANGE THE CORPORATE  
26 IDENTITY OF THE APPLICANT; THE AUTHORITY TO APPOINT MEMBERS OF THE BOARD OR DIRECTORS, BOARD OF  
27 TRUSTEES, OR OTHER APPLICABLE GOVERNING BODY OF THE HEALTH CARE ENTITY; THE ABILITY TO CONTROL  
28 ANY OF THE ASSETS OR OTHER PROPERTY OF THE HEALTH CARE ENTITY OR TO DISSOLVE OR SELL THE HEALTH  
29 CARE ENTITY.

- 1 2.2.4 "DEFICIENCY" MEANS A FAILURE TO FULLY COMPLY WITH ANY STATUTORY AND/OR REGULATORY REQUIREMENTS  
2 APPLICABLE TO A LICENSED HEALTH FACILITY.
- 3 2.2.5 "DEPARTMENT" MEANS THE DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT.
- 4 2.2.6 "DIRECT OWNERSHIP" MEANS THE POSSESSION OF STOCK, EQUITY IN CAPITAL OR ANY INTEREST GREATER THAN  
5 5 PERCENT OF THE HEALTH CARE ENTITY.
- 6 2.2.7 "HEALTH CARE ENTITY" MEANS A HEALTH CARE FACILITY OR AGENCY THAT IS REQUIRED TO OBTAIN A LICENSE  
7 FROM THE DEPARTMENT PURSUANT TO SECTION 25-3-101, C.R.S. UNLESS OTHERWISE INDICATED, THE TERM  
8 "HEALTH CARE ENTITY" IS SYNONYMOUS WITH THE TERMS "HEALTH FACILITY" OR "FACILITY" AS USED  
9 ELSEWHERE IN 6 CCR 1011-1, STANDARDS FOR HOSPITALS AND HEALTH FACILITIES.
- 10 2.2.8 "INDIRECT OWNERSHIP" MEANS ANY OWNERSHIP INTEREST IN AN ENTITY THAT HAS AN OWNERSHIP INTEREST IN  
11 THE APPLICANT, INCLUDING AN OWNERSHIP INTEREST IN ANY ENTITY THAT HAS AN INDIRECT OWNERSHIP  
12 INTEREST IN THE APPLICANT.
- 13 2.2.9 "LICENSEE" MEANS THE PERSON, BUSINESS ENTITY OR AGENCY THAT IS GRANTED A LICENSE OR CERTIFICATE OF  
14 COMPLIANCE TO OPERATE A HEALTH CARE ENTITY AND THAT BEARS LEGAL RESPONSIBILITY FOR COMPLIANCE  
15 WITH ALL APPLICABLE FEDERAL AND STATE STATUTES AND REGULATIONS.
- 16 2.2.10 "MANAGEMENT COMPANY" MEANS THE PERSON, BUSINESS ENTITY OR AGENCY THAT IS PAID BY THE LICENSEE  
17 AND HAS A CONTRACTUAL AGREEMENT WITH THE LICENSEE TO MANAGE THE DAY-TO-DAY OPERATION OF THE  
18 HEALTH CARE ENTITY ON BEHALF OF THE LICENSEE.
- 19 2.2.11 "REVIEW" MEANS ANY TYPE OF ADMINISTRATIVE OVERSIGHT BY THE DEPARTMENT INCLUDING, BUT NOT LIMITED  
20 TO, EXAMINATION OF DOCUMENTS, DESK AUDIT, COMPLAINT INVESTIGATION OR ON-SITE INSPECTION.
- 21 **2.3 LICENSE REQUIRED**
- 22 2.3.1 NO PERSON OR BUSINESS ENTITY SHALL ESTABLISH, MAINTAIN OR OPERATE A HEALTH CARE ENTITY WITHOUT  
23 FIRST HAVING OBTAINED A LICENSE THEREFOR OR, IN THE CASE OF GOVERNMENTAL FACILITIES, A CERTIFICATE  
24 OF COMPLIANCE FROM THE DEPARTMENT. FOR PURPOSES OF THESE RULES, THE HOLDER OF A CERTIFICATE OF  
25 COMPLIANCE SHALL BE CONSIDERED A LICENSEE.
- 26 (A) ANY PERSON OR BUSINESS ENTITY OPERATING A HEALTH CARE ENTITY SHALL NOT PROVIDE SERVICES  
27 IN AREAS SUBJECT TO PLAN REVIEW EXCEPT AS APPROVED BY THE DEPARTMENT.
- 28 (B) ANY PERSON OR BUSINESS ENTITY OPERATING A HEALTH CARE ENTITY WHO DOES NOT HAVE A  
29 PROVISIONAL, CONDITIONAL OR REGULAR LICENSE FROM THE DEPARTMENT IS GUILTY OF A  
30 MISDEMEANOR AND, UPON CONVICTION THEREOF, SHALL BE PUNISHED BY A FINE OF NOT LESS THAN  
31 FIFTY DOLLARS (\$50), NOR MORE THAN FIVE HUNDRED DOLLARS (\$500). EACH DAY OF OPERATION  
32 SHALL BE CONSIDERED A SEPARATE OFFENSE.
- 33 2.3.2 EACH HEALTH CARE ENTITY OFFERING SERVICES THAT ARE REGULATED BY MORE THAN ONE CHAPTER OF 6  
34 CCR 1011-1, STANDARDS FOR HOSPITALS AND HEALTH FACILITIES, CHAPTERS IV THROUGH XXII SHALL HAVE  
35 A SEPARATE LICENSE FOR EACH REGULATED CATEGORY OF SERVICES.
- 36 (A) IF ANY LICENSED HEALTH CARE ENTITY OFFERS SERVICES WITHIN THE SAME BUILDING OR ON THE SAME  
37 CAMPUS AS ANOTHER LICENSEE, THE TREATMENT FACILITIES AND ADMINISTRATIVE OFFICES OF ONE  
38 LICENSEE SHALL BE PHYSICALLY SEPARATED WITH CLEAR SIGNAGE FROM THE TREATMENT FACILITIES  
39 AND ADMINISTRATIVE OFFICE OF ANY OTHER LICENSEE.
- 40 (1) TREATMENT FACILITIES SHALL INCLUDE, BUT NOT BE LIMITED TO; PATIENT BEDS WINGS,  
41 DIAGNOSTIC, PROCEDURE AND OPERATING ROOMS. ADMINISTRATIVE OFFICES SHALL INCLUDE,  
42 BUT NOT BE LIMITED TO, RECORDS ROOMS AND PERSONNEL OFFICES.

- 1 2.3.3 EACH HEALTH CARE ENTITY THAT IS FEDERALLY CERTIFIED SHALL HAVE A STATE LICENSE FOR EACH CATEGORY  
2 OF SERVICES FOR WHICH IT IS CERTIFIED, IF SUCH A LICENSE CATEGORY EXISTS.
- 3 2.3.4 EFFECTIVE MARCH 1, 2010, ANY APPLICANT SEEKING AN INITIAL LICENSE TO PROVIDE SERVICES WITHIN THE  
4 SAME BUILDING AS ANOTHER LICENSED OR UNLICENSED OCCUPANCY, SHALL ENSURE THERE IS AN INTACT, TWO-  
5 HOUR FIRE RATED WALL, FLOOR OR CEILING ASSEMBLY BETWEEN IT AND EACH ADJOINING OCCUPANT.
- 6 2.3.5 EACH HEALTH CARE ENTITY APPLYING FOR A LICENSE SHALL USE A DISTINCTIVE NAME THAT ALSO CLEARLY  
7 IDENTIFIES THE SERVICES FOR WHICH IT WILL BE LICENSED. DUPLICATION OF AN EXISTING NAME IS PROHIBITED.
- 8 (A) EACH HEALTH CARE ENTITY SHALL BE IDENTIFIED BY THIS DISTINCTIVE NAME, USING CLEARLY VISIBLE  
9 SIGNAGE AT THE LOCATION, ON STATIONERY, BILLING MATERIALS AND ON ADVERTISEMENTS THAT  
10 IDENTIFY THE LICENSED ENTITY.
- 11 **2.4 INITIAL LICENSE APPLICATION PROCEDURE**
- 12 2.4.1 ANY PERSON OR ENTITY SEEKING A LICENSE TO OPERATE A HEALTH CARE ENTITY SHALL INITIALLY NOTIFY THE  
13 DEPARTMENT BY SUBMITTING A LETTER OF INTENT IN THE FORMAT SPECIFIED BY THE DEPARTMENT. SUCH  
14 NOTIFICATION SHALL INCLUDE THE PROPOSED NAME, LOCATION, LICENSE CATEGORY, SERVICES AND DATE OF  
15 OPENING OF SAID ENTITY. UPON RECEIPT OF THE LETTER OF INTENT, THE DEPARTMENT WILL PROVIDE THE  
16 APPLICANT WITH THE APPROPRIATE APPLICATION.
- 17 2.4.2 THE APPLICANT SHALL PROVIDE THE DEPARTMENT WITH A COMPLETE APPLICATION INCLUDING ALL INFORMATION  
18 AND ATTACHMENTS SPECIFIED IN THE APPLICATION FORM AND ANY ADDITIONAL INFORMATION REQUESTED BY  
19 THE DEPARTMENT. THE APPROPRIATE NON-REFUNDABLE FEE(S) FOR THE LICENSE CATEGORY REQUESTED  
20 SHALL BE SUBMITTED WITH THE APPLICATION, UNLESS PREVIOUSLY TENDERED IN CONNECTION WITH A PLAN  
21 REVIEW. APPLICATIONS SHALL BE SUBMITTED AT LEAST NINETY (90) DAYS BEFORE THE ANTICIPATED START-UP  
22 DATE.
- 23 2.4.3 EACH APPLICANT SHALL PROVIDE THE FOLLOWING INFORMATION:
- 24 (A) THE LEGAL NAME OF THE ENTITY AND ALL OTHER NAMES USED BY IT TO PROVIDE HEALTH CARE  
25 SERVICES. THE LEGAL NAME SHALL NOT BE CHANGED WITHOUT APPROVAL FROM THE DEPARTMENT.
- 26 (B) CONTACT INFORMATION FOR THE ENTITY INCLUDING MAILING ADDRESS, TELEPHONE AND FACSIMILE  
27 NUMBERS, E-MAIL ADDRESS AND, IF APPLICABLE, WEBSITE ADDRESS.
- 28 (C) THE IDENTITY OF ALL PERSONS AND BUSINESS ENTITIES WITH A CONTROLLING INTEREST IN THE HEALTH  
29 CARE ENTITY, INCLUDING ADMINISTRATORS, DIRECTORS, MANAGERS, MANAGEMENT CONTRACTORS AND  
30 HOLDING COMPANIES.
- 31 (1) A NON-PROFIT CORPORATION SHALL LIST THE GOVERNING BODY AND OFFICERS.
- 32 (2) A FOR-PROFIT CORPORATION SHALL LIST THE NAMES OF THE OFFICERS AND STOCKHOLDERS  
33 WHO DIRECTLY OR INDIRECTLY OWN OR CONTROL FIVE PERCENT OR MORE OF THE SHARES OF  
34 THE CORPORATION.
- 35 (3) A SOLE PROPRIETOR SHALL INCLUDE PROOF OF LAWFUL PRESENCE IN THE UNITED STATES IN  
36 COMPLIANCE WITH SECTION 24-76.5-101, *ET SEQ.*, C.R.S.
- 37 (D) THE NAME, HOME ADDRESS, AND BUSINESS TELEPHONE NUMBER OF EVERY PERSON IDENTIFIED IN  
38 2.4.3(C) AND THE INDIVIDUAL DESIGNATED BY THE APPLICANT AS THE CHIEF EXECUTIVE OFFICER OF  
39 THE ENTITY.
- 40 (E) PROOF OF PROFESSIONAL LIABILITY INSURANCE AS REQUIRED BY THE COLORADO HEALTH CARE  
41 AVAILABILITY ACT, SECTION 13-64-301, *ET SEQ.*, C.R.S., WITH THE DEPARTMENT IDENTIFIED AS A  
42 CERTIFICATE HOLDER. SUCH COVERAGE SHALL BE MAINTAINED FOR THE DURATION OF THE LICENSE

- 1 TERM AND THE DEPARTMENT SHALL BE NOTIFIED OF ANY CHANGE IN THE AMOUNT, TYPE OR PROVIDER  
2 OF PROFESSIONAL LIABILITY INSURANCE COVERAGE DURING THE LICENSE TERM.
- 3 (F) ARTICLES OF INCORPORATION, ARTICLES OF ORGANIZATION, PARTNERSHIP AGREEMENT, OR OTHER  
4 ORGANIZING DOCUMENTS REQUIRED BY THE SECRETARY OF STATE TO CONDUCT BUSINESS IN  
5 COLORADO; AND BY-LAWS OR EQUIVALENT DOCUMENTS THAT GOVERN THE RIGHTS, DUTIES AND  
6 CAPITAL CONTRIBUTIONS OF THE BUSINESS ENTITY.
- 7 (G) THE ADDRESS OF THE PHYSICAL LOCATION THAT IS TO CONSTITUTE THE ENTITY, TOGETHER WITH THE  
8 NAME(S) OF THE OWNER(S) OF EACH STRUCTURE.
- 9 (H) A MAP FOR EACH FLOOR OF THE HEALTH CARE ENTITY'S BUILDING INDICATING ROOM LAYOUT, LOCATION  
10 OF SERVICES TO BE PROVIDED, AND THE PROPOSED PHYSICAL EXTENT OF THE LICENSE WITHIN THE  
11 BUILDING. IF MULTIPLE BUILDINGS ARE INVOLVED, A MAP OF THE CAMPUS SHALL ALSO BE SUBMITTED.
- 12 (I) A COPY OF ANY MANAGEMENT AGREEMENT PERTAINING TO OPERATION OF THE ENTITY THAT SETS  
13 FORTH THE FINANCIAL AND ADMINISTRATIVE RESPONSIBILITIES OF EACH PARTY.
- 14 (J) IF AN APPLICANT LEASES ONE OR MORE BUILDING(S) TO OPERATE AS A LICENSED HEALTH CARE ENTITY,  
15 A COPY OF THE LEASE SHALL BE FILED WITH THE LICENSE APPLICATION AND SHOW CLEARLY IN ITS  
16 CONTEXT WHICH PARTY TO THE AGREEMENT IS TO BE HELD RESPONSIBLE FOR THE MAINTENANCE AND  
17 UPKEEP OF THE PROPERTY.
- 18 (K) A STATEMENT SIGNED AND DATED CONTEMPORANEOUS WITH THE APPLICATION STATING WHETHER ONE  
19 OR MORE INDIVIDUALS OR ENTITIES IDENTIFIED IN RESPONSE TO SECTION 2.4.3(C) AND (D) HAS A  
20 CONTROLLING OR OWNERSHIP INTEREST IN ANY TYPE OF HEALTH FACILITY AND HAS BEEN THE SUBJECT  
21 OF, OR A PARTY TO, ONE OF MORE OF THE FOLLOWING EVENTS, REGARDLESS OF WHETHER ACTION HAS  
22 BEEN STAYED IN A JUDICIAL APPEAL OR OTHERWISE SETTLED BETWEEN THE PARTIES.
- 23 (1) BEEN CONVICTED OF A FELONY UNDER THE LAWS OF ANY STATE OR OF THE UNITED STATES.  
24 A GUILTY VERDICT, A PLEA OF GUILTY OR A PLEA OF NOLO CONTENDERE (NO CONTEST)  
25 ACCEPTED BY THE COURT IS CONSIDERED A CONVICTION,
- 26 (2) A DISCIPLINARY ACTION IMPOSED UPON THE APPLICANT BY AN AGENCY IN ANOTHER  
27 JURISDICTION THAT REGISTERS OR LICENSES HEALTH FACILITIES INCLUDING, BUT NOT LIMITED  
28 TO, A CITATION, SANCTION, PROBATION, CIVIL PENALTY, OR A DENIAL, SUSPENSION,  
29 REVOCATION, OR MODIFICATION OF A LICENSE OR REGISTRATION WHETHER IT IS IMPOSED BY  
30 CONSENT DECREE, ORDER, OR OTHER DECISION, FOR ANY CAUSE OTHER THAN FAILURE TO  
31 PAY A LICENSE FEE BY THE DUE DATE;
- 32 (3) LIMITATION, REVOCATION OR SUSPENSION BY ANY STATE BOARD, MUNICIPALITY, FEDERAL OR  
33 STATE AGENCY OF ANY HEALTH CARE RELATED LICENSE,
- 34 (4) THE REFUSAL TO GRANT OR RENEW A LICENSE FOR OPERATION OF A HEALTH CARE ENTITY,  
35 CONTRACT FOR PARTICIPATION OR CERTIFICATION FOR MEDICAID, MEDICARE, OR OTHER  
36 PUBLIC HEALTH OR SOCIAL SERVICES PAYMENT PROGRAM; OR
- 37 (5) ANY JUDGMENT, AWARD OR SETTLEMENT OF A CIVIL ACTION OR ARBITRATION PROCEEDING IN  
38 WHICH THE APPLICANT WAS A PARTY, IF THE ACTION OR PROCEEDING INCLUDED ANY  
39 ALLEGATION OF GROSS NEGLIGENCE, VIOLATION OF SPECIFIC STANDARDS OF PRACTICE,  
40 FRAUD, OR MISAPPROPRIATION OF FUNDS.
- 41 (L) ANY STATEMENT REGARDING THE INFORMATION REQUESTED IN (K) SHALL INCLUDE THE FOLLOWING:
- 42 (1) IF THE EVENT IS AN ACTION BY A GOVERNMENTAL AGENCY (AS DESCRIBED ABOVE) THE NAME  
43 OF THE AGENCY, ITS JURISDICTION, THE CASE NAME, AND THE DOCKET, PROCEEDING OR CASE  
44 NUMBER BY WHICH THE EVENT IS DESIGNATED, AND A COPY OF THE CONSENT DECREE, ORDER  
45 OR DECISION.

