COLORADO
Department of Public Health & Environment

To: Members of the State Board of Health

From: Kara Johnson-Hufford, Associate Division Director, Health Facilities & Emergency Medical Services Division

Through: D. Randy Kuykendall, Director, Health Facilities & Emergency Medical Services Division, DRK

Date: September 18, 2019

Subject: Request for a Rulemaking Hearing concerning 6 CCR 1011-1, Standards for Hospitals and Health Facilities Chapter 2 – General Licensure Standards, and for conforming amendments to the following chapters of 6 CCR 1011-1, Standards for Hospitals and Health Facilities:
Chapter 4 - General Hospitals
Chapter 5 - Nursing Care Facilities
Chapter 6 - Acute Treatment Units
Chapter 8 - Facilities for Persons with Intellectual and Developmental Disabilities
Chapter 9 - Community Clinics and Community Clinics and Emergency Services
Chapter 10 - Rehabilitation Hospitals
Chapter 15 - Dialysis Treatment Clinics
Chapter 18 - Psychiatric Hospitals
Chapter 19 - Hospital Units
Chapter 20 – Ambulatory Surgical Center and Ambulatory Surgical Center with a Convalescent Center
Chapter 21 – Hospices
Chapter 22 – Birth Centers
Chapter 26 – Home Care Agencies

Pursuant to Section 24-4-103.3, C.R.S., and Department policy, the Department must review its rules every five to seven years to ensure the rules continue to be efficient, effective, and essential. Accordingly, in 2018 the Department reviewed the existing 6 CCR 1011-1, Standards for Hospitals and Health Facilities, Chapter 2 General Licensure Standards.

The Department licenses a wide range of facilities pursuant to Section 25-3-101, C.R.S., and 6 CCR 1011-1, Chapter 2, houses the requirements that pertain to all facilities and agencies, such as licensure requirements or client rights. During the course of the rule review, the Department identified areas where technical changes should be made and where substantive regulatory additions are necessary.

Areas of technical changes include the consolidation and movement of the definitions, which were previously throughout the Chapter, to Part 1. This change ensures consistency in the use of terms throughout the Chapter and enables readers to easily find definitions. Parts within the Chapter were also relocated to provide better clarity, and duplication of information was removed as much as possible. Terminology was also updated to remove the total focus on

health care facilities and services to recognize that not all facilities and agencies licensed by the Department are medical in nature.

While the statutory authority for licensing facilities and agencies has not been significantly changed in a number of years, statutes that inform Chapter 2 have been. Therefore, Part 8, Protection of Clients from Involuntary Restraint or Seclusion, was updated to align with changes made to Section 26-20-108, C.R.S. Nomenclature was also changed to align with Section 25-3-607, C.R.S, from “hospital-acquired” infection reporting to “health-care-acquired” infection reporting.

The major substantive change to the Chapter is the addition of Part 3, General Building and Fire Safety Provisions. The changes update the Facilities Guidelines Institute (FGI) standard from the 2010 edition to the 2018 edition, which previously existed within each of the individual licensing chapters, and also create a process, in regulation for the first time, as to how the FGI compliance review will take place. In placing the incorporation of FGI in Chapter 2, the Department is also making conforming amendments to all other chapters within 6 CCR 1011-1 to remove the FGI references, expect for Chapter 7 Assisted Living Residences. Chapter 7 has already been updated to reference the 2018 edition of FGI and is currently in a separate review process that will result in a rule making in the future.

Other substantive changes to the Chapter include the removal of language that an applicant shall pay a 100% late fee if a license renewal is not submitted 30 days in advance, which is now replaced with a tiered late fee based on receipt of the renewal application after expiration of a license; clarification as to the time period over which a transfer of ownership that equals 50% interest takes place; clarification as to when the Department considers that a non-profit transfer of ownership has taken place; and a process for facilities and agencies to cease operations.

Due to the nature of Chapter 2 being a reference for all other chapters within 6 CCR 1011-1, the Department is also proposing conforming amendments to those chapters. The conforming amendments will remove the references to FGI as mentioned above, as well as update references to Chapter 2 to accurately reflect the proposed structure.

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for Amendments to
6 CCR 1011-1, Standards for Hospitals and Health Facilities
Chapter 2 – General Licensure Standards,
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Basis and Purpose.

Chapter 2 of 6 CCR 1011-1 contains the general licensing requirements for all facilities and agencies licensed by the Department pursuant to Section 25-3-101, C.R.S. The proposed changes to Chapter 2 were brought about by a regulatory review. Throughout the Chapter, language changes were made to more accurately reflect the wide variance of facility and agency types covered by Chapter 2, to reflect substantive changes to Colorado law and business practices, and to recognize that regulations were inadequate in some places. Additionally, the Chapter was restructured to move all definitions to Part 1, instead of being placed throughout the Chapter and additional restructuring and re-ordering of Parts occurred to help readability and flow. While the Department is proposing several changes to Chapter 2, it is important to note that substantively much remains the same.

Standard language changes made throughout are the removal of medical-centric language Including:

- Replacement of term “health care entity” with “facility or agency.”
- Replacement of the terms “patient” and “resident” with “client.”
- Changes made as appropriate to remove the term “medical” throughout the Chapter.

Re-ordering of the Chapter took place as a result of the introduction of Part 3 General Building and Fire Safety Provisions. All facility and agency types licensed by the Department are currently subject to the Federal Guidelines Institute (FGI) 2010 addition, except for Assisted Living Residences which are subject to the 2018 edition. As all initial constructions and renovations of facilities or agencies are subject to the FGI, the Department determined it would be more appropriate to place the FGI regulations in Chapter 2, with a reference in all

other chapters to comply with the regulations in as set out therein. At the same time, the Department is adopting the 2018 FGI standard for all facility and agencies types for initial constructions and renovations starting after January 1, 2020. As such, conforming amendments to the following chapters of 6 CCR 1011-1 are also being proposed at this time:

- Chapter 4 - General Hospitals
- Chapter 5 - Nursing Care Facilities
- Chapter 8 - Facilities for Persons with Intellectual and Developmental Disabilities
- Chapter 9 - Community Clinics and Community Clinics and Emergency Services
- Chapter 15 - Dialysis Treatment Clinics
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Part 3 also puts in place, for the first time, the regulatory expectations of the Department when a facility or agency will be submitting documentation for FGI review, including:

- When a FGI compliance review will need to take place,
- The timeline for document submittal,
- Which documents are to be submitted,
- Parameters for how documents should be submitted,
- A single point of contact for Department staff to interact with in regards to FGI reviews, and
- A waiver process for FGI compliance.

Additional re-ordering was proposed by stakeholders to bring Parts related to Client Rights and Protection of Clients from Involuntary Restraint or Seclusion proximate to each other instead of being separated by an intervening Part.

Substantive changes to Part 2 Licensure Process are as follows:

- Part 2.3.2 clarifies that failure to complete an application within twelve (12) months from initiation will result in the application being administratively closed and an applicant will need to submit a new application and fee.
- Part 2.5.2 removes language that late fees were due to the Department if a license renewal was not submitted thirty (30) days in advance of expiration. Proposed language creates tiered late fees based on the tardiness of submittal, and states that after ninety (90) days an applicant will need to submit an initial application.
- Part 2.6.2 clarifies that a transfer of fifty percent (50%) ownership through a series of transactions over the course of 5 years will need to be noticed to the Department in the same manner as a transfer that takes place in one transaction. Additionally, based on stakeholder questions and support, the Department has clarified the situation in which a non-profit licensee undergoes a transfer of ownership and that a change in the legal structure of a licensee is also considered a change of ownership.
- Part 2.9.6 adds that a change in scope of services or in a service area of a facility or agency are actions that need to be noticed to and approved by the Department thirty (30) days prior to implementation.

- Part 2.14 creates a process by which facilities or agencies can notify the Department of a closure; whether temporary, emergent, or permanent.

Within Part 4 entitled Quality Management, Occurrence Reporting, Palliative Care, Part 4.1 Quality Management Program, was re-written to reflect that a quality management program is to be client focused, not business focused. Other changes throughout Part 4 are meant to offer clarity without making substantive changes.

Part 5 Waiver of Regulations formerly laid out an extensive process. The Department has opted to remove much of the process formerly found at Part 5.2 as it is redundant with the waiver application form.

In Part 6 Access to Client Records, the use of the term “inpatient” was removed and instead the language focuses on whether the client is currently being served by the facility or agency or has been discharged.

- Part 6.1.3 creates timelines by which records requested by the client are to be made available.
- Part 6.1.8 clarifies that the Health Insurance Portability and Accountability Act of 1996 governs access to any subset of medical records that are contained within the client’s records.

Part 7 Client Rights did not require substantive changes. Proposed amendments throughout this part focused on providing clarity to existing regulations and increasing readability.

Part 8 Protection of Clients from Involuntary Restraint or Seclusion required several changes as a result of changes to the statute, Section 26-20-101, C.R.S et seq., by HB16-1328, HB 17-1276, and SB 18-92. Of note is the addition of protection from involuntary seclusion, consistent with the statutory changes, as previously this part included only protection from involuntary restraint.

- Part 8.1.2 clarifies that Part 8 does not apply to the Department of Corrections or an entity that has entered into a contract to provide services for that department.
- Part 8.2.1(B) clarifies that methods used for surgical care, prescribed orthopedic devices, or use of a drug that is standard for a client’s condition are not restraints for purposes of Part 8.
- Part 8.3.2 was added by HB 16-1328.

Part 9 Medications, Medical Devices, and Medical Supplies was rewritten to focus on the areas the Department may survey, and then informs facilities and agencies to review Section 12-42.5-133, C.R.S., governing the Department of Regulatory Agencies, for further guidance. This change was reviewed and supported by the Department’s Hazardous Waste Division as well as outside stakeholders that were involved in the introduction into statute of donated medical supplies.

In Part 10 Health-Care-Associated Infection Reporting, language was clarified as to the Health Facilities and Emergency Medical Services Division’s enforcement role. The reporting and collection of data related to health-care-associated infection reporting is performed by the Disease Control and Environmental Epidemiology Division within the Department. Part 10 was revised to focus on the role of the Health Facilities and Emergency Medical Services Division as the licensing entity.

Part 11 Influenza Immunization of Employees and Direct Contractors was initially introduced to Chapter 2 in 2012 and contained a phased in approach. Since 2014, all facilities and agencies are to meet a ninety percent (90%) seasonal influenza vaccination rate of employees or direct contractors. The changes proposed by the Department do not expand the universe of employees or direct contractors who are required to be vaccinated, or substantively change the requirements.

- Changes were made throughout Part 11 to clarify which persons the facility or agency is responsible for counting to ensure the ninety percent (90%) requirement is meet.
- Reporting deadlines were changed at Part 11.5.3 and Part 11.6.3 due to deadline changes made at the federal level.

Specific Statutory Authority.
Statutes that require or authorize rulemaking:

Section 25-1-107.5, C.R.S.
Section 25-1-108, C.R.S.
Section 25-1-120, C.R.S.
Section 25-1-124(3), C.R.S
Section 25-1.5-101, C.R.S.
Section 25-1.5-103, C.R.S.
Section 25-1.5-108, C.R.S.
Section 25-3-101, C.R.S. et seq
Section 25-27.5-101, C.R.S. et seq
Section 26-20-108, C.R.S. et seq

Other relevant statutes:
Section 25-1-801, C.R.S.
Section 12-42.5-133, C.R.S.
Section 25-3-607, C.R.S.
Section 25-1.5-102, C.R.S.

Is this rulemaking due to a change in state statute?

_____ Yes, the bill number is _____. Rules are ___ authorized ___ required.
____X__ No

Does this rulemaking include proposed rule language that incorporate materials by reference?

___X___ Yes ___ URL
_____ No

Does this rulemaking include proposed rule language to create or modify fines or fees?

___X___ Yes, modifying timeframes for late fees only
_____ No

Does the proposed rule language create (or increase) a state mandate on local government?

___X__ No.

- The proposed rule does not require a local government to perform or increase a specific activity for which the local government will not be reimbursed;

- The proposed rule requires a local government to perform or increase a specific activity because the local government has opted to perform an activity, or;
- The proposed rule reduces or eliminates a state mandate on local government.

REGULATORY ANALYSIS

For Amendments to
6 CCR 1011-1, Standards for Hospitals and Health Facilities
Chapter 2 – General Licensure Standards,
And Conforming Amendments to the following chapters of
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1. A description of the classes of persons affected by the proposed rule, including the classes that will bear the costs and the classes that will benefit from the proposed rule.

Group of persons/entities Affected by the Proposed Rule	Size of the Group	Relationship to the Proposed Rule Select category: C/S/B
All facilities or agencies licensed by the Department: hospitals, nursing care facilities, acute treatment units, home care agencies, dialysis treatment clinics, ambulatory surgical centers, hospice, community mental health centers, community clinics, convalescent centers, assisted living residences, birth centers, acute treatment units, home care placement agencies, and facilities for persons with intellectual and developmental disabilities.	2,364	C
Clients receiving services at licensed facilities and agencies.	Unknown	B

While all are stakeholders, groups of persons/entities connect to the rule and the problem being solved by the rule in different ways. To better understand those different relationships, please use this relationship categorization key:

C = individuals/entities that implement or apply the rule.
S = individuals/entities that do not implement or apply the rule but are interested in others applying the rule.
B = the individuals that are ultimately served, including the customers of our customers. These individuals may benefit, be harmed by or be at-

risk because of the standard communicated in the rule or the manner in which the rule is implemented.

More than one category may be appropriate for some stakeholders.

2. To the extent practicable, a description of the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.

   The proposed amendments to Chapter 2 are primarily non-substantive in nature and are intended to provide clarity to the regulations as well as to improve readability. Areas that are substantive in nature, such as those related to FGI, should not have an economic impact on the facility as it operates routinely. Licensees do not have to undertake renovations for the purpose of meeting FGI. However, any new construction after July 1, 2020, be it an initial build or a renovation, will need to meet the 2018 FGI standards being incorporated.

   The Department does not foresee an economic impact to any facility or agency type. It is the Department's intent that clearer regulations will result in improved health, safety, and welfare for Colorado citizens and visitors who make use of licensed facilities and agencies.

3. The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.

   A. Anticipated CDPHE personal services, operating costs or other expenditures:

      The proposed amendments are cost neutral.

      Anticipated CDPHE Revenues:

      The changes to the late fee provisions could marginally decrease the amount of revenue collected in those cases, but it is not expected to be a material change. Given that late fees are paid at the same time as the application fee, there is no data available as to how much is collected as a late fee currently.

   B. Anticipated personal services, operating costs or other expenditures by another state agency:

      N/A

      Anticipated Revenues for another state agency:

      N/A

4. A comparison of the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.

   Along with the costs and benefits discussed above, the proposed revisions:

___ Comply with a statutory mandate to promulgate rules.
___ Comply with federal or state statutory mandates, federal or state regulations, and department funding obligations.
_X_ Maintain alignment with other states or national standards.
_X_ Implement a Regulatory Efficiency Review (rule review) result
___ Improve public and environmental health practice.
_X_ Implement stakeholder feedback.

Advance the following CDPHE Strategic Plan priorities (select all that apply):

1. Reduce Greenhouse Gas (GHG) emissions economy-wide from 125.716 million metric tons of CO2e (carbon dioxide equivalent) per year to 119.430 million metric tons of CO2e per year by June 30, 2020 and to 113.144 million metric tons of CO2e by June 30, 2023. ___ Contributes to the blueprint for pollution reduction ___ Reduces carbon dioxide from transportation ___ Reduces methane emissions from oil and gas industry ___ Reduces carbon dioxide emissions from electricity sector
2. Reduce ozone from 83 parts per billion (ppb) to 80 ppb by June 30, 2020 and 75 ppb by June 30, 2023. ___ Reduces volatile organic compounds (VOC) and oxides of nitrogen (NOx) from the oil and gas industry. ___ Supports local agencies and COGCC in oil and gas regulations. ___ Reduces VOC and NOx emissions from non-oil and gas contributors
3. Decrease the number of Colorado adults who have obesity by 2,838 by June 30, 2020 and by 12,207 by June 30, 2023. ___ Increases the consumption of healthy food and beverages through education, policy, practice and environmental changes. ___ Increases physical activity by promoting local and state policies to improve active transportation and access to recreation. ___ Increases the reach of the National Diabetes Prevention Program and Diabetes Self-Management Education and Support by collaborating with the Department of Health Care Policy and Financing.
4. Decrease the number of Colorado children (age 2-4 years) who participate in the WIC Program and have obesity from 2120 to 2115 by June 30, 2020 and to 2100 by June 30, 2023. ___ Ensures access to breastfeeding-friendly environments.
5. Reverse the downward trend and increase the percent of kindergartners protected against measles, mumps and rubella (MMR) from 87.4% to 90% (1,669 more kids) by June 30, 2020 and increase to 95% by June 30, 2023. ___ Reverses the downward trend and increase the percent of kindergartners protected

against measles, mumps and rubella (MMR) from 87.4% to 90% (1,669 more kids) by June 30, 2020 and increase to 95% by June 30, 2023. ___ Performs targeted programming to increase immunization rates. ___ Supports legislation and policies that promote complete immunization and exemption data in the Colorado Immunization Information System (CIIS).
6. Colorado will reduce the suicide death rate by 5% by June 30, 2020 and 15% by June 30, 2023. ___ Creates a roadmap to address suicide in Colorado. ___ Improves youth connections to school, positive peers and caring adults, and promotes healthy behaviors and positive school climate. ___ Decreases stigma associated with mental health and suicide, and increases help-seeking behaviors among working-age males, particularly within high-risk industries. ___ Saves health care costs by reducing reliance on emergency departments and connects to responsive community-based resources.
7. The Office of Emergency Preparedness and Response (OEPR) will identify 100% of jurisdictional gaps to inform the required work of the Operational Readiness Review by June 30, 2020. ___ Conducts a gap assessment. ___ Updates existing plans to address identified gaps. ___ Develops and conducts various exercises to close gaps.
8. For each identified threat, increase the competency rating from 0% to 54% for outbreak/incident investigation steps by June 30, 2020 and increase to 92% competency rating by June 30, 2023. ___ Uses an assessment tool to measure competency for CDPHE's response to an outbreak or environmental incident. ___ Works cross-departmentally to update and draft plans to address identified gaps noted in the assessment. ___ Conducts exercises to measure and increase performance related to identified gaps in the outbreak or incident response plan.
9. 100% of new technology applications will be virtually available to customers, anytime and anywhere, by June 20, 2020 and 90 of the existing applications by June 30, 2023. ___ Implements the CDPHE Digital Transformation Plan. ___ Optimizes processes prior to digitizing them. ___ Improves data dissemination and interoperability methods and timeliness.
10. Reduce CDPHE's Scope 1 & 2 Greenhouse Gas emissions (GHG) from 6,561 metric tons (in FY2015) to 5,249 metric tons (20% reduction) by June 30, 2020 and 4,593 tons (30% reduction) by June 30, 2023. ___ Reduces emissions from employee commuting ___ Reduces emissions from CDPHE operations

11. Fully implement the roadmap to create and pilot using a budget equity assessment by June 30, 2020 and increase the percent of selected budgets using the equity assessment from 0% to 50% by June 30, 2023. ___ Used a budget equity assessment

_X__ Advance CDPHE Division-level strategic priorities.

The costs and benefits of the proposed rule will not be incurred if inaction was chosen. Costs and benefits of inaction not previously discussed include:

The most significant change being proposed to Chapter 2 is Part 3 General Building and Fire Safety Provisions. Part 3 not only updates the FGI standards adopted by the state to the 2018 edition from the 2010 edition, but it also puts in rule for the first time expectations as to what information is to be submitted for review, when a review is necessary, and the manner in which the Department and applicants and licensees will interact during the FGI compliance review process. Inaction on the addition of these important changes would result in uncertainty related to the FGI compliance review process.

5. A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.

Rulemaking is proposed when it is the least costly method or the only statutorily allowable method for achieving the purpose of the statute. The specific revisions proposed in this rulemaking were developed in conjunction with stakeholders. The benefits, risks and costs of these proposed revisions were compared to the costs and benefits of other options. The proposed revisions provide the most benefit for the least amount of cost, are the minimum necessary or are the most feasible manner to achieve compliance with statute.

6. Alternative Rules or Alternatives to Rulemaking Considered and Why Rejected.

A wide variety of stakeholders were included in the process, and several options were discussed. The proposed rule reflects the consensus reached through the stakeholder process.

7. To the extent practicable, a quantification of the data used in the analysis; the analysis must take into account both short-term and long-term consequences.

N/A

STAKEHOLDER ENGAGEMENT
for Amendments to
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State law requires agencies to establish a representative group of participants when considering to adopt or modify new and existing rules. This is commonly referred to as a stakeholder group.

Early Stakeholder Engagement:
The following individuals and/or entities were invited to provide input and included in the development of these proposed rules:

The Department created an on-line interested party sign up form that was sent through the Health Facilities Web Portal (Portal) for individuals to provide their information to the Department. These individuals were emailed one week prior to all meetings as a reminder of the meeting, as well as sent the agenda and updated draft of the proposed rule revisions. General notice of the monthly meetings was also provided through the Portal to all facilities licensed by the Department with a link to the agenda and updated draft of proposed rule revisions. The Department held monthly stakeholder meetings from August 2018 to August 2019. These meetings could be attended in person at the Department and were also available via webinar and phone call in.

Name	Organization, if known (Titles of the individual within the Organization is largely unknown)
Aaron A Williams	Littleton Adventist Hospital CENTURA
Adam Miller	Pagosa Springs Medical Center
Alisa Rice	HKS Inc.
Alisha Martinez	Mackenzie Place Fort Collins
Amber Berenz	
Amber Burkhart	Colorado Hospital Association

Amelia Bumgarner	Community Reach Center
Amy Higgins	Bridges of Colorado
Andrea Sanchez	Adult Day Service Provider
Angela M. Gallegos	BeeHive Homes of Pagosa Springs, LLC
ANGELA MCCORVEY	
Angela Waterbury	The Aspen at Woodland Park
Ann Chione	A Caring Heart Home Health, LLC
Anna Spencer	Comfort Keepers
Anna Kassner	Alpine Homecare
Anne Meier	State Long-Term Care Ombudsman
Anne Seglem	Griswold Home Care
Anthony Hanlon	Hanlon Bush Investments, LLC
Arlene Miles	Capitoline Consulting
Ben Budraitis	Synergy Home Care
Beth Coleman	Mental Health Center of Denver
Beth Hepola	SCL Health- System Regulatory Director
Bettina Haro Oliva Boudezoque	Bettina Services with love and compassion
Beverly Kirchner	Highline South Surgery Center
Beverly Shamley	Park Forest Care Center Inc
Bonnie Stumph	Starpoint PASA and CCB
Brad Schlesinger	
Brandie Harrison	M.A.T.A LLC
Brenda Haaksma	
Caitlin Phillips	DRCOG
Camy Rea	Broomfield Skilled Nursing
Carmen Musina	Leawood assisted living
Carol Howard	Community Hospital, Grand Junction
Carol Keller	The Center for Mental Health
Carol Mitchell	Seniors' Resource Center
Carolyn	Bright Assisted Living
Cassandra Keller	HCPF
Cassie Elder	Hospice
Cathy Story	Hilltop - ALs
Charlene Korrell	Kiowa County Hospital District
Chery Arroyave	The Chateaus, LLC
Christine Duran	AHCA
Christine Jacobson	Solvista Health
Christine Vittum	Saint Joseph Hospital
Cindy Dutton	Continuum of Colorado-PASA
Colleen	Colorado Mental Health Institute at Fort Logan
Patricia Cook	Colorado Gerontological Society
Connie Hampton Thierolf	Belmar ASC, LLC / Pain Centers of America, LLC
Constance McWilliams	Colorado Health Care Training
Courtney Hansen	5280 Home Care
Cynthia Espinoza	Blue Peaks Developmental Services
Cynthia Parson	Colorado Hospital Association
Dave Koehler	Lighthouse Elder Care
David Hayden	Mind Springs Health
David Bolin	AOI Homecare and Colorado Longterm Assistance Service

	Providers (CLASP)
Dawn Darvalics	The Denver Hospice
Deb Majors	Continuum Health Management
Debbie Wolf	Vail Valley Hospital
Debra Fowler	Communi-Care, LLC
Denisa Jusic	Surginsite
Diana Loshak	Blue Spruce Home Care Inc
Diana Patty	DDRC
Diane Bricker	Community Hospital
Diane Rossi MacKay	Colorado Hospital Association
Dick Kandiko	Bloomin' Babies Birth Center
Donna Koehler	Lighthouse Elder Care
Doug Bonino	Developmental Pathways
Dwan Gant	United Providers
Eddy Boyles	Julia Temple
Eileen Doherty	Colorado Gerontological Society
Eliza Schultz	Home Care Association of Colorado
Elizabeth Lee	Home Care Assisted Living Homes
Ellen Stern	Children's Hospital Colorado
Ellie Blasco	Broomfield Hospital Quality/Safety/Infection Prevention
Emily Wilson	FirstLight Home Care
Erica Jones	consulting on quality
Erin Amengual	Evergreen Home Healthcare
Erin Satsky	Vail Health Hospital
Erin Youngblood	Comfort Keepers
Fred Miles	Greenberg Traurig LLP
Gabrrielle Stein McCormick	NSMC
Gary Prager	Architect
George Augustini	SSR
George Wang	SIRUM - med donation
Georgiana Russell	Program Director for Community Options
Gerald Niederman	Polsinelli PC
Gil Yildiz	HomeLife LLC
GINNY HALLAGIN	DDI
Gulchehra Kuchakova	Summit Home Care
Heather De Vries	Right By Your Side Home Care, LLC
Heather Han	
Holly Hall RHIA	SCL Health
Holly Raymer	Nursing Home Administrator
Indy Frazee	The Independence Center
Jason	Life Care of Westminster
Jean DiMicco	Vibra Hospital - Denver
Jeanette Ortiz	ABC HOME HEALTH PERSONAL SERVICES
Jeanne Terrell	Residential Director DDRC/QLO
Jenn Palmer	GCI Stephens Farm
Jennifer Klaers	UCHealth
Jennifer Nelson	JJN HOME HEALTH AGENCY INC
Jennifer Wingenbach	Evergreen Home Healthcare
Jeny Knight	Hilltop Life Adjustment Program

Jerri Schomaker	Home Instead Senior Care
Jessica Bousselaire	SCL Health- Lutheran Medical Center
Jessica Fucito	Axis Health System
Jill Finan	Care and Comfort at Home
Jimmy Trujillo III	Interim HealthCare of Pueblo
Joanie Ackerman	Christian Living Communities - Holly Creek
JoAnn Toney	Mental Health Center of Denver
Jodi Walters	PPCH
Jody Davenport	Benefit Home Health
Joe Stanton	Administrator, Family Home Health
Joe Zamarripa	Care Giver
Jonna Kay McClure	Boone Guest Home
josh sparks	Monarch Manor
Joshua Shipman	
Justin Martinez	ICF
Kaitlin Stanton	Family Home Health
Karen Martinez	CG Health Inc
Karen Beaugh	Orthopedic & Spine Center of the Rockies
Karen L Kirkpatrick	Monte Vista Estates(Invigorate Healthcare)
Karen Loughlin	Denver Center for Birth and Wellness
Karen Mooney	AllHealth Network
Karen Sturgis	Small ALR
Karen Sundby	
Katherine Mataev	Home Health
Katherine Mataev	Amazing Care
Kathy Richie	Lincoln Community Hospital
Katie Shuey	HealthSouth
Kayte Mollendor	Jacon J. & Anne B. Walter Memorial Living Center
Kelley Degarate	Vibra Hospital of Denver
Kelly Mincinski	Pristine Care at Home
Kendra Coco	Vivage Senior Living
Kendra Jessen-Smith	Centura Health - Mercy Regional Medical Center
Kevin D. Peters	Vivage Senior Living
Kevin J.D. Wilson	Children's Hospital Colorado
Kim Boe	West Springs Hospital
Kimberly Diodosio	Hildebrand Home Care, Inc.
Kimberly Smith	Colorado Acute Long Term Hospital
Kisha C. Raby	Community Link Inc.
Kris McCoy	Vibra Rehabilitation Hospital of Denver
Krispen Maske	Mountain Valley Developmental Services
Kristen LeBlanc	Balfour Care
Kristi young	Administrator assisted living
Kristie Braaten	Developmental Disabilities Resource Center
Kristin Stocker	Centura
Kristin Waldrop	NTSOC
Kristy Frihauf	Heritage Healthcare Management, LLC
Kyle Brown	UCHealth
Kym	Shawnee-Gardens
Larry Pedersen	Lighthouse Elder Care

Laura Evans, MS, RN, CCRN	University of Colorado Health
Laura Schiele	Amazing Care Home Health
Laura Simi	Safer Living
Leah Pogoriler	HCPF
Leigh Ann Frost	Overture
Leilani Glaser	LANI s CARE NETWORK
Leslie Lane	Senior Housing Options
LIBAN GURHAN	EXCLUSIVE HEALTH CARE
Lily Smith	The Academy
Linda Ellegard	Special Kids Special Families
Linda Michael	Children's Hospital Colorado
LISA A CZOLOWSKI	BEATRICE HOVER ASSISTED LIVING
Lisa Foster	Administrator/Home Health VP
Lisa Foster	HCA/HealthONE
Lisa Foster	Saint Joseph Hospital Office of Patient Relations
Lori Palmisano	Administrator, Paragon Healthcare
Lori Pereira	Community Reach Center
Lori Swanson-Lamm	Jefferson Center
Lourae King	South Central Council of Governments
Maggie Sparks	Monarch Manor
Maggie Blake	Visiting Angels
Margaret Cozza	Leading Age
Maria Blaylock	Memory Care Director Harvard Square
Maribeth Muhonen	Home Helpers Home Care
Marilyn Jansen	Assisted Living
Mark Bradshaw	FirstLight HomeCare of Northern Colorado
Mark Jelinske	Representing ASHE, Employed by RMH Group Inc.
Marlene Wilcox	
Martin Snow	AllStaff HomeCare, LLC
Mary Beth Bouhall	CHI Living Communities
Mary C. Turner	Bruce McCandless Veterans Community Living Center
Mary Crumbaker	Vail Health
Mary Jo Hallaert	UC Health
MARZIEH Z GHAVIPANJEH	
Matthew Compton	Eating Recovery Center
Maureen Lessig	Boulder Medical Center ASC
Meghan Hucke	Rocky Mountain Healthcare Services
Melissa Joseph	New Century Hospice
Melissa Latham	Larchwood Inns
Mergen Mittleider, MSW	Andrea's Angels, Inc.
Micaela	AORN
Michael Dunn	Union Printers Home
Michelle Gay	San Luis Valley Health
Michelle Glasgow	Electronic Assisted Living Documentation Software Company
Michelle Layman	Castle Country Assisted Living, Inc.
Michelle Lee	RCS
Michelle Westerman	Live to Assist
Mike Goldman	

Mina Akbari	
Monica Londono	Owner Non-Medical Homecare Agency
Moses Gur	Colorado Behavioral Healthcare Council
Nancy Timothy	Wellage, Arborview assisted living
Olesya Galimova	Inspiration Home Health Care
Oluwole Jolaoso	President/CEO
Pamela Franklin	South Denver Endoscopy Center and Ridge View Endoscopy Center
Pat Mehnert	Care Synergy
Paula Padilla	Belmont Lodge Health Care
Phyllis K Sanchez	
Priscilla Bapp	Master's Touch Homes, Inc.
Raquel Martin	Compass Care Supports
Regina DiPadova	Cheyenne village
Rhonda Brown	The Villa's at Sunny Acres
Richard C Koons	
Richard Clark	HCPF
Richard Quintanilla	5280 Home Care
Rita Hetrick	Walsh Health Care Center
Rochelle Fehrn	
Ron Berge	
Ronda Worrall	Rangely District Hospital Home Health
Rosalinda Lozano	CNA
Rose McCallin	DORA-DPO
Rosemarie Romano	Personal Touch Senior Services
Sallie Bernard	
Sandra Acevedo	SENIORS Helping SENIORS
Sandra McCarthy	Hall Render Killian Heath & Lyman
Sara Seeburger	Centura Health
Sarah Hall-Shalvoy	Presbyterian St. Luke's Medical Center
Sarita Reddy	Greeley Center for Independence
Scot Houska	Licensed facility
Serena Akinahew	Angels Service LLC
Shari Karmen	TLC Learning Center
Sharmarke Gaani	Home Health Care
Shelly	Business Owner
Shelly Wilson	Continuum of Colorado
Sonya Vick	Chateau at Rifle
Sophia Akrami	Owner
Stacey Johnson	Sunny Vista Living Center
Stacy Newman-Roolf	Senior Solutions, Inc.
Stacy Santiago	PASCO
Stacy Tennant	Ashley Manor
Steve Eberle	UCHealth
Steve Henry	Harvard Park Surgery Center
Steven Stock	Cheyenne Village, Inc.
Sue Cox	Family Caregiver Agency
Susan Dellinger	FirstLight Home Care
Susan Grayson	CLC

Susie O'Dell	Porter Place Assisted Living
Suzanne Fairbanks	
Suzanne Golden	University of Colorado Hospital
Suzie Swanson	hospice
Tammy Valdez	South Central Council of Governments
Tammy Ford	Facility Admin
Tatihana Quinteros	Colorado Healthcare Solutions, Inc
Teddi Samuel	SLP Colorado
Teresa Hornbuckle	PASA
Theresa Wrangham	National Vaccine Information Center
Tim Johnson	Blue Peaks
Tina Nelson	Healthcare Regulatory Consultant
Tom Hill	Nurse Next Door
Tracy Flitcraft	RN
Tracy Waite	Aspen Ridge Alzheimer's Special Care Center
Valley Jean Williford	Aspen Gardens Assisted Living
Veronica Howell	Good Samaritan Bonell/Greeley
Whitney Bartels	Colorado Hospital Association
Yelli Moningka	Owner
Yuliya Gostishcheva	
Zachary Strunk	Balfour Senior Living

Stakeholder Group Notification

The stakeholder group was provided notice of the rulemaking hearing and provided a copy of the proposed rules or the internet location where the rules may be viewed. Notice was provided prior to the date the notice of rulemaking was published in the Colorado Register (typically, the 10th of the month following the Request for Rulemaking).