- 1 (2) IF THE EVENT IS A FELONY CONVICTION, THE COURT, ITS JURISDICTION, THE CASE NAME, THE  
2 CASE NUMBER, A DESCRIPTION OF THE MATTER OR A COPY OF THE INDICTMENT OR CHARGES,  
3 AND ANY PLEA OR VERDICT ENTERED BY THE COURT.
- 4 (3) IF THE EVENT CONCERNS A CIVIL ACTION OR ARBITRATION PROCEEDING, THE COURT OR  
5 ARBITER, THE JURISDICTION, THE CASE NAME, THE CASE NUMBER, A DESCRIPTION OF THE  
6 MATTER OR A COPY OF THE COMPLAINT, AND A COPY OF THE VERDICT, THE COURT OR  
7 ARBITRATION DECISION, OR, IF SETTLED, THE SETTLEMENT AGREEMENT AND THE COURT'S  
8 ORDER OF DISMISSAL.
- 9 2.4.4 EACH APPLICATION SHALL BE SIGNED UNDER PENALTY OF PERJURY BY AN AUTHORIZED CORPORATE OFFICER,  
10 GENERAL PARTNER, OR SOLE PROPRIETOR OF THE APPLICANT AS APPROPRIATE.
- 11 2.4.5 FAILURE OF THE APPLICANT TO ACCURATELY ANSWER OR REPORT ANY OF THE INFORMATION REQUESTED BY  
12 THE DEPARTMENT SHALL BE CONSIDERED GOOD CAUSE TO DENY THE LICENSE APPLICATION.
- 13 2.4.6 THE DEPARTMENT SHALL CONDUCT A PRELIMINARY ASSESSMENT OF THE APPLICATION AND NOTIFY THE  
14 APPLICANT OF ANY APPLICATION DEFECTS.
- 15 (A) THE APPLICANT SHALL RESPOND WITHIN FOURTEEN (14) CALENDAR DAYS TO WRITTEN NOTICE OF ANY  
16 APPLICATION DEFECT.
- 17 2.4.7 A LICENSE APPLICATION SHALL BE CONSIDERED ABANDONED IF THE APPLICANT FAILS TO ADDRESS ALL  
18 APPLICATION DEFECTS WITHIN THE TIMEFRAMES ESTABLISHED BY THE DEPARTMENT AND MAY RESULT IN  
19 ADMINISTRATIVE CLOSURE OF THE APPLICATION PROCESS.
- 20 (A) AFTER AN ADMINISTRATIVE CLOSURE, THE APPLICANT MAY FILE A NEW LICENSE APPLICATION ALONG  
21 WITH THE CORRESPONDING INITIAL LICENSE FEE.
- 22 **2.5 PROVISIONAL LICENSES**
- 23 2.5.1 WHERE A HEALTH CARE ENTITY FAILS TO FULLY CONFORM TO THE APPLICABLE STATUTES AND REGULATIONS BUT  
24 THE DEPARTMENT DETERMINES THE ENTITY IS MAKING A SUBSTANTIAL GOOD FAITH ATTEMPT TO COMPLY, THE  
25 DEPARTMENT MAY REFUSE TO ISSUE AN INITIAL LICENSE AND INSTEAD GRANT THE APPLICANT A PROVISIONAL  
26 LICENSE UPON PAYMENT OF THE NON-REFUNDABLE PROVISIONAL LICENSE FEE.
- 27 2.5.2 A PROVISIONAL LICENSE SHALL BE VALID FOR NINETY (90) DAYS.
- 28 2.5.3 EXCEPT FOR ASSISTED LIVING FACILITIES, A SECOND PROVISIONAL LICENSE MAY BE ISSUED IF THE DEPARTMENT  
29 DETERMINES THAT SUBSTANTIAL PROGRESS CONTINUES TO BE MADE AND IT IS LIKELY COMPLIANCE CAN BE  
30 ACHIEVED BY THE DATE OF EXPIRATION OF THE SECOND PROVISIONAL LICENSE.
- 31 2.5.4 THE SECOND PROVISIONAL LICENSE SHALL BE ISSUED FOR THE SAME DURATION AS THE FIRST UPON PAYMENT  
32 OF A SECOND NON-REFUNDABLE PROVISIONAL LICENSE FEE.
- 33 2.5.5 DURING THE TERM OF THE PROVISIONAL LICENSE, THE DEPARTMENT SHALL CONDUCT ANY REVIEW IT DEEMS  
34 NECESSARY TO DETERMINE IF THE APPLICANT MEETS THE REQUIREMENTS FOR A REGULAR LICENSE.
- 35 2.5.6 IF THE DEPARTMENT DETERMINES, PRIOR TO EXPIRATION OF THE PROVISIONAL LICENSE, THAT THE APPLICANT  
36 HAS ACHIEVED REASONABLE COMPLIANCE, IT SHALL ISSUE A REGULAR LICENSE UPON PAYMENT OF THE  
37 APPLICABLE INITIAL LICENSE FEE. THE REGULAR LICENSE SHALL BE VALID FOR ONE YEAR FROM THE DATE OF  
38 ISSUANCE, UNLESS OTHERWISE ACTED UPON PURSUANT TO SECTION 2.9.3 OF THIS CHAPTER.
- 39 **2.6 RENEWAL APPLICATION PROCEDURE**
- 40 2.6.1 EXCEPT FOR THOSE RENEWAL APPLICANTS DESCRIBED IN PARAGRAPH (A) BELOW, A LICENSEE SEEKING TO  
41 RENEWAL SHALL PROVIDE THE DEPARTMENT WITH A LICENSE APPLICATION, SIGNED UNDER PENALTY OF PERJURY

- 1 BY AN AUTHORIZED CORPORATE OFFICER, GENERAL PARTNER, OR SOLE PROPRIETOR OF THE APPLICANT AS  
2 APPROPRIATE, CONTAINING THE INFORMATION REQUIRED IN SECTION 2.4.3 OF THIS CHAPTER AND THE  
3 APPROPRIATE FEE AT LEAST SIXTY (60) DAYS PRIOR TO THE EXPIRATION OF THE EXISTING LICENSE.
- 4 (A) IN ORDER TO COMPLY WITH COLORADO DIVISION OF INSURANCE RULE 2-1-1, A LICENSEE THAT HAS AN  
5 INSURANCE POLICY WITH ANY PORTION OF SELF-INSURED RETENTION OR ALTERNATE FORM OF  
6 SECURITY SHALL SUBMIT ITS LICENSE APPLICATION AND FEE TO THE DEPARTMENT AT LEAST NINETY (90)  
7 DAYS PRIOR TO THE EXPIRATION OF THE EXISTING LICENSE.
- 8 2.6.2 FAILURE TO SUBMIT A COMPLETED RENEWAL APPLICATION TO THE DEPARTMENT THIRTY (30) DAYS PRIOR TO  
9 EXPIRATION OF THE EXISTING LICENSE SHALL RESULT IN ASSESSMENT OF A LATE FEE IN AN AMOUNT EQUAL TO  
10 THE APPLICABLE RENEWAL FEE INCLUDING ANY BED FEES OR OPERATING/PROCEDURE ROOM FEES.
- 11 2.6.3 FAILURE OF THE LICENSEE TO ACCURATELY ANSWER OR REPORT ANY OF THE INFORMATION REQUESTED BY THE  
12 DEPARTMENT SHALL BE CONSIDERED GOOD CAUSE TO DENY THE LICENSE RENEWAL APPLICATION.
- 13 2.6.4 THE DEPARTMENT SHALL CONDUCT A PRELIMINARY ASSESSMENT OF THE RENEWAL APPLICATION AND NOTIFY  
14 THE LICENSEE OF ANY APPLICATION DEFECTS.
- 15 (A) THE APPLICANT SHALL RESPOND WITHIN FOURTEEN (14) CALENDAR DAYS TO WRITTEN NOTICE OF ANY  
16 APPLICATION DEFECT.
- 17 **2.7 CHANGE OF OWNERSHIP**
- 18 2.7.1 WHEN A CURRENTLY LICENSED HEALTH CARE ENTITY ANTICIPATES A CHANGE OF OWNERSHIP, THE CURRENT  
19 LICENSEE SHALL NOTIFY THE DEPARTMENT AT LEAST NINETY (90) DAYS BEFORE THE ANTICIPATED CHANGE OF  
20 OWNERSHIP AND THE PROSPECTIVE NEW LICENSEE SHALL SUBMIT AN INITIAL LICENSE APPLICATION ALONG WITH  
21 THE REQUISITE FEES AND DOCUMENTATION WITHIN THE SAME TIME FRAME.
- 22 2.7.2 THE DEPARTMENT SHALL CONSIDER ANY OF THE FOLLOWING CIRCUMSTANCES TO CONSTITUTE A CHANGE OF  
23 OWNERSHIP.
- 24 (A) PARTNERSHIPS: DISSOLUTION OF THE PARTNERSHIP AND CONVERSION THEREOF INTO ANY OTHER  
25 ENTITY OR THE SUBSTITUTION OR ATTEMPTED SUBSTITUTION OF ONE OR MORE OF THE PARTNERS.
- 26 (1) CHANGE OF OWNERSHIP DOES NOT INCLUDE DISSOLUTION OF THE PARTNERSHIP TO FORM A  
27 CORPORATION WITH THE SAME PERSONS RETAINING THE SAME SHARES OF OWNERSHIP IN THE  
28 NEW CORPORATION. FOR PURPOSES OF THIS SUBSECTION, "SUBSTITUTION" MEANS ANY  
29 ARRANGEMENT WHEREBY A PERSON OTHER THAN THE ORIGINAL PARTNER CAN PARTICIPATE IN  
30 THE MANAGEMENT OR ADMINISTRATION OF THE PARTNERSHIP BUSINESS OR AFFAIRS.
- 31 (B) SOLE PROPRIETORS: TRANSFER OF TITLE TO THE BUSINESS, WHETHER OR NOT TITLE TO REAL  
32 PROPERTY IS TRANSFERRED TO ANOTHER PERSON.
- 33 (1) CHANGE OF OWNERSHIP DOES NOT INCLUDE FORMING A CORPORATION FROM THE SOLE  
34 PROPRIETORSHIP WITH THE PROPRIETOR AS THE SOLE SHAREHOLDER.
- 35 (C) CORPORATIONS: CONSOLIDATION OF TWO OR MORE CORPORATIONS RESULTING IN THE CREATION OF  
36 A NEW CORPORATE ENTITY OR FORMATION OF A CORPORATION FROM A PARTNERSHIP OR A SOLE  
37 PROPRIETORSHIP EXCEPT AS PROVIDED IN SUBSECTIONS (A)(1) AND (B)(1) ABOVE.
- 38 (D) MANAGEMENT CONTRACTS, LEASES OR OTHER ARRANGEMENTS: ANY ACTION THAT RESULTS IN THE  
39 CURRENT LICENSEE RETAINING NO CONTROL OF THE OPERATION OR MANAGEMENT OF THE ENTITY.
- 40 (E) LIMITED LIABILITY COMPANIES: THE TRANSFER OF 50 PERCENT OR MORE OF THE OWNERSHIP INTEREST  
41 IN THE COMPANY WITH A 12-MONTH PERIOD OR THE TERMINATION OR DISSOLUTION OF THE LIMITED  
42 LIABILITY COMPANY IF THE ENTITY CONTINUES OPERATION AFTER SUCH TERMINATION OR DISSOLUTION  
43 AND THERE ARE CHANGES IN THE PRINCIPALS WITH OWNERSHIP INTEREST.

1 (1) CHANGE OF OWNERSHIP DOES NOT INCLUDE TRANSFERS OF OWNERSHIP INTEREST BETWEEN  
2 EXISTING MEMBERS IF THE TRANSACTION DOES NOT INVOLVE THE ACQUISITION OF OWNERSHIP  
3 INTEREST BY A NEW MEMBER. FOR THE PURPOSES OF THIS SUBSECTION, "MEMBER" MEANS A  
4 PERSON OR ENTITY WITH AN OWNERSHIP INTEREST IN THE LIMITED LIABILITY COMPANY.

5 2.7.3 THE EXISTING LICENSEE SHALL BE RESPONSIBLE FOR CORRECTING ALL RULE VIOLATIONS AND DEFICIENCIES IN  
6 ANY CURRENT PLAN OF CORRECTION BEFORE THE CHANGE OF OWNERSHIP BECOMES EFFECTIVE. IN THE EVENT  
7 THAT SUCH CORRECTIONS CANNOT BE ACCOMPLISHED IN THE TIME FRAME SPECIFIED, THE PROSPECTIVE  
8 LICENSEE SHALL BE RESPONSIBLE FOR ALL UNCORRECTED RULE VIOLATIONS AND DEFICIENCIES INCLUDING ANY  
9 CURRENT PLAN OF CORRECTION SUBMITTED BY THE PREVIOUS LICENSEE UNLESS THE PROSPECTIVE LICENSEE  
10 SUBMITS A REVISED PLAN OF CORRECTION, APPROVED BY THE DEPARTMENT, BEFORE THE CHANGE OF  
11 OWNERSHIP BECOMES EFFECTIVE.

12 2.7.4 IF THE DEPARTMENT ISSUES A LICENSE TO THE NEW OWNER, THE PREVIOUS OWNER SHALL RETURN ITS LICENSE  
13 TO THE DEPARTMENT WITHIN FIVE CALENDAR DAYS OF THE NEW OWNER'S RECEIPT OF ITS LICENSE.

## 14 2.8 FITNESS REVIEW PROCESS

15 2.8.1 UPON RECEIPT OF ANY COMPLETED LICENSE APPLICATION, THE DEPARTMENT SHALL CONDUCT A REVIEW TO  
16 DETERMINE THE APPLICANT'S FITNESS TO CONDUCT AND MAINTAIN A LICENSED OPERATION. THE DEPARTMENT  
17 SHALL CONSIDER ALL INFORMATION SUBMITTED WITH THE APPLICATION. THE DEPARTMENT MAY ALSO CONSIDER  
18 OTHER INFORMATION INCLUDING, BUT NOT LIMITED TO, THE FOLLOWING:

19 (A) WHETHER THE APPLICANT HAS LEGAL CAPACITY TO PROVIDE THE SERVICES FOR WHICH THE LICENSE IS  
20 SOUGHT,

21 (B) WHETHER THE APPLICANT'S FINANCIAL RESOURCES AND SOURCES OF REVENUE APPEAR ADEQUATE TO  
22 PROVIDE STAFF, SERVICES, AND THE PHYSICAL ENVIRONMENT SUFFICIENT TO COMPLY WITH THE  
23 APPLICABLE STATE STATUTES AND REGULATIONS. SUCH AN INQUIRY MAY INCLUDE AN APPLICANT'S  
24 CREDIT REPORT.

25 (C) THE APPLICANT'S PREVIOUS COMPLIANCE HISTORY;

26 (D) REVIEW OF THE APPLICANT'S POLICIES AND PROCEDURES;

27 (E) REVIEW OF THE APPLICANT'S QUALITY IMPROVEMENT PLANS, OTHER QUALITY IMPROVEMENT  
28 DOCUMENTATION AS MAY BE APPROPRIATE, AND ACCREDITATION REPORTS;

29 (F) PHYSICAL INSPECTION OF THE ENTITY;

30 (G) CREDENTIALS OF STAFF;

31 (H) INTERVIEWS WITH STAFF; AND

32 (J) OTHER DOCUMENTS DEEMED APPROPRIATE BY THE DEPARTMENT.

## 33 2.9 ISSUANCE OF LICENSE

34 2.9.1 NO LICENSE SHALL BE ISSUED UNTIL THE APPLICANT CONFORMS TO ALL APPLICABLE STATUTES AND  
35 REGULATIONS.

36 2.9.2 EACH LICENSE SHALL CONTAIN THE NAME OF THE HEALTH CARE ENTITY, LICENSE CATEGORY, TERM OF LICENSE,  
37 HOLDER OF LICENSE AND THE LICENSED CAPACITY. EACH DIALYSIS TREATMENT CLINIC AND AMBULATORY  
38 SURGICAL CENTER SHALL BE LICENSED FOR ITS MAXIMUM OPERATIONAL CAPACITY AS DETERMINED BY THE  
39 DEPARTMENT. NO PERSON SHALL ADMIT A PATIENT OR RESIDENT TO A HEALTH CARE ENTITY IF SUCH ADMISSION  
40 WOULD EXCEED THE ENTITY'S LICENSED CAPACITY.

- 1 (A) IF THE ENTITY HAS THE PHYSICAL SPACE AND STAFF CAPACITY TO MEET THE NEEDS OF AN ADDITIONAL  
2 PATIENT OR RESIDENT, THE DEPARTMENT MAY, UPON REQUEST, ALLOW ADMISSION ABOVE THE  
3 LICENSED CAPACITY FOR NO LONGER THAN ONE MONTH IF THE PATIENT OR RESIDENT REQUIRES  
4 IMMEDIATE ADMISSION AND THE DEPARTMENT DETERMINES THAT THERE IS NO CONVENIENT  
5 ALTERNATIVE SOURCE OF ADMISSION.
- 6 2.9.3 A LICENSE ISSUED BY THE DEPARTMENT MAY BE REVOKED, SUSPENDED, ANNULLED, LIMITED, OR MODIFIED AT  
7 ANY TIME DURING THE LICENSE TERM BECAUSE OF A LICENSEE'S FAILURE TO COMPLY WITH ANY OF THE  
8 APPLICABLE STATUTES OR REGULATIONS, OR TO MAKE THE REPORTS REQUIRED BY SECTION 25-3-104, C.R.S.  
9 UNLESS CONSENTED TO BY THE APPLICANT, A LIMITATION IMPOSED PRIOR TO ISSUANCE OF AN INITIAL OR  
10 RENEWAL LICENSE SHALL BE TREATED AS A DENIAL. A MODIFICATION OF AN EXISTING LICENSE DURING ITS TERM,  
11 UNLESS CONSENTED TO BY THE LICENSEE, SHALL BE TREATED AS A REVOCATION.
- 12 2.9.4 THE DEPARTMENT MAY IMPOSE CONDITIONS UPON A LICENSE PRIOR TO ISSUING AN INITIAL OR RENEWAL LICENSE  
13 OR DURING AN EXISTING LICENSE TERM. IF THE DEPARTMENT IMPOSES CONDITIONS ON A LICENSE, THE  
14 LICENSEE SHALL IMMEDIATELY COMPLY WITH ALL CONDITIONS UNTIL AND UNLESS SAID CONDITIONS ARE  
15 OVERTURNED OR STAYED ON APPEAL.
- 16 (A) IF CONDITIONS ARE IMPOSED AT THE SAME TIME AS AN INITIAL OR RENEWAL LICENSE, THE APPLICANT  
17 SHALL PAY THE APPLICABLE INITIAL OR RENEWAL LICENSE FEE PLUS THE CONDITIONAL FEE. IF  
18 CONDITIONS ARE IMPOSED DURING THE LICENSE TERM, THE LICENSEE SHALL PAY THE CONDITIONAL FEE  
19 AND THE CONDITIONS SHALL RUN CONCURRENTLY WITH THE EXISTING LICENSE TERM. IF THE  
20 CONDITIONS ARE RENEWED IN WHOLE OR IN PART FOR THE NEXT LICENSE TERM, THE LICENSEE SHALL  
21 PAY THE APPLICABLE RENEWAL FEE ALONG WITH THE CONDITIONAL FEE IN EFFECT AT THE TIME OF  
22 RENEWAL.
- 23 (B) IF THE DEPARTMENT IMPOSES A CONDITION OF CONTINUING DURATION THAT REQUIRES ONLY MINIMAL  
24 ADMINISTRATIVE OVERSIGHT, IT MAY WAIVE THE CONDITIONAL FEE AFTER THE LICENSEE HAS COMPLIED  
25 WITH THE CONDITION FOR A FULL LICENSE TERM.
- 26 2.9.5 IF A LICENSEE HOLDS A CONDITIONAL LICENSE, IT SHALL POST A CLEARLY LEGIBLE COPY OF THE LICENSE  
27 CONDITIONS IN A CONSPICUOUS PUBLIC PLACE IN THE HEALTH CARE ENTITY AND SHALL INFORM ANY POTENTIAL  
28 PATIENT, RESIDENT, CONSUMER OR AUTHORIZED REPRESENTATIVE ABOUT THE CONDITIONS BEFORE ENTERING  
29 INTO A SERVICE OR ADMISSION AGREEMENT WITH THAT INDIVIDUAL.
- 30 2.9.6 THE HOLDER OF EACH LICENSE OR CERTIFICATE OF COMPLIANCE ISSUED BY THE DEPARTMENT SHALL  
31 SURRENDER THE LICENSE OR CERTIFICATE WITHIN FIVE CALENDAR DAYS OF NON-RENEWAL, DISCONTINUANCE  
32 OF THE OPERATION OR FINAL AGENCY ACTION SUSPENDING OR REVOKING THE LICENSE OF THE HEALTH CARE  
33 ENTITY.
- 34 2.9.7 EACH HEALTH CARE ENTITY THAT SURRENDERS ITS LICENSE OR CERTIFICATE SHALL:
- 35 (A) INFORM ALL PATIENTS, RESIDENTS, CONSUMERS OR AUTHORIZED REPRESENTATIVES THEREOF, IN  
36 WRITING HOW AND WHERE TO OBTAIN THEIR INDIVIDUAL RECORDS; AND
- 37 (B) PROVIDE SECURE STORAGE FOR ANY REMAINING PATIENT, RESIDENT OR CONSUMER RECORDS.
- 38 **2.10 CONTINUING OBLIGATIONS OF LICENSEE**
- 39 2.10.1 EACH LICENSEE SHALL HAVE AND MAINTAIN ELECTRONIC BUSINESS COMMUNICATION TOOLS, INCLUDING, BUT  
40 NOT LIMITED TO, A FACSIMILE MACHINE, INTERNET ACCESS AND A VALID E-MAIL ADDRESS. THE LICENSEE SHALL  
41 USE THESE TOOLS TO RECEIVE AND SUBMIT INFORMATION, AS REQUIRED BY THE DEPARTMENT.
- 42 2.10.2 THE LICENSE SHALL BE DISPLAYED IN A CONSPICUOUS PLACE READILY VISIBLE TO PATIENTS, RESIDENTS OR  
43 CLIENTS WHO ENTER AT THE ADDRESS THAT APPEARS ON THE LICENSE. THE LICENSE IS ONLY VALID WHILE IN  
44 THE POSSESSION OF THE LICENSEE TO WHOM IT IS ISSUED AND SHALL NOT BE SUBJECT TO SALE, ASSIGNMENT  
45 OR OTHER TRANSFER, VOLUNTARY OR INVOLUNTARY, NOR SHALL A LICENSE BE VALID FOR ANY PREMISES OTHER  
46 THAN THOSE FOR WHICH IT WAS ORIGINALLY ISSUED.

1 2.10.3 THE LICENSEE SHALL PROVIDE, UPON REQUEST, ACCESS TO SUCH INDIVIDUAL PATIENT, RESIDENT, CLIENT OR  
2 CONSUMER RECORDS AS THE DEPARTMENT REQUIRES FOR THE PERFORMANCE OF ITS REGULATORY OVERSIGHT  
3 RESPONSIBILITIES.

4 (A) A LICENSEE SHALL PROVIDE, UPON REQUEST, ACCESS TO OR COPIES OF REPORTS AND INFORMATION  
5 REQUIRED BY THE DEPARTMENT INCLUDING, BUT NOT LIMITED TO, STAFFING REPORTS, CENSUS DATA,  
6 STATISTICAL INFORMATION, AND SUCH BUSINESS RECORDS AS THE DEPARTMENT REQUIRES FOR THE  
7 PERFORMANCE OF ITS REGULATORY OVERSIGHT RESPONSIBILITIES.

8 (B) THE DEPARTMENT SHALL NOT RELEASE TO ANY UNAUTHORIZED PERSON ANY INFORMATION DEFINED AS  
9 CONFIDENTIAL UNDER STATE LAW.

10 2.10.4 WHERE A LICENSED HEALTH CARE ENTITY IS SUBJECT TO INSPECTION, CERTIFICATION, OR REVIEW BY OTHER  
11 AGENCIES, ACCREDITING ORGANIZATION, OR INSPECTING COMPANIES, THE LICENSEE SHALL PROVIDE AND/OR  
12 RELEASE TO THE DEPARTMENT, UPON REQUEST, ANY CORRESPONDENCE, REPORTS OR RECOMMENDATIONS  
13 CONCERNING THE LICENSEE THAT WERE PREPARED BY SUCH ORGANIZATIONS.

14 2.10.5 EACH LICENSEE SHALL NOTIFY THE DEPARTMENT IN WRITING OF ANY CHANGE IN THE INFORMATION REQUIRED  
15 BY SECTION 2.4.3 OF THIS CHAPTER FROM WHAT WAS CONTAINED IN THE LAST SUBMITTED LICENSE  
16 APPLICATION. EXCEPT FOR THE OPERATIONAL CHANGES THAT REQUIRE DEPARTMENT APPROVAL AS SET FORTH  
17 IN PARAGRAPH (A) BELOW, THE LICENSEE SHALL NOTIFY THE DEPARTMENT OF ALL CHANGES IN INFORMATION AS  
18 SOON AS PRACTICABLE, BUT NO LATER THAN TEN (10) DAYS AFTER THE CHANGE BECOMES EFFECTIVE.

19 (A) THE FOLLOWING CHANGES TO THE OPERATION OF THE LICENSED HEALTH CARE ENTITY SHALL NOT BE  
20 IMPLEMENTED WITHOUT PRIOR APPROVAL FROM THE DEPARTMENT. A LICENSEE SHALL, AT LEAST  
21 THIRTY (30) DAYS IN ADVANCE, SUBMIT A WRITTEN REQUEST TO THE DEPARTMENT REGARDING ANY OF  
22 THESE PROPOSED CHANGES.

23 (1) INCREASE OR DECREASE IN LICENSED CAPACITY.

24 (A) IF A LICENSEE REQUESTS AN INCREASE IN LICENSED CAPACITY THAT IS APPROVED BY  
25 THE DEPARTMENT, A NEW LICENSE TERM SHALL COMMENCE AND A NEW LICENSE  
26 SHALL BE ISSUED UPON PAYMENT OF THE APPLICABLE LICENSE RENEWAL FEE  
27 INCLUDING ANY BED FEES OR OPERATING/PROCEDURE ROOM FEES.

28 (2) CHANGE IN MANAGEMENT COMPANY OR PROPOSED USE OF MANAGEMENT AGREEMENT NOT  
29 PREVIOUSLY DISCLOSED IN SECTION 2.4.3.

30 (3) CHANGE IN LEGAL NAME OR ANY OTHER NAME USED BY THE HEALTH CARE ENTITY TO PROVIDE  
31 SERVICES.

32 (4) CHANGE IN LICENSE CATEGORY OR CLASSIFICATION.

## 33 **2.11 DEPARTMENT OVERSIGHT**

34 2.11.1 THE DEPARTMENT AND ANY DULY AUTHORIZED REPRESENTATIVES THEREOF SHALL HAVE THE RIGHT TO ENTER  
35 UPON AND INTO THE PREMISES OF ANY LICENSEE OR APPLICANT FOR A LICENSE IN ORDER TO DETERMINE THE  
36 STATE OF COMPLIANCE WITH THE LAW AND REGULATIONS, AND SHALL INITIALLY IDENTIFY THEMSELVES TO THE  
37 PERSON IN CHARGE OF THE HEALTH CARE ENTITY AT THE TIME.

38 (A) IN ACCORDANCE WITH SECTION 25-1.5-103, C.R.S., ROUTINE UNANNOUNCED ONSITE INSPECTIONS  
39 SHALL BE MADE ONLY BETWEEN THE HOURS OF 7 A.M. AND 7 P.M.

40 2.11.2 IF THE DEPARTMENT HAS INFORMATION ABOUT AN APPLICANT OR LICENSEE OR ITS EMPLOYEES OR MANAGERS  
41 THAT HAS BEEN ACQUIRED IN THE CONTEXT OF A DEPARTMENT REVIEW, AND PROVIDES SUCH INFORMATION TO  
42 ANY STATE OR FEDERAL AGENCY THAT MAY HAVE A STATUTORY OR REGULATORY INTEREST IN THE ENTITY OR ITS  
43 EMPLOYEES, THE DEPARTMENT SHALL ALSO FORWARD TO THE OTHER AGENCY ANY RESPONSES IT HAS  
44 RECEIVED FROM THE LICENSEE OR APPLICANT TO THE MATTER UNDER REVIEW, IF APPLICABLE.

1 2.11.3 THE DEPARTMENT MAY USE THE FOLLOWING MEASURES TO ENSURE A LICENSEE'S FULL COMPLIANCE WITH THE  
2 APPLICABLE STATUTORY AND REGULATORY CRITERIA.

3 (A) UNSCHEDULED OR UNANNOUNCED REVIEWS.

4 THE DEPARTMENT MAY CONDUCT AN UNSCHEDULED OR UNANNOUNCED REVIEW OF A CURRENT LICENSEE BASED  
5 UPON, BUT NOT LIMITED TO, THE FOLLOWING CRITERIA:

6 (1) ROUTINE COMPLIANCE INSPECTION.

7 (2) REASONABLE CAUSE TO QUESTION THE APPLICANT'S CONTINUED FITNESS TO CONDUCT OR  
8 MAINTAIN LICENSED OPERATIONS.

9 (3) A COMPLAINT ALLEGING NON-COMPLIANCE WITH LICENSE REQUIREMENTS,

10 (4) DISCOVERY OF PREVIOUSLY UNDISCLOSED INFORMATION REGARDING A LICENSEE OR ANY OF  
11 ITS OWNERS, OFFICERS, MANAGERS OR OTHER EMPLOYEES IF SUCH INFORMATION AFFECTS OR  
12 HAS THE POTENTIAL TO AFFECT THE LICENSEE'S PROVISION OF CARE, OR

13 (5) THE OMISSION OF RELEVANT INFORMATION FROM DOCUMENTS REQUESTED BY THE  
14 DEPARTMENT OR INDICATION OF FALSE INFORMATION SUBMITTED TO THE DEPARTMENT.

15 (B) PLAN OF CORRECTION

16 AFTER ANY DEPARTMENTAL REVIEW, THE DEPARTMENT MAY REQUEST A PLAN OF CORRECTION FROM A  
17 LICENSEE OR REQUIRE A LICENSEE'S COMPLIANCE WITH A DEPARTMENT DIRECTED PLAN OF CORRECTION.

18 (1) THE PLAN OF CORRECTION SHALL BE IN THE FORMAT SPECIFIED BY THE DEPARTMENT AND  
19 INCLUDE, BUT NOT BE LIMITED TO, THE FOLLOWING:

20 (A) A DESCRIPTION OF HOW THE LICENSEE WILL CORRECT EACH IDENTIFIED DEFICIENCY,

21 (B) A DESCRIPTION OF HOW THE LICENSEE WILL MONITOR THE CORRECTIVE ACTION TO  
22 ENSURE EACH DEFICIENCY IS REMEDIED AND WILL NOT RECUR, AND

23 (C) A TIMELINE WITH THE EXPECTED IMPLEMENTATION AND COMPLETION DATE. THE  
24 COMPLETION DATE IS THE DATE THAT THE ENTITY DEEMS IT CAN ACHIEVE  
25 COMPLIANCE.

26 (i) THE IMPLEMENTATION DATE SHALL BE NO LONGER THAN THIRTY (30)  
27 CALENDAR DAYS FROM THE DATE OF THE MAILING OF THE DEFICIENCY TO THE  
28 LICENSEE, UNLESS OTHERWISE REQUIRED OR APPROVED BY THE  
29 DEPARTMENT.

30 (2) A COMPLETED PLAN OF CORRECTION SHALL BE:

31 (A) SIGNED BY THE LICENSEE'S DIRECTOR, ADMINISTRATOR OR MANAGER, AND

32 (B) SUBMITTED TO THE DEPARTMENT WITHIN TEN (10) CALENDAR DAYS AFTER THE DATE  
33 OF THE DEPARTMENT'S WRITTEN NOTICE OF DEFICIENCIES.