__X__ Not applicable. This is a Request for Rulemaking Packet. Notification will occur if the Board of Health sets this matter for rulemaking.

____ Yes.

Summarize Major Factual and Policy Issues Encountered and the Stakeholder Feedback Received. If there is a lack of consensus regarding the proposed rule, please also identify the Department's efforts to address stakeholder feedback or why the Department was unable to accommodate the request.

The Department and stakeholders engaged in an extensive process in order to reach consensus on the proposed rules. Areas that were of most concern and discussion were:

- Part 3 General Building and Fire Safety Provisions: stakeholders had several questions regarding what was different between the 2010 edition of FGI that is currently referenced throughout all the chapters of 6 CCR 1011-1 and the 2018 edition. Once the Department was able to educate the stakeholders on the 2018 edition, as well as explain how the process of the review would take place, consensus was reached.
- Part 4.2 Occurrence Reporting: Multiple stakeholders asked that the Department review the timelines associated with the reporting of occurrences. The Department agreed to review and discuss any alternative timelines that were suggested, but no

alternatives were submitted to the Department. Thus, no changes were made because the Department determined that the timelines currently in regulation were appropriate.

- Part 11 Influenza Immunization of Employees and Direct Contractors: The Department received extensive comments that related to mandated vaccines generally from individuals who opposed the requirement that employees or direct contactors receive an annual influenza vaccination. Facilities and agencies that are subject to Chapter 2 regulation voiced that they found the requirements to be reasonable and not burdensome. The language changes made were agreed upon to clarify which employees and direct contractors were subject to the 90% vaccination rate required of facilities and agencies, and do not expand or decrease the requirements of the original rule.

Please identify the determinants of health or other health equity and environmental justice considerations, values or outcomes related to this rulemaking.

The proposed rule continues to hold all licensed facilities to the same standards, regardless of location or population served.

Overall, after considering the benefits, risks and costs, the proposed rule:

Select all that apply.

	Improves behavioral health and mental health; or, reduces substance abuse or suicide risk.		Reduces or eliminates health care costs, improves access to health care or the system of care; stabilizes individual participation; or, improves the quality of care for unserved or underserved populations.
	Improves housing, land use, neighborhoods, local infrastructure, community services, built environment, safe physical spaces or transportation.		Reduces occupational hazards; improves an individual's ability to secure or maintain employment; or, increases stability in an employer's workforce.
	Improves access to food and healthy food options.		Reduces exposure to toxins, pollutants, contaminants or hazardous substances; or ensures the safe application of radioactive material or chemicals.
X	Improves access to public and environmental health information; improves the readability of the rule; or, increases the shared understanding of roles and responsibilities, or what occurs under a rule.		Supports community partnerships; community planning efforts; community needs for data to inform decisions; community needs to evaluate the effectiveness of its efforts and outcomes.
	Increases a child's ability to participate in early education and educational opportunities through prevention efforts that increase protective factors and decrease risk factors, or stabilizes individual participation in the opportunity.		Considers the value of different lived experiences and the increased opportunity to be effective when services are culturally responsive.

	Monitors, diagnoses and investigates health problems, and health or environmental hazards in the community.	X	Ensures a competent public and environmental health workforce or health care workforce.
	Other:_____ _____		Other:_____ _____

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

STANDARDS FOR HOSPITALS AND HEALTH FACILITIES CHAPTER 2 – GENERAL LICENSURE STANDARDS

6 CCR 1011-1 Chapter 2

Adopted by the Board of Health _____, 2019. Effective _____, 2020.

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

Division Director
Colorado Department of Public Health and Environment
Health Facilities and Emergency Medical Services Division
4300 Cherry Creek Drive South
Denver, Colorado 80246
Main switchboard: (303) 692-2800

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

~~Division Director~~
~~Colorado Department of Public Health and Environment~~
~~Health Facilities and Emergency Medical Services Division~~
~~4300 Cherry Creek Drive South~~
~~Denver, Colorado 80246~~
~~Main switchboard: (303) 692-2800~~

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

PURSUANT TO 24-4-103(12.5), C.R.S., THE HEALTH FACILITIES AND EMERGENCY MEDICAL SERVICES DIVISION OF THE COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT MAINTAINS COPIES OF THE INCORPORATED MATERIALS FOR PUBLIC INSPECTION DURING REGULAR BUSINESS HOURS. THE REQUIREMENTS IN SECTION 3.2.3 DO NOT INCLUDE ANY AMENDMENTS, EDITIONS OR CHANGES PUBLISHED AFTER NOVEMBER 1, 2019. INTERESTED PERSONS MAY OBTAIN CERTIFIED COPIES OF ANY NON-COPYRIGHTED MATERIAL FROM THE DEPARTMENT AT COST UPON REQUEST. INFORMATION REGARDING HOW INCORPORATED MATERIAL MAY BE OBTAINED OR EXAMINED IS AVAILABLE BY CONTACTING:

DIVISION DIRECTOR
COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT
HEALTH FACILITIES AND EMERGENCY MEDICAL SERVICES DIVISION
4300 CHERRY CREEK DRIVE SOUTH
DENVER, COLORADO 80246-1530

MAIN SWITCHBOARD: (303) 692-2800

ADDITIONALLY, MATERIALS INCORPORATED BY REFERENCE HAVE BEEN SUBMITTED TO THE STATE PUBLICATIONS DEPOSITORY AND DISTRIBUTION CENTER AND ARE AVAILABLE FOR INTERLIBRARY LOANS AND THROUGH THE STATE LIBRARIAN.

INDEX

PART 1. DEFINITIONS ~~GENERAL BUILDING AND FIRE SAFETY PROVISIONS~~

Commented [HA1]: All definitions from throughout the Chapter will move to this part as need be.

~~1.100 SUBMISSION OF CONSTRUCTION PLANS/DOCUMENTS~~

~~Effective July 1, 2013, all health facility buildings and structures shall be constructed in conformity with the standards adopted by the Director of the Division of Fire Prevention and Control at the Colorado Department of Public Safety.~~

1.1 "ABUSE" MEANS THE WILLFUL INFLICTION OF INJURY, UNREASONABLE CONFINEMENT, INTIMIDATION, OR PUNISHMENT, WITH RESULTING PHYSICAL HARM, PAIN, OR MENTAL ANGUISH.

Commented [BF2]: Moved from 6.102(1)

1.2 "ADDITION" MEANS THE ADDITION OF MORE SPACE THAT WAS PREVIOUSLY NOT PART OF THE LICENSED FACILITY. THE ADDITION MAY BE NEW CONSTRUCTION OR EXISTING STRUCTURES THAT ARE BEING REPURPOSED FOR CLIENT USE.

1.3 "ADMINISTRATIVE OFFICER" MEANS THE PERSON APPOINTED BY THE GOVERNING BODY OF THE FACILITY OR AGENCY WHO IS RESPONSIBLE FOR THE DAY-TO-DAY MANAGEMENT OF THE FACILITY OR AGENCY.

Commented [BF3]: Moved from old 6.202(2)

1.4 "ADMISSION" MEANS THE ACCEPTANCE OF A PERSON AS A CLIENT OF THE FACILITY OR AGENCY.

Commented [BF4]: Moved from 6.102(2)

1.5 "ADVANCE DIRECTIVE" MEANS A WRITTEN INSTRUCTION CONCERNING MEDICAL TREATMENT DECISIONS TO BE MADE ON BEHALF OF THE ADULT WHO PROVIDED THE INSTRUCTION IN THE EVENT THAT THEY BECOME INCAPACITATED.

Commented [BF5]: New, modified from 15-18.7-102, C.R.S

1.6 "BOARD" MEANS THE STATE BOARD OF HEALTH.

Commented [HA6]: From Waivers

1.7 "BUILDING PERMIT" MEANS AN OFFICIAL DOCUMENT ISSUED BY THE LOCAL BUILDING DEPARTMENT OR OTHER LOCAL JURISDICTION WHICH AUTHORIZES ERECTION, ALTERATION, DEMOLITION AND/OR MOVING OF BUILDINGS AND STRUCTURES.

Commented [HA7]: New, adapted from 8 CCR 1507-31, Building, Fire, and Life Safety Code Enforcement

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

Commented [HA8]: Moved from 2.2.1

1.9 "CAMPUS" MEANS THE PHYSICAL AREA IMMEDIATELY ADJACENT TO THE FACILITY'S OR AGENCY'S MAIN BUILDING(S), OTHER AREAS AND STRUCTURES THAT ARE NOT STRICTLY CONTIGUOUS TO THE MAIN BUILDING(S) BUT ARE LOCATED WITHIN 250 YARDS OF THE MAIN BUILDING(S) AND ANY OTHER AREAS DETERMINED BY THE DEPARTMENT, ON AN INDIVIDUAL CASE BASIS, TO BE PART OF THE FACILITY'S OR AGENCY'S CAMPUS.

Commented [HA9]: Moved from 2.2.2

1.10 "CAPACITY" MEANS THE NUMBER OF CLIENTS TO WHOM A FACILITY OR AGENCY IS ABLE TO PROVIDE SERVICES. "CAPACITY" IS SYNONYMOUS WITH THE TERM "BED" AS USED IN THIS CHAPTER AND ELSEWHERE IN 6 CCR 1011.

1.11 "CHEMICAL RESTRAINT" MEANS GIVING AN INDIVIDUAL MEDICATION INVOLUNTARILY FOR THE PURPOSE OF RESTRAINING THAT INDIVIDUAL; EXCEPT THAT "CHEMICAL RESTRAINT" DOES NOT INCLUDE THE INVOLUNTARY ADMINISTRATION OF MEDICATION PURSUANT TO SECTION 27-65-111(5), C.R.S., OR ADMINISTRATION OF MEDICATION FOR VOLUNTARY OR LIFE-SAVING MEDICAL PROCEDURES.

Commented [BF10]: Moved from Restraint and Seclusion (old 8.102(1))

1.12 "CLIENT" MEANS ANY PERSON RECEIVING SERVICES FROM A FACILITY OR AGENCY THAT IS SUBJECT TO LICENSING PURSUANT TO SECTION 25-3-101, C.R.S. THE TERM "CLIENT" IS SYNONYMOUS WITH THE TERMS "PATIENT", "RESIDENT", OR "CONSUMER" AS USED ELSEWHERE IN 6 CCR 1011-1.

1.13 "CLIENT CARE ADVOCATE" MEANS THE PERSON OR PERSONS DESIGNATED BY A FACILITY OR AGENCY TO FUNCTION AS THE PRIMARY CONTACT TO RECEIVE COMPLAINTS FROM CLIENTS REGARDING SERVICES.

1.14 "CLIENT RECORD" IS THE DOCUMENTATION OF SERVICES THAT ARE PERFORMED FOR THE CLIENT BY THE FACILITY OR AGENCY. CLIENT RECORDS INCLUDE SUCH DIAGNOSTIC DOCUMENTATION AS X-RAYS AND EKG'S. CLIENT RECORDS DO NOT INCLUDE HEALTH CARE PROVIDER OFFICE NOTES, WHICH ARE THE NOTES OF OBSERVATIONS ABOUT THE CLIENT MADE WHILE THE CLIENT IS IN A NON-HOSPITAL SETTING AND MAINTAINED IN THE HEALTH CARE PROVIDER'S OFFICE.

1.15 "CONTROLLING INTEREST" MEANS THE OPERATIONAL DIRECTION OR MANAGEMENT OF A FACILITY OR AGENCY INCLUDING, BUT NOT LIMITED TO, THE AUTHORITY, EXPRESS OR RESERVED, TO CHANGE THE CORPORATE IDENTITY OF THE APPLICANT; THE AUTHORITY TO APPOINT MEMBERS OF THE BOARD OF DIRECTORS, BOARD OF TRUSTEES, OR OTHER APPLICABLE GOVERNING BODY OF THE FACILITY OR AGENCY; THE ABILITY TO CONTROL ANY OF THE ASSETS OR OTHER PROPERTY OF THE FACILITY OR AGENCY OR TO DISSOLVE OR SELL THE FACILITY OR AGENCY.

Commented [HA11]: Moved from 2.2.3

1.16 "DEFICIENCY" MEANS A FAILURE TO FULLY COMPLY WITH ANY STATUTORY AND/OR REGULATORY REQUIREMENTS APPLICABLE TO A LICENSEE.

Commented [HA12]: Moved from 2.2.4

1.17 "DEPARTMENT" MEANS THE COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT.

1.18 "DESIGN DOCUMENTS" MEANS CURRENT CONSTRUCTION PLANS, SPECIFICATIONS, AND ANY OTHER INFORMATION AS REQUESTED BY THE DEPARTMENT FOR A GUIDELINE COMPLIANCE REVIEW. DESIGN DOCUMENTS SHOULD BE COMPLETED IN A MANNER CONSISTENT WITH THE PRACTICE OF ARCHITECTURE AS FOUND AT SECTION 12-25-301, C,R.S., *ET SEQ.* AND 4 CCR 730-1, BYLAWS AND RULES OF THE STATE BOARD OF LICENSURE FOR ARCHITECTS, PROFESSIONAL ENGINEERS, AND PROFESSIONAL LAND SURVEYORS.

1.19 "DESIGNATED REPRESENTATIVE" MEANS A DESIGNATED REPRESENTATIVE OF A CLIENT OR SERVICE PROVIDER WHO IS A PERSON SO AUTHORIZED IN WRITING OR BY COURT ORDER TO ACT ON BEHALF OF THE

Commented [HA13]: Moved from 5.1.4

CLIENT OR SERVICE PROVIDER. IN THE CASE OF A DECEASED CLIENT, THE PERSONAL REPRESENTATIVE, AS DEFINED AT SECTION 15-10-201(39), C.R.S., OR, IF NONE HAS BEEN APPOINTED, HEIRS SHALL BE DEEMED TO BE DESIGNATED REPRESENTATIVES OF THE CLIENT.

1.20 "DIRECT OWNERSHIP" MEANS THE POSSESSION OF STOCK, EQUITY IN CAPITAL OR ANY INTEREST GREATER THAN 5 PERCENT OF THE FACILITY OR AGENCY.

Commented [HA14]: Moved from 2.2.6

1.21 "ENFORCEMENT ACTIVITY" MEANS THE IMPOSITION OF REMEDIES SUCH AS CIVIL MONEY PENALTIES; APPOINTMENT OF A RECEIVER OR TEMPORARY MANAGER; CONDITIONAL LICENSURE; SUSPENSION OR REVOCATION OF A LICENSE; A DIRECTED PLAN OF CORRECTION; INTERMEDIATE RESTRICTIONS OR CONDITIONS, INCLUDING RETAINING A CONSULTANT, DEPARTMENT MONITORING, OR PROVIDING ADDITIONAL TRAINING TO EMPLOYEES, OWNERS, OR OPERATORS; OR ANY OTHER REMEDY PROVIDED BY STATE OR FEDERAL LAW OR AUTHORIZED BY FEDERAL SURVEY, CERTIFICATION, AND ENFORCEMENT REGULATIONS AND AGREEMENTS FOR VIOLATIONS OF FEDERAL OR STATE LAW.

Commented [HA15]: Moved from 2.2.7

1.22 "FGI GUIDELINES" MEANS THE GUIDELINES FOR DESIGN AND CONSTRUCTION OF HOSPITALS, GUIDELINES FOR DESIGN AND CONSTRUCTION OF OUTPATIENT FACILITIES, AND GUIDELINES FOR DESIGN AND CONSTRUCTION OF RESIDENTIAL HEALTH, CARE, AND SUPPORT FACILITIES, PUBLISHED BY THE FACILITIES GUIDELINES INSTITUTE.

1.23 "GRIEVANCE" MEANS A WRITTEN OR VERBAL COMPLAINT THAT IS MADE BY A CLIENT OR THE CLIENT'S DESIGNATED REPRESENTATIVE TO A FACILITY OR AGENCY THAT CANNOT BE RESOLVED AT THE TIME BY A STAFF PERSON. IF THE COMPLAINT INVOLVES OCCURRENCES SPECIFIED IN SECTION 25-1-124(2), C.R.S., THE FACILITY OR AGENCY SHALL REPORT IT TO THE DEPARTMENT, AS REQUIRED BY SECTION 4.2 OF THESE RULES.

1.24 "GRIEVANCE MECHANISM" MEANS THE PROCESS WHEREBY COMPLAINTS BY CLIENTS OR THE CLIENT'S DESIGNATED REPRESENTATIVE MAY BE INITIATED AND RESOLVED BY THE FACILITY OR AGENCY.

Commented [HA16]: Moved from 6.202

1.25 "GUIDELINE COMPLIANCE REVIEW" MEANS THE REVIEW OF DESIGN DOCUMENTS SUBMITTED TO THE DEPARTMENT, IN THE FORMAT REQUIRED BY THE DEPARTMENT, FOR DETERMINATION OF COMPLIANCE WITH FGI GUIDELINES.

1.26 "GUIDELINE COMPLIANCE REVIEW REPRESENTATIVE" MEANS A PERSON DESIGNATED BY THE LICENSEE OR APPLICANT TO SUBMIT DESIGN DOCUMENTS TO THE DEPARTMENT ON BEHALF OF THE LICENSEE OR APPLICANT.

1.27 "INDIRECT OWNERSHIP" MEANS ANY OWNERSHIP INTEREST IN A BUSINESS ENTITY THAT HAS AN OWNERSHIP INTEREST IN THE APPLICANT OR LICENSEE, INCLUDING AN OWNERSHIP INTEREST IN ANY BUSINESS ENTITY THAT HAS AN INDIRECT OWNERSHIP INTEREST IN THE APPLICANT OR LICENSEE.

Commented [HA17]: Moved from 2.2.9

1.28 "INFLUENZA SEASON" MEANS NOVEMBER 1 THROUGH MARCH 31 OF THE FOLLOWING YEAR, OR AS OTHERWISE DEFINED BY THE DISEASE CONTROL AND ENVIRONMENTAL EPIDEMIOLOGY DIVISION WITHIN THE DEPARTMENT.

Commented [BF18]: moved from 10.5(H)

1.29 "INFLUENZA VACCINE" MEANS A CURRENTLY LICENSED UNITED STATES FOOD AND DRUG ADMINISTRATION APPROVED VACCINE PRODUCT.

Commented [BF19]: moved from 10.5.(I)

1.30 "INFORMED CONSENT" MEANS:

Commented [HA20]: moved from 6.102(3)

(A) AN EXPLANATION OF THE NATURE AND PURPOSE OF THE RECOMMENDED TREATMENT OR PROCEDURE IN LAYMAN'S TERMS AND IN A FORM OF COMMUNICATION UNDERSTOOD BY THE CLIENT OR THE CLIENT'S DESIGNATED REPRESENTATIVE;

(B) AN EXPLANATION OF THE RISKS AND BENEFITS OF A TREATMENT OR PROCEDURE, THE PROBABILITY OF SUCCESS, MORTALITY RISKS, AND SERIOUS SIDE EFFECTS;

(C) AN EXPLANATION OF THE ALTERNATIVES WITH THE RISKS AND BENEFITS OF THESE ALTERNATIVES;

(D) AN EXPLANATION OF THE RISKS AND BENEFITS IF NO TREATMENT IS PURSUED;

(E) AN EXPLANATION OF THE RECUPERATIVE PERIOD WHICH INCLUDES A DISCUSSION OF ANTICIPATED PROBLEMS; AND

(F) AN EXPLANATION THAT THE CLIENT, OR THE CLIENT'S DESIGNATED REPRESENTATIVE, IS FREE TO WITHDRAW CONSENT AND TO DISCONTINUE PARTICIPATION IN THE TREATMENT REGIMEN AT ANY TIME.

1.31 "INITIAL LICENSE" MEANS THE LICENSING OF A FACILITY OR AGENCY THAT IS NOT CURRENTLY LICENSED, AS WELL AS A LICENSURE CHANGE FROM ONE TYPE TO ANOTHER.

1.32 "LETTER OF INTENT" MEANS THE NOTIFICATION PROVIDED TO THE DEPARTMENT RELATED TO AN APPLICATION FOR A LICENSE, TO MAKE CHANGES TO AN EXISTING LICENSE, TO MAKE CHANGES IN SERVICES PROVIDED BY THE ENTITY, OR FOR ANY OTHER BUSINESS REASON THE DEPARTMENT REQUESTS.

1.33 "LICENSED INDEPENDENT PRACTITIONER" MEANS AN INDIVIDUAL PERMITTED BY LAW AND THE FACILITY OR AGENCY TO INDEPENDENTLY DIAGNOSE, INITIATE, ALTER, OR TERMINATE HEALTH CARE TREATMENT WITHIN THE SCOPE OF THEIR LICENSE.

Commented [HA21]: moved from 6.102(5)

1.34 "LICENSEE" MEANS A FACILITY OR AGENCY THAT IS REQUIRED TO OBTAIN A LICENSE, OR A CERTIFICATE OF COMPLIANCE FOR GOVERNMENTAL ENTITIES, FROM THE DEPARTMENT PURSUANT TO SECTION 25-3-101, C.R.S.

Commented [HA22]: moved from 2.2.10

1.35 "MANAGEMENT COMPANY" MEANS THE PERSON, BUSINESS ENTITY, OR AGENCY THAT IS PAID BY THE LICENSEE AND HAS A CONTRACTUAL AGREEMENT WITH THE LICENSEE TO MANAGE THE DAY-TO-DAY OPERATION OF THE FACILITY OR AGENCY ON BEHALF OF THE LICENSEE.

Commented [HA23]: moved from 2.2.11

1.36 "MECHANICAL RESTRAINT" MEANS A PHYSICAL DEVICE USED TO INVOLUNTARILY RESTRICT THE MOVEMENT OF AN INDIVIDUAL OR THE MOVEMENT OR NORMAL FUNCTION OF A PORTION OF HIS OR HER BODY. PHYSICAL RESTRAINTS USED FOR FALL PREVENTION, INCLUDING BUT NOT LIMITED TO RAISED BED RAILS, ARE CONSIDERED MECHANICAL RESTRAINTS.

Commented [HA24]: moved from 8.102(3), physical restraint clarification moved from 6.102(10)

1.37 "MEDICAL DEVICE" MEANS AN INSTRUMENT, APPARATUS, IMPLEMENT, MACHINE, CONTRIVANCE, IMPLANT, OR SIMILAR OR RELATED ARTICLE THAT IS REQUIRED TO BE LABELED PURSUANT TO 21 CFR PART 801.

Commented [HA25]: moved from 7.201(5)

1.38 "MEDICAL SUPPLY" MEANS A CONSUMABLE SUPPLY ITEM THAT IS DISPOSABLE AND NOT INTENDED FOR REUSE.

Commented [HA26]: moved from 7.201(6)

1.39 "MINOR ALTERATIONS" MEANS BUILDING CONSTRUCTION PROJECTS WHICH ARE NOT ADDITIONS, WHICH DO NOT AFFECT THE STRUCTURAL INTEGRITY OF THE BUILDING, WHICH DO NOT CHANGE FUNCTIONAL

OPERATION, AND/OR WHICH DO NOT ADD BEDS OR CAPACITY ABOVE WHAT THE FACILITY IS LIMITED TO UNDER THE EXISTING LICENSE.

1.40 "NEGLECT" MEANS THE FAILURE TO PROVIDE GOODS AND SERVICES NECESSARY TO ATTAIN AND MAINTAIN PHYSICAL AND MENTAL WELL-BEING.

Commented [HA27]: moved from 6.102(7)

1.41 "NEW CONSTRUCTION" MEANS THE CONSTRUCTION OF NEW BUILDINGS OR NEWLY CONSTRUCTED ADDITIONS.

1.41 "PALLIATIVE CARE" MEANS SPECIALIZED MEDICAL CARE FOR PEOPLE WITH SERIOUS ILLNESSES. THIS TYPE OF CARE IS FOCUSED ON PROVIDING CLIENTS WITH RELIEF FROM THE SYMPTOMS, PAIN, AND STRESS OF SERIOUS ILLNESS, WHATEVER THE DIAGNOSIS. THE GOAL IS TO IMPROVE QUALITY OF LIFE FOR BOTH THE CLIENT AND THE INDIVIDUALS WHO ARE IDENTIFIED AS THE CLIENT'S PERSONAL SUPPORT SYSTEM. PALLIATIVE CARE IS PROVIDED BY A TEAM OF PHYSICIANS, NURSES, AND OTHER SPECIALISTS WHO WORK WITH A CLIENT'S OTHER HEALTH CARE PROVIDERS TO PROVIDE AN EXTRA LAYER OF SUPPORT. PALLIATIVE CARE IS APPROPRIATE AT ANY AGE AND AT ANY STAGE IN A SERIOUS ILLNESS AND CAN BE PROVIDED TOGETHER WITH CURATIVE TREATMENT. UNLESS OTHERWISE INDICATED, THE TERM "PALLIATIVE CARE" IS SYNONYMOUS WITH THE TERMS "COMFORT CARE," "SUPPORTIVE CARE," AND SIMILAR DESIGNATIONS.

Commented [HA28]: moved from 2.2.12

1.42 "PHARMACIST" MEANS A PHARMACIST LICENSED IN THE STATE OF COLORADO.

Commented [BF29]: Moved from 7.201(8)

1.43 "PHASED SUBMITTAL" MEANS THE SUBMITTAL OF A SUBSET OF THE DESIGN DOCUMENTS AS RELATED TO WORK TASKS THAT ARE TO BEGIN PRIOR TO THE TIME THAT ALL BUILDING DETAILS ARE FINALIZED, IN ORDER TO ALLOW INITIAL WORK TO START ON PROJECTS THAT ARE COMPLEX AND LONG-TERM IN NATURE.

1.44 "PHYSICAL RESTRAINT" MEANS THE USE OF BODILY, PHYSICAL FORCE TO INVOLUNTARILY LIMIT AN INDIVIDUAL'S FREEDOM OF MOVEMENT; EXCEPT THAT "PHYSICAL RESTRAINT" DOES NOT INCLUDE THE HOLDING OF A CHILD BY ONE ADULT FOR THE PURPOSES OF CALMING OR COMFORTING THE CHILD.

Commented [HA30]: Moved from 8.102(4)

1.45 "PROOF OF IMMUNIZATION" MEANS AN ELECTRONIC ENTRY IN THE COLORADO IMMUNIZATION INFORMATION SYSTEM (CIIS) OR AN IMMUNIZATION RECORD FROM A LICENSED HEALTHCARE PROVIDER WHO HAS ADMINISTERED AN INFLUENZA VACCINE TO AN INDIVIDUAL WHO PROVIDES SERVICES FOR THE FACILITY OR AGENCY, SPECIFYING THE VACCINE ADMINISTERED, NAME AND TITLE OF THE PERSON WHO ADMINISTERED THE VACCINE, ADDRESS OF THE LOCATION WHERE THE VACCINE WAS ADMINISTERED, AND THE DATE IT WAS ADMINISTERED.

Commented [HA31]: Moved from 10.5(K)

1.46 "RENOVATION" MEANS THE MOVING OF WALLS AND RECONFIGURING OF EXISTING FLOOR PLANS. IT INCLUDES THE REBUILDING OR UPGRADING OF MAJOR SYSTEMS, INCLUDING BUT NOT LIMITED TO: HEATING, VENTILATIONS AND ELECTRICAL SYSTEMS. IT ALSO MEANS THE CHANGING OF THE FUNCTIONAL OPERATION OF THE SPACE. RENOVATIONS DO NOT INCLUDE "MINOR ALTERATIONS," AS DEFINED HEREIN.

1.47 "RESPONSIBLE DESIGN PROFESSIONAL" MEANS A REGISTERED ARCHITECT, LICENSED PROFESSIONAL, OR OTHER INDIVIDUAL WHO PREPARES AND SIGNS THE DESIGN DOCUMENTS SUBMITTED TO THE DEPARTMENT FOR THE GUIDELINE COMPLIANCE REVIEW.

1.48 "RESTRAINT" MEANS ANY METHOD OR DEVICE USED TO INVOLUNTARILY LIMIT FREEDOM OF MOVEMENT, INCLUDING BUT NOT LIMITED TO BODILY PHYSICAL FORCE, MECHANICAL DEVICES, OR CHEMICALS. "RESTRAINT" INCLUDES A CHEMICAL RESTRAINT, A MECHANICAL RESTRAINT, A PHYSICAL RESTRAINT, AND SECLUSION.

Commented [HA32]: Moved from 6.102(10)

1.49 "REVIEW" MEANS ANY TYPE OF ADMINISTRATIVE OVERSIGHT BY THE DEPARTMENT INCLUDING, BUT NOT LIMITED TO, EXAMINATION OF DOCUMENTS, DESK AUDIT, COMPLAINT INVESTIGATION OR ON-SITE INSPECTION.

Commented [HA33]: Moved from 2.2.13

1.50 "REVISIT" MEANS A FOLLOW-UP SURVEY CONDUCTED AFTER DEFICIENCIES HAVE BEEN CITED. THE PURPOSE IS TO DETERMINE IF THE LICENSEE IS NOW IN COMPLIANCE WITH THE APPLICABLE STATE REGULATIONS OR FEDERAL CONDITIONS OF PARTICIPATION.

Commented [HA34]: Moved from 2.2.13

1.51 "SECLUSION" MEANS THE INVOLUNTARY PLACEMENT OF A PERSON ALONE IN A ROOM FROM WHICH EGRESS IS INVOLUNTARILY PREVENTED.

Commented [BF35]: Moved from 8.102(6)

1.52 "SERVICE PROVIDER" MEANS AN INDIVIDUAL WHO IS RESPONSIBLE FOR A CLIENT'S CARE IN A FACILITY OR AGENCY.

1.53 "SURVEY" MEANS AN INSPECTION OF A FACILITY OR AGENCY FOR COMPLIANCE WITH APPLICABLE STATE REGULATIONS OR FEDERAL CONDITIONS OF PARTICIPATION.

Commented [HA36]: Moved from 2.2.15

1.54 "TIERED INSPECTION" MEANS AN ON-SITE RE-LICENSURE SURVEY THAT HAS A REDUCED SCOPE AND REVIEWS FEWER ITEMS FOR COMPLIANCE WITH APPLICABLE STATE REGULATIONS THAN A FULL RE-LICENSURE SURVEY.

Commented [HA37]: Moved from 1.54

PART 2. LICENSURE PROCESS

~~**Part 2 Licensure Process**~~

2.1 Statutory Authority and Applicability

2.1.1 The statutory authority for the promulgation of these rules is set forth in sections 25-1.5-103 and 25-3-~~101~~ 100.5, *et seq.*, C.R.S.

2.1.2 A FACILITY OR AGENCY ~~health care entity~~ licensed by the Department shall comply with all applicable federal and state statutes and regulations including this Chapter ~~II~~2. In the event of a discrepancy between the Department's regulations, the more specific standards shall apply.

2.1.3 A LICENSES SHALL EXPIRE ONE YEAR FROM THE DATE OF ISSUANCE, UNLESS OTHERWISE ACTED UPON PURSUANT TO PART 2.11 OF THIS CHAPTER.