34 (i) IF AN EXTENSION OF TIME IS NEEDED TO COMPLETE THE PLAN OF  
35 CORRECTION, THE LICENSEE SHALL REQUEST AN EXTENSION IN WRITING  
36 FROM THE DEPARTMENT PRIOR TO THE PLAN OF CORRECTION DUE DATE.  
37 THE DEPARTMENT MAY GRANT AN EXTENSION OF TIME.

- 1 (3) THE DEPARTMENT HAS DISCRETION TO APPROVE, IMPOSE, MODIFY OR REJECT A PLAN OF  
2 CORRECTION.
- 3 (A) IF THE PLAN OF CORRECTION IS ACCEPTED, THE DEPARTMENT SHALL NOTIFY THE  
4 ENTITY BY ISSUING A WRITTEN NOTICE OF ACCEPTANCE.
- 5 (B) IF THE PLAN OF CORRECTION IS UNACCEPTABLE, THE DEPARTMENT SHALL NOTIFY THE  
6 LICENSEE IN WRITING, AND THE LICENSEE SHALL RE-SUBMIT THE CHANGES WITHIN THE  
7 TIMEFRAME PRESCRIBED BY THE DEPARTMENT.
- 8 (C) IF THE LICENSEE FAILS TO COMPLY WITH THE REQUIREMENTS OR DEADLINES FOR  
9 SUBMISSION OF A PLAN OR FAILS TO SUBMIT REQUESTED CHANGES TO THE PLAN, THE  
10 DEPARTMENT MAY REJECT THE PLAN OF CORRECTION AND IMPOSE DISCIPLINARY  
11 SANCTIONS AS SET FORTH BELOW.
- 12 (D) IF THE LICENSEE FAILS TO IMPLEMENT THE ACTIONS AGREED TO BY THE CORRECTION  
13 DATE IN THE APPROVED PLAN OF CORRECTION, THE DEPARTMENT MAY IMPOSE  
14 DISCIPLINARY SANCTIONS AS SET FORTH BELOW.

## 15 **2.12 ENFORCEMENT AND DISCIPLINARY SANCTIONS**

### 16 LICENSE DENIALS

17 2.12.1 THE DEPARTMENT MAY DENY AN APPLICATION FOR A NEW OR RENEWAL LICENSE FOR REASONS INCLUDING, BUT  
18 NOT LIMITED TO, THE FOLLOWING:

- 19 (A) THE APPLICANT HAS NOT FULLY COMPLIED WITH ALL LOCAL, STATE AND FEDERAL LAWS AND  
20 REGULATIONS APPLICABLE TO THAT LICENSE CATEGORY OR CLASSIFICATION,
- 21 (B) THE APPLICATION OR ACCOMPANYING DOCUMENTS CONTAIN A FALSE STATEMENT OF MATERIAL FACT,
- 22 (C) THE APPLICANT FAILS TO RESPOND IN A TIMELY MANNER TO DEPARTMENTAL REQUESTS FOR  
23 ADDITIONAL INFORMATION,
- 24 (D) THE APPLICANT REFUSES ANY PART OF AN ON-SITE OR OFF-SITE INSPECTION,
- 25 (E) THE APPLICANT FAILS TO COMPLY WITH OR SUCCESSFULLY COMPLETE AN ACCEPTABLE PLAN OF  
26 CORRECTION,
- 27 (F) THE APPLICANT HAS FAILED TO COOPERATE WITH THE INVESTIGATION OF ANY LOCAL, STATE OR  
28 FEDERAL REGULATORY BODY, OR
- 29 (G) THE APPLICANT IS NOT IN COMPLIANCE WITH REGULATORY REQUIREMENTS OR HAS A DOCUMENTED  
30 PATTERN OF NON-COMPLIANCE THAT HAS HARMED OR HAS THE POTENTIAL TO HARM THE HEALTH OR  
31 SAFETY OF THE INDIVIDUAL(S) SERVED.

32 2.12.2 IF THE DEPARTMENT DENIES AN APPLICATION FOR A NEW OR RENEWAL LICENSE, IT SHALL PROVIDE THE  
33 APPLICANT WITH A WRITTEN NOTICE EXPLAINING THE BASIS FOR THE DENIAL AND AFFORDING THE APPLICANT OR  
34 LICENSEE THE OPPORTUNITY TO RESPOND AND COMPLY WITH ALL LICENSING REQUIREMENTS WITHIN THE  
35 SPECIFIED TIMEFRAME.

36 2.12.3 APPEALS OF LICENSURE DENIALS SHALL BE CONDUCTED IN ACCORDANCE WITH THE STATE ADMINISTRATIVE  
37 PROCEDURE ACT, SECTION 24-4-101, *ET SEQ.* C.R.S.

### 38 REVOCATION OR SUSPENSION OF A LICENSE

- 1 2.12.4 THE DEPARTMENT MAY REVOKE OR SUSPEND AN EXISTING LICENSE FOR GOOD CAUSE INCLUDING, BUT NOT  
2 LIMITED TO, CIRCUMSTANCES IN WHICH AN OWNER, OFFICER, DIRECTOR, MANAGER, ADMINISTRATOR, OR OTHER  
3 EMPLOYEE OF THE LICENSEE:
- 4 (A) FAILS OR REFUSES TO COMPLY WITH THE STATUTORY AND/OR REGULATORY REQUIREMENTS  
5 APPLICABLE TO THAT LICENSE TYPE;
- 6 (B) MAKES A FALSE STATEMENT OF MATERIAL FACT ABOUT INDIVIDUALS SERVED BY THE LICENSEE, ITS  
7 STAFF, CAPACITY, OR OTHER OPERATIONAL COMPONENTS VERBALLY OR IN ANY PUBLIC DOCUMENT OR  
8 IN A MATTER UNDER INVESTIGATION BY THE DEPARTMENT OR ANOTHER GOVERNMENTAL ENTITY.
- 9 (C) PREVENTS, INTERFERES WITH, OR ATTEMPTS TO IMPEDE IN ANY WAY THE WORK OF A REPRESENTATIVE  
10 OR AGENT OF THE DEPARTMENT IN INVESTIGATING OR ENFORCING THE APPLICABLE STATUTES OR  
11 REGULATIONS.
- 12 (D) FALSELY ADVERTISES OR IN ANY WAY MISREPRESENTS THE LICENSEE'S ABILITY TO CARE FOR THE  
13 INDIVIDUALS SERVED BASED ON ITS LICENSE TYPE OR STATUS.
- 14 (E) FAILS TO PROVIDE REPORTS AND DOCUMENTS REQUIRED BY REGULATION OR STATUTE IN A TIMELY AND  
15 COMPLETE FASHION, OR
- 16 (F) FAILS TO COMPLY WITH OR COMPLETE A PLAN OF CORRECTION IN THE TIME OR MANNER SPECIFIED.
- 17 (G) FALSIFICATION OF RECORDS OR DOCUMENTS.

18 2.12.5 IF THE DEPARTMENT REVOKES OR SUSPENDS A LICENSE, IT SHALL PROVIDE THE LICENSEE WITH A NOTICE  
19 EXPLAINING THE BASIS FOR THE ACTION. THE NOTICE SHALL ALSO INFORM THE LICENSEE OF ITS RIGHT TO  
20 APPEAL AND THE PROCEDURE FOR APPEALING THE ACTION.

21 2.12.6 APPEALS OF DEPARTMENT REVOCATIONS OR SUSPENSIONS SHALL BE CONDUCTED IN ACCORDANCE WITH THE  
22 STATE ADMINISTRATIVE PROCEDURE ACT, SECTION 24-4-101, *ET SEQ.*, C.R.S.

### 23 SUMMARY SUSPENSION OF A LICENSE

24 2.12.7 NOTWITHSTANDING OTHER REMEDIES AVAILABLE UNDER STATE LAW, THE DEPARTMENT MAY SUMMARILY  
25 SUSPEND A LICENSE PENDING PROCEEDINGS FOR REVOCATION OR REFUSAL TO RENEW A LICENSE IN CASES OF  
26 DELIBERATE OR WILLFUL VIOLATION OF APPLICABLE STATUTES AND REGULATIONS OR WHERE THE PUBLIC  
27 HEALTH, SAFETY OR WELFARE IMPERATIVELY REQUIRES EMERGENCY ACTION.

28 2.12.8 FOR PURPOSES OF THIS CHAPTER, DELIBERATE AND WILLFUL CONDUCT MAY BE SHOWN BY INTENTIONAL  
29 CONDUCT OR BY A PATTERN OR PRACTICE OF REPEATED, IDENTICAL OR SIMILAR VIOLATIONS.

30 2.12.9 SUMMARY SUSPENSION OF ANY LICENSE SHALL BE BY ORDER OF THE EXECUTIVE DIRECTOR OF THE  
31 DEPARTMENT OR AUTHORIZED DESIGNEE AND SHALL COMPLY WITH THE REQUIREMENTS OF SECTION 24-4-104,  
32 C.R.S.

33 2.12.10 APPEALS OF SUMMARY SUSPENSIONS SHALL BE CONDUCTED IN ACCORDANCE WITH THE STATE ADMINISTRATIVE  
34 PROCEDURE ACT, SECTION 24-4-101, *ET SEQ.*, C.R.S.

### 35 **2.13 LICENSE FEES**

36 UNLESS EXPLICITLY SET FORTH ELSEWHERE IN 6 CCR 1011-1 OR STATUTE, THE FOLLOWING NON-REFUNDABLE FEES  
37 SHALL APPLY AND BE SUBMITTED TO THE DEPARTMENT WITH THE CORRESPONDING APPLICATION OR NOTIFICATION.  
38 **MORE THAN ONE FEE MAY APPLY DEPENDING UPON THE CIRCUMSTANCES.**

39

INITIAL LICENSE	\$360
RENEWAL LICENSE	\$360
CONDITIONAL LICENSE	\$1,500
FIRST PROVISIONAL LICENSE	\$1,000
SECOND PROVISIONAL LICENSE	\$1,000
CHANGE OF OWNERSHIP	\$360
CHANGE OF HEALTH CARE ENTITY NAME	\$360
RENEWAL APPLICATION LATE FEE	EQUAL TO THE APPLICABLE RENEWAL LICENSE FEE INCLUDING BED FEES OR OPERATING/PROCEDURE ROOM FEES.

1 **PART 3. QUALITY MANAGEMENT**

2 3.2 **OCCURENCE** Reporting. Notwithstanding any other reporting required by state law or regulation, each  
3 health **facility** CARE ENTITY LICENSED PURSUANT TO 25-1.5-103 shall report to the Department the  
4 occurrences specified at 25-1-124 (2) C.R.S. *{Explanation: clarifies that home care agencies are also*  
5 *required to conduct occurrence reporting in accordance with statute.}*

6 3.2.1 The following occurrences shall be reported to the department **by telephone IN THE FORMAT**  
7 **REQUIRED BY THE DEPARTMENT** by the next business day after the occurrence or the **facility**  
8 **HEALTH CARE ENTITY** becomes aware of the occurrence:

9 (1) Any occurrence that results in the death of a patient or resident of the **facility** HEALTH  
10 CARE ENTITY and is required to be reported to the coroner pursuant to section ~~3-10-606,~~  
11 **30-10-606**, C.R.S., as arising from an unexplained cause or under suspicious  
12 circumstances; *{Explanation: the existing statutory reference has a typographical*  
13 *error.}*

14 ...

15

16 (3) Any time that a resident or patient of the **facility** HEALTH CARE ENTITY cannot be located  
17 following a search of **the facility** HEALTH CARE ENTITY, the **facility** HEALTH CARE ENTITY  
18 grounds, and the area surrounding the **facility** HEALTH CARE ENTITY and there are  
19 circumstances that place the resident's health, safety, or welfare at risk or, regardless of  
20 whether such circumstances exist, the patient or resident has been missing for eight  
21 hours;

22 (4) Any occurrence involving physical, sexual, or verbal abuse of a patient or resident, as  
23 described in section 18-3-202, 18-3-203, 18-3-204, 18-3-206, 18-3-402, 18-3-403, 18-3-  
24 404, or 18-3-405, C.R.S., by another patient or resident, an employee of the **facility**  
25 HEALTH CARE ENTITY or a visitor to the **facility** HEALTH CARE ENTITY,

26 ...

27 (6) Any occurrence involving misappropriation of a patient's or resident's property. For  
28 purposes of this paragraph ~~(f)~~, "misappropriation of a patient's or resident's property"  
29 means a pattern of or deliberately misplacing, exploiting, or wrongfully using, either  
30 temporarily or permanently, a patient's or resident's belongings or money without the  
31 patient's or resident's consent. *{Explanation: paragraph "f" was renumbered to*  
32 *paragraph "6" but the internal reference was not changed.}*

33 ...

34 (8) Any occurrence involving the malfunction or intentional or accidental misuse of patient  
35 or resident care equipment that occurs during treatment or diagnosis of a patient or  
36 resident and that significantly adversely affects or if not averted would have significantly  
37 adversely affected a patient or resident of the **facility** HEALTH CARE ENTITY.

38 ...

39 3.2.5 Every health **facility** HEALTH CARE ENTITY shall have a policy that defines the deaths reportable  
40 to the local county coroner under 30-10-606(1), C.R.S. (1977) and that is consistent with the  
41 local coroner's reporting policy.

- 1 3.2.6 Every health **facility HEALTH CARE ENTITY** shall have a policy for requiring its employees to  
2 report occurrences to it.
- 3 3.2.7 No health **facility HEALTH CARE ENTITY** or officer or employee thereof shall discharge or in any  
4 manner discriminate or retaliate against any patient or resident of a **facility HEALTH CARE ENTITY**,  
5 relative or sponsor thereof, employee of the **facility HEALTH CARE ENTITY**, or any other person  
6 because such person, relative, legal representative, sponsor, or employee has made in good  
7 faith or is about to make in good faith, a report pursuant to this section 3.2 or has provided in  
8 good faith or is about to provide in good faith evidence in any proceeding or investigation  
9 relating to any occurrence required to be reported by a health **facility HEALTH CARE ENTITY**.
- 10 3.2.9 The department shall investigate all reports made to it under this part, and make a summary  
11 report.
- 12 (1) Such report shall include: (a) a summary of finding(s) including the department's  
13 conclusion(s); (b) whether any violation of licensing standards was noted or whether a  
14 deficiency notice was issued; (c) whether the **facility HEALTH CARE ENTITY** acted  
15 appropriately in response to the occurrence, and (d) if the investigation was not  
16 conducted on site, how the investigation was conducted.
- 17 ...
- 18 (4) Prior to releasing a summary report that identifies a health **facility HEALTH CARE ENTITY**,  
19 the department shall notify the **facility HEALTH CARE ENTITY** and provide to it a copy of  
20 the summary report. The **facility HEALTH CARE ENTITY** shall be allowed seven days to  
21 review, comment, and verify such information. If immediate release of information is  
22 necessary and the department cannot provide at least prior oral notice to the **facility**  
23 **HEALTH CARE ENTITY** identified, it shall provide notice as soon as reasonably possible  
24 and shall explain why it could not provide prior notice.
- 25 ...

1 **Part 4. WAIVER OF REGULATIONS FOR HEALTH FACILITIES CARE ENTITIES**

2 4.101 Statutory Authority, Applicability and Scope

3 (l) This Part 4 is promulgated by the State Board of Health pursuant to Section 25-1-108(l)(c),  
4 C.R.S., in accordance with the general licensing authority of the Department as set forth in  
5 Section ~~25-1-107(l)(1)(i)~~, 25-1.5-103, C.R.S. *{Explanation: Section 25-1-107 was repealed in*  
6 *2003 and relocated to article 1.5.}*

7 ...

8 (5) It is the policy of the State Board of Health and the Department that every licensed health  
9 **facility CARE ENTITY** complies in all respects with applicable regulations. Upon application to the  
10 Department, a waiver may be granted in accordance with this Part 4, generally for a limited  
11 term. Absent the existence of a current waiver issued pursuant to this part, ~~facilities~~-HEALTH  
12 CARE ENTITIES are expected to comply at all times with all applicable regulations.

13 4.102 Definitions For This Part 4

14 (1) "Applicant" means a current health **facility CARE ENTITY** licensee, or an applicant for federal  
15 certification or for an initial license to operate a health **facility CARE ENTITY** in the state of  
16 Colorado.

17 ...