~~2.2 Definitions~~

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

~~2.2.1 "Business Entity" means any organization or enterprise and includes, but is not limited to, a sole proprietor, an association, corporation, business trust, joint venture, limited liability company, limited liability partnership, partnership or syndicate.~~

~~2.2.2 "Campus" means the physical area immediately adjacent to the FACILITY'S OR AGENCY'S health care entity's main building(s), other areas and structures that are not strictly contiguous to the main building(s) but are located within 250 yards of the main building(s) and any other areas determined by the Department, on an individual case basis, to be part of the FACILITY'S OR AGENCY'S health care entity's campus.~~

2.2.3 "CLIENT" MEANS ANY PERSON RECEIVING SERVICES FROM A FACILITY OR AGENCY THAT IS SUBJECT TO LICENSING PURSUANT 25-3-101, C.R.S. THE TERM "CLIENT" IS SYNONYMOUS WITH THE TERMS "PATIENT", "RESIDENT", OR "CONSUMER" AS USED ELSEWHERE IN 6 CCR 1011-1.

2.2.3 "Controlling Interest" means the operational direction or management of a health care entity FACILITY OR AGENCY including, but not limited to, the authority, express or reserved, to change the corporate identity of the applicant; the authority to appoint members of the board of directors, board of trustees, or other applicable governing body of the FACILITY OR AGENCY health care entity; the ability to control any of the assets or other property of the FACILITY OR AGENCY health care entity or to dissolve or sell the FACILITY OR AGENCY health care entity.

2.2.4 "Deficiency" means a failure to fully comply with any statutory and/or regulatory requirements applicable to a licensed health facility LICENSEE.

2.2.5 "Department" means the Colorado Department of Public Health and Environment.

2.2.6 "Direct Ownership" means the possession of stock, equity in capital or any interest greater than 5 percent of the FACILITY OR AGENCY health care entity.

2.2.7 "Enforcement Activity" means the imposition of remedies such as civil money penalties; appointment of a receiver or temporary manager; conditional licensure; suspension or revocation of a license; a directed plan of correction; intermediate restrictions or conditions, including retaining a consultant, department monitoring, or providing additional training to employees, owners, or operators; or any other remedy provided by state or federal law or as authorized by federal survey, certification, and enforcement regulations and agreements for violations of federal or state law.

2.2.8 "Health Care Entity" means a health care facility or agency that is required to obtain a license from the Department pursuant to section 25-3-101, C.R.S. Unless otherwise indicated, the term "health care entity" is synonymous with the terms "health facility" or "facility" as used elsewhere in 6 CCR 1011-1, Standards for Hospitals and Health Facilities.

2.2.9 "Indirect Ownership" means any ownership interest in an BUSINESS entity that has an ownership interest in the applicant OR LICENSEE, including an ownership interest in any BUSINESS entity that has an indirect ownership interest in the applicant OR LICENSEE.

2.2.10 "LETTER OF INTENT" MEANS THE NOTIFICATION PROVIDED TO THE DEPARTMENT RELATED TO AN APPLICATION FOR A LICENSE, TO MAKE CHANGES TO AN EXISTING LICENSE, CHANGES IN SERVICES PROVIDED BY THE ENTITY, OR FOR ANY OTHER BUSINESS REASON THE DEPARTMENT REQUESTS.

2.2.10 "Licensee" MEANS A FACILITY OR AGENCY THAT IS REQUIRED TO OBTAIN A LICENSE, OR A CERTIFICATE OF COMPLIANCE FOR GOVERNMENTAL ENTITIES, FROM THE DEPARTMENT PURSUANT TO SECTION 25-3-101, C.R.S. means the person, business entity or agency that is granted a license or certificate of compliance to operate a health care entity and that bears legal responsibility for compliance with all applicable federal and state statutes and regulations.

2.2.11 "Management Company" means the person, business entity or agency that is paid by the licensee and has a contractual agreement with the licensee to manage the day-to-day operation of the FACILITY OR AGENCY health care entity on behalf of the licensee.

2.2.12 "Palliative Care" means specialized medical care for people with serious illnesses. This type of care is focused on providing patients CLIENTS with relief from the symptoms, pain and stress of serious illness, whatever the diagnosis. The goal is to improve quality of life for both the patient

~~CLIENT~~ ~~and the family. Palliative care is provided by a team of physicians, nurses and other specialists who work with a patient's~~ ~~CLIENT'S~~ ~~other health care providers to provide an extra layer of support. Palliative care is appropriate at any age and at any stage in a serious illness and can be provided together with curative treatment. Unless otherwise indicated, the term "palliative care" is synonymous with the terms "comfort care," "supportive care," and similar designations.~~

~~2.2.13 "Review" means any type of administrative oversight by the Department including, but not limited to, examination of documents, desk audit, complaint investigation or on-site inspection.~~

~~2.2.14 "Revisit" means a follow-up survey conducted after deficiencies have been cited. The purpose is to determine if the health care entity~~ ~~LICENSEE~~ ~~is now in compliance with the applicable state regulations or federal conditions of participation.~~

~~2.2.15 "Survey" means an inspection of a health care entity~~ ~~FACILITY OR AGENCY~~ ~~for compliance with applicable state regulations or federal conditions of participation.~~

~~2.2.16 "Tiered Inspection" means an on-site relicensure~~ ~~RE-LICENSURE~~ ~~survey that has a reduced scope and reviews fewer items for compliance with applicable state regulations than a full re-licensure survey.~~

2.3~~2~~2 License Required

2.3~~2~~2.1 No person or business entity shall establish, maintain, or operate a ~~health care entity~~ FACILITY OR AGENCY THAT IS SUBJECT TO SECTION 25-3-101, C.R.S. without first having obtained a license ~~therefore~~ or, in the case of governmental facilities, a certificate of compliance from the Department. ~~For purposes of these rules, the holder of a certificate of compliance from the Department of Public Health and Environment shall be considered a licensee.~~

(A) A ~~licensed health care entity~~ LICENSEE that is subject to fire prevention and life safety code requirements shall not provide services in areas subject to plan review except as approved by the Department of Public Safety, Division of Fire Prevention and Control.

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

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

2.3~~2~~2.2 A separate license shall be required for each physical location or campus of a FACILITY OR AGENCY ~~health care entity~~, except as otherwise specified in Chapter ~~IV~~4, General Hospitals and Chapter ~~XXVI~~26, Home Care Agencies.

2.3~~2~~2.3 Each LICENSEE ~~health care entity~~ offering services that are regulated by more than one chapter of 6 CCR 1011-1, Standards for Hospitals and Health Facilities, shall obtain a separate license for each category of services that requires a state license.

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

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

2.~~3~~2.4 Each ~~health care entity~~ FACILITY OR AGENCY that is federally certified shall have a state license for each category of services for which it is certified, if such a license category exists.

~~2.3.5 Each health care entity applying for initial licensure shall submit a distinctive license name that does not mislead or confuse the public regarding the type of health services to be provided. The entity name need not include the services to be provided. If, however, those services are included in the name, that inclusion shall not mislead or confuse the public. Duplication of an existing name is prohibited except between health care entities that are affiliated through ownership or controlling interest.~~

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

Commented [HA38]: Moved to 2.4.3 (A) as (1)-(5)

2.4~~3~~ Initial License Application Procedure

2.4~~3~~.1 Any person or BUSINESS entity seeking a license to operate a ~~health care entity~~ FACILITY OR AGENCY THAT IS SUBJECT TO SECTION 25-3-101, C.R.S. shall initially notify the Department by submitting a letter of intent upon such form and in such manner as prescribed by the Department. ~~Such notification shall include the proposed name, location, license category, services and date of opening of said entity~~. Upon receipt of the letter of intent, the Department will provide the applicant with the appropriate application.

2.4~~3~~.2 The applicant shall provide the Department with a complete application including all information and attachments specified in the application form and any additional information requested by the Department. The appropriate non-refundable fee(s) for the license category requested shall be submitted with the application. Applications shall be submitted at least ninety (90) calendar days before the anticipated start-up date.

(A) A LICENSE APPLICATION MAY BE CONSIDERED ABANDONED IF THE APPLICANT FAILS TO COMPLETE THE APPLICATION WITHIN TWELVE MONTHS AND FAILS TO RESPOND TO THE DEPARTMENT. THE DEPARTMENT MAY ADMINISTRATIVELY CLOSE THE APPLICATION PROCESS.

(B) AFTER AN ADMINISTRATIVE CLOSURE, THE APPLICANT MAY FILE A NEW LICENSE APPLICATION ALONG WITH THE CORRESPONDING INITIAL LICENSE FEE.

2.4~~3~~.3 Each applicant shall provide the following information:

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

(1) APPLICANTS FOR INITIAL LICENSURE SHALL SUBMIT A DISTINCTIVE LICENSE NAME THAT DOES NOT MISLEAD OR CONFUSE THE PUBLIC REGARDING THE LICENSE OR TYPE OF SERVICES TO BE PROVIDED.

(2) THE NAME NEED NOT INCLUDE THE SERVICES TO BE PROVIDED. IF, HOWEVER, THOSE SERVICES ARE INCLUDED IN THE NAME, THAT INCLUSION SHALL NOT MISLEAD OR CONFUSE THE PUBLIC.

(3) DUPLICATION OF AN EXISTING NAME IS PROHIBITED EXCEPT BETWEEN LICENSEES THAT ARE AFFILIATED THROUGH OWNERSHIP OR CONTROLLING INTEREST.

(4) EACH LICENSEE SHALL BE IDENTIFIED BY THIS DISTINCTIVE NAME ON STATIONERY, BILLING MATERIALS, AND EXTERIOR SIGNAGE THAT CLEARLY IDENTIFIES THE LICENSED ENTITY. EXTERIOR SIGNAGE SHALL CONFORM TO THE APPLICABLE LOCAL ZONING REQUIREMENTS.

(5) IF THE LICENSEE HAS A "DOING BUSINESS AS" NAME, IT SHALL HOLD ITSELF OUT TO THE PUBLIC USING SUCH NAME, AS IT APPEARS ON THE LICENSE.

Commented [DLA39]: Language in part 2.4.3 subsections 1-4 was moved from 2.3.5. Subsection 5 is new language discussed at Sept meeting.

(B) Contact information for the ~~entity~~ APPLICANT SHALL ~~including~~ INCLUDE A mailing address, telephone NUMBER ~~and facsimile numbers,~~ and e-mail addresses. ~~and, if~~ IF applicable, THE FACILITY'S OR AGENCY'S website AND FACSIMILE NUMBER are to be provided. ~~address.~~

(C) The identity, ADDRESS, AND TELEPHONE NUMBER of all persons and business entities with a controlling interest in the ~~health care entity~~ FACILITY OR AGENCY, ~~including administrators, directors, managers and management contractors~~ INCLUDING, BUT NOT LIMITED TO:

(1) A non-profit corporation shall list the governing body and officers.

(2) A for-profit corporation shall list the names of the officers and stockholders who directly or indirectly own or control five percent or more of the shares of the corporation.

(3) A sole proprietor shall include proof of lawful presence in the United States in compliance with section 24-76.5-103(4), C.R.S.

(4) A PARTNERSHIP SHALL LIST THE NAMES OF ALL PARTNERS.

(5) THE CHIEF EXECUTIVE OFFICER OF THE FACILITY OR AGENCY.

(A) IF THE ADDRESSES AND TELEPHONE NUMBERS PROVIDED ABOVE ARE THE SAME AS THE CONTACT INFORMATION FOR THE FACILITY OR AGENCY ITSELF, THE APPLICANT SHALL ALSO PROVIDE AN ALTERNATE ADDRESS AND TELEPHONE NUMBER FOR AT LEAST ONE INDIVIDUAL FOR USE IN THE EVENT OF AN EMERGENCY OR CLOSURE OF THE FACILITY OR AGENCY.

~~(D) The name, address and business telephone number of every person identified in section 2.4.3(C) and the individual designated by the applicant as the chief executive officer of the FACILITY OR AGENCY entity.~~

~~(1) If the addresses and telephone numbers provided above are the same as the contact information for the entity FACILITY OR AGENCY itself, the applicant shall also provide an alternate address and telephone number for at least one individual for use in the event of an emergency or closure of the FACILITY OR AGENCY health care entity.~~

Commented [HA40]: Comments to stakeholders: moved above.

(~~E~~D) Proof of professional liability insurance obtained and held in the name of the ~~license~~ applicant as required by the Colorado Health Care Availability Act, section 13-64-301, *et seq.*, C.R.S., with the Department identified as a certificate holder. Such coverage shall be maintained for the duration of the license term and the Department shall be notified of

any change in the amount, type, or provider of professional liability insurance coverage during the license term. INSURANCE POLICIES THAT COVER MULTIPLE ENTITIES MUST DELINEATE THE PER-INCIDENT AND AGGREGATE INDEMNITY AMOUNTS SPECIFIC TO THE LICENSEE, AND SUCH AMOUNTS MUST MEET THE REQUIREMENTS ESTABLISHED BY LAW.

(~~F~~E) Articles of incorporation, articles of organization, partnership agreement, or other organizing documents required by the Secretary of State to conduct business in Colorado; and by-laws or equivalent documents that govern the rights, duties, and capital contributions of the business entity.

(~~G~~F) The address(s) of the physical location WHERE SERVICES ARE DELIVERED, AS WELL AS, IF DIFFERENT, WHERE RECORDS ARE STORED FOR DEPARTMENT REVIEW. ~~that is to constitute the entity, and the name(s) of the owner(s) of each structure on the campus where licensed services are provided if different than those identified in paragraph (C) of this section.~~

(~~H~~G) A map for each floor of the ~~health care entity's~~ APPLICANT'S buildings indicating room layout, services to be provided in each of the rooms, ~~and~~ the proposed physical extent of the license within each building, AND ALL OCCUPANCIES CONTIGUOUS TO THE APPLICANT REGARDLESS IF SERVICES ARE BEING DELIVERED UNDER THE TERMS OF THE LICENSE. ~~If multiple buildings are involved, a map of the campus shall also be submitted that indicates which floor and which buildings are occupied as part of the license. Maps shall be submitted in the format prescribed by the Department.~~

(1) IF SERVICES ARE DELIVERED IN MULTIPLE BUILDINGS LOCATED ON A CAMPUS, A STREET MAP OF THE CAMPUS SHALL BE SUBMITTED THAT INDICATES WHICH BUILDINGS AND FLOORS ARE OCCUPIED AS PART OF THE LICENSE.

(2) MAPS SHALL BE SUBMITTED IN THE FORMAT PRESCRIBED BY THE DEPARTMENT.

(~~I~~H) A copy of any management agreement pertaining to operation of the entity that sets forth the financial and administrative responsibilities of each party.

(~~J~~I) If an applicant leases one or more building(s) to operate UNDER THE LICENSE ~~as a licensed health care entity~~, a copy of the lease shall be filed with the license application and show clearly in its context which party to the agreement is to be held responsible for the physical condition of the property.

(~~K~~J) A statement, ON THE APPLICANT'S LETTERHEAD, IF AVAILABLE, signed and dated ~~contemporaneous with the~~ AND SUBMITTED WITH THE application stating whether, ~~within the previous ten years, one or more individuals or entities identified in response to sections 2.4.3(C) and (D) has a controlling or ownership interest in any type of health facility and has been the subject of, or a party to, one of more of the following events,~~ ANY OF THE FOLLOWING ACTIONS HAVE OCCURRED, regardless of whether THE action has been stayed in a judicial appeal or otherwise settled between the parties. THE ACTIONS ARE TO BE REPORTED IF THEY OCCURRED WITHIN TEN (10) YEARS PRECEDING THE DATE OF THE APPLICATION. FOR INITIAL LICENSURE, THE DEPARTMENT MAY, BASED UPON INFORMATION RECEIVED IN THE STATEMENT, REQUEST ADDITIONAL INFORMATION FROM THE APPLICANT BEYOND THE TEN-YEAR TIME FRAME.

(1) FOR INITIAL LICENSURE OF THE FACILITY OR AGENCY, WHETHER ONE OR MORE INDIVIDUALS OR ENTITIES IDENTIFIED IN THE RESPONSE TO SECTION 2.3.3 (C) HAS A CONTROLLING OR OWNERSHIP INTEREST IN ANY TYPE OF HEALTH FACILITY AND HAS BEEN THE SUBJECT OR PARTY TO ANY OF THE FOLLOWING:

(a) ~~(1) Been convicted~~ A CONVICTION of a felony OR MISDEMEANOR INVOLVING MORAL TURPITUDE under the laws of any state or of the United States. A guilty verdict, a plea of guilty or a plea of nolo contendere (no contest) accepted by the court is considered a conviction~~,~~.

(b) ~~(5)~~ A civil judgment or criminal conviction resulting from conduct or an offense in the operation, management or ownership of a ~~health~~ facility OR AGENCY OR OTHER ENTITY RELATED TO SUBSTANDARD CARE OR HEALTH CARE FRAUD. ~~related to patient or resident care or fraud in public health or social service payment program~~. A guilty verdict, a plea of guilty or a plea of nolo contendere (no contest) accepted by the court is considered a conviction.

(c) ~~(2)~~ A disciplinary action imposed upon the applicant by an agency in another jurisdiction that registers or licenses ~~health~~ facilities OR AGENCIES including, but not limited to, a ~~citation,~~ sanction, probation, civil penalty, or a denial, suspension, revocation, or modification of a license or registration ~~whether it is imposed by consent decree, order, or other decision, for any cause other than failure to pay a license fee by the due date~~,.

(d) ~~(3)~~ Limitation, DENIAL, revocation or suspension by any FEDERAL, STATE, OR LOCAL AUTHORITIES ~~state board, municipality, federal or state agency~~ of any health care related license~~,~~.

(e) ~~(4)~~ The refusal to grant or renew a license for operation of a ~~-~~FACILITY OR AGENCY ~~health care entity,~~ contract for participation or certification for Medicaid, Medicare, or other public health or social services payment program. ~~, o~~

(2) FOR A CHANGE OF OWNERSHIP OF A FACILITY OR AGENCY, WHETHER ANY OF THE NEW OWNERS HAVE BEEN THE SUBJECT OF, OR A PARTY TO, ONE OF MORE OF THE FOLLOWING EVENTS:

(a) ~~2.7.4 (A)(1) Been convicted~~ A CONVICTION OF a felony or misdemeanor involving moral turpitude under the laws of any state or of the United States. A guilty verdict, a plea of guilty, or a plea of nolo contendere (no contest) accepted by the court is considered a conviction,

(b) ~~2.7.4 (A)(3) Had a~~ A civil judgment or a criminal conviction in a case brought by the federal, state, or local authorities that resulted from the operation, management, or ownership of a ~~health~~ facility OR AGENCY or other entity related to substandard ~~patient~~ care or health care fraud.

(c) ~~2.7.4 (A)(2) Had a state license of federal certification denied, revoked, or suspended by another jurisdiction.~~ DENIAL, REVOCATION, OR SUSPENSION OF A STATE LICENSE OR FEDERAL CERTIFICATION BY ANOTHER JURISDICTION.

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

(1) If the event is an action by a governmental agency, ~~(~~as described IN 2.3.3(J)(2): ~~above~~ the name of the agency, its jurisdiction, the case name and the docket proceeding or case number by which the event is designated, and a copy of the consent decree, order, or decision.

(2) If the event is a felony conviction OR MISDEMEANOR INVOLVING MORAL TURPITUDE: the court, its jurisdiction, the case name, the case number, a description of the matter or a copy of the indictment or charges, and any plea or verdict entered by the court.

(3) If the event concerns a civil action or arbitration proceeding: the court or arbiter, the jurisdiction, the case name, the case number, a description of the matter or a copy of the complaint, and a copy of the verdict of the court or arbitration decision.

2.~~4~~3.4 Each application shall be signed under penalty of perjury by an authorized corporate officer, general partner, or sole proprietor of the applicant as appropriate.

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

Commented [HA41]: This is captured in 2.12.1.B

Commented [HA42]: Moved to 2.4.3 (K)

~~2.4.6~~ 2.3.5 The Department shall conduct a preliminary assessment of the application and notify the applicant of any application defects.

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

2.3.6. APPLICANTS MUST SHOW COMPLIANCE WITH THE COLORADO ADULT PROTECTIVE SERVICES DATA SYSTEM (CAPS CHECK) REQUIREMENTS AS SET FORTH IN SECTION 26-3.1-111, C.R.S.

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

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

Commented [D43]: Moved to 2.4.2

2.~~5~~4 Provisional License

~~2.5.1~~2.4.1 Where aN ~~health care entity~~ APPLICANT fails to fully conform to the applicable statutes and regulations but the Department determines the ~~entity~~ APPLICANT is making a substantial good faith attempt to comply, the Department may refuse to issue an initial license and instead grant the applicant a provisional license upon payment of the non-refundable provisional license fee.

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

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

~~2.5.4~~ (C) The second provisional license shall be issued for the same duration as the first upon payment of a second non-refundable provisional license fee. THE DEPARTMENT MAY NOT ISSUE A THIRD OR SUBSEQUENT PROVISIONAL LICENSE TO THE ENTITY, AND IN NO EVENT SHALL AN ENTITY BE PROVISIONALLY LICENSED FOR A PERIOD TO EXCEED ONE HUNDRED EIGHTY (180) CALENDAR DAYS.

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

~~2.5.6~~ (E) If the Department determines, prior to expiration of the provisional license, that the applicant has achieved reasonable compliance, it shall issue a regular license upon payment of the applicable initial license fee. The regular license shall be valid for one year from the date of issuance OF THE REGULAR LICENSE, unless otherwise acted upon pursuant to ~~section 2.9.3~~ PART 2.11 of this chapter.

2.6~~5~~ Renewal License Application Procedure

2.6~~5~~.1 Except for those renewal applicants described in ~~subsection~~ (A) below, a licensee seeking renewal shall provide the Department with a license application, signed under penalty of perjury by an authorized corporate officer, general partner, or sole proprietor of the applicant, as appropriate, and the appropriate fee at least sixty (60) calendar days prior to the expiration of the existing license. Renewal applications shall contain the information required in ~~section 2.4.3~~ PART 2.3.3, ABOVE, ~~of this Chapter~~ unless the information has been previously submitted and no changes have been made to the information currently held by the Department.

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

2.6~~5~~.2 ~~Failure to submit a completed renewal application to the Department thirty (30) calendar days prior to expiration of the existing license shall result in assessment of a late fee in an amount equal to the applicable renewal fee including any bed fees or operating/procedure room fees~~.

FAILURE TO SUBMIT A COMPLETE RENEWAL APPLICATION AND APPROPRIATE FEES TO THE DEPARTMENT BY THE LICENSE EXPIRATION DATE WILL RESULT IN THE FOLLOWING LATE FEES:

(A) SIX (6) TO TWENTY-NINE (29) CALENDAR DAYS AFTER EXPIRATION, A LATE FEE OF TEN PERCENT (10%) OF THE RENEWAL FEE IS DUE IN ADDITION TO THE RENEWAL FEE,

(B) THIRTY (30) TO FIFTY-NINE (59) CALENDAR DAYS AFTER EXPIRATION, A LATE FEE OF FIFTY PERCENT (50%) OF THE RENEWAL FEE IS DUE IN ADDITION TO THE RENEWAL FEE,

(C) SIXTY (60) TO EIGHTY-NINE (89) CALENDAR DAYS AFTER EXPIRATION, A LATE FEE OF SEVENTY-FIVE PERCENT (75%) OF THE RENEWAL FEE IS DUE IN ADDITION TO THE RENEWAL FEE.

2.5.3 IF A LICENSE RENEWAL APPLICATION AND APPROPRIATE FEES ARE NOT RECEIVED BY THE DEPARTMENT BY DAY NINETY (90) FOLLOWING THE EXPIRATION OF THE LICENSE, THE LICENSEE SHALL CEASE OPERATION AND SUBMIT AN INITIAL APPLICATION AND ASSOCIATED INITIAL FEES TO THE DEPARTMENT IN ACCORDANCE WITH PART 2.3, ABOVE.

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

Commented [HA44]: Duplicative of 2.12.1(B)

~~2.6.4~~2.5.4 The Department shall conduct a preliminary assessment of the renewal application and notify the licensee of any application defects.

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

(B) LICENSEES MUST SHOW COMPLIANCE WITH THE COLORADO ADULT PROTECTIVE SERVICES DATA SYSTEM (CAPS CHECK) REQUIREMENTS SET FORTH IN SECTION 26-3.1-111, C.R.S.

2.~~7~~6 Change of Ownership/Management

2.~~7~~6.1 When a currently licensed FACILITY OR AGENCY ~~health care entity~~ anticipates a change of ownership, the current licensee shall SUBMIT A LETTER OF INTENT TO ~~notify~~ the Department within the specified time frame and the prospective new licensee shall submit an application AND SUPPORTING DOCUMENTATION for change of ownership along with the requisite fees ~~and documentation~~ within the same time frame. The time frame for submittal of THE LETTER OF INTENT ~~such notification~~ and THE APPLICATION AND SUPPORTING documentation shall be AT least ninety (90) calendar days before a change of ownership involving any FACILITY OR AGENCY ~~health care entity~~ except those specifically enumerated in ~~subsection~~ (A) below.

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

~~2.7.2 In general, the conversion of a health care entity's LICENSEE'S legal structure, or the legal structure of an A BUSINESS entity that has a direct or indirect ownership interest in the health care entity LICENSEE is not a change of ownership unless the conversion also includes a transfer of at least 50 percent of the licensed health care entity's LICENSEE'S direct or indirect ownership interest to one or more new owners. Specific instances of what does or does not constitute a change of ownership are set forth below in section 2.7.3.~~

Commented [HA45]: Moved to 2.7.3.(G)

~~2.7.3~~2.6.2 The Department shall consider the following criteria in determining whether there is a change of ownership of a ~~health care entity~~ FACILITY OR AGENCY that requires a new license. THE TRANSFER OF FIFTY PERCENT (50%) OF THE OWNERSHIP INTEREST REFERRED TO IN THIS PART 2.6.2 MAY OCCUR DURING THE COURSE OF ONE TRANSACTION OR DURING A SERIES OF TRANSACTIONS OCCURRING OVER A FIVE YEAR PERIOD.

(A) Sole proprietors:

(1) The transfer of at least ~~50~~ FIFTY percent (50%) of the ownership interest in a ~~health care entity~~ FACILITY OR AGENCY from a sole proprietor to another individual, whether or not the transaction affects the title to real property, shall be considered a change of ownership.

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

(B) Partnerships:

(1) Dissolution of the partnership and conversion into any other legal structure shall be considered a change of ownership if the conversion also includes a transfer of at least 50 percent of the direct or indirect ownership to one or more new owners.

(2) Change of ownership does not include dissolution of the partnership to form a corporation with the same persons retaining the same shares of ownership in the new corporation.

(C) Corporations:

(1) Consolidation of two or more corporations resulting in the creation of a new corporate entity shall be considered a change of ownership if the consolidation includes a transfer of at least 50 percent of the direct or indirect ownership to one or more new owners.

(2) Formation of a corporation from a partnership, a sole proprietorship, or a limited liability company shall be considered a change of ownership if the change includes a transfer of at least 50 percent of the direct or indirect ownership to one or more new owners.

(3) The transfer, purchase, or sale of shares in the corporation such that at least 50 percent of the direct or indirect ownership of the corporation is shifted to one or more new owners shall be considered a change of ownership.

(D) Limited Liability Companies:

(1) The transfer of at least ~~50~~ FIFTY percent (50%) of the direct or indirect ownership interest in the company shall be considered a change of ownership.

(2) The termination or dissolution of the company and the conversion thereof into any other entity shall be considered a change of ownership if the conversion also includes a transfer of at least ~~50~~ FIFTY percent (50%) of the direct or indirect ownership to one or more new owners.

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

(E) NON-PROFITS:

(1) THE TRANSFER OF AT LEAST FIFTY PERCENT (50%) OF THE CONTROLLING INTEREST IN THE NON-PROFIT IS CONSIDERED A CHANGE OF OWNERSHIP.

(2) THE CONVERSION OF A NON-PROFIT TO A FOR-PROFIT ORGANIZATION IS CONSIDERED A CHANGE OF OWNERSHIP.

(3) THE CONVERSION OF A FOR-PROFIT ORGANIZATION TO A NON-PROFIT IS CONSIDERED A CHANGE IN OWNERSHIP.

~~(E)~~(F) Management contracts, leases or other operational arrangements:

(1) If the LICENSEE ~~owner of a health care entity~~ enters into a lease arrangement or management agreement whereby the owner retains no authority or responsibility for the operation and management of the FACILITY OR AGENCY ~~health care entity~~, the action shall be considered a change of ownership that requires a new license.

(G) LEGAL STRUCTURES:

(1) THE CONVERSION OF A LICENSEE'S LEGAL STRUCTURE, OR THE LEGAL STRUCTURE OF A BUSINESS ENTITY THAT HAS A DIRECT OR INDIRECT OWNERSHIP INTEREST IN THE LICENSEE IS A CHANGE OF OWNERSHIP IF THE CONVERSION ALSO INCLUDES A TRANSFER OF AT LEAST FIFTY PERCENT (50%) OF THE FACILITY'S OR AGENCY'S DIRECT OR INDIRECT OWNERSHIP INTEREST TO ONE OR MORE NEW OWNERS.

~~2.7.4~~2.6.3 Each applicant for a change of ownership shall SUBMIT AN APPLICATION AS PRESCRIBED IN 2.3.2 THROUGH 2.3.7 OF THIS CHAPTER. ~~provide the following information:~~

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

Commented [HA46]: Moved to 2.10.6(A)(6)

~~(B) Contact information for the entity including mailing address, telephone and facsimile numbers, e-mail address and, if applicable, the facsimile number address.~~

~~(C) The identity of all persons and business entities with a controlling interest in the health care entity, including administrators, directors, managers and management contractors.~~

~~(1) A non-profit corporation shall list the governing body and officers.~~

~~(2) A for-profit corporation shall list the names of the officers and stockholders who directly or indirectly own or control five percent or more of the shares of the corporation.~~

~~(3) A sole proprietor shall include proof of lawful presence in the United States in compliance with section 24-76.5-103(4), C.R.S..~~

~~(D) The name, address and business telephone number of every person identified in section 2.7.4(C) and the individual designated by the applicant as the chief executive officer of the entity.~~

~~(1) If the addresses and telephone numbers provided above are the same as the contact information for the entity itself, the applicant shall also provide an alternate address and telephone number for at least one individual for use in the event of an emergency or closure of the health care entity.~~

~~(E) Proof of professional liability insurance obtained and held in the name of the license applicant as required by the Colorado Health Care Availability Act, section 13-64-301, *et seq.*, C.R.S., with the Department identified as a certificate holder. Such coverage shall be maintained for the duration of the license term and the Department shall be notified of any change in the amount, type or provider of professional liability insurance coverage during the license term.~~

~~(F) Articles of incorporation, articles of organization, partnership agreement, or other organizing documents required by the Secretary of State to conduct business in Colorado; and by-laws or equivalent documents that govern the rights, duties and capital contributions of the business entity.~~

~~(G) The address of the physical location that is to constitute the entity and the name(s) of the owner(s) of each structure on the campus where licensed services are provided if different than those identified in paragraph (C) of this section.~~

~~(H) A copy of any management agreement pertaining to operation of the entity that sets forth the financial and administrative responsibilities of each party.~~

~~(I) If an applicant leases one or more building(s) to operate as a licensed health care entity, a copy of the lease shall be filed with the license application and show clearly in its context which party to the agreement is to be held responsible for the physical condition of the property.~~

~~(J) A statement signed and dated contemporaneously with the application stating whether, within the previous ten (10) years, any of the new owners have been the subject of, or a party to, one of more of the following events, regardless of whether action has been stayed in a judicial appeal or otherwise settled between the parties.~~

~~(1) Been convicted of a felony or misdemeanor involving moral turpitude under the laws of any state or of the United States. A guilty verdict, a plea of guilty or a plea of nolo contendere (no contest) accepted by the court is considered a conviction,~~

~~(2) Had a state license of federal certification denied, revoked, or suspended by another jurisdiction.~~

~~(3) Had a civil judgment or a criminal conviction in a case brought by the federal, state or local authorities that resulted from the operation, management, or ownership of a health facility or other entity related to substandard patient care or health care fraud.~~

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

~~(1) If the event is an action by federal, state or local authorities;~~, ~~the full name of the authority, its jurisdiction, the case name, and the docket, proceeding or case number by which the event is designated, and a copy of the consent decree, order or decision.~~

~~(2) If the event is a felony or misdemeanor conviction involving moral turpitude, the court, its jurisdiction, the case name, the case number, a description of the matter or a copy of the indictment or charges, and any plea or verdict entered by the court.~~

~~(3) If the event involves a civil action or arbitration proceeding, the court or arbiter, the jurisdiction, the case name, the case number, a description of the matter or a copy of the complaint, and a copy of the verdict, the court or arbitration decision.~~

~~2.7.5~~2.6.4 The existing licensee shall be responsible for correcting all rule violations and deficiencies in any current plan of correction before the change of ownership becomes effective.

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

~~2.7.6~~2.6.5 ~~If~~ WHEN the Department issues a license to the new owner, the previous owner shall return its license to the Department within five (5) calendar days of the new owner's receipt of its license.