18 (4) "~~Facility~~" "**HEALTH CARE ENTITY**" means a health facility OR AGENCY licensed pursuant to  
19 Sections ~~25-1-107(1)(1)(i)~~ 25-1.5-103 and 25-3-102, C.R.S., and/or certified pursuant to federal  
20 regulations to participate in a federally funded health care program. *{Explanation: Section 25-*  
21 *1-107 was repealed in 2003 and relocated to article 1.5.}*

22 (5) "Regulation(s)" means:

23 (a) Any state regulation promulgated by the Board relating to standards for operation or  
24 licensure of a **Facility CARE ENTITY**, or

25 (b) Any federal regulation pertaining to certification of a **Facility CARE ENTITY**, but only when  
26 final authority for waiver of such federal regulation is vested in the Department.  
27 "Regulation(s)" includes the terms "standard(s)" and "rule(s)."

28 4.103 Application Procedure

29 ...

30 (2) At a minimum, each waiver application shall include the following:

31 ...

32

33 (b) If the waiver application pertains to building requirements, schematic drawings of the  
34 areas affected and a description of the effect of the requested waiver on the total  
35 **Facility HEALTH CARE ENTITY**;

36 (c) A description of the programs or services offered by the **Facility HEALTH CARE ENTITY**  
37 that are anticipated to be affected by the waiver;

- 1 (d) A description of the number of residents or patients in the **Facility HEALTH CARE ENTITY**  
2 and the level of care they require;
- 3 ...
- 4 (g) An explanation of why granting the waiver would not adversely affect the health, safety  
5 or welfare of the **Facility's HEALTH CARE ENTITY'S** residents or patients;
- 6 (h) If the waiver is being sought for state Regulation, a description of how any applicable  
7 federal Regulation similar to the state Regulation for which the waiver is sought (if any)  
8 is being met.
- 9 (3) A waiver application shall address the following matters, to the extent applicable or relevant:  
10 ...
- 11
- 12 (e) The extent and duration of the disruption of normal use of resident or patient areas to  
13 bring the **Facility HEALTH CARE ENTITY** into compliance with the Regulation;
- 14 (f) Life safety code factors, including but not limited to:
- 15 ...
- 16 (iv) The availability, extent and types of automatic fire detection and fire  
17 extinguishment systems provided in the **Facility HEALTH CARE ENTITY**;
- 18 ...
- 19 (g) Financial factors, including but not limited to:
- 20 ...
- 21 (ii) How application of the Regulation would create a demonstrated financial  
22 hardship on the **Facility HEALTH CARE ENTITY** that would jeopardize its ability to  
23 deliver necessary health care services to residents or patients;
- 24 ...
- 25 (h) Why waiver of the Regulation is necessary for specific **Facility HEALTH CARE ENTITY**  
26 programs to meet specific patient or resident needs, and why other patient or resident  
27 needs are not thereby jeopardized.
- 28 (4) *Notice and Opportunity to Comment on Application*
- 29 ~~(a) No later than the date of submitting the waiver application to the Department, the~~  
30 ~~Applicant shall post notice of the application and a meaningful description of the~~  
31 ~~substance of the waiver request at all public entrances to the Facility, as well as in at~~  
32 ~~least one area commonly used by patients or residents, such as a waiting room, lounge,~~  
33 ~~or dining room. The notice must reflect the date of posting, and indicate that an~~  
34 ~~application for a waiver has been made and that a copy of the waiver application shall~~  
35 ~~be provided by the Facility upon request.~~
- 36

1 (a) NO LATER THAN THE DATE OF SUBMITTING THE WAIVER APPLICATION TO THE DEPARTMENT,  
2 THE APPLICANT SHALL POST WRITTEN NOTICE OF THE APPLICATION AT ALL PUBLIC ENTRANCES  
3 TO THE HEALTH CARE ENTITY, AS WELL AS IN AT LEAST ONE AREA COMMONLY USED BY  
4 PATIENTS OR RESIDENTS, SUCH AS A WAITING ROOM, LOUNGE, OR DINING ROOM. APPLICANTS  
5 THAT DO NOT PROVIDE SERVICES ON THEIR OWN LICENSED PREMISES, SUCH AS HOME CARE  
6 AGENCIES AND HOSPICES, SHALL INSTEAD PROVIDE SUCH WRITTEN NOTICE DIRECTLY TO  
7 PATIENTS. THE NOTICE SHALL BE DATED AND INCLUDE THAT AN APPLICATION FOR A WAIVER  
8 HAS BEEN MADE, A MEANINGFUL DESCRIPTION OF THE SUBSTANCE OF THE WAIVER, AND THAT A  
9 COPY OF THE WAIVER SHALL BE PROVIDED BY THE HEALTH CARE ENTITY UPON REQUEST.  
10 **{Explanatory note: This reworded language contains a new requirement**  
11 **for hospices that do not provide services on their own licensed premises**  
12 **and home care agencies. These entities would be required to provide**  
13 **written notification directly to patients when a waiver application has been**  
14 **made.}**

15 ...

16 4.104 Department Action Regarding Waiver Application

17 (1) *General* Upon an Applicant's submission of a completed waiver application to the Department, a  
18 waiver of a particular Regulation with respect to a **Facility HEALTH CARE ENTITY** may be granted  
19 in accordance with this Part 4.

20 (2) *Decision on Waiver Application*

21 (a) In acting on a waiver application, the Department shall consider:

22 ...

23 (iii) Whether granting the waiver would adversely affect the health, safety or welfare  
24 of the **Facility's HEALTH CARE ENTITY'S** residents or patients.

25 (b) In making its determination, the Department may also consider any other information it  
26 deems relevant, including but not limited to occurrence and complaint investigation  
27 reports, and licensure or certification survey reports and findings related to the **Facility**  
28 **HEALTH CARE ENTITY** and/or the operator or owner thereof.

29 ...

30 4.105 Termination, Expiration and Revocation of Waiver

31 ...

32 (2) *Termination*

33 (a) Change of Ownership. A waiver shall automatically terminate upon a change of  
34 ownership of the **Facility HEALTH CARE ENTITY**, as defined in **Section 2.9.1** of **Pan Part**  
35 **2**, Chapter II of these Regulations. However, to prevent such automatic termination, the  
36 prospective new owner may submit a waiver application to the Department prior to the  
37 effective date of the change of ownership. Provided the Department receives the new  
38 application by this date, the waiver will be deemed to remain effective until such time as  
39 the Department acts on the application.

40 ...

41 4.106 Waiver of Building and Fire Safety Regulations for Skilled and Intermediate Health Facilities

- 1 (1) Notwithstanding anything in this Part 4 to the contrary, an application for waiver of building or  
2 fire safety Regulations promulgated by the Board that is submitted with respect to a **Facility**  
3 **HEALTH CARE ENTITY** that is a skilled or intermediate health care **Facility** shall be reviewed and  
4 acted upon in accordance with this Section 4.106. To the extent they do not conflict with the  
5 express provisions of this Section 4.106, the remaining provisions of this Part 4 shall also apply  
6 to this type of waiver application.
- 7 ...
- 8 (3) The Department shall review the application in accordance with Section 4.104(2), and shall  
9 make a recommendation to the Board within ninety (90) calendar days of receipt of the  
10 complete application as to whether or not the requested waiver should be granted.
- 11 (a) The Department may recommend granting a waiver only upon finding that:
- 12 (i) Rigid application of the Regulation would result in demonstrated financial  
13 hardship to the **Facility** **HEALTH CARE ENTITY**, and
- 14 (ii) Granting the requested waiver would not adversely affect the health and safety  
15 of the **Facility's** **HEALTH CARE ENTITY'S** residents or patients.
- 16 ...
- 17

1 5.2 **FACILITY HEALTH CARE ENTITY RECORDS.**

2 5.2.1 Except as hereinafter provided, patient records in the custody of health facilities-CARE ENTITIES  
3 required to be certified under section ~~25-1-107(I),(II)~~ **25-1.5-103 (1)(II)** or licensed under Part 1  
4 of Article 3 of Title 25 of the C.R.S. shall be available to a patient or his/her designated  
5 representative through the attending health care provider or his/her designated representative  
6 at reasonable times and upon reasonable notice. *{Explanation: Section 25-1-107 was*  
7 *repealed in 2003 and relocated to article 1.5.}*

8 5.4 EFFECT OF THIS PART 5 ON SIMILAR RIGHTS OF A PATIENT

9 5.4.1 Nothing in this Part 5 shall be construed so as to limit the right of a patient or ~~his~~ **THE PATIENT'S**  
10 designated representative to inspect **PATIENT RECORDS, INCLUDING** the patient's medical or  
11 psychological data pursuant to section 24-72-204 (3) ~~(4)~~ **(a)(I)**, C.R.S. 1973. *{Explanation:*  
12 *Consolidation of 5.4.1 and 5.4.2 and correction of a typographical error.}*

13 ~~5.4.2 Nothing in this Part 5 shall be construed as to limit a right to inspect patient records which is~~  
14 ~~otherwise granted by state statute to the patient or his designated representative.~~

15 ***Renumber succeeding sections accordingly.***

- 1 ~~Part 6. PATIENT GRIEVANCE MECHANISM AND FACILITY'S OBLIGATIONS TO THE PATIENT~~
- 2 ~~Part 9. PATIENT RIGHTS~~
- 3 PART 6. PATIENT RIGHTS
- 4 6.100 PATIENT RIGHTS
- 5 6.200 PATIENT GRIEVANCE MECHANISM
- 6 6.100 PATIENT RIGHTS
- 7 6.101 STATUTORY AUTHORITY AND APPLICABILITY
- 8 (1) AUTHORITY TO ESTABLISH MINIMUM STANDARDS THROUGH REGULATION AND TO ADMINISTER AND ENFORCE
- 9 SUCH REGULATIONS IS PROVIDED BY SECTIONS 25-1.5-103 AND 25-3-101, ET. SEQ.
- 10 (2) APPLICABILITY. SUBPART 6.100 APPLIES TO AMBULATORY SURGICAL CENTERS, BIRTH CENTERS, CHIROPRACTIC
- 11 CENTERS AND HOSPITALS, COMMUNITY CLINICS, COMMUNITY CLINICS WITH EMERGENCY CENTERS,
- 12 CONVALESCENT CENTERS, DIALYSIS TREATMENT CLINICS, HOSPITALS AND HOSPITAL UNITS.
- 13 ~~9.4 Applicability. The provisions of 9.1 And 9.2 shall not apply to any facility currently covered under section~~
- 14 ~~25-1-121 and the regulations promulgated pursuant to said section in Chapter II, Part 6 of the~~
- 15 ~~regulations. The provisions of 9.1 and 9.2 shall not apply to long term care facilities, personal care~~
- 16 ~~boarding homes, residential facilities for the developmentally disabled, and hospice that are regulated~~
- 17 ~~pursuant to section 25-1-120 and 6 CCR 1011-1, chapter V, chapter VI I, chapter VI II, Part 5, and~~
- 18 ~~Chapter XXI respectively.~~
- 19 6.102 DEFINITIONS.
- 20 (1) "ABUSE" MEANS THE WILLFUL INFLICTION OF INJURY, UNREASONABLE CONFINEMENT, INITIMIDATION, OR
- 21 PUNISHMENT, WITH RESULTING PHYSICAL HARM, PAIN, OR MENTAL ANGUISH.
- 22 (2) "ADMISSION": MEANS THE ACCEPTANCE OF A PERSON AS A PATIENT WHETHER ON AN INPATIENT OR OUTPATIENT
- 23 BASIS.
- 24 (3) ~~9.3~~ For the purposes of this regulation, the term, "informed consent", shall include, but not be
- 25 limited to, the following: "INFORMED CONSENT" MEANS:
- 26 (a) an explanation of the NATURE AND PURPOSE OF THE recommended treatment or procedure in
- 27 layman's terms and in a form of communication understood by the patient, or the patient's legal
- 28 DESIGNATED representative;
- 29 (b) an explanation of the risks and benefits of a treatment or procedure; the probability of success,
- 30 mortality risks, and serious side effects;
- 31 (c) an explanation of the alternatives with the risks and benefits of these alternatives;
- 32 (d) an explanation of the ~~consequences~~ RISKS AND BENEFITS if no treatment is pursued;
- 33 (e) an explanation of the recuperative period which includes a discussion of anticipated problems
- 34 and the anticipated length of the recuperative period; and
- 35 (f) an explanation that the patient, or the patient's legal DESIGNATED representative, is free to
- 36 withdraw his or her consent and to discontinue participation in the treatment regimen.

- 1 (4) "DEPARTMENT" MEANS THE COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT, UNLESS THE  
2 CONTEXT DICTATES OTHERWISE.
- 3 (5) "LICENSED INDEPENDENT PRACTITIONER" MEANS AN INDIVIDUAL PERMITTED BY LAW AND THE FACILITY TO  
4 INDEPENDENTLY DIAGNOSE, INITIATE, ALTER OR TERMINATE HEALTH CARE TREATMENT WITHIN THE SCOPE OF HIS  
5 OR HER LICENSE.
- 6 (6) "FINANCIAL INTEREST" MEANS DIRECT OR INDIRECT OWNERSHIP OF 5 PERCENT OR MORE OF THE CAPITAL, STOCK  
7 OR PROPERTY.
- 8 (7) "NEGLECT" MEANS THE FAILURE TO PROVIDE GOODS AND SERVICES NECESSARY TO ATTAIN AND MAINTAIN  
9 PHYSICAL AND MENTAL WELL-BEING.
- 10 (8) ~~6.3.3 Patient:~~ A "PATIENT " MEANS person accepted on either an inpatient or outpatient basis. Where a  
11 patient is incompetent or unable to act on his or her own behalf, such interest devolves on the PATIENT  
12 DESIGNATED REPRESENTATIVE OR next of kin ~~or legal guardian~~, if possible.
- 13 (9) "PATIENT DESIGNATED REPRESENTATIVE" IS A PERSON AUTHORIZED ~~IN WRITING OR BY COURT ORDER TO ACT ON~~  
14 **BEHALF OF THE PATIENT - BY STATE LAW, BY COURT ORDER OR IN WRITING IN ACCORDANCE WITH THE POLICIES**  
15 **AND PROCEDURES OF THE FACILITY.**
- 16 (10) "RESTRAINT" MEANS A PHYSICAL, MECHANICAL OR CHEMICAL RESTRAINT THAT IMMOBILIZES OR REDUCES THE  
17 ABILITY OF THE PATIENT TO MOVE HIS OR HER ARMS, LEGS, HEAD OR BODY FREELY. METHODS TYPICALLY USED  
18 FOR MEDICAL-SURGICAL CARE SHALL NOT BE CONSIDERED RESTRAINTS, SUCH AS: THE USE OF BANDAGES AND  
19 ORTHOPEDICALLY PRESCRIBED DEVICES, THE USE OF A REQUIRED DEVICE TO LIMIT MOBILITY DURING A MEDICAL  
20 PROCEDURE, OR THE USE OF A DRUG WHEN IT IS PART OF A STANDARD TREATMENT OR DOSAGE FOR THE  
21 PATIENT'S CONDITION. FOR THE PURPOSES OF THIS DEFINITION, PHYSICAL RESTRAINTS USED FOR FALL  
22 PREVENTION (INCLUDING BUT NOT LIMITED TO RAISED BED RAILS) SHALL NOT BE CONSIDERED METHODS  
23 TYPICALLY USED FOR MEDICAL SURGICAL CARE.
- 24 6.103 DEPARTMENT OVERSIGHT. THIS SECTION 6.103 APPLIES ONLY TO HEALTH CARE ENTITIES HAVING IN  
25 EXCESS OF FIFTY (50) BEDS. THE DEPARTMENT SHALL APPROVE THE PATIENT RIGHTS POLICY OF APPLICABLE  
26 HEALTH CARE ENTITIES PRIOR TO ISSUANCE OF AN INITIAL OR RENEWAL LICENSE IN ACCORDANCE WITH SECTION  
27 25-1-121, C.R.S. THE FACILITY SHALL SUBMIT THE POLICY IN THE MANNER PRESCRIBED BY THE DEPARTMENT.
- 28 ~~6.7 The grievance plan and performance of the facility thereunder shall be approved by the Colorado~~  
29 ~~Department of Public Health and Environment prior to certification of compliance or issuance or renewal~~  
30 ~~of a license. The Department shall notify the facility as to the acceptance or rejection of its plan within~~  
31 ~~fourteen days of receipt. If unacceptable, the Department shall provide a detailed written statement of~~  
32 ~~the reasons for the plan's unacceptability and suggested changes.~~
- 33 ~~6.2 PLAN SUBMISSION. Each facility meeting the above applicability clause shall submit to the Health~~  
34 ~~Facilities Division, Colorado Department of Public Health and Environment, for approval, a plan for a~~  
35 ~~grievance mechanism and a policy statement with respect to the obligations of the facility to patients~~  
36 ~~using the facilities of such facility.~~
- 37 6.104 PATIENT RIGHTS POLICY
- 38 (1) THE HEALTH CARE ENTITY SHALL DEVELOP AND IMPLEMENT A POLICY REGARDING PATIENT RIGHTS. THE POLICY  
39 SHALL ENSURE THAT EACH PATIENT OR, WHERE APPROPRIATE, PATIENT DESIGNATED REPRESENTATIVE HAS THE  
40 RIGHT TO: ~~9.2 The patient rights statement shall include but not be limited to the following:~~
- 41 (a) ~~the right to~~ participate in all decisions involving the patient's care or treatment;
- 42 (b) ~~the right to~~ know if the facility HEALTH CARE ENTITY is participating in teaching programs,  
43 research, and/or experimental programs RELATING TO THE PATIENT'S OWN CASE AND TO ~~CONSENT~~  
44 REFUSE TO PARTICIPATE;