2.8~~7~~ Fitness Review Process

2.8~~7~~.1 The Department shall review the applicant's fitness to conduct or maintain a licensed operation. The Department shall determine by on-site inspection or other appropriate investigation the applicant's compliance with applicable statutes and regulations. The Department shall consider the information contained in an entity's application and may request access to and consider other information including, but not limited to, the following:

(A) Whether the applicant has legal status to provide the services for which the license is sought as conferred by articles of incorporation, statute, or other governmental declaration.

(B) Whether the applicant's financial resources and sources of revenue appear adequate to provide staff, services, and the physical environment sufficient to comply with the applicable state statutes and regulations; including, if warranted, review of an applicant's credit report,

(C) The applicant's previous compliance history,

(D) Review of the applicant's policies and procedures,

(E) Review of the applicant's quality improvement plans, other quality improvement documentation as may be appropriate, and accreditation reports,

(F) Physical inspection of the entity,

(G) Credentials of staff,

(H) Interviews with staff, and

(~~J~~I) Other documents deemed appropriate by the Department.

2.8~~7~~.2 The Department may conduct a fitness review of an existing owner of a LICENSED FACILITY OR AGENCY ~~licensed health care entity~~ that has submitted an application for a change of ownership only when the Department has new information not previously available or disclosed that bears on the fitness of the existing owner to operate or maintain a LICENSE ~~licensed health care entity~~.

2.9~~8~~ Issuance of License

2.9~~8~~.1 No license shall be issued until the applicant conforms to all applicable statutes and regulations.

(A) The Department shall not issue or renew any license unless it has received a DEPARTMENT OF PUBLIC SAFETY CERTIFICATE OF COMPLIANCE ~~certificate of compliance from~~

~~the Division of Fire Prevention and Control~~ certifying that the building or structure of the ~~health~~ facility OR AGENCY is in conformity with the standards adopted by the Director of the Division of Fire Prevention and Control. This requirement does not apply to out-patient hospice or home care agency licenses because they do not provide~~s~~ services on their own premises.

2.9~~8~~.2 Each license shall contain the name of the FACILITY OR AGENCY ~~health care entity~~, license category, term of license, holder of license, and the licensed capacity.

(A) Each ~~D~~ dialysis ~~T~~ treatment ~~C~~ clinic and ~~A~~ ambulatory ~~S~~ surgical ~~C~~ center shall be licensed for its maximum operational capacity as determined by the Department.

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

(1) ~~(A)~~ If the ~~entity~~ FACILITY OR AGENCY has the physical space and staff capacity to meet the needs of ~~an~~ ONE additional ~~patient or resident~~ CLIENT, the LICENSEE MAY ~~Department may, upon~~ request FROM THE DEPARTMENT A~~,~~ THIRTY (30) DAY EXCEPTION FROM THE ~~allow admission above the~~ licensed capacity ~~for no longer than one month~~ if the ~~patient or resident~~ CLIENT requires immediate admission and the Department determines that there is no convenient APPROPRIATE alternative source of admission.

(2) ~~(B)~~ In the event of ~~a health~~ AN emergency involving multiple ill or injured persons, hospitals and other LICENSEES ~~licensed facilities~~ providing essential emergent or continued care SERVICES may admit ~~patients or residents~~ CLIENTS that exceed their maximum bed capacity. THE LENGTH OF STAY MAY BE FOR UP TO ~~for a period of no more than 14~~ THIRTY (30) consecutive days.~~, as long as the facility remains in compliance with its life safety code, patient staffing requirements, and existing emergency/disaster plan. One extension for no more than an additional~~ ONE OR MORE EXTENSIONS OF UP TO~~14~~ THIRTY (30) consecutive days may be requested based upon extenuating circumstances. ~~(1)~~ Any ~~facility~~ LICENSEE implementing the emergency bed increase shall provide the Department with verbal notice at the time of implementation and a written report within FOURTEEN (14) calendar days after implementation explaining the emergent situation and the actions taken by the ~~facility~~ LICENSEE.

(3) IF A LICENSEE EXCEEDS ITS LICENSED CAPACITY, IT SHALL CONTINUE TO PROVIDE SERVICES THAT MEET THE HEALTH AND SAFETY NEEDS OF THE CLIENTS, INCLUDING BUT NOT LIMITED TO, LIFE SAFETY CODE REQUIREMENTS, STAFFING REQUIREMENTS, AND AN EXISTING EMERGENCY DISASTER PLAN.

~~2.9.3 A license issued by the Department may be revoked, suspended, annulled, limited, or modified at any time during the license term because of a licensee's failure to comply with any of the applicable statutes or regulations, or to make the reports required by section 25-3-104, C.R.S.~~

~~(A) Unless consented to by the applicant, a limitation imposed prior to issuance of an initial or renewal license shall be treated as a denial.~~

~~(B) A modification of an existing license during its term, unless consented to by the licensee, shall be treated as a revocation.~~

Commented [HA47]: Moved to 2.12

~~2.9.4~~2.8.3 The Department may impose conditions upon a license prior to issuing an initial or renewal license or during an existing license term. If the Department imposes conditions on a license, the licensee shall immediately comply with all conditions until and unless said conditions are overturned or stayed on appeal.

(A) If conditions are imposed at the same time as an initial or renewal license, the applicant shall pay the applicable initial or renewal license fee plus the conditional fee.

(B) If conditions are imposed during the license term, the licensee shall pay the conditional fee and the conditions shall run concurrently with the existing license term.

(C) If the conditions are renewed in whole or in part for the next license term, the licensee shall pay the applicable renewal fee along with the conditional fee in effect at the time of renewal.

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

(E) IF A LICENSEE HOLDS A CONDITIONAL LICENSE, IT SHALL POST A CLEARLY LEGIBLE COPY OF THE LICENSE CONDITIONS IN A CONSPICUOUS PUBLIC PLACE IN THE FACILITY OR AGENCY.

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

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

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

~~(A) Ten (10) calendar days prior to closure, inform the Department in writing of the specific plan for storage and retrieval of individual records,~~

~~(B) Within ten (10) calendar days of closure, inform all patients, residents, consumers or authorized representatives thereof, in writing how and where to obtain their individual records; and~~

~~(C) Provide secure storage for any remaining patient, resident or consumer records.~~

2.~~10~~9 Continuing Obligations of Licensee

2.~~10~~9.1 Each licensee shall have and maintain electronic business communication tools, including, but not limited to, ~~a facsimile machine,~~ internet access and a valid e-mail address. The licensee shall use these tools to receive and submit information, as required by the Department.

2.~~10~~9.2 The license shall be displayed in a conspicuous place readily visible to ~~patients, residents or~~ clients who enter at the address that appears on the license. ~~The license is only valid while in the possession of the licensee to whom it is issued and shall not be subject to sale, assignment or other transfer, voluntary or involuntary, nor shall a license be valid for any premises other than those for which it was originally issued.~~

Commented [HA48]: Moved to (E) above

Commented [HA49]: Parts 2.9.5 & 2.9.6 have been moved to a new part: 2.15 Facility closure

2.9.3 THE LICENSE IS ONLY VALID WHILE IN THE POSSESSION OF THE LICENSEE TO WHOM IT IS ISSUED AND SHALL NOT BE SUBJECT TO SALE, ASSIGNMENT, OR OTHER TRANSFER, VOLUNTARY OR INVOLUNTARY, NOR SHALL A LICENSE BE VALID FOR ANY PREMISES OTHER THAN THOSE FOR WHICH IT WAS ORIGINALLY ISSUED.

2.9.4 ~~2.10.3~~ The licensee shall provide accurate and truthful information to the Department during inspections, investigations, and licensing activities.

~~2.10.4 The licensee shall provide, upon request, access to such individual patient, resident, client or consumer records as the Department requires for the performance of its regulatory oversight responsibilities.~~

Commented [DLA50]: Moved in its entirety to Section 2.11.5, under Department Oversight

~~(A) A licensee shall provide, upon request, access to or copies of reports and information required by the Department including, but not limited to, staffing reports, census data, statistical information, and such other records as the Department requires for the performance of its regulatory oversight responsibilities.~~

~~(B) The Department shall not release to any unauthorized person any information defined as confidential under state law.~~

2.~~10~~9.5 Where a FACILITY OR AGENCY ~~licensed health care entity~~ is subject to inspection, certification, or review by other agencies, accrediting organizations, or inspecting companies, the licensee shall provide and/or release to the Department, upon request, any correspondence, reports or recommendations concerning the licensee that were prepared by such organizations.

2.~~10~~9.6 Each licensee shall ~~notify~~ SUBMIT TO the Department A LETTER OF INTENT ~~in writing~~ of any change in the information required by PART 2.4~~3~~.3 ~~or 2.7.4~~ of this Chapter from what was contained in the last submitted license application. ~~Except for the operational changes that require Department approval as set forth in subsection (A) below or the changes requiring advance notice as set forth in subsection (B), the licensee shall notify the Department of all changes in information as soon as practicable, but no later than thirty (30) calendar days after the change becomes effective.~~

(A) ~~Except as otherwise provided in 6 CCR 1011-1, Chapter IV, Part 3.200, the following changes~~ CHANGES to the operation of the FACILITY OR AGENCY ~~licensed health care entity~~ shall not be implemented without prior approval from the Department. A licensee shall, at least thirty (30) calendar days in advance, submit a ~~written~~ LETTER OF INTENT ~~request~~ to the Department regarding any of ~~these~~ THE FOLLOWING proposed changes.

(1) Increase in licensed capacity.

(a) If a licensee requests an increase in ~~licensed~~ capacity that is approved by the Department, an amended license shall be issued upon payment of the appropriate fee.

(b) The Department has the discretion to deny a requested increase in ~~licensed~~ capacity if it determines that the increase poses a potential risk to the health, safety, or welfare of the ~~health care entity's~~ LICENSEE'S ~~patients,~~ clients ~~or residents~~ based upon the ~~entity's~~ LICENSEE'S compliance history, or because the ~~entity~~ LICENSEE is unable to meet the required health and environmental criteria for the increased capacity.

(2) Change in a management company or proposed use of a management agreement not previously disclosed in PART ~~sectionS~~ 2.4~~3~~.3 ~~or 2.7.4~~.

(3) Change in license category or classification.

(4) CHANGE IN THE SCOPE OF SERVICES.

(a) FOR A NURSING CARE FACILITY, THE ADDITION OR REMOVAL OF A SECURE ENVIRONMENT.

(b) FOR AN ASSISTED LIVING RESIDENCE, THE ADDITION OR REMOVAL OF A SECURE ENVIRONMENT.

(c) FOR AN AMBULATORY SURGICAL CENTER, THE ADDITION OR REMOVAL OF AN OPERATING ROOM OR PROCEDURE ROOM.

(d) FOR DIALYSIS TREATMENT CLINICS, THE ADDITION OR REMOVAL OF A TREATMENT MODALITY, SUCH AS IN-HOME PERITONEAL DIALYSIS.

(5) CHANGE IN SERVICE TERRITORY.

(a) FOR A HOME CARE AGENCY.

(b) FOR A HOSPICE.

(6) CHANGE IN LEGAL NAME OF THE LICENSEE AND ALL OTHER NAMES USED BY IT TO PROVIDE SERVICES.

2.~~11~~10 Department Oversight

2.~~11~~10.1 The Department and any duly authorized representatives thereof shall have the right to enter upon and into the premises of any licensee or applicant ~~for a license~~ in order to determine the state of compliance with the ~~law~~ STATUTES and regulations, and shall initially identify themselves to the person in charge of the ~~health care entity~~ FACILITY OR AGENCY at the time.

(A) In accordance with section 25-1.5-103, C.R.S., routine unannounced onsite inspections shall be made only between the hours of 7 a.m. and 7 p.m.

2.~~11~~10.2 Licensure Surveys and Tiered Inspections

For each ~~health care entity~~ LICENSEE that is eligible, the Department will either extend the standard licensure survey cycle up to three (3) years or utilize a tiered licensure inspection system. ~~The Department will implement the extended survey cycle or tiered licensure inspection system in phases by license category with full implementation to be accomplished no later than July 1, 2014~~.

~~The extended survey cycle or tiered inspection system is designed to reduce the time needed for and costs of licensure inspections for both the Department and the licensed health care entity; reduce the number, frequency, and duration of on-site inspections; reduce the scope of data and information that health care entities are required to submit or provide to the Department in connection with the licensure inspection; reduce the amount and scope of duplicative data, reports, and information required to complete the licensure inspection; and be based on a sample of the facility size.~~

(A) In order to be eligible, the ~~health care entity~~ LICENSEE shall meet all of the following criteria:

(1) Licensed for at least three (3) years;

(2) No enforcement activity within three (3) years prior to the date of the survey;

(3) No patterns of deficient practices, as documented in the inspection and survey reports issued by the Department within the three (3) years prior to the date of the inspection; and

(4) No substantiated complaint resulting in the discovery of significant deficiencies that may negatively affect the life, health, or safety of ~~patients, residents or consumers~~CLIENTS of the ~~health care entity~~ LICENSEE within the three (3) years prior to the date of the survey.

(B) The Department may expand the scope of a tiered inspection to an extended or full survey if the Department finds deficient practice during the tiered inspection process.~~:~~

(C) Nothing in this PART 2.~~11~~10.2 limits the ability of the Department to conduct a periodic inspection or survey that is required to meet its obligations as a state survey agency on behalf of the Centers for Medicare and Medicaid Services or the Department of Health Care Policy and Financing to assure that the ~~health facility~~ LICENSEE meets the requirements for participation in the Medicare and Medicaid programs.

2.~~11~~10.3 ~~If the Department has information about an applicant or licensee or its employees or managers that has been acquired in the context of a Department review, and provides such information to any state or federal agency that may have a statutory or regulatory interest in the entity or its employees, the Department shall also forward to the other agency any responses it has received from the licensee or applicant to the matter under review, if applicable.~~

THE DEPARTMENT MAY SHARE INFORMATION REGARDING AN APPLICANT'S OR LICENSEE'S EMPLOYEES OR MANAGERS THAT IT ACQUIRES IN THE CONTEXT OF A DEPARTMENT REVIEW WITH OTHER STATE OR FEDERAL AGENCIES THAT HAVE A STATUTORY OR REGULATORY INTEREST IN THE APPLICANT OR LICENSEE OR APPLICANT OR LICENSEE EMPLOYEES.

(A) THE DEPARTMENT SHALL FORWARD ANY RESPONSES IT RECEIVES FROM THE APPLICANT OR LICENSEE FOR THE MATTER UNDER REVIEW TO OTHER STATE OR FEDERAL AGENCIES.

2.~~11~~10.4 The Department may use the following measures to ensure a licensee's full compliance with the applicable statutory and regulatory criteria.

(A) Unscheduled or unannounced reviews.

The Department may conduct an unscheduled or unannounced review of a current licensee based upon, but not limited to, the following criteria:

(1) Routine compliance inspection,

(2) Reasonable cause to question the ~~applicant's~~ LICENSEE'S continued fitness to conduct or maintain licensed operations,

(3) A complaint alleging non-compliance with license requirements,

(4) Discovery of previously undisclosed information regarding a licensee or any of its owners, officers, managers or other employees if such information affects or has the potential to affect the licensee's provision of ~~care~~ SERVICES, or

(5) The omission of relevant information from documents requested by the Department or indication of false information submitted to the Department.

(B) Plan of Correction

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

(1) The plan of correction shall be in the format prescribed by the Department and include, but not be limited to, the following:

(a) A description of how the licensee will correct each identified deficiency,

(i) IF DEFICIENT PRACTICE WAS CITED FOR A SPECIFIC CLIENT(S), THE DESCRIPTION SHALL INCLUDE THE MEASURES THAT WILL BE PUT IN PLACE OR SYSTEMIC CHANGES MADE TO ENSURE THAT THE DEFICIENT PRACTICE WILL NOT REOCCUR FOR THE AFFECTED CLIENTS(S) AND/OR OTHER CLIENTS HAVING THE POTENTIAL TO BE AFFECTED.

(b) A description of how the licensee will monitor the corrective action to ensure each deficiency is remedied and will not ~~recur~~ REOCCUR, and

(c) ~~A timeline with the expected implementation and completion date.~~ A COMPLETION DATE THAT SHALL BE NO LONGER THAN THIRTY (30) CALENDAR DAYS FROM THE ISSUANCE OF THE DEFICIENCY LIST, UNLESS OTHERWISE REQUIRED OR APPROVED BY THE DEPARTMENT. The completion date is the date that the entity deems it can achieve compliance.

~~(i) The implementation date shall be no longer than thirty (30) calendar days from the date of the mailing of the deficiency to the licensee, unless otherwise required or approved by the Department.~~

(2) A completed plan of correction shall be:

(a) Signed by the licensee's director, administrator or manager, and

(b) Submitted to the Department within ten (10) calendar days after the date of the Department's written notice of deficiencies.

(i) If an extension of time is needed to complete the plan of correction, the licensee shall request an extension in writing from the Department prior to the plan of correction due date. The Department may grant an extension of time.

(3) The Department has discretion to approve, impose, modify, or reject a plan of correction.

(a) If the plan of correction is accepted, the Department shall notify the ~~entity~~ LICENSEE by issuing a written notice of acceptance.

(b) If the plan of correction is unacceptable, the Department shall notify the licensee in writing, and the licensee shall re-submit the changes within the timeframe prescribed by the Department.

(c) If the licensee fails to comply with the requirements or deadlines for submission of a plan or fails to submit requested changes to the plan, the Department may reject the plan of correction and impose disciplinary sanctions as set forth below.

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

2.10.5 THE LICENSEE SHALL PROVIDE, UPON REQUEST, ACCESS TO OR COPIES OF THE FOLLOWING TO THE DEPARTMENT FOR THE PERFORMANCE OF ITS REGULATORY OVERSIGHT RESPONSIBILITIES:

Commented [HA51]: COMMENT TO STAKEHOLDERS: Moved from Section 2.10.4

(A) INDIVIDUAL CLIENT RECORDS.

(B) REPORTS AND INFORMATION REQUIRED BY THE DEPARTMENT INCLUDING, BUT NOT LIMITED TO, STAFFING REPORTS, CENSUS DATA, STATISTICAL INFORMATION, AND OTHER RECORDS, AS DETERMINED BY THE DEPARTMENT.

2.~~12~~11 Enforcement and Disciplinary Sanctions

2.11.1 License Denials

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

~~(A)~~(1) The applicant has not fully complied with all local, state, and federal laws and regulations applicable to that license category or classification,

~~(B)~~(2) The application or accompanying documents contain a false statement of material fact,

~~(C)~~(3) The applicant fails to respond in a timely manner to Departmental requests for additional information,

~~(D)~~(4) The applicant refuses any part of an on-site or off-site inspection,

~~(E)~~(5) The applicant fails to comply with or successfully complete an acceptable plan of correction,

~~(F)~~(6) The results of the fitness review and/or background check reveal issues that have harmed or have the potential to harm the health or safety of the ~~individual~~CLIENT(s) served,

~~(G)~~(7) The applicant has failed to cooperate with the investigation of any local, state, or federal regulatory body, or

~~(H)~~(8) The applicant is not in compliance with regulatory requirements or has a documented pattern of non-compliance that has harmed or has the potential to harm the health or safety of the ~~individual~~CLIENT(s) served.

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

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

2.11.2 Revocation or suspension of a license

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

~~(A)~~ (1) Fails or refuses to comply with the statutory and/or regulatory requirements applicable to that license type,

~~(B)~~(2) Makes a false statement of material fact about ~~individuals~~CLIENTS served by the licensee, its staff, capacity, or other operational components verbally or in any public document or in a matter under investigation by the Department or another governmental entity,

~~(C)~~(3) Prevents, interferes with, or attempts to impede in any way the work of a representative or agent of the Department in investigating or enforcing the applicable statutes or regulations,

~~(D)~~(4) Falsely advertises or in any way misrepresents the licensee's ability to ~~care~~ PROVIDE SERVICES for the ~~individuals~~CLIENTS served based on its license type or status,

~~(E)~~(5) Fails to provide reports and documents required by regulation or statute in a timely and complete fashion,

~~(F)~~(6) Fails to comply with or complete a plan of correction in the time or manner specified, or

~~(G)~~(7) Falsifies records or documents.

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

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

2.11.3 Summary suspension of a license

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

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

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

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

2.11.4 A LICENSE ISSUED BY THE DEPARTMENT MAY BE REVOKED, SUSPENDED, ANNULLED, LIMITED, OR MODIFIED AT ANY TIME DURING THE LICENSE TERM BECAUSE OF A LICENSEE'S FAILURE TO COMPLY WITH ANY OF THE APPLICABLE STATUTES OR REGULATIONS, OR TO MAKE THE REPORTS REQUIRED BY SECTION 25-3-104, C.R.S.

(A) UNLESS CONSENTED TO BY THE APPLICANT, A LIMITATION IMPOSED PRIOR TO ISSUANCE OF AN INITIAL OR RENEWAL LICENSE SHALL BE TREATED AS A DENIAL.

(B) UNLESS CONSENTED TO BY THE LICENSEE, A MODIFICATION OF AN EXISTING LICENSE DURING ITS TERM SHALL BE TREATED AS A REVOCATION.

Commented [HA52]: Moved from 2.9.3

2.~~13~~12 License Fees

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

Initial license	$371.44
Renewal license	$371.44
Conditional license	$1,547.65
First provisional license	$1,031.77
Second provisional license	$1,031.77
Change of ownership	$371.44
Change in licensed capacity	$371.44
Change of name	$ 77.38
Renewal application late fee	~~Equal to the applicable renewal license fee including bed fees or operating/procedure room fees.~~ SEE PART 2.5.2, ABOVE.

2.~~14~~13 Performance Incentive

2.13.1~~(A)~~ A ~~licensed health care entity~~ LICENSEE shall be eligible for a performance incentive if the ~~department's~~DEPARTMENT'S on-site ~~relicensure~~ RE-LICENSURE inspection demonstrates that:

~~(1)~~(A) The licensee has no significant deficiencies that have negatively affected the life, safety, or health of its ~~consumers~~ CLIENTS;

~~(2)~~(B) The licensee has fully and timely cooperated with the Department during the on-site inspection;

~~(3)~~(C) The Department has found no documented actual or potential harm to ~~consumers~~ CLIENTS; and

~~(4)~~(D) ~~I~~if significant deficiencies are found that do not negatively affect the life, safety or health of ~~consumers~~ CLIENTS, the licensee has submitted and the Department has accepted a plan of correction and the Department has verified that the deficient practice was corrected within the period required by the Department.

2.13.2~~(B)~~The incentive payment shall be calculated at 10 percent of the ~~agency's~~ LICENSEE'S renewal license fee and shall apply when:

~~(1)~~(A) The inspection is completed with the full and timely cooperation of the ~~agency~~ LICENSEE,

~~(2)~~(B) Inspection findings do not document harm or potential harm to ~~consumers~~ CLIENTS, and

~~(3)~~(C) Correction of the deficient practice is verified by the ~~department~~ DEPARTMENT on or prior to the respective due dates.

~~(C)~~(D) The incentive payment shall be paid to the licensee within 60 days following the acceptance of the validation of correction of all cited deficiencies, or within 60 days of the inspection exit date if no deficiencies were cited.

2.14 FACILITY CLOSURE

2.14.1 EACH LICENSE ISSUED BY THE DEPARTMENT SHALL BECOME INVALID WHEN THE LICENSEE FAILS TO TIMELY RENEW THE LICENSE, CEASES OPERATION, OR THERE IS FINAL AGENCY ACTION SUSPENDING OR REVOKING THE LICENSE. THE LICENSE SHALL BE RETURNED TO THE DEPARTMENT WITHIN TEN (10) CALENDAR DAYS OF THE EVENT THAT INVALIDATED IT.

2.14.2 TEMPORARY CLOSURES

(A) IF A LICENSEE WANTS TO MAINTAIN ITS CURRENT LICENSE DURING A TEMPORARY SUSPENSION OF OPERATION, THE LICENSEE SHALL SUBMIT A LETTER OF INTENT TO THE DEPARTMENT FOR THE DEPARTMENT'S APPROVAL AT LEAST 30 DAYS PRIOR TO THE SUSPENSION OF OPERATION. A LICENSEE MAY BE ALLOWED TO MAINTAIN A CURRENT LICENSE DURING A SUSPENSION OF OPERATION IF ALL OF THE FOLLOWING ARE MET:

(1) THE SUSPENSION OF OPERATION WILL BE NINETY (90) DAYS OR LESS,

(2) THE LICENSEE WILL NOT BE DISCHARGING ITS CLIENTS, AND

(3) THE LICENSEE PLANS TO REOPEN AT THE SAME LOCATION WITH THE SAME SERVICES.

2.14.2 EMERGENCY CLOSURES

(A) IN THE EVENT OF AN EMERGENCY AFFECTING THE PHYSICAL SPACE OF THE FACILITY OR AGENCY THAT NECESSITATES THE REMOVAL OF CLIENTS AND EMPLOYEES OR CONTRACTORS FROM THE FACILITY OR AGENCY, A LICENSEE SHALL PROVIDE THE DEPARTMENT WITH VERBAL NOTICE OF THE EVENT AT THE TIME OF REMOVAL AND A WRITTEN REPORT WITHIN FOURTEEN (14) CALENDAR DAYS AFTER THE REMOVAL EXPLAINING THE EMERGENT SITUATION AND THE ACTIONS TAKEN BY

THE LICENSEE TO PROVIDE SERVICES THAT MEET THE HEALTH AND SAFETY NEEDS OF THE CLIENTS. BASED ON THE EXTENUATING CIRCUMSTANCES, THE DEPARTMENT MAY APPROVE THE CONTINUATION OF THE LICENSE DURING THE TIME PERIOD THAT IT TAKES TO MAKE THE PHYSICAL SPACE APPROPRIATE FOR CLIENTS AND EMPLOYEES OR CONTRACTORS TO RETURN.

2.14.3 PERMANENT CLOSURES

(A) EACH LICENSEE THAT SURRENDERS ITS LICENSE SHALL ACCOMPLISH THE FOLLOWING WITH REGARD TO ANY INDIVIDUAL CLIENT RECORDS THAT THE ENTITY IS LEGALLY OBLIGATED TO MAINTAIN:

(1) TEN (10) CALENDAR DAYS PRIOR TO CLOSURE, INFORM THE DEPARTMENT IN WRITING OF THE SPECIFIC PLAN FOR STORAGE AND RETRIEVAL OF INDIVIDUAL CLIENT RECORDS,

(2) WITHIN TEN (10) CALENDAR DAYS OF CLOSURE, INFORM ALL CLIENTS OR DESIGNATED REPRESENTATIVES THEREOF, IN WRITING HOW AND WHERE TO OBTAIN THEIR INDIVIDUAL RECORDS; AND

(3) PROVIDE SECURE STORAGE FOR ANY REMAINING CLIENT RECORDS.

PART 3. GENERAL BUILDING AND FIRE SAFETY PROVISIONS

3.1 IN THE EVENT THAT DISCREPANCIES BETWEEN THIS CHAPTER 2 AND OTHER FACILITY OR AGENCY SPECIFIC REGULATIONS WITHIN 6 CCR 1011-1 CONCERNING FGI GUIDELINES COMPLIANCE EXIST, THE FACILITY OR AGENCY SPECIFIC REGULATION SHALL APPLY.

3.2 PHYSICAL PLANT STANDARDS

3.2.1 EACH FACILITY OR AGENCY SHALL BE IN COMPLIANCE WITH ALL APPLICABLE LOCAL ZONING, HOUSING, FIRE, AND SANITARY CODES AND ORDINANCES OF THE CITY, CITY AND COUNTY, OR COUNTY WHERE IT IS SITUATED, TO THE EXTENT THAT SUCH CODES AND ORDINANCES ARE CONSISTENT WITH FEDERAL LAW.

3.2.2 ALL PHYSICAL LOCATIONS OF A FACILITY OR AGENCY SHALL BE CONSTRUCTED IN CONFORMITY WITH THE STANDARDS ADOPTED BY THE DIRECTOR OF THE DIVISION OF FIRE PREVENTION AND CONTROL (DFPC) AT THE COLORADO DEPARTMENT OF PUBLIC SAFETY, AS APPLICABLE.

(A) AN APPLICANT OR LICENSEE THAT IS SUBJECT TO FIRE PREVENTION AND LIFE SAFETY CODE REQUIREMENTS SHALL NOT PROVIDE SERVICES IN AREAS SUBJECT TO PLAN REVIEW, EXCEPT AS APPROVED BY DFPC.

Commented [HA53]: Moved from 2.3.1(A)

3.2.3 FOR ANY CONSTRUCTION OR RENOVATIONS OF A FACILITY OR AGENCY INITIATED ON OR AFTER JULY 1, 2020, THE FOLLOWING REQUIREMENTS OF THE 2018 EDITIONS, FACILITIES GUIDELINES INSTITUTE (FGI) INCLUDING ANY ERRATA AND GUIDELINE INTERPRETATIONS ADOPTED AS OF NOVEMBER 1, 2019 ARE INCORPORATED BY REFERENCE, AS APPLICABLE TO FACILITY OR AGENCY LICENSE TYPE:

(A) FOR HOSPITALS, INCLUDING BUT NOT LIMITED TO GENERAL HOSPITALS, PSYCHIATRIC HOSPITALS, REHABILITATION CENTERS AND HOSPITAL UNITS: GUIDELINES FOR DESIGN AND CONSTRUCTION OF HOSPITALS;

(B) FOR OUTPATIENT FACILITIES INCLUDING BUT NOT LIMITED TO AMBULATORY SURGERY CENTERS, COMMUNITY CLINICS, COMMUNITY CLINICS AND EMERGENCY CENTERS,

DIALYSIS TREATMENT CLINICS, AND BIRTH CENTERS: GUIDELINES FOR DESIGN AND CONSTRUCTION OF OUTPATIENT FACILITIES; AND

(C) FOR RESIDENTIAL FACILITIES, INCLUDING BUT NOT LIMITED TO ASSISTED LIVING RESIDENCES, FACILITIES FOR PERSONS WITH DEVELOPMENTAL DISABILITIES, NURSING CARE FACILITIES, AND HOSPICE CARE: GUIDELINES FOR DESIGN AND CONSTRUCTION OF RESIDENTIAL HEALTH, CARE AND SUPPORT FACILITIES.

3.2.4 FACILITIES AND AGENCIES ARE EXPECTED TO MEET THE FGI GUIDELINES UNDER WHICH THE DEPARTMENT APPROVED THE FACILITY'S OR AGENCY'S INITIAL LICENSE UNTIL SUCH TIME AS A NEW GUIDELINE COMPLIANCE REVIEW OCCURS AS REQUIRED BY THIS PART 3.

3.3 GUIDELINE COMPLIANCE REVIEW

3.3.1 A GUIDELINE COMPLIANCE REVIEW IS REQUIRED BY THE FOLLOWING:

(A) ADDITION TO A FACILITY OR AGENCY, AS DEFINED IN PART 1.2 OF THESE RULES.

(B) NEW CONSTRUCTION OF A FACILITY OR AGENCY, AS DEFINED AT PART 1.41 OF THESE RULES.

(C) A RENOVATION OF A LICENSED FACILITY OR AGENCY, AS DEFINED AT PART 1.46 OF THESE RULES.

(D) A GUIDELINE COMPLIANCE REVIEW IS NOT NEEDED FOR MINOR ALTERATIONS, AS DEFINED AT PART 1.39 OF THESE RULES.

3.3.2 SUBMITTAL OF DESIGN DOCUMENTS FOR GUIDELINE COMPLIANCE REVIEW BY THE DEPARTMENT SHALL BE SUBMITTED AT THE TIME THAT THE FACILITY OR AGENCY APPLIES FOR THE BUILDING PERMITS FROM THE LOCAL AUTHORITY.

(A) IN THE EVENT THAT A BUILDING PERMIT IS NOT REQUIRED, THE DESIGN DOCUMENTS SHALL BE SUBMITTED TO THE DEPARTMENT FOR GUIDELINE COMPLIANCE REVIEW PRIOR TO THE START OF CONSTRUCTION OR RENOVATION.

(B) SUBMITTAL OF THE DESIGN DOCUMENTS SHALL BE MADE BY THE GUIDELINE COMPLIANCE REVIEW REPRESENTATIVE.

(C) DESIGN DOCUMENTS SUBMITTED TO THE DEPARTMENT FOR REVIEW SHALL BE SIGNED BY THE RESPONSIBLE DESIGN PROFESSIONAL.

(D) DESIGN DOCUMENTS SHALL BE COORDINATED AND THE SCALE OF DRAWINGS SUBMITTED SHALL BE CONSISTENT FOR ALL DISCIPLINES.

(1) IN THE EVENT THAT THE DESIGN DOCUMENTS PREVIOUSLY SUBMITTED TO THE DEPARTMENT FOR GUIDELINE COMPLIANCE REVIEW CEASE TO BE CURRENT, THE RESPONSIBLE DESIGN PROFESSIONAL SHALL SUBMIT UPDATED DESIGN DOCUMENTS TO THE DEPARTMENT.

(2) PHASED SUBMITTALS OF DESIGN DOCUMENTS MAY BE SUBMITTED FOR APPROVAL UPON THE DISCRETION OF THE DEPARTMENT.

3.3.3 THE COMPLIANCE GUIDELINE REVIEW IS COMPLETED AT THE TIME THE INITIAL LICENSE IS ISSUED OR WHEN THE DEPARTMENT HAS NOTIFIED THE RESPONSIBLE DESIGN PROFESSIONAL THAT THERE ARE NO OUTSTANDING ISSUES.

(A) THE COMPLIANCE GUIDELINE REVIEW SHALL BE COMPLETED BY THE DEPARTMENT PRIOR TO RENOVATIONS TO AN EXISTING FACILITY OR AGENCY TAKE.

3.4 REQUESTS FOR WAIVERS OF FGI GUIDELINES

3.4.1 REQUESTS FOR WAIVERS OF FGI GUIDELINES SHALL BE SUBMITTED TO THE DEPARTMENT ON THE FORM AND IN THE MANNER REQUIRED BY THE DEPARTMENT.

(A) THE DEPARTMENT WILL ACCEPT AND REVIEW WAIVER REQUESTS RELATED TO FGI GUIDELINES PRIOR TO THE SUBMITTAL OF A LICENSE APPLICATION.

(B) ANY CONSIDERATION OF A WAIVER FROM THE FGI GUIDELINES WILL BE BASED ON DESIGN DOCUMENTS SUBMITTED AT THE TIME OF THE WAIVER REQUEST. IF THE DESIGN DOCUMENTS ARE CHANGED, A NEW WAIVER REQUEST MUST BE SUBMITTED.

(C) IN THE EVENT THAT THE FGI GUIDELINES ARE IN CONFLICT WITH CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS) REQUIREMENTS FOR FACILITIES OR AGENCIES THAT ARE SEEKING OR ARE SUBJECT TO CERTIFICATION, THE CMS REQUIREMENTS WILL APPLY AND NO WAIVER IS NECESSARY.

3.5 FAILURE TO COMMENCE CONSTRUCTION WITHIN TWELVE (12) MONTHS OF APPROVAL BY THE DEPARTMENT, OR A PERIOD OF CONSTRUCTION INACTIVITY EXCEEDING TWELVE (12) MONTHS FOLLOWING COMMENCEMENT OF CONSTRUCTION, WILL RESULT IN TERMINATION OF THE DEPARTMENT'S APPROVAL OF THE PROJECT. RESUBMISSION OF THE DESIGN DOCUMENTS FOR REVIEW BY THE DEPARTMENT WILL BE REQUIRED IF THE PROJECT IS RESTARTED.

3.6 NO APPROVAL OF, OR FAILURE TO REVIEW DESIGN DOCUMENTS BY THE DEPARTMENT SHALL RELIEVE THE OWNER, DEVELOPER, DESIGNING ARCHITECT OR ENGINEER OF THEIR RESPECTIVE RESPONSIBILITIES FOR COMPLIANCE WITH APPLICABLE LAWS, RULES, OR CODES RESPECTING FIRE PREVENTION, FIRE PROTECTION, BUILDING CONSTRUCTION SAFETY AND THE FGI GUIDELINES.

PART ~~3~~4. QUALITY MANAGEMENT, OCCURRENCE REPORTING, PALLIATIVE CARE

~~3.1 QUALITY MANAGEMENT PROGRAM. Every health care entity licensed or certified by the Department pursuant to Section 25-1.5-103(1)(a), C.R.S., shall establish a quality management program appropriate to the size and type of facility that evaluates the quality of patient or resident CLIENT care and safety, and that complies with this Part 3. Assisted living residences and community residential homes shall have until December 31, 2015, to achieve full compliance with this regulation.~~

~~3.1.1 Every health care entity identified in section 3.1 shall develop a quality management program that shall be available for Department review during the initial licensure survey and each re-licensure survey. Each program shall include the following elements:~~

~~(1)(A) A general description of the types of cases, problems, or risks to be reviewed and criteria for identifying potential risks, including without limitation any incidents that may be required by Department regulations to be reported to the Department;~~

~~(2)(B) Identification of the personnel or committees responsible for coordinating quality management activities and the means of reporting to the administrator or governing body of the facility.~~

~~(3)(C) A description of the method for systematically reporting information to a person designated by the facility within a prescribed time;~~

~~(4)(D) A description of the method for investigating and analyzing the frequency and causes of individual problems and patterns of problems;~~

~~(5)(E) A description of the methods for taking corrective action to address the problems, including prevention and minimizing problems or risks;~~

~~(6)(F) A description of the method for the follow-up of corrective action to determine the effectiveness of such action;~~

~~(7)(G) A description of the method for coordinating all pertinent case, problem, or risk review information with other applicable quality assurance and/or risk management activities, such as procedures for granting staff or clinical privileges; review of patient or resident CLIENT care; review of staff or employee conduct; the patient grievance system; and education and training programs;~~

~~(8)(H) Documentation of required quality management activities, including cases, problems, or risks identified for review; findings of investigations; and any actions taken to address problems or risks; and~~

~~(9)(I) A schedule for program implementation not to exceed 90 days after the date of the initial survey.~~

4.1 QUALITY MANAGEMENT PROGRAM.

4.1.1 EVERY FACILITY OR AGENCY SHALL HAVE A QUALITY MANAGEMENT PROGRAM (QMP) DESIGNED TO IMPROVE CLIENT SAFETY AND WELL-BEING. THE CLIENT SAFETY COMPONENT OF THE PROGRAM SHALL IMPLEMENT IMPROVEMENTS IN RESPONSE TO PATTERNS AND TRENDS ASSOCIATED WITH SERVICE DELIVERY ERRORS AND POTENTIAL FOR ERROR. THE CLIENT WELL-BEING COMPONENT OF THE PROGRAM SHALL IMPLEMENT IMPROVEMENTS THAT ARE NOT NECESSARILY TIED TO ERRORS OR POTENTIAL FOR ERROR BUT INSTEAD TO THE CONTINUOUS QUALITY IMPROVEMENT PRINCIPLE THAT OPPORTUNITIES ALWAYS EXIST TO ENHANCE SERVICE DELIVERY.

4.1.2 THE PROGRAM SHALL BE IMPLEMENTED IN ACCORDANCE WITH A QUALITY MANAGEMENT PLAN THAT IS REVIEWED AND APPROVED ANNUALLY BY THE GOVERNING BODY, OR IF THE FACILITY OR AGENCY IS NOT REQUIRED TO HAVE A GOVERNING BODY, BY THE ADMINISTRATOR OR THE ADMINISTRATOR'S DESIGNEE(S). THE PLAN SHALL HAVE THE FOLLOWING ELEMENTS:

(A) IDENTIFICATION OF QUALITY MANAGEMENT PROJECTS

(1) FOR THE CLIENT SAFETY COMPONENT OF THE PROGRAM, THE PLAN SHALL IDENTIFY:

(a) THE TYPES OF SERVICE DELIVERY ERRORS AND POTENTIAL FOR ERROR THAT WILL BE MONITORED, WHICH ~~MAY~~ SHALL BE BASED, AT MINIMUM, ON A REVIEW OF NEGATIVE CLIENT OUTCOMES THAT ARE UNANTICIPATED, CLIENT GRIEVANCES, DEFICIENCIES CITED BY REGULATORY AGENCIES, OCCURRENCES AND/OR ERRORS, AND POTENTIAL FOR ERRORS REPORTED BY STAFF.

(b) A PROCESS FOR STAFF TO REPORT SERVICE DELIVERY ERROR AND POTENTIAL FOR ERROR WITHIN A PRESCRIBED PERIOD OF TIME AND A PLAN FOR HOW STAFF WILL BE TRAINED REGARDING SUCH REPORTING.

(c) THE METHODS USED TO COLLECT AND ANALYZE DATA IN ORDER TO FIND PATTERNS AND TRENDS. THE PLAN SHALL ALSO INCLUDE HOW THE GOVERNING BODY, IF APPLICABLE, AND THE ADMINISTRATOR WILL BE INFORMED OF SUCH PATTERNS AND TRENDS.

(d) THE METHOD(S) USED TO SELECT QUALITY MANAGEMENT PROJECTS.

(e) THE METHOD(S) FOR SELECTING THE SERVICE DELIVERY PRACTICE(S) THAT WILL BE REVIEWED.

(B) IMPLEMENTATION OF IMPROVEMENT STRATEGIES.

(1) THE PLAN SHALL INCLUDE HOW IMPROVEMENT STRATEGIES WILL BE DEVELOPED. THIS MAY INCLUDE IDENTIFYING THE PERSONNEL THAT WILL BE INVOLVED IN DESIGNING THE INTERVENTION, OPPORTUNITIES FOR CLIENT INPUT, AND THE ADMINISTRATIVE APPROVALS NEEDED TO FINALIZE THE INTERVENTION DESIGN.

(2) THERE SHALL BE DOCUMENTATION FOR EACH IMPROVEMENT STRATEGY THAT INCLUDES:

(a) A DESCRIPTION OF THE INTERVENTION DESIGN. FOR CLIENT SAFETY IMPROVEMENTS, THIS SHALL INCLUDE HOW INFORMATION ABOUT PATTERNS AND TRENDS WILL BE SHARED WITH STAFF AND HOW THE UNDERLYING SYSTEMIC PROBLEM(S) THAT LED TO THE PATTERN OR TREND WILL BE ADDRESSED.

(b) HOW STAFF WILL BE ALLOCATED AND/OR TRAINED TO IMPLEMENT THE STRATEGY.

(c) HOW THE STRATEGY WILL BE EVALUATED FOR EFFECTIVENESS.

(d) TIMELINES FOR IMPLEMENTATION AND EVALUATION OF THE STRATEGY AND HOW THE FACILITY OR AGENCY IS TRACKING THE MEETING OF THESE MILESTONES.

~~3.1.2 FOR THE PURPOSES OF SECTION 25-3-109 (2), C.R.S, A QUALITY MANAGEMENT PROGRAM SHALL BE CONSIDERED APPROVED UNLESS THE DEPARTMENT CITES DEFICIENT PRACTICE ALLEGING IMMEDIATE JEOPARDY DIRECTLY RELATED TO THE PROGRAM. A health care entity's quality management program shall be considered approved if the Department does not cite any deficient practice related to it. If the Department finds that a quality management program does not meet the requirements of these regulations, the Department shall inform the facility in writing of the deficiency of the quality management program and request or direct a plan of correction in accordance with Section 2.11.4(B) of this Chapter 2. A finding of deficient practice and submittal of a plan of correction will not affect the confidentiality and immunity applicable to quality management activities under Section 25-3-109, C.R.S~~

~~3~~4.1.3 If a ~~health care entity~~ LICENSEE has a quality management program that complies with the quality standards of a Medicare deemed status accrediting organization, Medicare conditions of participation or Medicare conditions for coverage, as applicable, it shall not be required to develop a separate state quality management program as long as the entity can show that its program includes the elements in PART 4.1.2 ~~3.1.1~~.

~~3~~4.1.4 The Department may audit a licensee's quality management program to determine its compliance with this ~~Section~~ PART ~~3~~4.1.

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

4.1.5 ANY RECORDS, REPORTS, AND OTHER INFORMATION OF A LICENSEE THAT IS PART OF THE QUALITY MANAGEMENT PROGRAM SHALL NOT BE SUBJECT TO SUBPOENA OR DISCOVERABLE OR ADMISSIBLE IN EVIDENCE IN ANY CIVIL OR ADMINISTRATIVE PROCEEDING, SO LONG AS THE QUALITY MANAGEMENT PROGRAM MEETS THE DEFINITION AND STANDARDS AS PUT FORTH IN 25-3-109, C.R.S. AND THESE RULES.

(A) THE DEPARTMENT OR ANY OTHER APPROPRIATE REGULATORY AGENCY HAVING JURISDICTION FOR DISCIPLINARY OR LICENSING SANCTIONS SHALL HAVE ACCESS TO ANY RECORDS, REPORTS, AND OTHER INFORMATION OF THE QUALITY MANAGEMENT PROGRAM.

~~3~~4.2 OCCURRENCE REPORTING ~~OCCURRENCE REPORTING. Notwithstanding any other reporting required by state law or regulation, each health care entity licensed pursuant to 25-1.5-103 shall report to the Department the occurrences specified at 25-1-124 (2) C.R.S.~~

~~3~~4.2.1 NOTWITHSTANDING ANY OTHER REPORTING REQUIRED BY STATE STATUTE OR REGULATION, EACH FACILITY OR AGENCY LICENSED PURSUANT TO SECTION 25-1.5-103, C.R.S. SHALL REPORT TO THE DEPARTMENT THE OCCURRENCES SPECIFIED AT SECTION 25-1-124 (2), C.R.S.

~~3.2.1~~4.2.2 The following occurrences shall be reported to the ~~department~~ DEPARTMENT WITHIN ONE ~~in the format required by the Department by the next~~ business day after the occurrence OR WHEN THE LICENSEE ~~or the health care entity~~ becomes aware of the occurrence, IN THE FORMAT REQUIRED BY THE DEPARTMENT:

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

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

~~(a)~~(1) Brain or spinal cord injuries;

~~(b)~~(2) Life-threatening complications of anesthesia or life-threatening transfusion errors or reactions;

~~(c)~~(3) Second or third degree burns involving twenty percent or more OF the body surface area of an adult ~~patient or resident~~ CLIENT or fifteen percent or more of the body surface area of a child ~~patient or resident~~ CLIENT;

~~(3)~~(C) Any time that a ~~resident or patient~~ CLIENT of the ~~health care entity~~ FACILITY OR AGENCY cannot be located following a search of the ~~health care entity~~ FACILITY OR AGENCY, ~~the health care entity~~ ITS grounds, and the area surrounding ~~the health care entity~~ FACILITY OR AGENCY and there are circumstances that place the ~~resident's~~ CLIENT'S health, safety, or welfare at risk or, regardless of whether such circumstances exist, the ~~patient or resident~~ CLIENT has been missing for eight hours;

~~(4)~~(D) Any occurrence involving physical, sexual, or verbal abuse of a ~~patient or resident~~ CLIENT, as described in sections 18-3-202, 18-3-203, 18-3-204, 18-3-206, 18-3-402, 18-3-403, AS IT EXISTED PRIOR TO JULY 1, 2000, 18-3-404, or 18-3-405, C.R.S., by another ~~patient or resident~~ CLIENT, an employee of the ~~health care entity~~ LICENSEE or a visitor to the ~~health care entity~~ FACILITY OR AGENCY;

~~(5)~~(E) Any occurrence involving neglect of a ~~patient or resident~~ CLIENT, as described in section 26-3.1-101(2.3),~~(7)(b)~~ C.R.S.

~~(6)~~(F) Any occurrence involving misappropriation of a ~~patient's or resident's~~ CLIENT'S property. For purposes of this paragraph, "misappropriation of a CLIENT'S ~~patient's or resident's~~ property" means a pattern of or deliberately misplacing, exploiting, or wrongfully using, either temporarily or permanently, a ~~patient's or resident's~~ CLIENT'S belongings or money without the ~~patient's or resident's~~ CLIENT'S consent;

~~(7)~~(G) Any occurrence in which drugs intended for use by ~~patients or residents~~ CLIENTS are diverted to use by other persons. IF THE DIVERTED DRUGS ARE INJECTABLE, THE LICENSEE SHALL ALSO REPORT THE FULL NAME AND DATE OF BIRTH OF ANY INDIVIDUAL WHO DIVERTED THE INJECTABLE DRUGS; and

~~(8)~~(H) Any occurrence involving the malfunction or intentional or accidental misuse of ~~patient or resident~~ CLIENT ~~care~~ equipment that occurs during treatment or diagnosis of a ~~patient or resident~~ CLIENT and that significantly adversely affects or if not averted would have significantly adversely affected a ~~patient or resident~~ CLIENT of the ~~health care entity~~ FACILITY OR AGENCY.

~~3.2.2~~ 4.2.3 Any reports submitted shall be strictly confidential in accordance with and pursuant to SECTION 25-1-124 (4),(5), and (6) C.R.S.

~~3.2.3 (not used)~~

~~3~~4.2.4 The ~~department~~ DEPARTMENT may request further oral reports or a written report of the occurrence if it determines a report is necessary for the ~~department's~~ DEPARTMENT'S further investigation.

~~3~~4.2.5 Every ~~health care entity~~ LICENSEE shall have a policy that defines the deaths reportable to the local county coroner under SECTION 30-10-606(1), C.R.S. ~~(1977)~~ and that is consistent with the local coroner's reporting policy.

~~3~~4.2.6 Every ~~health care entity~~ LICENSEE shall have a policy for requiring its employees to report occurrences to it.

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

4.2.7 NO LICENSEE, NOR ANY EMPLOYEE, OFFICER, OR ANY OTHER PERSON WITH CONTROLLING INTEREST IN THE FACILITY OR AGENCY, SHALL DISCHARGE OR DISCRIMINATE OR RETALIATE AGAINST ANY INDIVIDUAL BECAUSE THE INDIVIDUAL HAS MADE OR IS ABOUT TO A MAKE A GOOD FAITH REPORT PURSUANT TO THIS

PART 4.2, OR HAS PROVIDED OR IS ABOUT TO PROVIDE EVIDENCE IN ANY PROCEEDING OR INVESTIGATION RELATING TO ANY OCCURRENCES REQUIRED TO BE REPORTED TO THE DEPARTMENT. SUCH INDIVIDUALS INCLUDE CLIENTS AND EMPLOYEES OR CONTRACTORS OF THE FACILITY OR AGENCY, AS WELL AS THEIR RELATIVES, SPONSORS, OR LEGAL REPRESENTATIVES.

(A) A LICENSEE CANNOT DISCHARGE OR DISCRIMINATE OR RETALIATE AGAINST A CLIENT OR EMPLOYEE OR CONTRACTOR DUE TO THE REPORTING OR THE PROVISION OF EVIDENCE BY A THIRD PARTY WHO IS RELATED, SPONSORING, OR IS A LEGAL REPRESENTATIVE OF THE CLIENT OR EMPLOYEE OR CONTRACTOR.

~~3.2.9~~4.2.8 The ~~department~~ DEPARTMENT shall investigate all reports made to it under this part, and make a summary report.

~~(1)~~(A) ~~Such~~ THE report shall include: ~~(a) a summary of finding(s) including the department's conclusion(s); (b) whether any violation of licensing standards was noted or whether a deficiency notice was issued; (c) whether the health care entity acted appropriately in response to the occurrence, and (d) if the investigation was not conducted on site, how the investigation was conducted.~~

(1) A SUMMARY OF FINDING(S) INCLUDING THE DEPARTMENT'S CONCLUSION(S),

(2) WHETHER ANY VIOLATION OF LICENSING STANDARDS WAS NOTED OR WHETHER A DEFICIENCY NOTICE WAS ISSUED,

(3) WHETHER THE LICENSEE ACTED APPROPRIATELY IN RESPONSE TO THE OCCURRENCE, AND

(4) IF THE INVESTIGATION WAS NOT CONDUCTED ON SITE, HOW THE INVESTIGATION WAS CONDUCTED.

~~(2)~~(B) A summary report shall not identify a ~~patient, resident~~ CLIENT or health care professional.

~~(3)~~(C) In response to an inquiry, the ~~department~~DEPARTMENT may confirm that it has obtained a report concerning the occurrence and that an investigation is pending.

~~(4)~~(D) Prior to releasing a summary report that identifies a ~~health care entity~~ FACILITY OR AGENCY, the ~~department~~DEPARTMENT shall notify the ~~health care entity~~ LICENSEE and provide ~~to it a~~ IT WITH A copy of the summary report. The ~~health care entity~~ LICENSEE shall be allowed seven days to review, comment, and verify ~~such information~~ THE REPORT. If immediate release of information is necessary and the ~~department~~ DEPARTMENT cannot provide at least prior oral notice to the ~~health care entity~~ LICENSEE ~~identified~~, ~~it~~ THE DEPARTMENT shall provide notice as soon as reasonably possible ~~and shall explain~~ WITH AN EXPLANATION OF why it could not provide prior notice.

~~3.2.10~~4.2.9 Nothing in this ~~part 3~~ PART 4 shall be construed to limit or modify any statutory or common law right, privilege, confidentiality or immunity.

~~3.2.11~~4.2.10 Nothing in this ~~part 3~~ PART 4 shall affect a person's access to ~~his or her~~ THEIR OWN medical record(S) as provided in section 25-1-801, C.R.S., nor shall it affect the right of a family member or any other person to obtain medical record information upon the consent of the ~~patient~~ CLIENT or ~~his/her~~ THE CLIENT'S ~~authorized~~ DESIGNATED representative.

~~3~~4.3 ~~PALLIATIVE CARE STANDARDS~~ **Palliative Care Standards**

~~3~~4.3.1 If palliative care is provided within OR BY a ~~licensed healthcare entity~~ FACILITY OR AGENCY, the licensee shall have written policies and procedures for the comprehensive delivery of these services. For each ~~patient~~ CLIENT receiving palliative care, there shall be documentation in the plan of care regarding evaluation of the ~~patient~~ CLIENT and what services will be provided. The licensee's policies and procedures shall address the following elements of palliative care and how they will be provided and documented:

~~(1)~~(A) Assessment and management of the ~~patient's~~ CLIENT'S pain and other distressing symptoms,~~ and~~

~~(2)~~(B) Goals of care and advance care planning, ~~and~~

~~(3)~~(C) Provision of, or access to, services to meet the psychosocial and spiritual needs of the ~~patient~~ CLIENT and THE INDIVIDUALS WHO ARE IDENTIFIED AS THE CLIENT'S PERSONAL SUPPORT SYSTEM ~~family~~, ~~and~~

~~(4)~~(D) Provision of, or access to, a support system to help the ~~family~~ THE INDIVIDUALS WHO ARE IDENTIFIED AS THE CLIENT'S PERSONAL SUPPORT SYSTEM cope during the ~~patient's~~ CLIENT'S illness, and

~~(5)~~(E) As indicated, the need for bereavement support for families by providing resources or referral.

~~Part 4~~PART 5. WAIVER OF REGULATIONS FOR ~~HEALTH CARE ENTITIES~~ FACILITIES AND AGENCIES

4.~~10~~15.1 **Statutory Authority, Applicability and Scope**

~~(1)~~5.1.1 This Part 45 is promulgated by the State Board of Health pursuant to ~~SECTION~~ SECTION 25-1-108(l)(c)(2), C.R.S., in accordance with the general licensing authority of the Department as set forth in ~~Section~~ SECTION 25-1.5-103, C.R.S.

~~(2)~~5.1.2 This Part 45 applies to ~~health facilities~~ FACILITIES AND AGENCIES licensed by the Department and establishes procedures with respect to waiver of regulations relating to state licensing and federal certification of ~~health facilities~~ FACILITIES AND AGENCIES. FOR WAIVERS OF THE FACILITY GUIDELINES INSTITUTE (FGI) PROVISIONS, SEE PART 3.

~~(3)~~5.1.3 Nothing contained in these provisions abrogates the applicant's obligation to meet minimum requirements under local safety, fire, electrical, building, zoning, and similar codes.

~~(4)~~5.1.4 Nothing herein shall be deemed to authorize a waiver of any statutory requirement under state or federal law, except to the extent permitted therein.

~~(5)~~5.1.5 It is the policy of the State Board of Health and the Department that every licensed ~~health care entity~~ FACILITY AND AGENCY complies in all respects with applicable regulations. Upon application to the Department, a waiver may be granted in accordance with this Part 5 ~~4, generally for a limited term~~. Absent the existence of a current waiver issued pursuant to this part, ~~health care entities~~ FACILITIES AND AGENCIES are expected to comply at all times with all applicable regulations.

5.1.6 THE DEPARTMENT MAY WAIVE FEDERAL REGULATIONS PERTAINING TO CERTIFICATION OF A FACILITY OR AGENCY ONLY WHEN FINAL AUTHORITY FOR WAIVER OF THE FEDERAL REGULATION SEEKING TO BE WAIVED IS VESTED IN THE DEPARTMENT. "REGULATION(S)" INCLUDES THE TERMS "STANDARD(S)" AND "RULE(S)."

~~4.102 Definitions For This Part 4~~

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

~~(2) "Board" means the State Board of Health.~~

~~(3) "Department" means the Colorado Department of Public Health and Environment.~~

~~(4) "Health Care Entity" means a health facility or agency licensed pursuant to Sections 25-1.5-103 and 25-3-102, C.R.S., and/or certified pursuant to federal regulations to participate in a federally funded health care program.~~

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

~~(a) Any state regulation promulgated by the Board relating to standards for operation or licensure of a health care entity, or~~

~~(b) Any federal regulation pertaining to certification of a care entity, but only when final authority for waiver of such federal regulation is vested in the Department. "Regulation(s)" includes the terms "standard(s)" and "rule(s)."~~

Commented [HA54]: Moved to 4.1.6

~~4.103~~**5.2 Application Procedure**

~~(1)~~5.2.1 ~~General~~ ~~w~~WAIVER applications shall be submitted to the Department on the form and in the manner required by the Department.

~~(a)~~(A) Only one regulation per waiver application will be considered.

~~(b)~~(B) The WAIVER APPLICATION ~~applicant~~ shall provide the Department ~~such~~ THE information and documentation ~~as the Department may~~ requireD to validate the conditions under which the waiver is being sought.

~~(c) The application must include the applicant's name and specify the regulation that is the subject of the application, identified by its citation.~~

~~(d)~~(C) The WAIVER application must be signed by an authorized representative of the ~~applicant~~ FACILITY OR AGENCY, who shall be the primary contact person ~~for the Department~~ and the individual responsible for ensuring that accurate and complete information is provided to the Department.

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

~~(a) A copy of the notice required to be posted pursuant to Section 4.103(4);~~

~~(b) If the waiver application pertains to physical plant issues that affect the health and/or environment of the residents or patients, schematic drawings of the areas affected and a description of the effect of the requested waiver on the total health care entity;~~

(c) A description of the programs or services offered by the health care entity that are anticipated to be affected by the waiver;

(d) A description of the number of residents or patients in the health care entity and the level of care they require;

(e) A description of the nature and extent of the applicant's efforts to comply with the Regulation;

(f) An explanation of the applicant's proposed alternative(s) to meet the intent of the regulation that is the subject of the waiver application;

(g) An explanation of why granting the waiver would not adversely affect the health, safety or welfare of the health care entity's residents or patients;

(h) If the waiver is being sought for state regulation, a description of how any applicable federal regulation similar to the state regulation for which the waiver is sought (if any) is being met.

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

(a) Staffing considerations, such as staff/resident or patient ratios, staffing patterns, scope of staff training, and cost of extra or alternate staffing;

(b) The location and number of ambulatory and non-ambulatory residents or patients;

(c) The decision-making capacity of the residents or patients;

(d) Recommendations of attending physicians and other care-givers;

(e) The extent and duration of the disruption of normal use of resident or patient areas to bring the health care entity into compliance with the regulation;

(f) Financial factors, including but not limited to:

(i) The estimated cost of complying with the regulation, including capital expenditures and any other associated costs, such as moving residents or patients;

(ii) How application of the regulation would create a demonstrated financial hardship on the health care entity that would jeopardize its ability to deliver necessary health care services to residents or patients;

(iii) The availability of financing to implement the regulation, including financing costs, repayment requirements, if any, and any financing or operating restrictions that may impede delivery of health care to residents or patients; and

(iv) The potential increase in the cost of care to residents or patients as a result of implementation of the regulation.

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

~~(4)~~**5.3** ~~*Notice and Opportunity to Comment on Application*~~ **NOTICE AND OPPORTUNITY TO COMMENT**

~~(a)~~5.3.1 No later than the date of submitting the waiver application to the Department, ~~the applicant shall post~~ written notice of the application SHALL BE POSTED for thirty (30) days at all public entrances to the ~~health care entity~~ FACILITY OR AGENCY, as well as in at least one area commonly used by ~~patients or residents~~ CLIENTS, such as a waiting room, lounge, or dining room. ~~Applicants that do not provide~~ IF services ARE NOT PROVIDED on ~~their own~~ THE ~~licensed~~ premises, such as home care agencies and hospices, WRITTEN NOTICE shall instead BE provideD ~~such written notice~~ directly to ~~patients~~ CLIENTS. The notice shall be dated and include that an application for a waiver has been made, a meaningful description of the substance of the waiver, and that a copy of the waiver shall be provided ~~by the health care entity~~ TO CLIENTS upon request.

~~(b)~~5.3.2 The notice must also indicate that any person interested in commenting on the waiver application may forward written comments directly to the Department at the following address:

~~CDPHE - HFD, A2 - Waiver Program~~
COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT
HEALTH FACILITIES AND EMERGENCY MEDICAL SERVICES DIVISION
LICENSING & CERTIFICATION PROGRAM
4300 Cherry Creek Drive South C1
Denver, CO 80246

~~(c)~~5.3.3 The notice must specify that written comments from interested persons must be submitted to the Department within thirty (30) calendar days of the date the notice is posted ~~by the applicant~~, and that persons wishing to be notified of the Department's action on the waiver application may submit to the Department at the above address a written request for notification and a self-addressed stamped envelope.

~~4.104~~**5.4** **Department Action Regarding Waiver Application**

~~(1) *General*~~

~~Upon an applicant's submission of a completed waiver application to the Department, a waiver of a particular regulation with respect to a health care entity may be granted in accordance with this Part 4.~~

~~(2) *Decision on Waiver Application*~~

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

~~(i) The information submitted by the applicant;~~

~~(ii) The information timely submitted by interested persons, pursuant to Section 4.103 (4); and~~

~~(iii) Whether granting the waiver would adversely affect the health safety or welfare of the health care entity's residents or patients.~~

~~(b)~~5.4.1 In making its determination, the Department may ~~also~~ consider any ~~other~~ information it deems relevant, including but not limited to, occurrence and complaint investigation reports, ~~and~~ licensure or certification survey reports, and findings related to the ~~health care entity~~ FACILITY OR AGENCY and/or the operator or owner thereof.

~~(c)~~5.4.2 The Department shall act on a waiver application within ninety (90) calendar days of receipt of the completed application. An application shall not be deemed complete until such time as the applicant has provided all information and documentation requested by the Department.

~~(3)~~5.4.3 ~~*Terms and conditions of the waiver.*~~ The Department may specify terms and conditions under which any waiver is granted, INCLUDING which terms and conditions must be met in order for the waiver to remain effective.

~~4.105~~**5.5 Termination, Expiration and Revocation of Waiver**

~~(1)~~5.5.1 ~~*General.*~~ The term for which each waiver granted will remain effective shall be specified at the time of issuance, BUT SHALL NOT EXCEED THE TERM OF THE CURRENT LICENSE.

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

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

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

~~(2) *Termination*~~

~~(a)~~5.5.2 Change of Ownership. A waiver shall automatically terminate upon a change of ownership of the ~~health care entity~~ FACILITY OR AGENCY, as defined in ~~Section~~ PART 2.~~7~~6. ~~of Part 2, Chapter II of these regulations.~~ However, to prevent such automatic termination, the prospective new owner may submit a waiver application to the Department prior to the effective date of the change of ownership. Provided the Department receives the new application by this date, the waiver will be deemed to remain effective until such time as the Department acts on the application.

~~(3)~~5.5.3 ~~*Expiration*~~ EXPIRATION

~~(a)~~(A) Except as otherwise provided in this Part ~~4~~5, ~~no~~ A waiver shall NOT be granted for a term that exceeds THE CURRENT LICENSE TERM.~~one year from the date of issuance~~.

~~(b)~~(B) If an applicant wishes to maintain a waiver beyond the stated term, it must submit a new waiver application to the Department not less than ninety (90) calendar days prior to the expiration of the current term of the waiver OR WITH A LICENSE RENEWAL.

~~(4)~~5.5.4 ~~*Revocation*~~ REVOCATION

~~(a)~~(A) Notwithstanding anything in this ~~Pan~~ PART 5 ~~4~~ to the contrary, the Department may revoke a waiver if it determines that:

~~(i)~~(1) The waiver's continuation jeopardizes the health, safety, or welfare of CLIENTS OF THE FACILITY OR AGENCY~~residents or patients~~;

~~(ii)~~(2) The WAIVER APPLICATION ~~applicant has provided~~ CONTAINED false or misleading information ~~in the waiver application~~;

~~(iii)~~(3) The ~~applicant has failed to comply with the~~ terms and conditions of the waiver HAVE NOT BEEN COMPLIED WITH;

~~(iv)~~(4) The conditions under which a waiver was granted no longer exist or have changed materially; or

~~(v)~~(5) A change in a federal or state ~~law~~ STATUTE or regulation prohibits, or is inconsistent with, the continuation of the waiver.