- 1 (c) ~~the right to~~ refuse any drug, test, procedure, or treatment AND TO BE INFORMED OF RISKS AND  
2 BENEFITS OF THIS ACTION;
- 3 (d) ~~the right to care or~~ AND treatment that is respectful, recognizes a person's dignity, CULTURAL  
4 VALUES AND RELIGIOUS BELIEFS, and provides for personal privacy to the extent possible during  
5 the course of treatment;
- 6 (e) ~~6.6.1.3 Staff identification (how different staff members are identified; i.e., uniforms, badges,  
7 etc.) (A) The policy statement shall also inform the patient or the patient's legal representative  
8 of the right to know the names, professional status, and experience of the staff that are  
9 providing care or treatment to the patient;~~
- 10 (f) ~~the right to~~ be informed of the ~~facility~~ HEALTH CARE ENTITY'S ~~rules~~ POLICIES AND PROCEDURES  
11 REGARDING THE PROVISION OF CARE ~~and regulations~~ as they apply to the patient; ~~and~~
- 12 ~~(g) The right to be informed, upon request, prior to the initiation of care or treatment that is non-~~  
13 ~~emergent/of the charge(s) for service(s) that is routine, usual, and customary; or the estimated~~  
14 ~~charge(s) for service (s) based upon an average patient with a diagnosis similar to the tentative~~  
15 ~~or preliminary admission diagnosis of the patient being admitted; and, based upon insurance~~  
16 ~~information supplied by the patient, to be given assistance obtaining an estimate of any co-~~  
17 ~~payment, deductible, or other charges that will not be covered by a third party payer and must~~  
18 ~~be paid by the patient; and, the right to be informed prior to the initiation of care or treatment of~~  
19 ~~the facility's general billing procedures. A facility may include a disclaimer with the disclosure of~~  
20 ~~any charges. Such disclaimer may include further information on variables which may alter any~~  
21 ~~disclosed charge. If charges to the patient are prohibited by law, or by third party payer contract,~~  
22 ~~then a disclaimer of no charge shall meet the requirements of this paragraph;~~
- 23
- 24 (g) RECEIVE, UPON REQUEST:
- 25 (i) PRIOR TO INITIATION OF CARE OR TREATMENT, THE ESTIMATED CHARGE FOR NON-EMERGENT  
26 CARE. THIS INCLUDES, BUT IS NOT LIMITED TO, ASSISTANCE WITH DETERMINING THE CHARGES  
27 SUCH AS DEDUCTIBLES AND CO-PAYMENTS THAT WOULD NOT BE COVERED BY A THIRD-PARTY  
28 PAYER BASED ON THE INSURANCE INFORMATION SUPPLIED BY THE PATIENT OR PATIENT  
29 DESIGNATED REPRESENTATIVE. A HEALTH CARE ENTITY MAY PROVIDE THE ESTIMATED  
30 CHARGE FOR AN AVERAGE PATIENT WITH A SIMILAR DIAGNOSIS ALONG WITH INFORMATION ON  
31 THE VARIABLES THAT MAY ALTER THE ESTIMATED CHARGE.
- 32 (ii) THE HEALTH CARE ENTITY'S GENERAL BILLING PROCEDURES.
- 33 (iii) AN ITEMIZED BILL AND AN EXPLANATION OF CHARGES WITHIN 7 CALENDAR DAYS OF REQUEST.  
34 TREATMENT AND SERVICES SHALL BE IDENTIFIED AS TO DATE, TYPE IN PLAIN LANGUAGE, AND  
35 UNIT COST/UNIT MEASUREMENT, AS APPLICABLE. DRUGS SHALL BE LISTED BY BRAND OR  
36 GENERIC NAME AND NOT SOLELY BY DRUG CODE NUMBERS.
- 37 (h) ~~the right to~~ give informed consent for all treatment and procedures. **IT IS THE RESPONSIBILITY OF**  
38 **THE PHYSICIAN OR INDEPENDENT LICENSED PRACTITIONER TO OBTAIN INFORMED CONSENT.**
- 39 (i) ~~The right to be informed of the facility's grievance procedure~~ REGISTER COMPLAINTS WITH THE  
40 HEALTH CARE ENTITY AND THE DEPARTMENT AND TO BE INFORMED OF THE PROCEDURES FOR  
41 REGISTERING COMPLAINTS INCLUDING CONTACT INFORMATION.
- 42 (j) BE FREE OF ABUSE AND NEGLECT. TO EFFECTUATE THIS PATIENT RIGHT, THE HEALTH CARE ENTITY  
43 SHALL DEVELOP AND IMPLEMENT POLICIES AND PROCEDURES TO PREVENT, DETECT, INVESTIGATE, AND  
44 RESPOND TO INCIDENTS OF ABUSE OR NEGLECT. PREVENTION INCLUDES, BUT IS NOT LIMITED TO,  
45 ADEQUATE STAFFING TO MEET THE NEEDS OF THE PATIENTS, SCREENING EMPLOYEES FOR RECORDS OF  
46 ABUSE AND NEGLECT AND PROTECTING PATIENTS FROM ABUSE DURING INVESTIGATION OF

- 1 ALLEGATIONS. DETECTION INCLUDES, BUT IS NOT LIMITED TO, ESTABLISHING A REPORTING SYSTEM  
2 AND TRAINING EMPLOYEES REGARDING IDENTIFYING, REPORTING, AND INTERVENING IN INCIDENCES OF  
3 ABUSE AND NEGLECT. THE HEALTH CARE ENTITY SHALL INVESTIGATE, IN A TIMELY MANNER, ALL  
4 ALLEGATIONS OF ABUSE OR NEGLECT AND IMPLEMENT CORRECTIVE ACTIONS IN ACCORDANCE WITH  
5 SUCH INVESTIGATIONS.
- 6 (k) BE FREE OF THE INAPPROPRIATE USE OF RESTRAINTS. INAPPROPRIATE USE INCLUDES IMPROPER  
7 APPLICATION OF A RESTRAINT OR THE USAGE OF A RESTRAINT AS A MEANS OF COERCION, DISCIPLINE,  
8 CONVENIENCE, OR RETALIATION BY STAFF. TO EFFECTUATE THIS PATIENT RIGHT, THE HEALTH CARE  
9 ENTITY SHALL DEVELOP AND IMPLEMENT POLICIES AND PROCEDURES REGARDING:
- 10 (i) THE PROVISION OF TRAINING ON THE USE OF RESTRAINTS.
- 11 (ii) ONGOING INDIVIDUAL PATIENT ASSESSMENT TO DETERMINE: WHEN A MEDICAL CONDITION OR  
12 SYMPTOM INDICATES USE OF RESTRAINT TO PROTECT THE PATIENT OR OTHERS FROM HARM;  
13 THE LEAST RESTRICTIVE INTERVENTION; AND THE DISCONTINUATION OF THE INTERVENTION AT  
14 THE EARLIEST POSSIBLE TIME.
- 15 (iii) DOCUMENTATION OF THE USE OF RESTRAINT IN THE PATIENT'S MEDICAL RECORD.
- 16 (l) BE ACCEPTED FOR ONGOING TREATMENT ON THE BASIS OF A REASONABLE EXPECTATION THAT THE  
17 PATIENT'S MEDICAL, NURSING AND OTHER HEALTH CARE NEEDS CAN BE MET ADEQUATELY AT THE  
18 HEALTH CARE ENTITY.
- 19 (l) CARE DELIVERED BY THE HEALTH CARE ENTITTY IN ACCORDANCE WITH THE NEEDS OF THE PATIENT.
- 20 (m) CONFIDENTIALITY OF MEDICAL RECORDS.
- 21 (n) RECEIVE CARE IN A SAFE SETTING.
- 22 (o) DISCLOSURE AS TO WHETHER REFERRALS TO OTHER PROVIDERS ARE ENTITIES IN WHICH THE HEALTH  
23 CARE ENTITY HAS A FINANCIAL INTEREST.
- 24 (p) BE EXAMINED AND TREATED IN SURROUNDINGS DESIGNED TO GIVE VISUAL AND AUDITORY PRIVACY.
- 25 (q) TO FORMULATE ADVANCE DIRECTIVES AND HAVE THE HEALTH CARE ENTITY COMPLY WITH SUCH  
26 DIRECTIVES, AS APPLICABLE.
- 27 (2) THE HEALTH CARE ENTITY SHALL DISCLOSE THE POLICY REGARDING PATIENT RIGHTS PRIOR TO TREATMENT OR  
28 UPON ADMISSION, WHERE POSSIBLE. ~~9.1 Any facility licensed by the department, unless exempted under~~  
29 ~~section 9.4, shall make available, upon admission for care or treatment, a disclosure of its policy on~~  
30 ~~patient rights. The disclosure shall be made available through the use of an appropriate communication~~  
31 ~~medium, and in a manner understood by the patient, or the patient's legal representative. For any~~  
32 ~~patient care or treatment course requiring multiple patient encounters, disclosure provided at the~~  
33 ~~beginning of such care or treatment course shall meet the intent of the regulations. A facility shall treat~~  
34 ~~patients in accordance with the provisions of the patient rights statement.~~
- 35 (3) EACH HEALTH CARE ENTITY SHALL POST A CLEAR AND UNAMBIGUOUS NOTICE IN A PUBLIC LOCATION IN THE  
36 HEALTH CARE ENTITYSPECIFYING THAT COMPLAINTS MAY BE REGISTERED WITH THE HEALTH CARE ENTITY, THE  
37 DEPARTMENT, AND WITH THE APPROPRIATE OVERSIGHT BOARD AT THE DEPARTMENT OF REGULATORY  
38 AGENCIES (DORA). UPON REQUEST, THE ~~NOTICE~~HEALTH CARE ENTITY SHALL PROVIDE THE PATIENT AND ANY  
39 INTERESTED PERSON WITH CONTACT INFORMATION FOR REGISTERING COMPLAINTS. ~~9.5 Each facility shall~~  
40 ~~post notice, in a conspicuous place in the facility, of the existence of its internal grievance procedure.~~  
41 ~~The notice shall also inform patients, or their legal representatives, that if still dissatisfied with a~~  
42 ~~physician, dental, or podiatric patient care services, excluding fee disputes, a complaint may be filed~~  
43 ~~with the Colorado State Board of Medical Examiners, the State Board of Dental Examiners, and the~~  
44 ~~Colorado Podiatry Board. Upon request, the facility shall provide the patient, or the patient's legal~~  
45 ~~representative, with the address of the appropriate board and inform such person that these boards are~~

1 prohibited from arbitrating or adjudicating fee disputes between licensees or between a licensee and  
2 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  
3 may post such notice in a manner that is conducive to a positive customer relations approach as long as  
4 the above provisions are incorporated in a manner that is consistent with the intent of the regulation.

## 5 6.6 Policy Statement

6 (A) In addition to any posting requirements under this part of the regulations, each facility shall  
7 make available, upon admission, a disclosure of its policy statement on patient rights pursuant  
8 to 25-1-121(4), C.R.S. And this part 6 of the regulations. The disclosure shall be made available  
9 through the use of an appropriate communication medium and in a manner understood by the  
10 patient, or the patient's legal representative. For any patient care or treatment course requiring  
11 multiple patient encounters, disclosure provided at the beginning of such care or treatment  
12 course shall meet the intent of the regulations.

13 6.6.1 The policy statement shall include, at least, the following explanations:

### 14 6.6.1.1 The physician's, dentist's, or podiatrist's duty to obtain informed consent.

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

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

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

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

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

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

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

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

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

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

### 41 6.6.1.2 Admission procedures.

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

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

8                                    (1) ~~the right to participate in all decisions involving the patient's care or~~  
9                                    ~~treatment consistent with other state and federal statutes;~~

10                                  (2) ~~the right to refuse any drug, test, procedure, or treatment consistent~~  
11                                  ~~with other state and federal statutes; and to be informed of the~~  
12                                  ~~probable or likely medical consequences of this action;~~

13                                  (3) ~~the right to be informed of the facility's rules and regulations as they~~  
14                                  ~~apply to the patient;~~

15                                  (4) ~~the right to be informed of the facility's grievance procedure.~~

16                                  6.6.1.3 ~~Staff identification (how different staff members are identified; i.e., uniforms, badges,~~  
17                                  ~~etc.)~~

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

21                                  6.6.1.4 ~~Privacy concerning medical treatment and care.~~

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

26                                  6.6.1.5 ~~Medical records will be maintained in confidence and in accordance with medical staff~~  
27                                  ~~bylaws, rules and regulations. The right of patient access will be specified pursuant to~~  
28                                  ~~25-1-801, C.R.S., et. seq. And consistent with part 5 of this chapter II of the regulations.~~

29                                  6.6.1.6 ~~Billing procedures.~~

30                                  (A) ~~The patient, or the patient's legal representative, has the right to be informed~~  
31                                  ~~upon request, prior to the initiation of care or treatment, that is non-emergent of~~  
32                                  ~~the charge(s) for service(s) that is routine, usual, and customary; or the~~  
33                                  ~~estimated charge(s) for service(s) based upon an average patient with a~~  
34                                  ~~diagnosis similar to the tentative or preliminary admission diagnosis of the~~  
35                                  ~~patient being admitted; and, based upon insurance information supplied by the~~  
36                                  ~~patient, to be given assistance on obtaining an estimate of any co-payment,~~  
37                                  ~~deductible, or other charges that will not be covered by a third party payer and~~  
38                                  ~~must be paid by the patient. The patient, or the patient's legal representative,~~  
39                                  ~~has the right to be informed prior to the initiation of care or treatment, of the~~  
40                                  ~~facility's general billing procedures. A facility may include a disclaimer with the~~  
41                                  ~~disclosure of any charges. Such disclaimer may include further information on~~  
42                                  ~~variables which may alter any disclosed charge. If charges to the patient are~~  
43                                  ~~prohibited by law or by third party payer contract, then a disclaimer of no~~  
44                                  ~~charge shall meet the requirements of this paragraph.~~

1                   6.6.1.7 ~~The facility shall provide information to the patient, or the patient's legal representative,~~  
2                   ~~if the facility or the patient's physician, dentist, or podiatrist is participating in teaching~~  
3                   ~~programs and/or in research, experimental, or educational projects relating to the~~  
4                   ~~patient's own case.~~

5                   6.6.2 ~~The policy statement, with respect to the obligations of the facility to patients, shall be~~  
6                   ~~conspicuously posted in a public place on the premises of the facility preferably in, but not~~  
7                   ~~limited to, the admissions area.~~

8                   6.6.3 ~~Each facility shall adhere to, treat, and provide services to patients in accordance with, the~~  
9                   ~~provisions of the facility's policy statement.~~

10                  6.8 ~~Each facility shall post notice, in a conspicuous place in the facility, of the existence of its~~  
11                  ~~internal grievance procedure. The notice shall also inform patients, or their legal representatives, that if~~  
12                  ~~still dissatisfied with physician, dental, or podiatric patient care services, excluding fee disputes, a~~  
13                  ~~complaint may be filed with the Colorado State Board of Medical Examiners, the State Board of Dental~~  
14                  ~~Examiners, and the Colorado Podiatry Board. Upon request, the facility shall provide the patient, or the~~  
15                  ~~patient's legal representative, with the address of the appropriate board and inform such person that~~  
16                  ~~these boards are prohibited from arbitrating or adjudicating fee disputes between licensees or between~~  
17                  ~~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.~~  
18                  ~~(A) A facility may post such notice in a manner that is conducive to a positive customer relations~~  
19                  ~~approach as long as the above provisions are incorporated in a manner that is consistent with the intent~~  
20                  ~~of the regulation.~~

21                  *{Explanatory Note: This amended Part 6 represents the merging of the existing Chap II Part 6 and Part 9.*  
22                  *There was significant duplication between the two parts. Much of the stricken language above eliminates*  
23                  *duplicative language.}*

24                  **6.200 Patient Grievance Mechanism**

25                  6.201 STATUTORY AUTHORITY AND APPLICABILITY

- 26                  (1) AUTHORITY TO ESTABLISH MINIMUM STANDARDS THROUGH REGULATION AND TO ADMINISTER AND ENFORCE  
27                  SUCH REGULATIONS IS PROVIDED BY SECTIONS 25-1-121, 25-1.5-103 AND 25-3-101, C.R.S., ET. SEQ.
- 28                  (2) APPLICABILITY. SUBPART 6.200 APPLIES TO THE FOLLOWING HEALTH CARE ENTITIES HAVING IN EXCESS OF  
29                  FIFTY (50) BEDS: BIRTH CENTERS, CHIROPRACTIC CENTERS AND HOSPITALS, COMMUNITY CLINICS WITH  
30                  EMERGENCY CENTERS, CONVALESCENT CENTERS, HOSPITALS AND HOSPITAL UNITS.