~~(b)~~(B) Notice of the revocation of a waiver shall be provided to the applicant in accordance with the Colorado Administrative Procedures Act, ~~Section~~SECTION 24-4-101, et seq., C.R.S.

~~4.106~~5.6 ~~Appeal Rights~~ AN APPLICANT MAY APPEAL THE DECISION OF THE DEPARTMENT REGARDING A WAIVER APPLICATION OR REVOCATION, AS PROVIDED IN THE COLORADO ADMINISTRATIVE PROCEDURES ACT, SECTION 24-4-101, ET SEQ., C.R.S.

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

~~Part 5~~PART 6.~~ -~~ ACCESS TO ~~PATIENT~~ CLIENT ~~MEDICAL~~ RECORDS

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

~~5.1 DEFINITIONS~~

~~5.1.1 PATIENT - A patient is any individual admitted to or treated in a health facility defined in 5.2 or treated by any of the providers defined in 5.3.~~

~~5.1.2~~1.7 ~~PATIENT~~ CLIENT ~~RECORD - A patient~~ CLIENT ~~record is a documentation of services pertaining to medical and health care that are performed~~ FOR THE CLIENT BY THE FACILITY OR AGENCY ~~at the direction of a physician or other licensed health care provider on behalf of the patient~~ CLIENT ~~by physicians/dentists, nurses, technicians and other health care personnel. Patient~~ CLIENT ~~records include such diagnostic documentation as X-rays and EKG's. Patient~~ CLIENT ~~records do not include doctors' office notes, which are the notes by a physician of observations about the patient~~ CLIENT ~~made while the patient~~ CLIENT ~~is in a non-hospital setting and maintained in the physician's office~~

~~5.1.3~~1.2 ~~ATTENDING HEALTH CARE~~ SERVICE ~~PROVIDER - An attending health care~~ A SERVICE ~~provider is the physician currently or most recently~~ INDIVIDUAL ~~responsible for coordinating the patient's~~ CLIENT'S ~~care in a facility~~ OR AGENCY, ~~or in the case of outpatient services, is the custodian of the record of the outpatient service. If the attending health care~~ SERVICE ~~provider is deceased or unavailable, the current custodian of the record~~

~~shall designate a substitute attending health care SERVICE provider for purposes of compliance with these regulations.~~

Commented [BF55]: Moved to 6.1.1(A)

~~5.1.41.11 DESIGNATED REPRESENTATIVE - A designated representative of a patient CLIENT or attending health care SERVICE provider is a person so authorized in writing or by court order to act on behalf of the patient CLIENT or attending health care SERVICE provider. In the case of a deceased patient CLIENT, the personal representative or, if none has been appointed, heirs shall be deemed to be designated representatives of the patient CLIENT.~~

~~5.26.1~~ ~~HEALTH CARE ENTITY RECORDS~~ FACILITY OR AGENCY RECORDS

~~5~~6.21.1 Except as hereinafter provided, ~~patient~~ client records in the custody of A FACILITY OR AGENCY ~~health care entities~~ required to be certified under ~~Section~~SECTION 25-1.5-103 (1)(II) or licensed under Part 1 of Article 3 of Title 25 of the C.R.S. shall be available to a ~~patient~~ CLIENT or ~~his/her~~ THEIR designated representative through the ~~attending health care~~ SERVICE provider or ~~his/her~~ THEIR designated representative at reasonable times and upon reasonable notice.

(A) If the SERVICE provider is deceased or unavailable, the current custodian of the record shall designate a substitute SERVICE provider for purposes of compliance with these regulations.

Commented [BF56]: Moved from definition of service provider

6.1.2 A STATEMENT OF THE FACILITY'S OR AGENCY'S PROCEDURES FOR OBTAINING RECORDS, AND THE RIGHT TO APPEAL GRIEVANCES REGARDING ACCESS TO RECORDS TO THE DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT SHALL BE POSTED IN CONSPICUOUS PUBLIC PLACES ON THE PREMISES AND MADE AVAILABLE TO EACH CLIENT UPON ADMISSION TO THE FACILITY OR AGENCY.

Commented [HA57]: Moved From 5.2.2.4

~~5.2.2 Inpatient Records~~

6.1.3~~5.2.2.1~~ ~~While an inpatient~~ A CLIENT, WHETHER CURRENT OR DISCHARGED, ~~in~~ OF a facility OR AGENCY ~~described in 5.2.1, a person~~ may inspect ~~his/her~~ THEIR OWN ~~patient~~ record within a reasonable time~~, which should normally not exceed 24 hours of request (excluding weekends and holidays)~~.

(A) IF A CLIENT IS CURRENTLY BEING PROVIDED SERVICES BY THE AGENCY OR FACILITY, RECORDS WILL NORMALLY BE AVAILABLE FOR INSPECTION BY THE CLIENT WITHIN THREE (3) BUSINESS DAYS.

(B) IF A CLIENT HAS BEEN DISCHARGED FROM THE FACILITY OR AGENCY, RECORDS WILL NORMALLY BE AVAILABLE FOR INSPECTION BY THE CLIENT WITHIN TEN (10) BUSINESS DAYS.

6.1.4 The ~~patient~~ CLIENT or designated representative shall sign and date the request. The ~~attending health care~~ SERVICE provider or ~~his/her~~ THEIR designated representative shall acknowledge in writing the ~~patient's~~ CLIENT'S or representative's request. After inspection, the ~~patient~~ CLIENT or designated representative shall sign and date the ~~patient~~ record to acknowledge inspection.

6.1.5~~5.2.2.2~~ The ~~patient~~ CLIENT or designated representative shall not be charged for inspection OF THE CLIENT RECORD.

6.1.6 A COPY OF THE RECORDS MUST BE MADE AVAILABLE TO THE CLIENT OR THEIR DESIGNATED REPRESENTATIVE, UPON REQUEST AND PAYMENT OF FEES AS SET FORTH AT SECTION 25-1-801(5)(C), C.R.S. THE RECORDS MUST BE PROVIDED IN ELECTRONIC FORMAT IF THE REQUEST IS FOR ELECTRONIC FORMAT, THE ORIGINAL RECORDS ARE STORED IN ELECTRONIC FORMAT, AND THE RECORDS ARE READILY PRODUCIBLE IN ELECTRONIC FORMAT.

Commented [HA58]: From 25-1-801(1)(b)

6.1.7 RECORDS SHALL BE KEPT IN ACCORDANCE WITH ALL APPLICABLE STATE AND FEDERAL LAWS AND REGULATIONS.

6.1.8 ACCESS TO MEDICAL RECORDS CONTAINED WITHIN THE CLIENT'S RECORDS SHALL BE ACCESSED IN A MANNER THAT IS CONSISTENT WITH THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996.

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

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

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

Commented [HA59]: Moved to 6.2.2.2

~~5.2.3 Discharged Inpatient Record~~

~~5.2.3.1 A discharged inpatient or his/her designated representative may inspect or obtain a copy of his/her record after submitting a signed and dated request to the facility. The attending health care provider or his/her designated representative shall acknowledge in writing the patient's or representative's request. After inspection, the patient or designated representative shall sign and date the record to acknowledge inspection.~~

~~5.2.3.2 The facility shall make a copy of the record available or make the record available for inspection within a reasonable time, from the date of the signed request, normally not to exceed ten days, excluding weekends and holidays, unless the attending health care provider or designated representative is unavailable to acknowledge the request, in which case the facility shall so inform the patient and provide the patient record as soon as possible.~~

~~5.2.3.3 Discharged patients or their representatives shall not be charged for inspection of patient records.~~

~~5.2.3.4 Reserved.~~

~~5.2.3.5 If the patient or the patient's designated representative so approves, the facility may supply a written interpretation by the attending health care provider or his/her designated representative of records, such as X-rays, which cannot be reproduced without special equipment. If the requestor prefers to obtain a copy of such records, he/she must pay the actual cost of such reproduction.~~

~~5.2.3.6 If the attending health care provider feels that any portion of the patient record pertaining to psychiatric or psychological problems or any doctor's notes would have a significant negative psychological impact upon the patient, the attending health care provider shall so indicate on his/her acknowledgment of the patient's or representative's request to inspect or obtain a copy of the patient's record. The attending health care provider or his/her designated representative shall so inform the patient or representative within a reasonable time of the date of the request, normally not to exceed five days, excluding weekends and holidays. The facility shall permit inspection or provide a copy of the remaining portion of the record within that time. The portion of the patient record pertaining to psychiatric or fpsychological problems may then be withheld from the patient or representative until completion of the treatment program if, in the opinion of an independent third party who is a licensed physician practicing psychiatry, the portion of the patient record would have a significant negative psychological impact upon the patient. The Department of Public Health and Environment, upon request of either the patient or the attending health care provider, shall identify an independent third party psychiatrist to review the record and render a final decision.~~

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

~~5.2.4~~6.2 Nothing in this ~~section~~ PART shall apply to any nursing facility conducted by or for the adherents of any well-recognized church or religious denomination for the purpose of providing facilities for the care and treatment of the sick who depend exclusively upon spiritual means through prayer for healing and the practice of the religion of such church or denomination.

Commented [HA60]: From the statute: 25-1-801(3)

~~5.2.5 EMERGENCY ROOM RECORDS. Patient records in the custody of emergency rooms of facilities described in 5.2.1 shall be available to patients or their designated representatives in the same manner as inpatient or discharged inpatient records.~~

~~5.2.6~~6.3 If any changes/corrections, deletions, or other modifications are made to any portion of a ~~patient~~ CLIENT record, the person WHO IS MAKING THE CHANGES must note in the record the date, time, nature, reason, correction, deletion, or other modification, ~~his/her~~ AND THEIR name~~ and the name of a witness,~~ to the change, correction, deletion, or other modification.

~~5.3 RESERVED~~

~~5.4~~6.4 EFFECT OF THIS PART ~~5~~6 ON SIMILAR RIGHTS OF A ~~PATIENT~~CLIENT

~~5.4.1~~6.4.1 Nothing in this Part ~~5~~6 shall be construed so as to limit the right of a ~~patient~~ CLIENT or the ~~patient's~~ CLIENT'S designated representative to inspect ~~patient~~ CLIENT records, including the CLIENT'S medical or psychological data pursuant to section 24-72-204 (3) (a)(I), C.R.S.

~~5.4.2~~6.4.2 Nothing in this Part ~~5~~6 shall be construed to require a person responsible for the diagnosis or treatment of venereal diseases or addiction to or use of drugs in the case of minors, pursuant to sections 25-4-402(4) and 13-22-102, C.R.S. to release records of such diagnosis or treatment to a parent, guardian, or person other than the minor or their designated representative.

~~5.4.3~~6.4.3 Nothing in this Part ~~5~~6 shall be construed to waive the responsibility of a custodian of medical records in facilities OR AGENCIES to maintain confidentiality of those records in its possession.

6.7.4 NOTHING IN THIS PART 6 SHALL LIMIT THE RIGHT OF A CLIENT, THE CLIENT'S PERSONAL REPRESENTATIVE, OR A PERSON WHO REQUESTS THE MEDICAL RECORDS UPON SUBMISSION OF AN AUTHORIZATION COMPLIANT WITH THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996, A VALID SUBPOENA, OR A COURT ORDER TO INSPECT THE CLIENT'S RECORDS.

PART ~~6~~7. -- ~~PATIENT~~ CLIENT RIGHTS

~~6.100 PATIENT RIGHTS~~

~~6.200 PATIENT GRIEVANCE MECHANISM~~

~~**6.100 PATIENT RIGHTS**~~

~~6.101 STATUTORY AUTHORITY AND APPLICABILITY~~

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

~~(2) Applicability. Subpart 6.100 applies to ambulatory surgical centers, birth centers, chiropractic centers and hospitals, community clinics, community clinics with emergency centers, convalescent centers, dialysis treatment clinics, hospitals and hospital units.~~

~~6.102 DEFINITIONS~~

~~(1) "Abuse" means the willful infliction of injury, unreasonable confinement, intimidation, or punishment, with resulting physical harm, pain, or mental anguish.~~

~~(2) "Admission" means the acceptance of a person as a patient CLIENT OF THE FACILITY OR AGENCY. whether on an inpatient or outpatient basis.~~

(3) "Informed consent" means:

(a) an explanation of the nature and purpose of the recommended treatment or procedure in layman's terms and in a form of communication understood by the patient CLIENT, or the patient's CLIENT'S designated representative;

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

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

(d) an explanation of the risks and benefits if no treatment is pursued;

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

(f) an explanation that the patient CLIENT, or the patient's CLIENT'S designated representative, is free to withdraw his or her consent and to discontinue participation in the treatment regimen AT ANY TIME.

(4) "Department" means the Colorado Department of Public Health and Environment, unless the context dictates otherwise.

(5) "Licensed independent practitioner" means an individual permitted by law and the facility OR AGENCY to independently diagnose, initiate, alter or terminate health care treatment within the scope of THEIR his or her license.

(6) "Financial interest" means direct or indirect ownership of 5 percent or more of the capital, stock or property.

(7) "Neglect" means the failure to provide goods and services necessary to attain and maintain physical and mental well-being.

(8) "Patient" means a person accepted on either an inpatient or outpatient basis. Where a patient is incompetent or unable to act on his or her own behalf, such interest devolves on the patient designated representative or next of kin, if possible.

(9) "Patient designated representative" is a person authorized to act on behalf of the patient by state law, by court order or in writing in accordance with the policies and procedures of the facility.

(10) "Restraint" means a physical, mechanical or chemical restraint that immobilizes or reduces the ability of the patient CLIENT to move his or her THEIR arms, legs, head or body freely. Methods typically used for medical-surgical care shall not be considered restraints, such as: the use of bandages and orthopedically prescribed devices, the use of a required device to limit mobility during a medical procedure, or the use of a drug when it is part of a standard treatment or dosage for the patient's condition. For the purposes of this definition, physical restraints used for fall prevention (including but not limited to raised bed rails) shall not be considered methods typically used for medical surgical care.

6.103 DEPARTMENT OVERSIGHT. This Section 6.103 applies only to health care entities having in excess of fifty (50) beds. The Department shall approve the patient rights policy of applicable

~~health care entities prior to issuance of an initial or renewal license in accordance with Section 25-1-121, C.R.S. The facility shall submit the policy in the manner prescribed by the Department.~~

~~6.104~~ 7.1 ~~PATIENT RIGHTS POLICY~~ **CLIENT RIGHTS POLICY**

~~(1)~~7.1.1 The ~~health care entity~~ FACILITY OR AGENCY shall develop and implement a policy regarding ~~patient~~ CLIENT rights. The policy shall ensure that each ~~patient~~ CLIENT or, where appropriate, ~~patient~~ THE CLIENT'S designated representative, has the right to:

~~(a)~~(A) ~~participate~~ PARTICIPATE in all decisions involving the ~~patient's~~ CLIENT'S care or treatment~~;~~.

~~(b)~~(B) ~~be~~ BE informed about whether the ~~health care entity~~ FACILITY OR AGENCY is participating in teaching programs, and to provide informed consent prior to being included in any clinical trials relating to the ~~patient's~~ CLIENT'S care.

~~(c)~~(C) ~~refuse~~ REFUSE any drug, test, procedure, or treatment and to be informed of risks and benefits of this action~~;~~.

~~(d)~~(D) ~~to~~ RECEIVE care and treatment, in compliance with state statute, that is respectful; recognizes a person's dignity, cultural values and religious beliefs; and provides for personal privacy to the extent possible during the course of treatment~~;~~.

~~(e)~~(E) BE INFORMED OF, AT A MINIMUM, ~~know~~ the FIRST names AND CREDENTIALS OF THE INDIVIDUALS THAT ARE PROVIDING SERVICES TO THE CLIENT. FULL NAMES AND EXPERIENCE OF THE SERVICE PROVIDERS SHALL BE PROVIDED UPON REQUEST TO THE CLIENT OR THE CLIENT'S DESIGNATED REPRESENTATIVE.~~, professional status, and experience of the staff that are providing care or treatment to the patient~~;~~

~~(f)~~(F) ~~receive~~ RECEIVE, upon request:

~~(i)~~(1) P~~p~~rior to initiation of NON-EMERGENT care or treatment, the estimated average charge to the CLIENT ~~patient for non-emergent care~~. This INFORMATION SHALL BE PRESENTED TO THE CLIENT IN A MANNER THAT IS CONSISTENT WITH ALL STATE AND FEDERAL LAWS AND REGULATIONS. ~~includes reasonable assistance with determining the charges which may include deductibles and co-payments that would not be covered by a third-party payer based on the coverage information supplied by the patient or patient designated representative. In discharging its responsibility hereunder, a health care entity may provide the estimated charge for an average patient with a similar diagnosis and inform the patient or the patient designated representative that there are variables that may alter the estimated charge.~~

~~(ii)~~(2) T~~t~~he ~~health care entity's~~ FACILITY'S OR AGENCY'S general billing procedures.

~~(iii)~~(3) A~~a~~n itemized bill that identifies treatment and services by date. The itemized bill shall enable ~~patients~~ CLIENTS to validate the charges for items and services provided and shall include contact information, including a telephone number for ~~patient~~ billing inquiries. The itemized bill shall be made available either within 10 business days of the request, or 30 days after discharge ~~for inpatients~~, or 30 days after the service is rendered ~~for outpatients~~ – whichever is later.

~~(g)~~(G) ~~give~~ GIVE informed consent for all treatment and procedures. It is the responsibility of the licensed independent practitioner and other SERVICE PROVIDERS ~~health professionals~~ to obtain informed consent for procedures that they provide to the CLIENT ~~patient~~.

~~(h)~~(H) ~~register~~ REGISTER complaints with the ~~health care entity~~ FACILITY OR AGENCY and the Department and to be informed of the procedures for registering complaints including contact information.

~~(i)~~(I) ~~be~~ Be free of abuse and neglect. ~~To effectuate this patient right, the health care entity shall develop and implement policies and procedures to prevent, detect, investigate, and respond to incidents of abuse or neglect. Prevention includes, but is not limited to, adequate staffing to meet the needs of the patients, screening employees for records of abuse and neglect and protecting patients from abuse during investigation of allegations. Detection includes, but is not limited to, establishing a reporting system and training employees regarding identifying, reporting, and intervening in incidences of abuse and neglect. The health care entity shall investigate, in a timely manner, all allegations of abuse or neglect and implement corrective actions in accordance with such investigations.~~

Commented [HA61]: Moved to directly below

(1) THE FACILITY OR AGENCY SHALL DEVELOP AND IMPLEMENT POLICIES AND PROCEDURES THAT PREVENT, DETECT, INVESTIGATE, AND RESPOND TO INCIDENTS OF ABUSE OR NEGLECT.

(A) PREVENTION INCLUDES, BUT IS NOT LIMITED TO, ADEQUATE STAFFING TO MEET THE NEEDS OF THE CLIENTS, SCREENING EMPLOYEES FOR RECORDS OF ABUSE AND NEGLECT, AND PROTECTING CLIENTS FROM ABUSE DURING INVESTIGATION OF ALLEGATIONS.

(B) DETECTION INCLUDES, BUT IS NOT LIMITED TO, ESTABLISHING A REPORTING SYSTEM AND TRAINING EMPLOYEES REGARDING IDENTIFYING, REPORTING, AND INTERVENING IN INCIDENCES OF ABUSE AND NEGLECT.

(2) THE FACILITY OR AGENCY SHALL INVESTIGATE, IN A TIMELY MANNER, ALL ALLEGATIONS OF ABUSE OR NEGLECT AND IMPLEMENT CORRECTIVE ACTIONS IN ACCORDANCE WITH SUCH INVESTIGATIONS.

~~(j)~~(J) ~~be~~ BE free FROM THE IMPROPER APPLICATION OF ~~of the inappropriate use of~~ restraints OR SECLUSION. RESTRAINTS OR SECLUSION SHALL BE USED ONLY IN A MANNER CONSISTENT WITH PART 8 OF THESE RULES. ~~Inappropriate use includes improper application of a restraint or the usage of a restraint as a means of coercion, discipline, convenience, or retaliation by staff. A health care entity that does not use restraints shall include a written statement in their policies and procedures to that effect. A health care entity that does use restraints shall develop and implement policies and procedures regarding:~~

~~(i) the provision of training on the use of restraints.~~

~~(ii) ongoing individual patient assessment to determine: when a medical condition or symptom indicates use of restraint to protect the patient or others from harm; the least restrictive intervention; and the discontinuation of the intervention at the earliest possible time.~~

~~(iii) documentation of the use of restraint in the patient's medical record.~~

Commented [HA62]: Moved to section 8.

~~(k)~~(K) ~~except in emergent situations, patients shall only be accepted for care and services when the facility can meet their identified and reasonable anticipated care, treatment, and service needs.~~ EXPECT THAT THE FACILITY OR AGENCY IN WHICH THE CLIENT IS ADMITTED, CAN MEET THE IDENTIFIED AND REASONABLY ANTICIPATED CARE, TREATMENT, AND SERVICE NEEDS OF THE CLIENT.

~~(l)~~(L) ~~care~~ CARE delivered by the ~~health care entity~~ FACILITY OR AGENCY in accordance with the needs of the ~~patient~~ CLIENT.

~~(m)~~(M) ~~confidentiality~~ CONFIDENTIALITY of ~~medical~~ ALL CLIENT records.

~~(n)~~(N) ~~receive~~ RECEIVE care in a safe setting.

~~(o)~~(O) ~~disclosure~~ DISCLOSURE as to whether referrals to other providers are entities in which the ~~health care entity~~ FACILITY OR AGENCY has a financial interest.

~~(p)~~(P) ~~to formulate~~ FORMULATE advance directives and have the FACILITY OR AGENCY ~~health care entity~~ comply with such directives, as applicable, and in compliance with applicable state statute.

~~(2)~~7.1.2 The ~~health care entity~~ FACILITY OR AGENCY shall disclose the policy regarding patient rights TO THE CLIENT OR THE CLIENT'S DESIGNATED REPRESENTATIVE prior to treatment or upon admission, where possible. For any ~~patient care or treatment course~~ SERVICES requiring multiple ~~patient~~ CLIENT encounters, disclosure provided at the beginning of such care or treatment course shall meet the intent of the regulations.

~~(3)~~7.1.3 Each ~~health care entity~~ FACILITY OR AGENCY shall post a clear and unambiguous notice in a public location in the ~~health care entity~~ FACILITY OR AGENCY specifying that complaints may be registered with the ~~health care entity~~ FACILITY OR AGENCY, the Department, and with the appropriate oversight board at the Department of Regulatory Agencies (DORA). Upon request, the ~~health care entity~~ FACILITY OR AGENCY shall provide the ~~patient~~ CLIENT and any interested person with contact information for registering complaints.

~~6.200~~ 7.2 ~~Patient~~ CLIENT Grievance Mechanism

~~6.201 STATUTORY AUTHORITY AND APPLICABILITY~~

~~(1) Authority to establish minimum standards through regulation and to administer and enforce such regulations is provided by Sections 25-1-121, 25-1.5-103 and 25-3-101, C.R.S., et. seq.~~

~~(2) Applicability. Subpart 6.200 applies to the following health care entities having in excess of fifty (50) beds: birth centers, chiropractic centers and hospitals, community clinics with emergency centers, convalescent centers, hospitals and hospital units. This Subpart 6.200 does not apply to billing disputes other than those that pertain to the rights established in Chapter II2, Subpart 6.100, Section 6.104 (1)(f).~~

~~6.202 DEFINITIONS~~

~~(1) "Admission" means the acceptance of a person as a patient whether on an inpatient or outpatient basis.~~

~~(2) "Administrative officer" means the person appointed by the governing body OF THE FACILITY OR AGENCY who is responsible for the day-to-day management of the FACILITY OR AGENCY health care entity.~~

Commented [BF63]: Moved to Definitions, Part 1

~~(3) "Patient" means a person accepted on either an inpatient or outpatient basis. Unless the context dictates otherwise, where a patient is incompetent or unable to act on his or her own behalf, such interest devolves on the next of kin or patient designated representative, if possible.~~

~~(4) "Patient CLIENT care advocate" means the person or persons designated by FACILITY OR AGENCY each health care entity to function as the primary contact to receive complaints from patients CLIENTS regarding health care entity services.~~

Commented [BF64]: Moved to Definitions, Part 1

~~(5) "Patient designated representative" is a person authorized to act on behalf of the patient by state law, by court order or in writing in accordance with the policies and procedures of the health care entity.~~

~~(6) "Grievance mechanism" means the process whereby complaints by patients CLIENTS may be initiated and resolved by FACILITY OR AGENCY the health care entity.~~

~~"CAPACITY" MEANS THE NUMBER OF CLIENTS TO WHOM A FACILITY OR AGENCY IS ABLE TO PROVIDED SERVICES. "CAPACITY" IS SYNONYMOUS WITH THE TERM "BED" AS USED IN THIS CHAPTER AND ELSEWHERE IN 6 CCR 1011.~~

Commented [BF65]: Moved to Definitions, Part 1

7.2.1 ALL FACILITIES OR AGENCIES THAT HAVE A CLIENT CAPACITY OF FIFTY (50) OR HIGHER SHALL HAVE A CLIENT GRIEVANCE MECHANISM PLAN THAT SHALL BE SUBMITTED TO THE DEPARTMENT IN THE MANNER AND FORM PRESCRIBED BY THE DEPARTMENT.

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

~~6.204~~**7.2.2** ~~PATIENT GRIEVANCE MECHANISM~~ **CLIENT GRIEVANCE PLAN AND PROCEDURE**

~~(1)~~(A) ~~Patient Grievance Mechanism Plan~~. The ~~health care entity~~ FACILITY OR AGENCY shall develop and implement a ~~patient~~ WRITTEN CLIENT grievance mechanism plan that shall include, but not be limited, to the following:

~~(a)~~(1) A~~a patient~~ CLIENT care advocate that serves as a liaison between the ~~patient~~ CLIENT and the ~~health care entity~~ FACILITY OR AGENCY. The plan shall describe:

~~(i)~~(a) T~~t~~he qualifications, job description, and level of decision-making authority of the ~~patient~~ CLIENT care advocate.

~~(ii)~~(b) Hhow each ~~patient~~ CLIENT will be made aware of the ~~patient~~ CLIENT grievance mechanism and how the ~~patient~~ CLIENT care advocate may be contacted.

(c) THE PROCESS FOR RECEIVING AND INVESTIGATING A CLIENT GRIEVANCE IN SITUATIONS WHEN THE CLIENT CARE ADVOCATE IS NOT AVAILABLE OR IS THE SUBJECT OF THE GRIEVANCE.

~~(b)~~(2) ~~Patient grievance procedure.~~ The ~~health care entity~~ FACILITY OR AGENCY shall implement a grievance procedure with, at minimum, the following components:

~~(i)~~(a) T~~t~~he ability for ~~patients~~ CLIENTS to submit grievances ~~24 hours per day~~, either orally or in writing, to a ~~health care entity~~ FACILITY OR AGENCY staff member. If the grievance is submitted to a staff member other than the ~~patient~~ CLIENT care advocate, the staff member shall submit the grievance to the ~~patient~~ CLIENT care advocate by the next working day.

~~(ii)~~(b) PRIOR TO INITIATING AN INVESTIGATION, ~~The patient~~ THE CLIENT care advocate shall contact the ~~patient~~ CLIENT within three (3) working days of receipt of the grievance to acknowledge receipt of such grievance.

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

(d) THE CLIENT CARE ADVOCATE SHALL PROVIDE THE CLIENT WITH A FINAL, WRITTEN OUTCOME OF THE INVESTIGATION WITHIN A REASONABLE TIME, NOT TO EXCEED 30 CALENDAR DAYS FOLLOWING THE CLIENT CARE ADVOCATE'S RECEIPT OF THE GRIEVANCE.

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

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

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

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

~~(c)~~(3) A means to inform the ~~patient~~ CLIENT regarding how to lodge a grievance and that the ~~health care entity~~ FACILITY OR AGENCY encourages ~~patients~~ CLIENTS to speak out and to present grievances without fear of retribution.

~~(d)~~(4) A requirement that new employees will be trained regarding the grievance mechanism plan and that all staff with direct ~~patient~~ CLIENT contact will be briefed at least annually regarding the plan.

~~(e)~~(5) How ~~patients~~ CLIENTS will be informed that interpretation and translation ~~needs~~ SERVICES are available regarding the grievance procedure for ~~patients~~ CLIENTS unable to understand or read English and how language assistance services will be provided.

PART 7. MEDICATIONS, MEDICAL DEVICES, AND MEDICAL SUPPLIES

7.100 USE OF REPROCESSED SINGLE USE MEDICAL DEVICES

7.101 STATUTORY AUTHORITY AND APPLICABILITY

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

(2) This Subpart 7.100 applies to all FACILITIES AND AGENCIES health care entities; however, this part does not apply to dialyzer regeneration WHICH IS ADDRESSED IN 6 CCR 1011-1, CHAPTER 15- DIALYSIS TREATMENT CLINICS.

7.102 DEFINITIONS

(1) "Health care entity" means a health facility or agency that is required to obtain a license from the Department pursuant to Sections 25-1.5-103 and 25-3-101, C.R.S.

(2) "Reprocessed single use device" means a single use device that has previously been used on a patient and has been subjected to additional processing and manufacturing for the purpose of an additional single use on a patient.

(3) "Reprocessor" means a medical device manufacturer who cleans, sterilizes and performance tests single use devices that have been previously used on a patient.

(4) "Single use device" means a device intended for one use on a single patient during a single procedure.

7.103 USE OF REPROCESSED SINGLE USE DEVICES

(1) A health care entityFACILITY OR AGENCY may use a reprocessed single use device:

(A) obtained OBTAINED from a reprocessor registered with the U.S. Food and Drug Administration (FDA) and in compliance with FDA regulations, including but not limited to, standards regarding the validation of infection control procedures and product integrity for the reprocessed single use device. The health care entity FACILITY OR AGENCY shall make available, upon department request, documentation evidencing reprocessor compliance with FDA regulations.

(B) for FOR which the number of times the device has been subjected to reprocessing is tracked when such data is relevant to ensuring optimal product function.

7.200 DONATION OF UNUSED MEDICATIONS, MEDICAL DEVICES AND MEDICAL SUPPLIES

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

(1) "Customized patient medication package" means a package prepared and dispensed by a pharmacist that contains two or more different drugs.

(2) "Donor" means a patient, resident or a patient's or resident's next of kin who donates unused medications, medical devices or medical supplies.

(3) "Licensed facility" means a hospital, hospital unit, community mental health center, acute treatment unit, hospice, nursing care facility, assisted living residence, or any other facility that is required to be licensed pursuant to Section 25-3-101, C.R.S., or a licensed long-term care facility as defined in Section 25-1-124(2.5)(b), C.R.S.

(4) "Medication" means a prescription that is not a controlled substance.

(5) "Medical device" means an instrument, apparatus, implement, machine, contrivance, implant, or similar or related article that is required to be labeled pursuant to 21 CFR Part 801.

(6) "Medical supply" means a consumable supply item that is disposable and not intended for reuse.

(7) "Person legally authorized to dispense medications" means, in accordance with Section 12-22-121 (6)(a), C.R.S., a pharmacist or a practitioner authorized to prescribe medications.

(8) "Pharmacist" means a pharmacist licensed in the State of Colorado.

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

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

7.202 RETURN AND REDISTRIBUTION OF ITEMS

(A) Consistent with Section 12-42.5-133, C.R.S., a licensed facility OR AGENCY may return unused medications or medical supplies and used or unused medical devices to a pharmacist within the licensed facility OR AGENCY or to a prescription drug outlet in order for the materials to be re-dispensed to another resident or patientCLIENT, or donated to a nonprofit entity that has the legal authority to possess the materials or to a practitioner authorized by law to dispense the materials when the following criteria are met:

(1) The medications, medical supplies and/or medical devices were donated by a patient, resident, home care consumer CLIENT or his/her THE CLIENT'S REPRESENTATIVE next of kin and, where possible, documented in writing;.

(2) A licensed pharmacist has reviewed the process of donating unused medications to a nonprofit entity;.

(3) Medication dispensed or donated under this section shall not be expired. A donated medication shall not be dispensed to another patient, resident or home care consumer CLIENT if it will expire before use by the patient, resident or home care consumer CLIENT based on the prescribing practitioner's directions for use;. and

(4) Medications, medical supplies and medical devices donated pursuant to this section shall not be resold for profit.