31                  ~~6.1 APPLICABILITY. (This section is applicable to general hospitals, psychiatric hospitals, rehabilitation~~  
32                  ~~hospitals, chiropractic centers, maternity hospitals and related facilities having in excess of fifty beds~~  
33                  ~~except for nursing facilities conducted by or for the adherents of any well-recognized church or religious~~  
34                  ~~denominations for the purpose of providing for the care and treatment of the sick who depend~~  
35                  ~~exclusively upon spiritual means through prayer for healing in the practice of the religion of such church~~  
36                  ~~or denomination, nursing care facilities, and intermediate health care facilities which are subject to the~~  
37                  ~~provisions of C.R.S. 25-1-120 as amended.)~~

38                  6.202 DEFINITIONS

39                  ~~6.3 DEFINITIONS~~

- 40                  (1) ~~6.3.1 "Admission": MEANS the acceptance of a person as a patient and for whom a record of treatment~~  
41                  ~~is instituted, whether on an inpatient or outpatient basis.~~
- 42                  (2) ~~6.3.5 "Chief Executive ADMINISTRATIVE Officer:" MEANS the person appointed by the governing body~~  
43                  ~~who is responsible for the continuous DAY-TO-DAY management of the facility HEALTH CARE ENTITY. The~~

- 1 chief executive officer shall authorize an individual to act for him in an absence which would preclude  
2 fulfillment of the regulations in a timely manner.
- 3 (3) ~~6.3.3~~ "Patient:" MEANS a person accepted on either an inpatient or outpatient basis. UNLESS THE  
4 CONTEXT DICTATES OTHERWISE, where a patient is incompetent or unable to act on his or her own behalf,  
5 such interest devolves on the next of kin or ~~legal guardian~~ PATIENT DESIGNATED REPRESENTATIVE, if  
6 possible.
- 7 (4) ~~6.3.4~~ "Patient Representative CARE ADVOCATE:" MEANS the person or persons designated by each  
8 facility HEALTH CARE ENTITY to function as the primary contact to receive complaints from patients  
9 regarding facility HEALTH CARE ENTITY services.
- 10 (5) "PATIENT DESIGNATED REPRESENTATIVE" IS A PERSON AUTHORIZED IN WRITING OR BY COURT ORDER TO ACT ON  
11 BEHALF OF THE PATIENT IS A PERSON AUTHORIZED TO ACT ON BEHALF OF THE PATIENT BY STATE LAW, BY COURT  
12 ORDER OR IN WRITING IN ACCORDANCE WITH THE POLICIES AND PROCEDURES OF THE HEALTH CAE ENTITY.
- 13 (6) ~~6.3.2~~ "Grievance Mechanism:" MEANS the established procedure PROCESS whereby complaints by  
14 patients may be initiated and resolved BY THE HEALTH CARE ENTITY.
- 15 6.203 DEPARTMENT OVERSIGHT. THE DEPARTMENT SHALL APPROVE THE PATIENT GRIEVANCE MECHANISM PLAN  
16 PRIOR TO ISSUANCE OF AN INITIAL OR RENEWAL LICENSE. THE HEALTH CARE ENTITY SHALL SUBMIT THE PLAN IN  
17 THE MANNER PRESCRIBED BY THE DEPARTMENT.
- 18 ~~6.7 The grievance plan and performance of the facility thereunder shall be approved by the Colorado  
19 Department of Public Health and Environment prior to certification of compliance or issuance or renewal  
20 of a license. The Department shall notify the facility as to the acceptance or rejection of its plan within  
21 fourteen days of receipt. If unacceptable, the Department shall provide a detailed written statement of  
22 the reasons for the plan's unacceptability and suggested changes.~~
- 23 ~~6.2 PLAN SUBMISSION. Each facility meeting the above applicability clause shall submit to the Health  
24 Facilities Division, Colorado Department of Public Health and Environment, for approval, a plan for a  
25 grievance mechanism and a policy statement with respect to the obligations of the facility to patients  
26 using the facilities of such facility.~~
- 27 6.204 PATIENT GRIEVANCE MECHANISM
- 28 (1) PATIENT GRIEVANCE MECHANISM PLAN. THE HEALTH CARE ENTITY SHALL DEVELOP AND IMPLEMENT A PATIENT  
29 GRIEVANCE MECHANISM PLAN THAT ~~6.4~~ The patient grievance mechanism plan shall include but not be  
30 limited to the following:
- 31 (a) ~~6.4.1~~ A provision for a patient representative CARE ADVOCATE to serve THAT SERVES as a  
32 liaison between the patient and the facility HEALTH CARE ENTITY. THE PLAN SHALL DESCRIBE:
- 33 (i) the qualifications, job description, and level of decision-making authority of the patient  
34 CARE ADVOCATE representative.
- 35 (ii) ~~6.4.5~~ A method by which HOW each patient will be made aware of the patient  
36 representative program GRIEVANCE MECHANISM and how the PATIENT CARE ADVOCATE  
37 representative of the program may be contacted.
- 38 ~~6.4.2~~ A description, of the qualifications of the patient representative.
- 39 ~~6.4.3~~ An outline of the job description of the patient representative.
- 40 ~~6.4.4~~ A description of the amount of decision-making authority given to the patient  
41 representative.

- 1 (b) A PATIENT GRIEVANCE PROCEDURE. THE HEALTH CARE ENTITY SHALL IMPLEMENT A GRIEVANCE  
2 PROCEDURE WITH, AT MINIMUM, THE FOLLOWING COMPONENTS:
- 3 (i) THE ABILITY FOR PATIENTS TO SUBMIT GRIEVANCES 24 HOURS PER DAY, EITHER ORALLY OR IN  
4 WRITING, TO A HEALTH CARE ENTITY STAFF MEMBER. IF THE GRIEVANCE IS SUBMITTED TO A  
5 STAFF MEMBER OTHER THAN THE PATIENT CARE ADVOCATE, THE STAFF MEMBER SHALL SUBMIT  
6 THE GRIEVANCE TO THE PATIENT CARE ADVOCATE BY THE NEXT WORKING DAY. ~~6.5.1 The~~  
7 ~~facility grievance mechanism will be so designed as to provide for the submission of~~  
8 ~~grievances by patients, orally and in writing, to the patient representative. 6.5.2 To~~  
9 ~~insure prompt action, the grievance mechanism will provide that a grievance may be~~  
10 ~~submitted to a staff member at any time, 24 hours per day, and that the grievance will~~  
11 ~~be submitted to the patient representative by the next working day.~~
- 12 (ii) THE PATIENT CARE ADVOCATE SHALL CONTACT THE PATIENT WITHIN THREE (3) WORKING DAYS  
13 OF RECEIPT OF THE GRIEVANCE TO ACKNOWLEDGE RECEIPT OF SUCH GRIEVANCE.
- 14 (iii) THE PATIENT CARE ADVOCATE SHALL INVESTIGATE THE GRIEVANCE AND RESPOND TO THE  
15 PATIENT IN WRITING WITHIN FIFTEEN (15) WORKING DAYS OF THE SUBMITTAL OF THE  
16 GRIEVANCE. ~~6.5.3 Complaints that cannot be resolved by the patient representative~~  
17 ~~shall be referred to the facility chief executive officer or his immediately, but in any~~  
18 ~~event no later than three days after receipt of the report of the patient representative to~~  
19 ~~the patient. The chief executive officer or his OR designee shall cause an additional~~  
20 ~~investigation to be made and provide results of his investigation to the complainant~~  
21 ~~within seven days.~~
- 22 (iv) IF THE PATIENT IS NOT SATISFIED, THE PATIENT CARE ADVOCATE SHALL FORWARD THE  
23 GRIEVANCE TO THE ADMINISTRATIVE OFFICER OR SUCH OFFICER'S DESIGNEE, WHO SHALL  
24 INVESTIGATE THE GRIEVANCE AND REPORT FINDINGS IN WRITING TO THE PATIENT WITHIN TEN  
25 (10) WORKING DAYS OF RECEIVING THE FORWARDED GRIEVANCE.
- 26 (v) IF THE PATIENT IS DISSATISFIED WITH THE REPORT OF THE ADMINISTRATIVE OFFICER OR SUCH  
27 OFFICER'S DESIGNEE, THE PATIENT SHALL BE INFORMED THAT UPON REQUEST, THE PATIENT  
28 CARE ADVOCATE WILL REFER THE GRIEVANCE AND THE HEALTH CARE ENTITY FINDINGS IN  
29 WRITING TO THE DEPARTMENT, AND THAT THE PATIENT MAY REGISTER THE GRIEVANCE  
30 DIRECTLY WITH THE DEPARTMENT. ~~6.5.4 If the complainant is dissatisfied with the report~~  
31 ~~of the facility chief executive officer, the complainant shall be informed that, the problem~~  
32 ~~may be referred in writing to the Executive Director, Colorado Department of Health, by~~  
33 ~~the patient representative if requested by complainant. The complainant shall also be~~  
34 ~~notified by the patient representative that the complainant may refer the register the~~  
35 ~~matter to the Executive Director as well.~~
- 36 ~~6.5.5 Upon receipt of the complaint, the Colorado Department of Public Health and Environment~~  
37 ~~shall, within seven days, notify the complaint and the facility that an investigation has been~~  
38 ~~initiated and a report in writing will be made to the complainant and to the facility as to its~~  
39 ~~findings and/or recommendations within fourteen days after notification.~~
- 40 (c) ~~6.4.7~~ A means to inform the patient **REGARDING HOW TO LODGE A GRIEVANCE** AND that the  
41 facility HEALTH CARE ENTITY encourages patients to speak out and to present grievances without  
42 fear of retribution.
- 43 (d) ~~6.4.8 Provision for inclusion in new employee orientation programs of a briefing on the~~  
44 ~~facility's grievance procedure and at least annually transmission of information to all staff~~  
45 ~~members who have direct patient contact covering the grievance mechanism. A REQUIREMENT~~  
46 ~~THAT NEW EMPLOYEES WILL BE TRAINED REGARDING THE GRIEVANCE MECHANISM PLAN AND THAT ALL~~  
47 ~~STAFF WITH DIRECT PATIENT CONTACT WILL BE BRIEFED AT LEAST ANNUALLY REGARDING THE PLAN.~~
- 48 (e) ~~6.4.6 Provision for informing patients that every effort will be made to translate the grievance~~  
49 ~~procedure into the language of the patient if the patient does not understand or is unable to read~~

1                    ~~English.~~ HOW PATIENTS WILL BE INFORMED THAT INTERPRETATION AND TRANSLATION NEEDS ARE  
2                    AVAILABLE REGARDING THE GRIEVANCE PROCEDURE FOR PATIENTS UNABLE TO UNDERSTAND OR READ  
3                    ENGLISH AND HOW LANGUAGE ASSISTANCE SERVICES WILL BE PROVIDED.

4   ~~6.5 — GRIEVANCE PROCEDURE~~

5   (2)   PATIENT GRIEVANCE PROCEDURE. THE FACILITY SHALL IMPLEMENT A GRIEVANCE PROCEDURE WITH, AT  
6       MINIMUM, THE FOLLOWING COMPONENTS:

1 **Part 7. SINGLE USE DISPOSABLE MEDICAL DEVICES**

2 7.1 Applicability. This section is applicable to all health facilities licensed by the Department.

3 7.2 Basis and Purpose. Statutory authority for adoption of these regulations is SECTIONS 25-1.5-103(1)(A)  
4 ~~C.R.S. 1973, 25-1-107(1)(1)(I)~~ and 25-1-108(1)(c)(I), C.R.S. The regulations are proposed to control the  
5 re-use of single-use or disposable medical devices. Without such regulations, the public health safety  
6 may be jeopardized.

7 7.3 Definitions:

8 7.3.1 A medical device is “an instrument, apparatus, implement, machine, contrivance, implant, in-  
9 vitro reagent or other similar or related article intended for use in the diagnosis of disease or in  
10 the cure, mitigation, treatment or prevention of disease.” Examples are cardiac pacemakers,  
11 glass clinical thermometers, catheters, cardiac guidewires, renal dialyzers, etc.

12 7.3.2 A single-use or disposable medical device is one labeled as such by the manufacturer, or one in  
13 which a caution is included in the accompanying literature or catalogue recommending one time  
14 only usage.

15 ~~7.3.3 Dialyzer Regeneration means the preparation for reuse of a single-use dialyzer in accordance~~  
16 ~~with this Section 7 of Chapter II.~~

17 7.4 Policy Statement.

18 7.4.1 The re-use of medical devices labeled as single-use or disposable shall be prohibited with the  
19 following exceptions:

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

23 7.4.2 Prior to re-use of any items except ~~dialyzers~~ those listed in 7.4.1 ~~(reuse of which is subject to~~  
24 ~~the provisions of 7.5, 7.6, 7.7)~~, the facility shall submit TO ~~the~~ the Department for approval  
25 written, processing procedures which shall meet the following guidelines based on F.D.A.  
26 standards:

- 27 1. The device can be adequately cleaned prior to disinfection and reuse.
- 28 2. The physical characteristics of the device material will not be adversely affected by  
29 cleaning, disinfection, or re-use.
- 30 3. The packaging material will allow effective penetration of the disinfecting agent and will  
31 prevent recontamination of the device under the storage conditions to which the devices  
32 will be subjected.
- 33 4. If disinfecting process is effective.
- 34 5. If the treated device is used parenterally, the process will not evoke pyrogenic  
35 response.
- 36 6. The device, after gas or chemical disinfection, will not contain toxic residues.

37 ~~7.5 Dialyzer Regeneration.~~

- 1           7.5.1 — ~~Regeneration shall not be permitted on dialyzers used for hepatitis antigen positive patients.~~
- 2           7.5.2 — ~~Prior to individual dialyzer regeneration, each patient shall be provided by the physician with a~~  
3           ~~presentation of possible complications and hazards and possible benefits of such regeneration.~~  
4           ~~This shall be incorporated into the consent for dialysis form and shall become a part of the~~  
5           ~~patient's dialysis record. Patients shall have access to the number of times their dialyzer has~~  
6           ~~been reused.~~
- 7           7.5.3 — ~~No person shall be denied access to dialysis in the facility as a result of that patient's refusal to~~  
8           ~~permit regeneration of his or her dialyzer. Refusal to permit regeneration shall be documented.~~
- 9           7.5.4 — ~~The facility shall document the qualifications of and the protocols for training personnel~~  
10          ~~responsible for the regeneration process.~~
- 11          7.5.5 — ~~The facility shall provide training for all personnel in the protocols and procedures for~~  
12          ~~regeneration at the time of employment and no less than annually.~~
- 13          7.5.6 — ~~The facility shall establish policies and procedures to ensure the safety of employees in regard~~  
14          ~~to the use of disinfecting agents and procedures to deal with accidents and spillage of~~  
15          ~~disinfectants.~~
- 16          7.6 — ~~Quality Control for Dialyzer Regeneration. Procedures shall be established and documented in the~~  
17          ~~facility procedure manual which shall include but not be limited to:?~~
- 18          7.6.1 — ~~Each dialyzer to be reused shall be indelibly and clearly labeled with the patient's name and~~  
19          ~~other unique identifying information before the initial use.~~
- 20          7.6.2 — ~~At each subsequent use, the label shall be checked by two separate individuals, the dialysis~~  
21          ~~staff member and the patient, if feasible.~~
- 22          7.6.3 — ~~The number of the uses shall be recorded both in a reuse record maintained for each dialyzer,~~  
23          ~~and in the patient's permanent dialysis record.~~
- 24          7.6.4 — ~~Water used to formulate cleaning solution and to rinse dialyzers shall be passed through a~~  
25          ~~reverse osmosis membrane, ultrafiltration membrane or a submicron filter (0.45 micron) which is~~  
26          ~~appropriately maintained. This water shall contain less than 200 bacteria per ml, which shall be~~  
27          ~~documented by bacteriologic sampling of the source water outlet in the reprocessing area~~  
28          ~~monthly. Where such sampling reveals bacterial counts that periodically approach or exceed~~  
29          ~~this limit, corrective measures and weekly sampling shall be accomplished. Results of such~~  
30          ~~samples shall be recorded.~~
- 31          7.6.5 — ~~Disinfection shall be achieved with an effective agent, the addition of which to each dialyzer~~  
32          ~~shall be documented and recorded. If formaldehyde is used as the disinfecting agent, a~~  
33          ~~mimimum concentration of 21 in both the blood and dialysate compartments, and minimum~~  
34          ~~exposure time of 24 hours if required.~~
- 35          7.6.6 — ~~Disinfection shall be monitored epidemiologically of all febrile reactions during dialysis with new~~  
36          ~~or used dialyzers and shall be documented in the patients record.~~
- 37          7.6.7 — ~~Blood and dialysate cultures shall be done on all patients during febrile reactions. Reports of~~  
38          ~~cultures shall be recorded in the dialysis record.~~
- 39          7.6.8 — ~~Documentation and recording of the addition of effective disinfectant concentrations in the~~  
40          ~~dialyzer to be reused shall be done.~~
- 41          7.6.9 — ~~Documentation and recording of effective disinfectant removal from each dialyzer immediately~~  
42          ~~prior to reapplication shall be done. Validation tests of methodologic achievement shall be made~~  
43          ~~monthly.~~