~~(B) Medications are only available to be dispensed to another person CLIENT or donated to a nonprofit entity under this section if the medications are:~~

~~(1) Liquid and the vial is still sealed and properly stored;.~~

~~(2) Individually packaged and the packaging has not been damaged;, or~~

~~(3) In the original, unopened, sealed and tamper-evident unit dose packaging.~~

~~(C) The following medications shall not be donated:~~

~~(1) Medications packaged in traditional brown or amber pill bottles;,~~

~~(2) Controlled substances;,~~

~~(3) Medications that require refrigeration, freezing or special storage;,~~

~~(4) Medications that require special registration with the manufacturer;, or~~

~~(5) Medications that are adulterated or misbranded, as determined by a person legally authorized to dispense the medications on behalf of the nonprofit entity.~~

~~7.203 IMMUNITY~~

~~A person or entity is not subject to civil or criminal liability or professional disciplinary action for donating, accepting, dispensing or facilitating the donation of material in good faith, without negligence, and in compliance with Colorado law.~~

Commented [BF66]: This part is being moved to come after restraint and seclusion. It is the new Part 9.

~~Part 8~~PART 8. PROTECTION OF ~~PERSONS~~CLIENTS FROM INVOLUNTARY RESTRAINT OR SECLUSION

8.~~10~~1 Statutory Authority and Applicability. This ~~part~~PART is promulgated pursuant to ~~Sections~~SECTION 26-20-10~~6~~1, ET. SEQ. ~~and 26-20-108~~, C.R.S. ~~This part applies to the use of involuntary restraint in all licensed health care facilities, except under the circumstances described:~~

8.1.1 THIS PART APPLIES TO THE USE OF INVOLUNTARY RESTRAINT AND SECLUSION IN ALL LICENSED HEALTH CARE FACILITIES, EXCEPT FOR:

(~~1~~A) ~~for h~~Hospitals as provided for in ~~Section~~PART ~~8.103 (I)(a)~~8.2.1(A)(1); and

(~~2~~B) ~~for~~ Medicare/Medicaid certified nursing homes as provided for in PART~~Section 8.103 (3)~~8.2.1(A)(2).

8.1.2 IN ACCORDANCE WITH SECTION 26-20-102(b)(I), C.R.S., THIS PART 8 DOES NOT APPLY TO FACILITIES OR AGENCIES WITHIN THE DEPARTMENT OF CORRECTIONS OR A PUBLIC OR PRIVATE ENTITY THAT HAS ENTERED INTO A CONTRACT FOR SERVICES WITH SUCH DEPARTMENT.

~~8.102 Definitions~~

~~(1) "Chemical restraint" means giving an individual medication involuntarily for the purpose of restraining that individual; except that "chemical restraint" does not include the involuntary administration of medication pursuant to Section 27-65-111(5), C.R.S., or administration of medication for voluntary or life-saving medical procedures.~~

~~(2) "Emergency" means a serious, probable, imminent threat of bodily harm to self or others where there is the present ability to effect such bodily harm.~~

~~(3) "Mechanical restraint" means a physical device used to involuntarily restrict the movement of an individual or the movement or normal function of a portion of his or her body.~~ ~~PHYSICAL RESTRAINTS USED FOR FALL PREVENTION, INCLUDING BUT NOT LIMITED TO RAISED BED RAILS, ARE CONSIDERED MECHANICAL RESTRAINTS.~~

~~(4) "Physical restraint" means the use of bodily, physical force to involuntarily limit an individual's freedom of movement; except that "physical restraint" does not include the holding of a child by one adult for the purposes of calming or comforting the child.~~

~~(5) "Restraint" means any method or device used to involuntarily limit freedom of movement, including but not limited to bodily physical force, mechanical devices, or chemicals. "Restraint" includes a chemical restraint, a mechanical restraint, a physical restraint, and seclusion.~~

~~(6) "Seclusion" means the~~ ~~INVOLUNTARY~~ ~~placement of a person alone in a room from which egress is involuntarily prevented.~~

~~8.103~~8.2 **Exemptions**

~~(1)~~8.2.1 "Restraint" does not include:

(~~a~~A) The use of any form of restraint in a licensed or certified hospital when such use:

(~~I~~1) Is in the context of providing medical or dental services that are provided with the consent of the ~~individual~~ CLIENT or the ~~individual's~~ CLIENT'S guardian. For the purposes of this ~~Section~~ PART (A)(1) ~~(1)(a)~~ the term "medical services" means the VOLUNTARY provision of care in a hospital where the primary goal of treatment is treatment of a medical condition as opposed to treatment of a psychiatric disorder, and

(~~II~~2) Is in compliance with industry standards adopted by a nationally recognized accrediting body or the conditions of participation adopted for federal Medicare and Medicaid programs;

(B) METHODS TYPICALLY USED FOR MEDICAL-SURGICAL CARE, SUCH AS THE USE OF BANDAGES AND ORTHOPEDICALLY PRESCRIBED DEVICES, THE USE OF A REQUIRED DEVICE TO LIMIT MOBILITY DURING A MEDICAL PROCEDURE, OR THE USE OF A DRUG WHEN IT IS PART OF A STANDARD TREATMENT OR DOSAGE FOR THE PATIENT'S CONDITION.

(~~b~~C) The use of protective devices or adaptive devices for providing physical support, prevention of injury, or voluntary or life-saving medical procedures;

(~~c~~D) The holding of an individual for less than five minutes by a staff person for protection of the individual or other persons;

(~~d~~E) Placement of A CLIENT ~~an inpatient or resident~~ in his or her room for the night IN AN INPATIENT OR RESIDENTIAL SETTING;

~~(e) The use of time-out as may be defined by written policies, rules, or procedures of a facility; or~~

Commented [BF67]: Repealed by HB16-1328

~~(f)~~8.2.2 THIS PART 8 DOES NOT APPLY TO A FACILITY OR AGENCY ~~Restraints used while the facility is~~ engaged in transporting a person from one facility, AGENCY or location to another facility, AGENCY or location when it is within the scope of that facility's OR AGENCY'S powers and authority to effect such transportation.

~~(2)~~8.2.3 A facility, as defined in ~~Section~~SECTION 27-65-102(7), C.R.S., that is designated by the Executive Director of the Department of Human Services to provide treatment pursuant to ~~Sections~~SECTIONS 27-65-105 through 27-65-107, C.R.S., to any person with a mental illness, as defined in ~~Section~~SECTION 27-65-102(14), C.R.S., may use seclusion to restrain a person with a mental illness when ~~such~~ THE seclusion is necessary to eliminate a continuous and serious disruption of the treatment environment.

~~(3)~~8.2.4 If the use of restraint in skilled nursing and nursing care facilities licensed under state law is in accordance with the federal statutes and regulations governing the Medicare program set forth in 42 U.S.C. sec. 1395i-3(c) and 42 C.F.R. part 483, subpart B and the Medicaid program set forth in 42 U.S.C. sec. 1396r(c) and 42 C.F.R. part 483, subpart B and with 6 CCR 1011-1, Chapter 5, Nursing Care Facilities, there shall be a conclusive presumption that such use of restraint is in accordance with this Part 8.

8.2.5 IF ANY PROVISION OF THIS PART 8 CONFLICTS WITH ANY PROVISION CONCERNING THE USE OF RESTRAINT OR SECLUSION ON AN INDIVIDUAL WITH AN INTELLECTUAL OR DEVELOPMENTAL DISABILITY AS STATED IN ARTICLE 10.5 OF TITLE 27, C.R.S., ARTICLE 10 OF TITLE 25.5, C.R.S. OR ANY RULE ADOPTED PURSUANT TO THOSE ARTICLES, THE PROVISIONS OF THOSE ARTICLES OR RULES SHALL PREVAIL.

~~(4)~~8.2.6 If any provision of this Part 8 concerning the use of restraint conflicts with any provision concerning the use of restraint stated in Article 65 of Title 27, C.R.S., or any regulation adopted pursuant thereto, the provision of Article 65 of Title 27, C.R.S., or the regulation adopted pursuant thereto shall prevail.

~~8.104~~**8.3 Basis for use of restraint OR SECLUSION**

~~(1)~~8.3.1 A facility may only use restraint OR SECLUSION:

(~~a~~A) In cases of emergency, AS DEFINED AT SECTION 26-20-102(3), C.R.S., TO BE A SERIOUS, PROBABLE, IMMINENT THREAT OF BODILY HARM TO SELF OR OTHERS WHERE THERE IS THE PRESENT ABILITY TO EFFECT SUCH BODILY HARM; and

(~~I~~1) After the failure of less restrictive alternatives; or

(~~II~~2) After a determination that such alternatives would be inappropriate or ineffective under the circumstances.

(~~2~~B) A facility OR AGENCY that uses restraint OR SECLUSION pursuant to the provisions of ~~subsection~~ (~~1~~A), ABOVE, ~~of this section~~ shall use such restraint OR SECLUSION:

(~~a~~1) ONLY ~~F~~for the purpose of preventing the continuation or renewal of an emergency;

(~~b~~2) ONLY ~~F~~for the period of time necessary to accomplish its purpose; and

(~~c~~3) In the case of physical restraint, using no more force than is necessary to limit the ~~individual's~~CLIENT'S freedom of movement.

8.3.2 RESTRAINT AND SECLUSION MUST NEVER BE USED:

(A) AS A PUNISHMENT OR DISCIPLINARY SANCTION,

(B) AS A MEANS OF COERCION BY STAFF,

(C) AS PART OF AN INVOLUNTARY TREATMENT PLAN OR BEHAVIOR MODIFICATION PLAN,

(D) FOR THE CONVENIENCE OF STAFF,

(E) FOR THE PURPOSE OF RETALIATION BY STAFF, OR

(F) FOR THE PURPOSE OF PROTECTION, UNLESS:

(1) THE RESTRAINT OR SECLUSION IS ORDERED BY THE COURT, OR

(2) IN AN EMERGENCY, AS PROVIDED FOR IN 8.3.1(A), ABOVE.

~~8.105~~**8.4 Duties relating to use of restraint OR SECLUSION**

(~~1~~)8.4.1 ~~Notwithstanding the following provisions - Section 8.103, subsections (1)(f), (2), (3)* and (4) and Section 8.104 - a~~ A facility OR AGENCY that uses restraint shall ensure that:

(~~a~~A) At least every fifteen minutes, staff shall monitor any ~~individual~~CLIENT held in mechanical restraints to assure that the ~~individual~~CLIENT is properly positioned, that the ~~individual's~~CLIENT'S blood circulation is not restricted, that the ~~individual's~~CLIENT'S airway is not obstructed, and that the ~~individual's~~ CLIENT'S other physical needs are met;

(~~b~~B) No physical or mechanical restraint of an ~~individual~~ CLIENT shall place excess pressure on the chest or back of that ~~individual~~ CLIENT or inhibit or impede the ~~individual's~~ CLIENT'S ability to breathe;

(~~c~~C) During physical restraint of a~~n individual,~~ CLIENT, an agent or employee of the facility OR AGENCY shall check to ensure that the breathing of the ~~individual~~ CLIENT in such physical restraint is not compromised;

(~~d~~D) A chemical restraint shall be given only on the order of a physician who has determined, either while present during the course of the emergency justifying the use of the chemical restraint or after telephone consultation with a registered nurse, certified physician assistant, or other authorized staff person who is present at the time and site of the emergency and who has participated in the evaluation of the ~~individual~~ CLIENT, that such form of restraint is the least restrictive, most appropriate alternative available;

(~~e~~E) An order for a chemical restraint, along with the reasons for its issuance, shall be recorded in writing at the time of its issuance;

(~~f~~F) An order for a chemical restraint shall be signed at the time of its issuance by such physician, if present at the time of the emergency;

(~~g~~G) An order for a chemical restraint, if authorized by telephone, shall be transcribed and signed at the time of its issuance by an individual with the authority to accept telephone medication orders who is present at the time of the emergency;

(~~h~~H) Staff trained in the administration of medication shall make notations in the record of the ~~individual~~ CLIENT as to the effect of the chemical restraint and the ~~individual's~~ CLIENT'S response to the chemical restraint.

~~(2)~~8.4.2 For ~~individuals~~ CLIENTS in mechanical restraints, ~~facility~~ staff shall provide relief periods, except when the ~~individual~~ CLIENT is sleeping, of at least ten minutes as often as every two hours, so long as relief from the mechanical restraint is determined to be safe. During such relief periods, the staff shall ensure proper positioning of the ~~individual~~ CLIENT and provide movement of limbs, as necessary. In addition, during such relief periods, staff shall provide assistance for use of appropriate ~~toiletting~~ TOILETING methods, as necessary. The ~~individual's~~ CLIENT'S dignity and safety shall be maintained during relief periods. Staff shall note in the record of the individual being restrained the relief periods granted.

~~(3)~~8.4.3 Relief periods from seclusion shall be provided for reasonable access to toilet facilities.

~~(4)~~8.4.4 ~~An~~ ~~individual~~ CLIENT in physical restraint shall be released from such restraint within fifteen minutes after the initiation of physical restraint, except when precluded for safety reasons.

~~8.106~~**8.5 Staff training CONCERNING THE USE OF RESTRAINT AND SECLUSION**

~~(1)~~8.5.1 All FACILITIES AND agencies shall ensure that ALL staff INVOLVED IN utilizing restraint OR SECLUSION ~~in facilities or programs~~ are trained in the appropriate use of restraint AND SECLUSION.

(~~2~~A) All FACILITIES AND agencies shall ensure that staff are trained to explain, where possible, the use of restraint OR SECLUSION to the ~~individual~~ CLIENT who is to be restrained OR SECLUDED and to the ~~individual's~~ CLIENT'S DESIGNATED REPRESENTATIVE, ~~family~~ if appropriate.

~~8.107~~**8.6 Documentation requirements RELATED TO THE USE OF RESTRAINT AND SECLUSION** ~~Each facility shall ensure that an appropriate notation of the use of restraint is documented in the record of the individual restrained. Each facility shall document the following in the patient record:~~

Commented [BF68]: Moved to 9.10.1

8.6.1 EACH FACILITY SHALL ENSURE THAT AN APPROPRIATE NOTATION OF THE USE OF RESTRAINT OR SECLUSION IS DOCUMENTED IN THE RECORD OF THE CLIENT WHO WAS RESTRAINED OR SECLUDED. EACH FACILITY SHALL DOCUMENT THE FOLLOWING IN THE CLIENT RECORD:

Commented [BF69]: Moved from 8.107

(~~1~~A) T~~t~~ype of restraint and length of time in the restraint OR SECLUSION;

(~~2~~B) I~~i~~dentification of staff involved in the initiation and application of the restraint OR SECLUSION;

(~~3~~C) C~~c~~are provided while in the restraint OR SECLUSION, including monitoring conducted and relief periods granted; and

(~~4~~D) T~~t~~he effect of the restraint OR SECLUSION on the ~~individual~~CLIENT.

~~8.108~~8.7 **Review PROCESS ~~of the use of restraint. Each facility that allows for the use of restraint under this Part 8 shall ensure that a review process is established for the appropriate use of the restraints.~~**

8.7.1 EACH FACILITY OR AGENCY THAT UTILIZES RESTRAINT OR SECLUSION UNDER THIS PART 8 SHALL ENSURE THAT A REVIEW PROCESS IS ESTABLISHED FOR THE APPROPRIATE USE OF THE RESTRAINT OR SECLUSION.

8.8 FACILITY OR AGENCY POLICIES REGARDING THE USE OF RESTRAINT AND SECLUSION

Commented [BF70]: Moved from Patient Rights

8.8.1 A FACILITY OR AGENCY THAT USES RESTRAINT OR SECLUSION SHALL DEVELOP AND IMPLEMENT POLICIES AND PROCEDURES CONSISTENT WITH THE REQUIREMENTS OF THIS PART 8.

(A) A FACILITY'S OR AGENCY'S POLICIES AND PROCEDURES REGARDING THE USE OF RESTRAINT AND SECLUSION MAY BE MORE STRINGENT THAN THIS PART 8, BUT SHALL NOT BE LESS STRINGENT.

8.8.2 A FACILITY OR AGENCY THAT DOES NOT USE RESTRAINT OR SECLUSION SHALL INCLUDE A WRITTEN STATEMENT IN ITS POLICIES AND PROCEDURES TO THAT EFFECT.

Commented [BF71]: Moved from Patient Rights

PART 9. MEDICATIONS, MEDICAL DEVICES, AND MEDICAL SUPPLIES

9.1 USE OF REPROCESSED SINGLE USE MEDICAL DEVICES

9.1.1 THIS PART 9.1 APPLIES TO ALL FACILITIES AND AGENCIES EXCEPT THOSE ADDRESSED IN 6 CCR 1011-1, CHAPTER 15-DIALYSIS TREATMENT CLINICS.

9.1.2 A FACILITY OR AGENCY MAY USE A REPROCESSED SINGLE USE DEVICE:

(A) OBTAINED FROM A REPROCESSOR REGISTERED WITH THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) AND IN COMPLIANCE WITH FDA REGULATIONS, INCLUDING BUT NOT LIMITED TO, STANDARDS REGARDING THE VALIDATION OF INFECTION CONTROL PROCEDURES AND PRODUCT INTEGRITY FOR THE REPROCESSED SINGLE USE DEVICE. THE FACILITY OR AGENCY SHALL MAKE AVAILABLE, UPON DEPARTMENT REQUEST, DOCUMENTATION EVIDENCING REPROCESSOR COMPLIANCE WITH FDA REGULATIONS.

(B) FOR WHICH THE NUMBER OF TIMES THE DEVICE HAS BEEN SUBJECTED TO REPROCESSING IS TRACKED WHEN SUCH DATA IS RELEVANT TO ENSURING OPTIMAL PRODUCT FUNCTION.

9.2 DONATION OF UNUSED MEDICATIONS, MEDICAL DEVICES AND MEDICAL SUPPLIES

9.2.1 A FACILITY OR AGENCY MAY ACCEPT UNUSED MEDICATIONS OR MEDICAL SUPPLIES, AND USED OR UNUSED MEDICAL DEVICES FROM A CLIENT OR A CLIENT'S PERSONAL REPRESENTATIVE.

(A) IN ACCORDANCE WITH SECTION 12-42.5-133, C.R.S., THE FACILITY OR AGENCY MAY CHOOSE TO EITHER:

(1) RETURN THE MEDICATIONS, MEDICAL SUPPLIES, OR MEDICAL DEVICES TO A PHARMACIST WITHIN THE LICENSED FACILITY OR A PRESCRIPTION DRUG OUTLET, OR

(2) DONATE TO A THIRD PARTY WHO HAS THE LEGAL AUTHORITY TO POSSESS THE MEDICATIONS, MEDICAL SUPPLIES, OR MEDICAL DEVICES.

9.2.2 A FACILITY OR AGENCY MAY DONATE UNUSED MEDICATIONS OR MEDICAL SUPPLIES, AND USED OR UNUSED MEDICAL DEVICES, THAT ARE IN THE FACILITY'S OR AGENCY'S POSSESSION, TO A NONPROFIT ENTITY THAT HAS LEGAL AUTHORITY TO POSSESS THE MATERIALS OR TO A PERSON LEGALLY AUTHORIZED TO DISPENSE THE MATERIALS.

(A) A LICENSED PHARMACIST SHALL REVIEW THE FACILITY'S OR AGENCY'S PROCESS OF DONATING UNUSED MEDICATIONS TO A NONPROFIT ENTITY.

9.2.3 MEDICATION DISPENSED OR DONATED UNDER THIS PART MUST MEET THE FOLLOWING REQUIREMENTS.

(A) THE MEDICATION MUST NOT BE EXPIRED, AND SHALL NOT BE DISPENSED IF IT WILL EXPIRE BEFORE USE BY THE PATIENT BASED ON THE PRESCRIBING PRACTITIONER'S DIRECTIONS FOR USE.

(B) MEDICATIONS ARE ONLY AVAILABLE TO BE DISPENSED TO ANOTHER CLIENT OR DONATED TO A NONPROFIT ENTITY IF THE MEDICATIONS ARE:

(1) LIQUID AND THE VIAL IS STILL SEALED AND PROPERLY STORED,

(2) INDIVIDUALLY PACKAGED AND THE PACKAGING HAS NOT BEEN DAMAGED, OR

(3) IN THE ORIGINAL, UNOPENED, SEALED, AND TAMPER-EVIDENT UNIT-DOSE PACKAGING.

(C) THE FOLLOWING MEDICATIONS MAY NOT BE DONATED:

(1) MEDICATIONS PACKAGED IN TRADITIONAL BROWN OR AMBER PILL BOTTLES,

(2) CONTROLLED SUBSTANCES,

(3) MEDICATIONS THAT REQUIRE REFRIGERATION, FREEZING OR SPECIAL STORAGE,

(4) MEDICATIONS THAT REQUIRE SPECIAL REGISTRATION WITH THE MANUFACTURER, OR

(5) MEDICATIONS THAT ARE ADULTERATED OR MISBRANDED, AS DETERMINED BY A PERSON LEGALLY AUTHORIZED TO DISPENSE THE MEDICATIONS ON BEHALF OF THE NONPROFIT ENTITY.

9.2.4 MEDICATIONS, MEDICAL SUPPLIES AND MEDICAL DEVICES DONATED PURSUANT TO THIS PART SHALL NOT BE RESOLD FOR PROFIT.

9.2.5 A PERSON OR ENTITY IS NOT SUBJECT TO CIVIL OR CRIMINAL LIABILITY OR PROFESSIONAL DISCIPLINARY ACTION FOR DONATING, ACCEPTING, DISPENSING OR FACILITATING THE DONATION OF MATERIAL IN GOOD FAITH, WITHOUT NEGLIGENCE, AND IN COMPLIANCE WITH COLORADO LAW.

~~**Part 9**~~**PART 10. ~~Hospital-Acquired Infection Reporting~~ HEALTH-CARE-ASSOCIATED INFECTION REPORTING**

~~**Section 1**~~ **10.1 Statutory Authority and Applicability**

~~9~~10.1.1 The statutory authority for the promulgation of these rules is set forth in sections 25-1.5-103, 25-3-103 and 25-3-607, C.R.S.

~~9.1.2 Each hospital, hospital unit, ambulatory surgical center or outpatient dialysis treatment clinic that is licensed or certified by the Department shall comply with this Part 910.~~

10.1.2 THIS PART 10 APPLIES ONLY TO HOSPITALS, HOSPITAL UNITS, AMBULATORY SURGICAL CENTERS, DIALYSIS TREATMENT CLINICS, OR ANY OTHER FACILITY OR AGENCY THAT SUBMITS DATA TO THE NATIONAL HEALTHCARE SAFETY NETWORK, OR ITS SUCCESSOR, THAT IS LICENSED OR CERTIFIED BY THE DEPARTMENT PURSUANT TO SECTION 25-1.5-103, C.R.S.

~~Section 2 - Definitions~~

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

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

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

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

~~Section 3 General Provisions~~

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

~~(A) Cardiac surgical site infections;~~

~~(B) Orthopedic surgical site infections;~~

~~(C) Abdominal surgical site infections; and~~

~~(D) Central line-related bloodstream infections.~~

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

~~(A) Mandatory national certification requirements shall not apply to individuals collecting data on hospital-acquired infections in hospitals licensed for 50 beds or less, licensed ambulatory surgical centers, and certified dialysis treatment centers. Qualifications for these individuals may be met through ongoing education, training, experience or certification as directed by the Department.~~

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

~~Section 4 Reporting~~

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

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

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

10.2 ENFORCEMENT ACTIVITIES ~~Section 5 Plan of Correction~~

10.2.1 IF THE DEPARTMENT DETERMINES THAT A FACILITY OR AGENCY IS OUT OF COMPLIANCE WITH SECTION 25-3-601, *ET SEQ.*, C.R.S. IT MAY IMPOSE ANY OF THE FOLLOWING ENFORCEMENT ACTIVITIES, CONSISTENT WITH PART 2.11, ABOVE:

(A) THE DEPARTMENT MAY REQUEST, OR REQUIRE COMPLIANCE WITH, A PLAN OF CORRECTION,

(B) REVOCATION OF THE FACILITY'S OR AGENCY'S LICENSE,

(C) DENIAL OF THE FACILITY'S OR AGENCY'S APPLICATION FOR LICENSE RENEWAL, OR

(D) A CIVIL PENALTY OF UP TO $1,000 PER VIOLATION FOR EACH DAY THE FACILITY OR AGENCY IS DEEMED TO BE OUT OF COMPLIANCE.

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

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

~~**Section 6 – Enforcement and Disciplinary Sanctions**~~

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

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

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

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

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

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

PART ~~10~~ 11 - INFLUENZA IMMUNIZATION OF ~~HEALTHCARE WORKERS~~ EMPLOYEES AND DIRECT CONTRATORS

11.1 Statutory Authority and Applicability

Commented [RM72]: Need to change the index on page 1 of the rules to match this title.

~~10.1~~11.1.1 The statutory authority for the promulgation of these rules is set forth in sections 25-1.5-102, 25-1.5-103 and 25-3-103,C.R.S.

~~10.2 Each Healthcare entity that is licensed by the Department shall comply with this Part 10.~~

~~10.3~~ 11.1.2 The requirements of this Part ~~10~~11 shall be overseen and enforced by the Department in a manner consistent with ~~sections 2.11 and 2.12 of Part 2~~ PARTS 2.10 AND 2.11 of this Chapter.

11.2 General Provisions

~~10.4~~11.2.1 ~~Healthcare entities and healthcare workers~~ LICENSEES AND FACILITY OR AGENCY EMPLOYEES AND DIRECT CONTRACTORS have a shared responsibility to prevent the spread of infection and avoid causing harm to ~~their patients or residents~~ CLIENTS by taking reasonable precautions to prevent the transmission of vaccine-preventable diseases. Vaccine programs are, therefore, an essential part of infection prevention and control for slowing or stopping the transmission of seasonal influenza viruses from adversely affecting those individuals who are most susceptible.

11.2.2 ANY EMPLOYEE OR DIRECT CONTRACTOR WHO HAS THE POTENTIAL FOR EXPOSURE TO CLIENTS OF THE FACILITY OR AGENCY AND/OR TO INFECTIOUS MATERIALS, INCLUDING BODILY SUBSTANCES, CONTAMINATED MEDICAL SUPPLIES AND EQUIPMENT, CONTAMINATED ENVIRONMENTAL SURFACES, OR CONTAMINATED AIR ARE SUBJECT TO THIS PART 11.

(A) SUCH POSITIONS THAT MAY HAVE THE POTENTIAL FOR EXPOSURE INCLUDE, BUT ARE NOT LIMITED TO, LICENSED INDEPENDENT PRACTITIONERS; STUDENTS AND TRAINEES; INDIVIDUALS WHO DIRECTLY CONTRACT WITH THE FACILITY OR AGENCY TO PROVIDE SERVICES; HOME CARE PERSONNEL; INDIVIDUALS AGED 18 OR OLDER WHO ARE AFFILIATED WITH THE FACILITY OR AGENCY, BUT DO NOT RECEIVE WAGES OR OTHER REMUNERATION FROM THE FACILITY OR AGENCY; AND PERSONS NOT DIRECTLY INVOLVED IN CLIENT CARE BUT POTENTIALLY EXPOSED TO INFECTIOUS AGENTS THAT CAN BE TRANSMITTED TO AND FROM THE INDIVIDUAL PROVIDING SERVICES AND CLIENTS OF THE FACILITY OR AGENCY.

11.2.3 FACILITIES AND AGENCIES SHALL ENSURE THAT NINETY PERCENT (90%) OF EMPLOYEES AND DIRECT CONTRACTORS HAVE RECEIVED THE INFLUENZA VACCINE DURING A GIVEN INFLUENZA SEASON. IN ORDER TO DEMONSTRATE THAT THE NINETY PERCENT (90%) RATE HAS BEEN MEET, FACILITIES AND AGENCIES SHALL:

(A) BY MAY 15TH OF EVERY YEAR, REPORT TO THE DEPARTMENT, IN THE FORM AND MANNER SPECIFIED BY THE DEPARTMENT, THE VACCINATION RATE FOR EMPLOYEES AND DIRECT CONTRACTS FOR THE MOST RECENT INFLUENZA SEASON.

(B) HAVE DEFINED PROCEDURES TO PREVENT THE SPREAD OF INFLUENZA FROM UNVACCINATED HEALTHCARE WORKERS.

(C) MAINTAIN FOR THREE (3) YEARS THE FOLLOWING DOCUMENTATION THAT MAY BE EXAMINED BY THE DEPARTMENT IN A RANDOM AUDIT PROCESS:

(1) PROOF OF IMMUNIZATION, AS DEFINED AT PART 1.45 OF THIS CHAPTER OR

(2) A MEDICAL EXEMPTION SIGNED BY A PHYSICIAN, PHYSICIAN ASSISTANT, ADVANCED PRACTICE NURSE, OR CERTIFIED NURSE MIDWIFE LICENSED IN THE STATE OF COLORADO STATING THAT THE INFLUENZA VACCINATION FOR THE EMPLOYEE OR DIRECT

CONTRACTOR IS MEDICALLY CONTRAINDICATED AS DESCRIBED IN THE PRODUCT LABELING APPROVED BY THE UNITED STATE FOOD AND DRUG ADMINISTRATION.

11.2.4 LICENSED HOSPITALS, HOSPITAL UNITS, AMBULATORY SURGICAL CENTERS, AND NURSING FACILITIES SHALL PROVIDE OR MAKE AVAILABLE AN ANNUAL INFLUENZA VACCINE FOR EMPLOYEES AND DIRECT CONTRACTORS WHEN THE INFLUENZA VACCINE IS READILY AVAILABLE.

Commented [HA73]: Taken from what was 10.7

(A) ALL OTHER FACILITIES AND AGENCIES SHALL ENSURE THAT EMPLOYEES AND DIRECT CONTRACTORS ARE OFFERED THE OPPORTUNITY TO RECEIVE AN ANNUAL INFLUENZA IMMUNIZATION.

Commented [HA74]: Taken from what was 10.11(A)

~~**Definitions**~~

~~10.5 For purposes of this Part 10, the following definitions shall apply:~~

~~(A) Ambulatory Surgical Center means a facility that is licensed and regulated pursuant to 6 CCR 1011-1, Chapter XX, Ambulatory Surgical Center.~~

~~(B) "Department" means the Colorado Department of Public Health and Environment.~~

~~(C) "Employee" means any person who performs a service for wages or other remuneration for a licensed healthcare entity. For purposes of this Part 10, the definition of employee includes students, trainees, persons who have individual contracts with the healthcare entity, physicians with staff privileges and allied health professionals with privileges. The definition of employee does not include volunteers or persons who provide services through a contractual arrangement between the licensee and a separate organization, association or other healthcare entity.~~

~~(D) "Healthcare Entity" means a health care facility or agency that is required to obtain a license from the Department pursuant to section 25-3-101, C.R.S. Unless otherwise indicated, the term "healthcare entity "is synonymous with the terms "facility" or "agency" as used elsewhere in 6 CCR 1011-1, Standards for Hospitals and Health Facilities.~~

~~(E) "Healthcare Worker" means any person, working in a healthcare entity who has the potential for exposure to patients, residents, or consumers of the healthcare entity and/or to infectious materials, including body substances, contaminated medical supplies and equipment, contaminated environmental surfaces, or contaminated air.~~

~~Healthcare worker includes, but is not limited to, physicians, nurses, nursing assistants, therapists, technicians, emergency medical service personnel, dental personnel, pharmacists, laboratory personnel, autopsy personnel, students and trainees, contractual personnel, home care personnel, and persons not directly involved in patient care (e.g., clerical, dietary, house-keeping, laundry, security, maintenance, billing and chaplains) but potentially exposed to infectious agents that can be transmitted to and from the healthcare worker and patients, residents or consumers of the healthcare entity. The definition of healthcare worker does not include volunteers.~~

~~(F) "Hospital" means a facility that is licensed and regulated pursuant to 6 CCR 1011-1, Chapter IV, General Hospitals.~~

~~(G) "Hospital Unit" means a facility that is licensed and regulated pursuant to 6 CCR 1011-1, Chapter XIX, Hospital Units.~~

~~(H) "Influenza Season" means November 1 through March 31 of the following year, or as otherwise defined by the Department epidemiology and flu surveillance team.~~

~~(I) "Influenza Vaccine" means a currently licensed FDA approved vaccine product.~~

~~(J) "Nursing Care Facility" means a facility that is licensed and regulated pursuant to 6 CCR 1011-1, Chapter 5, Nursing Care Facilities.~~

~~(K) "Proof of Immunization" means a written statement from a licensed healthcare provider who has administered an influenza vaccine to a healthcare worker, specifying the vaccine administered and the date it was administered or electronic entry in the Colorado Immunization Information System (CIIS).~~

~~(L) "Volunteer" means a person who provides services without wages or other remuneration.~~

~~**Exemption For Healthcare Entities Meeting Vaccination Targets**~~

~~10.6 If a licensed healthcare entity demonstrates that it has vaccinated a targeted percentage of its employees in a given year, using its own methodology, it shall be exempt from the requirements of sections 10.7 through 10.12 of this Part for the following year as long as it continues to use the same or more stringent methodology.~~

~~(A) The minimum targets required for this exemption are:~~

~~(1) 60 percent of employees vaccinated by December 31, 2012;~~

~~(2) 75 percent of employees vaccinated by December 31, 2013; and~~

~~(3) 90 percent of employees vaccinated by December 31, 2014; and by December 31 of each year thereafter.~~

~~(B) To take advantage of this annual exemption, the licensee shall:~~

~~(1) Have defined procedures to prevent the spread of influenza from its unvaccinated healthcare workers;~~

~~(2) Maintain supporting documentation for a period of three (3) years that may be examined by the Department in a random audit process; and~~

~~(3) Report to the Department that the qualifying percentage of its employees was appropriately vaccinated (according to the annual recommendations of the Advisory Committee on Immunization Practices) against seasonal influenza by December 31st of the year specified. This report shall be submitted to the Department, in the form and manner specified, no later than March 31st of the following year.~~

Commented [HA75]: Substance moved to 11.2 above

11.3 Requirements For Hospitals, Hospital Units, Ambulatory Surgical Centers and ~~Long Term Care Facilities~~ NURSING FACILITIES THAT FAIL TO MEET VACCINATION RATE

~~10.7 Each licensed hospital, hospital unit, ambulatory surgical center and long-term care facility shall provide or make available an annual influenza vaccine for each of its healthcare workers when the influenza vaccine is readily available.~~

Commented [HA76]: Moved to 11.2.4 above

~~10.8~~11.3.1 Each licensed hospital, hospital unit, ambulatory surgical center, and ~~long-term care~~ NURSING facility THAT FAILS TO MEET THE NINETY PERCENT (90%) VACCINATION RATE FOR ANY GIVEN INFLUENZA SEASON shall ~~have a~~ REVIEW ITS CURRENT WRITTEN POLICY REGARDING THE ANNUAL INFLUENZA IMMUNIZATION OF EMPLOYEES AND DIRECT CONTRACTORS TO ENSURE THAT IT ADDRESSES THE FOLLOWING CRITERIA, OR CREATE A written policy IF NONE EXISTS: ~~regarding the annual influenza immunization of its healthcare workers that, at a minimum, addresses the following criteria:~~

(A) Ensuring that THE FACILITY OR AGENCY HAS EITHER OF THE FOLLOWING FOR EMPLOYEES AND DIRECT CONTRACTORS: ~~each of its healthcare workers has either:~~

(1) proof of immunization, or

(2) a medical exemption signed by a physician, physician~~'s~~ assistant, advanced practice nurse or CERTIFIED nurse midwife licensed in the State of Colorado stating that the influenza vaccination for that individual is medically contraindicated as described in the product labeling approved by the United States Food and Drug Administration.