- 1           7.6.10 ~~Removal of any other potentially toxic substances added as any part of the reprocessing~~  
2           ~~procedure shall be documented and recorded by routine testing and/or validation studies as~~  
3           ~~appropriate.~~
- 4           7.6.11 ~~The effectiveness of the reprocessing procedure must be documented before each subsequent~~  
5           ~~use of each dialyzer.~~
- 6           1. ~~For hollow fiber dialyzers, a hollow fiber bundle volume (HFBV) of not less than 80% of~~  
7           ~~the initial HFBV, measured at 0+10 MM of HG transmembrane pressure, shall be~~  
8           ~~maintained.~~
- 9           2. ~~For parallel plate or coil dialyzers, small molecular clearance tests shall be performed~~  
10           ~~during or after each use, performance less than 90% of original capacity will not be~~  
11           ~~permitted.~~
- 12           7.6.12 ~~Blood leaks during use of both new and reprocessed dialyzers shall be documented and~~  
13           ~~recorded. If the blood leak rate of used dialyzers exceeds that of new dialyzers, each dialyzer~~  
14           ~~must be pressure tested for possible blood compartment leak, before reuse.~~
- 15           7.6.13 ~~Dialyzers shall be discarded unless the following criteria are met at the time the dialyzer is to be~~  
16           ~~used on the patient:~~
- 17           1. ~~The dialyzer has no cracked or broken parts.~~
- 18           2. ~~The dialyzer appears clear and free of dissolved or residual blood manifest by a~~  
19           ~~brownish or pinkish tinge.~~
- 20           3. ~~Headers are visibly free of all but small peripheral clots.~~
- 21           7.6.14 ~~A clean storage space for disinfected dialyzers will be provided.~~
- 22           7.6.15 ~~Where such committee exists, all quality control procedures shall be approved by the Infection~~  
23           ~~Control Committee.~~
- 24           ~~7.7 Dialyzer Regeneration Facilities. A separate room shall be provided.~~
- 25           7.7.1 ~~Unless the room is equipped with an appropriate flushing system, the room shall be equipped~~  
26           ~~with a counter and counter sink.~~
- 27           7.7.2 ~~The room shall have approved hand washing facilities and storage cabinets.~~
- 28           7.7.3 ~~The room shall be separated in clean and soiled areas. Regeneration dialyzers shall be~~  
29           ~~maintained only in the clean area.~~
- 30           7.7.4 ~~The room shall be ventilated with fresh air at a minimum rate of six air changes per hour or~~  
31           ~~locally exhausted. Air shall not be recirculated through the ventilating system except at those~~  
32           ~~times when processing is not taking place. If general exhaustion of the room is selected, as~~  
33           ~~opposed to local exhaustion, the site of exhaustion must be, at a maximum, six inches from~~  
34           ~~floor level. (NOTE: Formaldehyde gas is heavier than air,)~~
- 35           7.7.5 ~~The rooms shall be lighted to a level of 50 foot candles throughout. Light levels shall be 100 foot~~  
36           ~~candles at the work surfaces.~~
- 37           7.7.6 ~~Storage space shall be provided for supplies and for regenerated dialyzers proportional to the~~  
38           ~~number of patients in the unit.~~

1 **Part 9. PATIENT RIGHTS**

2  
3 ~~9.1 Any facility licensed by the department, unless exempted under section 9.4, shall make available, upon~~  
4 ~~admission for care or treatment, a disclosure of its policy on patient rights. The disclosure shall be made~~  
5 ~~available through the use of an appropriate communication medium, and in a manner understood by the patient,~~  
6 ~~or the patient's legal representative. For any patientcare or treatment course requiring multiple patient~~  
7 ~~encounters, disclosure provided at the beginning of such care or treatment course shall meet the intent of the~~  
8 ~~regulations. A facility shall treat patients in accordance with the provisions of the patient rights statement.~~

9  
10 ~~9.2 The patient rights statement shall include but not be limited to the following:~~

11  
12 ~~(a) the right to participate in all decisions involving the patient's care or treatment;~~

13  
14 ~~(b) the right to know the names, professional status, and experience of the staff that are providing care or~~  
15 ~~treatment to the patient;~~

16  
17 ~~(c) the right to know if the facility is participating in teaching programs, research, and/or experimental programs;~~

18  
19 ~~(d) the right to refuse any drug, test, procedure, or treatment;~~

20  
21 ~~(e) the right to care or treatment that is respectful, recognizes a person's dignity, and provides for "personal~~  
22 ~~privacy to the extent possible during the course of treatment;~~

23  
24 ~~(f) the right to be informed of the facility's rules and regulations as they apply to the patient; and~~

25  
26 ~~(g) The right to be informed, upon request, prior to the initiation of care or treatment that is non-emergent/of the~~  
27 ~~charge(s) for service(s) that is routine, usual, and customary; or the estimated charge(s) for service (s) based~~  
28 ~~upon an average patient with a diagnosis similar to the tentative or preliminary admission diagnosis of the~~  
29 ~~patient being admitted; and, based upon insurance information supplied by the patient, to be given assistance~~  
30 ~~obtaining an estimate of any co-payment, deductible, or other charges that will not be covered by a third party~~  
31 ~~payer and must be paid by the patient; and, the right to be informed prior to the initiation of care or treatment of~~  
32 ~~the facility's general billing procedures. A facility may include a disclaimer with the disclosure of any charges.~~  
33 ~~Such disclaimer may include further information on variables which may alter any disclosed charge. If charges~~  
34 ~~to the patient are prohibited by law, or by third party payer contract, then a disclaimer of no charge shall meet~~  
35 ~~the requirements of this paragraph;~~

36  
37 ~~(h) the right to give informed consent for all treatment and procedures.~~

38  
39 ~~(i) The right to be informed of the facility's grievance procedure.~~

40  
41 ~~9.3 For the purposes of this regulation, the term, "informed consent", shall include, but not be limited to, the~~  
42 ~~following:~~

43

- 1 (a) an explanation of the recommended treatment or procedure in layman's terms and in a form of  
2 communication understood by the patient, or the patient's legal representative;
- 3  
4 (b) an explanation of the risks and benefits of a treatment or procedure; the probability of success, mortality  
5 risks, and serious side effects;
- 6  
7 (c) an explanation of the alternatives with the risks and benefits of these alternatives;
- 8  
9 (d) an explanation of the consequences if no treatment is pursued;
- 10  
11 (e) an explanation of the recuperative period which includes a discussion of anticipated problems and the  
12 anticipated length of the recuperative period; and
- 13  
14 (f) an explanation that the patient, or the patient's legal representative, is free to withdraw his or her consent  
15 and to discontinue participation in the treatment regimen.

16  
17 ~~9.4 Applicability. The provisions of 9.1 And 9.2 shall not apply to any facility currently covered under section  
18 25-1-121 and the regulations promulgated pursuant to said section in Chapter II, Part 6 of the regulations. The  
19 provisions of 9.1 and 9.2 shall not apply to long term care facilities, personal care boarding homes, residential  
20 facilities for the developmentally disabled, and hospice that are regulated pursuant to section 25-1-120 and 6  
21 CCR 1011-1, chapter V, chapter VI I, chapter VI II, Part 5, and Chapter XXI respectively.~~

22  
23 ~~9.5 Each facility shall post notice, in a conspicuous place in the facility, of the existence of its internal grievance  
24 procedure. The notice shall also inform patients, or their legal representatives, that if still dissatisfied with  
25 physician, dental, or podiatric patient care services, excluding fee disputes, a complaint may be filed with the  
26 Colorado State Board of Medical Examiners, the State Board of Dental Examiners, and the Colorado Podiatry  
27 Board. Upon request, the facility shall provide the patient, or the patient's legal representative, with the address  
28 of the appropriate board and inform such person that these boards are prohibited from arbitrating or adjudicating  
29 fee disputes between licensees or between a licensee and any other party, pursuant to sections 12-36-104.5,  
30 12-35-107.5, and 12-32-104.5, C.R.S.~~

31  
32 ~~(A) A facility may post such notice in a manner that is conducive to a positive customer relations approach as  
33 long as the above provisions are incorporated in a manner that is consistent with the intent of the regulation.~~  
34

35 **SINCE PART 9 HAS BEEN MERGED INTO PART 6, THE CURRENT VERSION OF PART 9, SHOWN IN**  
36 **STRIKE-OUT ABOVE, IS BEING REPLACED IN ITS ENTIRETY BY THE FOLLOWING:**

37 **PART 9 - HOSPITAL-ACQUIRED INFECTION REPORTING**

38 **SECTION 1 - STATUTORY AUTHORITY AND APPLICABILITY**

39 9.1.1 THE STATUTORY AUTHORITY FOR THE PROMULGATION OF THESE RULES IS SET FORTH IN SECTIONS 25-1.5-103,  
40 25-3-103 AND 25-3-607, C.R.S.

41 9.1.2 EACH HOSPITAL, HOSPITAL UNIT, AMBULATORY SURGICAL CENTER OR OUTPATIENT DIALYSIS TREATMENT CLINIC  
42 THAT IS LICENSED OR CERTIFIED BY THE DEPARTMENT SHALL COMPLY WITH THIS PART 9.

43 **SECTION 2 - DEFINITIONS**

1 FOR PURPOSES OF THIS PART 9, THE FOLLOWING DEFINITIONS SHALL APPLY:

2 9.2.1 "DEPARTMENT" MEANS THE DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT.

3 9.2.2 "HEALTH FACILITY" MEANS A HOSPITAL, A HOSPITAL UNIT, AN AMBULATORY SURGICAL CENTER, OR OUTPATIENT  
4 DIALYSIS TREATMENT CLINIC CURRENTLY LICENSED OR CERTIFIED BY THE DEPARTMENT.

5 9.2.3 "INFECTION" MEANS THE INVASION OF THE BODY BY PATHOGENIC MICROORGANISMS THAT REPRODUCE AND  
6 MULTIPLY, CAUSING DISEASE BY LOCAL CELLULAR INJURY, SECRETION OF A TOXIN, OR ANTIGEN-ANTIBODY  
7 REACTION IN THE HOST.

8 **SECTION 3 - GENERAL PROVISIONS**

9 9.3.1 EACH HEALTH FACILITY SHALL COLLECT DATA ON HOSPITAL-ACQUIRED INFECTION RATES FOR SPECIFIC CLINICAL  
10 PROCEDURES INCLUDING, BUT NOT LIMITED TO:

11 (A) CARDIAC SURGICAL SITE INFECTIONS;

12 (B) ORTHOPEDIC SURGICAL SITE INFECTIONS;

13 (C) ABDOMINAL SURGICAL SITE INFECTIONS; AND

14 (D) CENTRAL LINE-RELATED BLOODSTREAM INFECTIONS.

15 9.3.2 AN INDIVIDUAL WHO COLLECTS DATA ON HOSPITAL-ACQUIRED INFECTION RATES SHALL TAKE THE TEST FOR THE  
16 APPROPRIATE NATIONAL CERTIFICATION FOR INFECTION CONTROL AND BECOME CERTIFIED WITHIN SIX MONTHS  
17 AFTER THE INDIVIDUAL BECOMES ELIGIBLE TO TAKE THE CERTIFICATION TEST.

18 (A) MANDATORY NATIONAL CERTIFICATION REQUIREMENTS SHALL NOT APPLY TO INDIVIDUALS COLLECTING  
19 DATA ON HOSPITAL-ACQUIRED INFECTIONS IN HOSPITALS LICENSED FOR 50 BEDS OR LESS.  
20 QUALIFICATIONS FOR THESE INDIVIDUALS MAY BE MET THROUGH ONGOING EDUCATION, TRAINING,  
21 EXPERIENCE OR CERTIFICATION AS DIRECTED BY THE DEPARTMENT.

22 9.3.3 EACH HEALTH FACILITY SHALL DEVELOP A POLICY TO ENSURE THAT EACH PHYSICIAN WHO PERFORMS ONE OF  
23 THE PROCEDURES LISTED IN SECTION 9.3.1 AT THAT FACILITY PROMPTLY REPORTS TO IT ANY HOSPITAL-  
24 ACQUIRED INFECTION THAT THE PHYSICIAN DIAGNOSES AT A FOLLOW-UP APPOINTMENT WITH THE PATIENT.

25 **SECTION 4 - REPORTING**

26 9.4.1 A HEALTH FACILITY SHALL ENROLL IN THE NATIONAL HEALTH SAFETY NETWORK (NHSN) AND ROUTINELY  
27 SUBMIT ITS HOSPITAL-ACQUIRED INFECTION DATA TO NHSN IN ACCORDANCE WITH ITS REQUIREMENTS AND  
28 PROCEDURES.

29 (A) IF A HEALTH FACILITY IS A DIVISION OR SUBSIDIARY OF ANOTHER ENTITY THAT OWNS OR OPERATES  
30 OTHER HEALTH FACILITIES OR RELATED ORGANIZATIONS, THE DATA SUBMISSIONS REQUIRED UNDER  
31 THIS PART SHALL BE FOR THE SPECIFIC DIVISION OR SUBSIDIARY AND NOT FOR THE OTHER ENTITY.

32 9.4.2 EACH HEALTH FACILITY SHALL AUTHORIZE THE DEPARTMENT TO HAVE ACCESS TO THE HEALTH FACILITY SPECIFIC  
33 DATA CONTAINED IN THE NHSN DATABASE CONSISTENT WITH SECTION 25-3-601, *ET SEQ.*, C.R.S.

34 **SECTION 5 - PLAN OF CORRECTION**

35 9.5.1 IF A HEALTH FACILITY FAILS TO FULLY COMPLY WITH THE REQUIREMENTS OF THIS PART 9, THE DEPARTMENT MAY  
36 REQUEST A PLAN OF CORRECTION FROM THE FACILITY OR REQUIRE THE FACILITY'S COMPLIANCE WITH A  
37 DEPARTMENT DIRECTED PLAN OF CORRECTION.

38 9.5.2 PLANS OF CORRECTION SHALL CONFORM TO THE REQUIREMENTS SET FORTH IN PART 2 OF THIS CHAPTER.

1    **SECTION 6 – ENFORCEMENT AND DISCIPLINARY SANCTIONS**

2    9.6.1    IF THE DEPARTMENT DETERMINES THAT A HEALTH FACILITY IS OUT OF COMPLIANCE WITH ANY OF THE  
3            PROVISIONS OF SECTION 25-3-601, *ET. SEQ.*, C.R.S. OR THIS PART 9, IT MAY IMPOSE ANY OF THE FOLLOWING  
4            SANCTIONS.

5            (A)     REVOCATION OF THE HEALTH FACILITY’S LICENSE;

6            (B)     DENIAL OF THE HEALTH FACILITY’S APPLICATION FOR LICENSE RENEWAL; OR

7            (C)     A CIVIL PENALTY OF UP TO \$1,000 PER VIOLATION FOR EACH DAY THE HEALTH FACILITY IS DEEMED TO  
8            BE OUT OF COMPLIANCE.

9    9.6.2    IF THE DEPARTMENT REVOKES A LICENSE OR DENIES AN APPLICATION FOR A RENEWAL LICENSE, IT SHALL  
10            PROVIDE THE APPLICANT WITH A WRITTEN NOTICE EXPLAINING THE BASIS FOR THE REVOCATION OR DENIAL AND  
11            AFFORDING THE APPLICANT OR LICENSEE THE OPPORTUNITY TO RESPOND AND COMPLY WITH ALL LICENSING  
12            REQUIREMENTS WITHIN THE SPECIFIED TIMEFRAME.

13   9.6.3    Appeals of licensure revocations or denials shall be conducted in accordance with the State  
14            Administrative Procedure Act, Section 24-4-101, *et seq.* C.R.S.