(B) Ensuring that ~~each healthcare worker~~ ANY EMPLOYEE OR DIRECT CONTRACTOR who does not have proof of immunization wears a surgical or procedure mask during influenza season when in direct contact with ~~patients~~CLIENTS and in common areas, as specified by the licensee's policy. Such masks shall be in addition to other standard personal protective equipment.

(C) Ensuring it has established a procedure to:

(1) Maintain proof of annual immunization or medical exemption for ~~each employee~~ EMPLOYEES AND DIRECT CONTRACTORS and

(2) Inform other ~~healthcare workers~~ INDIVIDUALS who provide services on the licensee's premises that ARE NOT EMPLOYEES OR DIRECT CONTRACTORS OF THE FOLLOWING:

(a) The licensee has a policy regarding the annual influenza immunization of its ~~healthcare workers~~ EMPLOYEES AND DIRECT CONTRACTORS;

(b) The licensee requires each ~~healthcare worker~~ EMPLOYEE AND DIRECT CONTRACTOR who has not been immunized to wear a mask during influenza season when in direct contact with ~~patients or~~ CLIENTS AND in common areas specified by the ~~facility~~LICENSEE; and

(c) The licensee has masks available for those ~~healthcare workers~~ who have not been immunized.

~~10.9 Each licensed hospital, hospital unit, ambulatory surgical center and long- term care facility shall track and report the annual influenza vaccination rate for its employees through December 31st of each year. This report shall be submitted to the Department, in the form and manner specified, no later than March 31st of the following year.~~

Commented [HA77]: Now at 11.2.3(A)

11.4 Requirements for All Other Licensed ~~Healthcare Entities~~ FACILITIES AND AGENCIES THAT FAIL TO MEET VACCINATION RATE

~~10.10~~11.4.1 Each ~~licensed healthcare entity~~ LICENSEE, other than those identified in ~~sections 10.7 through 10.9~~PART 11.3, ABOVE, THAT FAILS TO MEET THE NINETY PERCENT (90%) VACCINATION RATE FOR ANY GIVEN INFLUENZA SEASON shall perform an ~~initial~~ assessment of ~~their~~ THE facility or agency to assist in the development of a written policy regarding influenza transmission from its ~~healthcare workers~~ EMPLOYEES AND DIRECT CONTRACTORS to CLIENTS ~~its patients, residents or consumers~~. The assessment shall, at a minimum, consider the following criteria:

(A) The number of EMPLOYEES AND DIRECT CONTRACTORS ~~healthcare workers~~ at the ~~healthcare entity~~FACILITY OR AGENCY;

(B) The number of ~~patients, residents or consumers~~ CLIENTS served by the FACILITY OR AGENCY ~~healthcare entity~~;

(C) Whether the FACILITY OR AGENCY ~~healthcare entity~~ has an ongoing ~~employee~~ wellness program that offers annual influenza vaccinations;

(D) Whether influenza transmission from ~~healthcare workers~~ EMPLOYEES OR DIRECT CONTRACTORS is addressed in the ~~healthcare entity's~~ FACILITY'S OR AGENCY'S infection control policy;

(E) What precautions are taken to prevent the transmission of influenza from unvaccinated EMPLOYEES OR DIRECT CONTRACTORS ~~healthcare workers~~; and

(F) What type of educational material is utilized by the ~~healthcare entity~~ FACILITY OR AGENCY to promote influenza immunization ~~for its healthcare workers~~.

~~10.11~~11.4.2 Each ~~licensed healthcare entity~~ LICENSEE THAT FAILS TO MEET THE NINETY PERCENT (90%) VACCINATION RATE, other than those identified in ~~sections 10.7 through 10.9~~PART 11.3, shall REVIEW ITS CURRENT WRITTEN POLICY REGARDING THE ANNUAL INFLUENZA IMMUNIZATION OF EMPLOYEES AND DIRECT CONTRACTORS TO ENSURE IT ADDRESSES THE FOLLOWING CRITERIA, OR CREATE A ~~have a~~ written policy, IF NONE EXISTS, ~~regarding the annual influenza immunization of its healthcare~~ that is based on that ~~licensee's~~ FACILITY'S OR AGENCY'S attributes and resources. The policy shall, at a minimum, address the following criteria:

~~(A) Ensuring that each employee is offered the opportunity to receive an annual influenza immunization;~~

(B) Maintaining records of ~~each~~ employee's AND DIRECT CONTRACTOR'S proof of ~~annual~~ immunization, ~~declination~~ or MEDICAL exemption from immunization; and

(C) Ensuring that all of the licensee's employees AND DIRECT CONTRACTORS are provided information regarding:

(1) The benefits and risks of influenza immunization;

(2) The availability of influenza immunization; and

(3) The importance of adhering to standard precautions.

~~10.12 Each licensed health care entity, other than those identified in sections 10.7 through 10.9, shall track and report the annual influenza vaccination rate for its employees through December 31st of each year. This report shall be submitted to the Department, in the form and manner specified, no later than March 31st of the following year.~~

Commented [HA78]: Now at 11.2.3(A)

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

STANDARDS FOR HOSPITALS AND HEALTH FACILITIES: CHAPTER 04 - GENERAL HOSPITALS

6 CCR 1011-1 Chap 04

Adopted by the Board of Health _____, 2019. Effective _____, 2020.

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

~~Division Director~~
~~Colorado Department of Public Health and Environment~~
~~Health Facilities Division~~
~~4300 Cherry Creek Drive South~~
~~Denver, Colorado 80222-1530~~
~~Main switchboard: (303) 692-2800~~

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

~~Division Director~~
~~Colorado Department of Public Health and Environment~~
~~Health Facilities Division~~
~~4300 Cherry Creek Drive South~~
~~Denver, Colorado 80222-1530~~
~~Main switchboard: (303) 692-2800~~

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

Part 1. STATUTORY AUTHORITY AND APPLICABILITY

****

1.101 STATUTORY AUTHORITY

(1) Authority to establish minimum standards through regulation and to administer and enforce such regulations is provided by Sections 25-1.5-103 and 25-3-~~101~~100.5, C.R.S., et seq.

1.102 APPLICABILITY

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

(a) 6 CCR 1011-1, Chapter ~~II~~ 2, except as noted below:

(i) Notwithstanding 6 CCR 1011-1, Chapter ~~II~~2, ~~Section~~ PART 2.~~3~~2.2, hospital services/departments provided for under this Chapter ~~IV~~ 4 shall not require a separate license if they are on the hospital campus. Services that are subject to separate licensure including, but not limited to, assisted living residences, hospices, hospital units, home care agencies, long term care facilities, and end stage renal dialysis treatment centers, shall not be considered part of the hospital campus.

****

Part 3. DEPARTMENT OVERSIGHT

****

3.200 INCREASE IN LICENSED CAPACITY

3.201 Each licensee shall comply with the requirements of 6 CCR 1011-1, Chapter ~~II~~2, ~~section~~ PART 2.~~10.5~~9.6 regarding ~~written~~ notification of changes affecting the licensee's operation or information, except that the procedure regarding a proposed increase in licensed capacity set forth in Chapter ~~II~~2, ~~section~~ PART 2.~~10.5~~9.6(A)(1) shall be as follows:

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

(a) If a licensee requesting an increase in licensed capacity has, within 12 months prior to giving notice thereof, been subject to conditions imposed upon its license pursuant to CHAPTER 2, PART ~~§~~ 2.~~9.4~~8.3 or been subject to a plan of correction pursuant to CHAPTER 2, PART ~~§~~ 2.~~11.3~~10.4(B), the licensee shall submit to the Department satisfactory evidence that the noted condition(s) have been met or the plan of correction implemented, as applicable, in connection with the notice of increased capacity.

****

Part 4. PHYSICAL PLANT STANDARDS

4.101 COMPLIANCE WITH FGI GUIDELINES

ANY CONSTRUCTION OR RENOVATION OF A HOSPITAL INITIATED ON OR AFTER JULY 1, 2020, SHALL CONFORM TO PART 3 OF 6 CCR 1011-1, CHAPTER 2, UNLESS OTHERWISE SPECIFIED IN THIS CURRENT CHAPTER.

~~Effective July 1, 2013, all hospitals shall be constructed in conformity with the standards adopted by the Director of the Division of Fire Prevention and Control (DFPC) at the Colorado Department of Public Safety. For construction initiated or systems installed on or after July 1, 2013, that affect patient health and safety and for which DFPC has no applicable standards, each facility shall conform to the relevant section(s) of the Guidelines for Design and Construction of Health Care Facilities, (2010 Edition), Facilities Guidelines Institute. The Guidelines for Design and Construction of Health Care Facilities, (2010 Edition), Facilities Guidelines Institute (FGI), is hereby incorporated by reference and excludes any later amendments to or editions of the Guidelines. The 2010 FGI Guidelines are available at no cost in a read only version at: http://openpub.realread.com/rrserver/browser?title=/FGI/2010_Guidelines~~

****

Part 10. ~~———~~PATIENT RIGHTS. The facility shall be in compliance with 6 CCR 1011-1, Chapter ~~II~~2, Part ~~6~~7.

****

Part 26. PSYCHIATRIC SERVICES

****

26.102 PROGRAMMATIC FUNCTIONS

****

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

(a) restraint and seclusion consistent with state and federal law and regulation, including 6 CCR 1011-1, Chapter ~~II~~2, Part 8, Protection of ~~Persons~~CLIENTS from Involuntary ~~r~~Restraint OR SECLUSION. Medications shall only be used for treatment and stabilization, not for staff convenience.

****

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

CHAPTER 5 - NURSING CARE FACILITIES

6 CCR 1011-1 Chap 05

Approved by the Board of Health _____, 2019. Effective _____, 2020.

SECTION 1 - STATUTORY AUTHORITY AND APPLICABILITY

1.1 The statutory authority for the promulgation of these rules is set forth in Sections 25-1-107.5(2), 25-1.5-103(1)(a) and 25-3-~~101~~100.5, et seq., C.R.S.

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SECTION 3 - GOVERNING BODY

****

3.3 QUALITY ASSURANCE

The governing body shall ensure that the facility has a quality management program that evaluates the quality of resident care and safety and meets all the requirements set forth in 6 CCR 1011-1, Chapter 2, General Licensure Standards, Part ~~3~~4.1. The facility shall have a committee that meets monthly to address the required quality management activities.

SECTION 4 - FACILITY ADMINISTRATION

****

4.6 WAIVERS

A facility may request waivers to these regulations pursuant to 6 CCR 1011-1, Chapter 2, General Licensure Standards, Part ~~4~~5, Waiver of Regulations for ~~Health Care Entities~~FACILITIES AND AGENCIES.

****

SECTION 9 NURSING SERVICES

****

9.5 EXCEPTIONS

Nothing contained in this section 9 shall require any rural nursing care facility that is a skilled nursing care facility to employ nursing staff beyond current federal certification requirements. Since federal standards require that nurse staffing be sufficient to meet the total nursing needs of all residents, resident conditions will determine the specific numbers and qualifications of staff that each facility must provide.

****

B) To the extent that these regulations require any facility to employ a registered nurse more than 40 hours per week, the Department may waive such requirements for such periods as it deems appropriate if, based on findings consistent with 6 CCR 1011-1, Chapter 2, Part ~~4~~5, it determines that:

****

SECTION 15 RESIDENT RIGHTS

15.1 STATEMENT OF RIGHTS

The facility shall adopt and make public a statement regarding of the rights and responsibilities of its residents and provide a copy to each resident and resident representative at or before admission. The facility and staff shall observe these rights in the care, treatment and supervision of the residents. The statement of rights shall include at a minimum, the following items:

*****

3) The right to review and obtain copies of his or her medical records in accordance with 6 CCR 1011-1, Chapter 2, Part ~~5~~6.

*****

SECTION 17 HEALTH INFORMATION RECORDS

****

17.7 NURSING CARE FACILITY RECORDS

The facility shall maintain, with current information, the following records:

****

F) File of all accident and incident reports including, without limitation, those required by 6 CCR 1011-1, Chapter 2, Part ~~3~~4.2.

****

SECTION 21 PHYSICAL PLANT STANDARDS

21.1 COMPLIANCE WITH FGI GUIDELINES

ANY CONSTRUCTION OR RENOVATION OF A NURSING CARE FACILITY INITIATED ON OR AFTER JULY 1, 2020, SHALL CONFORM TO PART 3 OF 6 CCR 1011-1, CHAPTER 2, UNLESS OTHERWISE SPECIFIED IN THIS CURRENT CHAPTER.

~~Effective July 1, 2013, all nursing care facilities shall be constructed in conformity with the standards adopted by the Director of the Division of Fire Prevention and Control (DFPC) at the Colorado Department of Public Safety. For construction initiated or systems installed on or after July 1, 2013, that affect patient health and safety and for which DFPC has no applicable standards, each facility shall conform to the relevant section(s) of the Guidelines for Design and Construction of Health Care Facilities, (2010 Edition), Facilities Guidelines Institute. The Guidelines for Design and Construction of Health Care Facilities, (2010 Edition), Facilities~~

~~Guidelines Institute (FGI), is hereby incorporated by reference consistent with section 1.3 of this chapter and excludes any later amendments to or editions of the Guidelines. The 2010 FGI Guidelines are available at no cost in a read-only version at:~~
~~http://fgiguidelines.org/digitalcopy.php~~

****

SECTION 31 ENFORCEMENT ACTIVITIES

For Nursing Care Facilities Certified to Provide Medicaid Services:

****

31.7 ~~Written p~~Plans of correction shall comply with 6 CCR 1011-1, Chapter 2, Part 2.~~11~~10.4(B).

31.8 Nothing in this section precludes the Department from imposing any other remedies allowed by state law including, but not limited to, those described in 6 CCR 1011-1, Chapter 2, Part 2.~~11~~10 and 2.~~12~~11.

****

SECTION 32 LICENSING FEES

****

32.4 Change of ownership - Change of ownership shall be determined in accordance with the criteria set forth in 6 CCR 1011-1, Chapter 2, Part 2.~~7~~6. The fee shall be $6,190.62 per facility.

****

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

STANDARDS FOR HOSPITALS AND HEALTH FACILITIES: CHAPTER 06 - ACUTE TREATMENT UNITS

6 CCR 1011-1 Chap 06

Adopted by the Board of Health on _____, 2019. Effective _____, 2020.

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

~~Division Director~~
~~Colorado Department of Public Health and Environment~~
~~Health Facilities Division~~
~~4300 Cherry Creek Drive South~~
~~Denver, Colorado 80222-1530~~
~~Main switchboard: (303) 692-2800~~

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

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~~Colorado Department of Public Health and Environment~~
~~Health Facilities Division~~
~~4300 Cherry Creek Drive South~~
~~Denver, Colorado 80222-1530~~
~~Main switchboard: (303) 692-2800~~

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

1.101 STATUTORY AUTHORITY AND APPLICABILITY

****

(2) Acute treatment units, as defined herein, shall be in compliance with all applicable federal and state statutes and regulations, including but not limited to, the following:

****

(b) The following parts of 6 CCR 1011-1, Chapter ~~II~~2, General Licensure Standards:

(i) Part 2, Licensure Process.

(ii) Part ~~3~~4.2, Occurrence Reporting

(iii) Part ~~4~~5, Waiver of Regulations for Health Facilities

****

1.102 DEFINITIONS.

****

(14) "Occurrences" means information reported to the Department in accordance with 25-1-124, C.R.S. and Chapter ~~II~~2, General Licensure, Part ~~3~~4.2 ~~o~~Occurrence Reporting.

****

1.103 DEPARTMENT OVERSIGHT

****

(7) Facility Reporting Requirements. The facility shall develop and implement policies and procedures for complying with the following reporting requirements.

(a) Occurrences

(i) Reporting. The facility shall be in compliance with occurrence reporting requirements pursuant to 6 CCR 1011, Chapter ~~II~~2, Section ~~3~~4.2.

****

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

STANDARDS FOR HOSPITALS AND HEALTH FACILITIES: CHAPTER 08 - FACILITIES FOR PERSONS WITH INTELLECTUAL AND DEVELOPMENTAL DISABILITIES

6 CCR 1011-1 Chap 08

Adopted by the Board of Health _____, 2019. Effective _____, 2020.

Section 1 – Statutory Authority and Applicability

1.1 The statutory authority for the promulgation of these rules is set forth in sections 25-1.5-103, 25-3-~~101~~100.5, *et seq.,* and 25.5-10-214(2) and (5), C.R.S.

****

Section 9 – Resident Rights

9.1 Each facility shall have written policies and procedures for residents' rights. Those policies and procedures shall address the patient rights set forth in 6 CCR 1011-1, Chapter ~~II~~2, Part ~~6~~7, and Section 25.5-10-218 through 225, C.R.S. (Effective March 1, 2014), which is incorporated by reference. Such policies and procedures shall also include specific provisions regarding the following:

****

9.2 The facility administrator shall ensure implementation of the following items.

****

(E) Reporting of any alleged incident or occurrence to the parent, guardian or authorized representative within 24 hours, and to the department by the next business day consistent with 6 CCR 1011-1, Chapter 2, section ~~3~~4.2; and

****

Section 18 – Facility Reporting Requirements

18.1 Each facility shall comply with the occurrence reporting requirements set forth in 6 CCR 1011-1, Chapter ~~II~~2, Part ~~3~~4.2.

****

Section 21 – Compliance with FGI Guidelines

ANY CONSTRUCTION OR RENOVATION OF A FACILITY FOR PERSONS WITH INTELLECTUAL AND DEVELOPMENTAL DISABILITIES INITIATED ON OR AFTER JULY 1, 2020, SHALL CONFORM TO PART 3 OF 6 CCR 1011-1, CHAPTER 2, UNLESS OTHERWISE SPECIFIED IN THIS CURRENT CHAPTER.

~~Effective July 1, 2013, all facilities for persons with developmental disabilities shall be constructed in conformity with the standards adopted by the Director of the Division of Fire Prevention and Control (DFPC) at the Colorado Department of Public Safety. For construction initiated or systems installed on or after July 1, 2013, that affect patient health and safety and for which DFPC has no applicable standards, each facility shall conform to the relevant section(s) of the Guidelines for Design and Construction of Health Care Facilities, (2010 Edition), Facilities Guidelines Institute. The Guidelines for Design and Construction of Health Care Facilities, (2010 Edition), Facilities Guidelines Institute (FGI), is hereby incorporated by reference and excludes any later amendments to or editions of the Guidelines. The 2010 FGI Guidelines are available at no cost in a read only version at:~~
~~http://openpub.realread.com/rrserver/browser?title=/FGI/2010_Guidelines~~

****

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

STANDARDS FOR HOSPITALS AND HEALTH FACILITIES: CHAPTER 09 - COMMUNITY CLINICS AND COMMUNITY CLINICS AND EMERGENCY CENTERS

6 CCR 1011-1 Chap 09

Adopted by the Board of Health on _____, 2019. Effective _____, 2020.

SUBCHAPTER IX.A - GENERAL REQUIREMENTS

SUBCHAPTER IX.B - ADDITIONAL REQUIREMENTS FOR CLINICS WITH INPATIENT BEDS AND COMMUNITY EMERGENCY CENTERS

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

~~Division Director~~
~~Colorado Department of Public Health and Environment~~
~~Health Facilities Division~~
~~4300 Cherry Creek Drive South~~
~~Denver, Colorado 80222-1530~~
~~Main switchboard: (303) 692-2800~~

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

Division Director
Colorado Department of Public Health and Environment
Health Facilities and Emergency Medical Services Division
4300 Cherry Creek Drive South
Denver, Colorado ~~80222-1530~~ 80246
Main switchboard: (303) 692-2800

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

SUBCHAPTER IX.A - GENERAL REQUIREMENTS

Part 1. STATUTORY AUTHORITY

1.101 Statutory Authority. Authority to establish minimum standards through regulation and to administer and enforce such regulations is provided by Sections 25-1.5-103 and 25-3-~~101~~100.5, C.R.S., et seq.

****

3.200 COMMERCIAL PROFESSIONAL LIABILITY INSURANCE

3.201 ~~Community clinics shall submit evidence to the Colorado Department of Public Health and Environment that they maintain at least $300,000 professional liability insurance per incident and $900,000 annual aggregate per year in order to demonstrate compliance with the Health Care Availability Act of 1988.~~COMMUNITY CLINICS SHALL COMPLY WITH THE LIABILITY INSURANCE REQUIREMENTS SET FORTH IN 6 CCR 1011-1, CHAPTER 2, PART 2.3(D).

****

Part 4. PHYSICAL PLANT STANDARDS

4.101 COMPLIANCE WITH FGI STANDARDS

ANY CONSTRUCTION OR RENOVATION OF A COMMUNITY CLINIC INITIATED ON OR AFTER JULY 1, 2020, SHALL CONFORM TO PART 3 OF 6 CCR 1011-1, CHAPTER 2, UNLESS OTHERWISE SPECIFIED IN THIS CURRENT CHAPTER.

~~Effective July 1, 2013, all community clinics and community clinics and emergency centers shall be constructed in conformity with the standards adopted by the Director of the Division of Fire Prevention and Control (DFPC) at the Colorado Department of Public Safety. For construction initiated or systems installed on or after July 1, 2013, that affect patient health and safety and for which DFPC has no applicable standards, each facility shall conform to the relevant section(s) of the Guidelines for Design and Construction of Health Care Facilities, (2010 Edition), Facilities Guidelines Institute. The Guidelines for Design and Construction of Health Care Facilities, (2010 Edition), Facilities Guidelines Institute (FGI), is hereby incorporated by reference and excludes any later amendments to or editions of the Guidelines. The 2010 FGI Guidelines are available at no cost in a read only version at: http://openpub.realread.com/rrserver/browser?title=/FGI/2010_Guidelines~~

~~****~~

Part 10. PATIENT RIGHTS

As a condition of licensure, the community clinic shall be in compliance with 6 CCR 1011-1, Chapter II, Part ~~6~~7.

*****

6 CCR 1011-1, Chapter II.DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

STANDARDS FOR HOSPITALS AND HEALTH FACILITIES: CHAPTER 10 - REHABILITATION HOSPITALS

6 CCR 1011-1 Chap 10

Adopted by the Board of Health on _____, 2019. Effective _____, 2020.

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~~Colorado Department of Public Health and Environment~~
~~Health Facilities Division~~
~~4300 Cherry Creek Drive South~~
~~Denver, Colorado 80222-1530~~
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~~Main switchboard: (303) 692-2800~~

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Part 1. STATUTORY AUTHORITY AND APPLICABILITY

1.101 STATUTORY AUTHORITY

(1) Authority to establish minimum standards through regulation and to administer and enforce such regulations is provided by Sections 25-1.5-103 and 25-3-~~101~~100.5, C.R.S., et seq.

****

Part 10. PATIENT RIGHTS

The facility shall be in compliance with 6 CCR 1011-1, Chapter II, Part ~~6~~7.

****

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

STANDARDS FOR HOSPITALS AND HEALTH FACILITIES: CHAPTER 15 - DIALYSIS TREATMENT CLINICS

6 CCR 1011-1 Chap 15

Adopted by the Board of Health on _____, 2019. Effective _____, 2020.

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

~~Division Director~~
~~Colorado Department of Public Health and Environment~~
~~Health Facilities Division~~
~~4300 Cherry Creek Drive South~~
~~Denver, Colorado 80222-1530~~
~~Main switchboard: (303) 692-2800~~

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~~Health Facilities Division~~
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~~Denver, Colorado 80222-1530~~
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Section 1. STATUTORY AUTHORITY AND APPLICABILITY

1.1 The statutory authority for the promulgation of these rules is set forth in Sections 25-1.5-103, 25-1.5-108, and 25-3-~~101~~100.5, et seq., C.R.S.

****

8.4 Compliance with FGI Guidelines

8.4.1 ANY CONSTRUCTION OR RENOVATION OF A DIALYSIS TREATMENT CLINIC INITIATED ON OR AFTER JULY 1, 2020, SHALL CONFORM TO PART 3 OF 6 CCR 1011-1, CHAPTER 2, UNLESS OTHERWISE SPECIFIED IN THIS CURRENT CHAPTER. ~~Effective July 1, 2013, all dialysis treatment clinics shall be constructed in conformity with the standards adopted by the Director of the Division of Fire Prevention and Control (DFPC) at the Colorado Department of Public~~

~~Safety. For construction initiated or systems installed on or after July 1, 2013, that affect patient health and safety and for which DFPC has no applicable standards, each facility shall conform to the relevant section(s) of the Guidelines for Design and Construction of Health Care Facilities, (2010 Edition), Facilities Guidelines Institute. The Guidelines for Design and Construction of Health Care Facilities, (2010 Edition), Facilities Guidelines Institute (FGI), is hereby incorporated by reference and excludes any later amendments to or editions of the Guidelines. The 2010 FGI Guidelines are available at no cost in a read only version at:~~
~~http://openpub.realread.com/rrserver/browser?title=/FGI/2010_Guidelines~~

****

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

STANDARDS FOR HOSPITALS AND HEALTH FACILITIES: CHAPTER 18 - PSYCHIATRIC HOSPITALS

6 CCR 1011-1 Chap 18

Adopted by the Board of Health on _____, 2019. Effective _____, 2020.

Part 1. STATUTORY AUTHORITY AND APPLICABILITY

1.101 STATUTORY AUTHORITY

(1) Authority to establish minimum standards through regulation and to administer and enforce such regulations is provided by Sections 25-1.5-103 and 25-3-~~101~~100.5, C.R.S., et seq.

****

Part 4. FIRE SAFETY AND PHYSICAL PLANT STANDARDS

4.101 COMPLIANCE WITH FGI GUIDELINES

ANY CONSTRUCTION OR RENOVATION OF A PSYCHIATRIC HOSPITAL INITIATED ON OR AFTER JULY 1, 2020, SHALL CONFORM TO PART 3 OF 6 CCR 1011-1, CHAPTER 2, UNLESS OTHERWISE SPECIFIED IN THIS CURRENT CHAPTER.
~~Effective July 1, 2013, all psychiatric hospitals shall be constructed in conformity with the standards adopted by the Director of the Division of Fire Prevention and Control (DFPC) at the Colorado Department of Public Safety. For construction initiated or systems installed on or after July 1, 2013, that affect patient health and safety and for which DFPC has no applicable standards, each facility shall conform to the relevant section(s) of the Guidelines for Design and Construction of Health Care Facilities, (2010 Edition), Facilities Guidelines Institute. The Guidelines for Design and Construction of Health Care Facilities, (2010 Edition), Facilities Guidelines Institute (FGI), is hereby incorporated by reference and excludes any later amendments to or editions of the Guidelines. The 2010 FGI Guidelines are available at no cost in a read only version at:~~
~~http://openpub.realread.com/rrserver/browser?title=/FGI/2010_Guidelines~~

****

Part 10. PATIENT RIGHTS.

The facility shall be in compliance with 6 CCR 1011-1, Chapter II, Part ~~6~~7.

****

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

STANDARDS FOR HOSPITALS AND HEALTH FACILITIES: CHAPTER 19 - HOSPITAL UNITS

6 CCR 1011-1 Chap 19

Adopted by the Board of Health on _____, 2019. Effective _____, 2020.

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

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~~Colorado Department of Public Health and Environment~~
~~Health Facilities Division~~
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~~Denver, Colorado 80222-1530~~
~~Main switchboard: (303) 692-2800~~

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

~~Division Director~~
~~Colorado Department of Public Health and Environment~~
~~Health Facilities Division~~
~~4300 Cherry Creek Drive South~~
~~Denver, Colorado 80222-1530~~
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Part 1. STATUTORY AUTHORITY AND APPLICABILITY

1.101 STATUTORY AUTHORITY

(1) Authority to establish minimum standards through regulation and to administer and enforce such regulations is provided by Sections 25-1.5-103 and 25-3-~~101~~100.5, C.R.S.

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Part 5. GENERAL HOSPITAL SERVICES

5.101 If the hospital unit is providing general hospital services, the hospital unit shall comply with the following parts of Chapter IV, General Hospitals:

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(10) Part 10. PATIENT RIGHTS. The facility shall be in compliance with 6 CCR 1011-1, Chapter II, Part ~~6~~7.

****

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

CHAPTER 20 - AMBULATORY SURGICAL CENTER AND AMBULATORY SURGICAL CENTER WITH A CONVALESCENT CENTER

6 CCR 1011-1 Chap 20

Adopted by the Board of Health on _____, 2019. Effective _____, 2020.

SECTION 1 - STATUTORY AUTHORITY AND APPLICABILITY

1.1 The statutory authority for the promulgation of these rules is set forth in section 25-1.5-103 and 25-3-~~101~~100.5, *et seq.*, C.R.S

****

SECTION 3 - AMBULATORY SURGICAL CENTER CLASSIFCATIONS

3.1 An ambulatory surgical center shall be issued a license consistent with the type and extent of services provided, as outlined below.

(A) Class C Center – A Class C center shall have at least one sterile operating room with the capacity to administer general anesthesia to patients. The operating room(s), as well as the pre and post surgical areas, shall be located in a way that provides control over the movement of patients and personnel. This classification of operating room is equivalent to a ~~Class C~~ operating room as described in the Guidelines for Design and Construction of ~~Health Care~~ OUTPATIENT Facilities, (201~~0~~8 Edition), Facilities Guidelines Institute, ~~which is~~ AS incorporated by reference IN CHAPTER 2.

(B) Class A or B Center – A Class A or B Center shall have a dedicated procedure room(s) with the capacity to provide oxygen and patient monitoring in a clean environment that supports infection control. The procedure room(s) shall only be used for endoscopic or interventional procedures or non-invasive examinations/treatments unless first terminally cleaned. Low-risk versus high-risk exposure areas shall be identified, along with the attire and personal protective equipment necessary for each area. This classification of procedure room is equivalent to ~~Class A or B operating~~ PROCEDURE rooms as described in the Guidelines for Design and Construction of ~~Health Care~~ OUTPATIENT Facilities, (201~~0~~8 Edition), Facilities Guidelines Institute, ~~which is~~ AS incorporated by reference IN CHAPTER 2.

****

SECTION 23 - COMPLIANCE WITH FGI GUIDELINES

ANY CONSTRUCTION OR RENOVATION OF AN AMBULATORY SURGICAL CENTER INITIATED ON OR AFTER JULY 1, 2020, SHALL CONFORM TO PART 3 OF 6 CCR 1011-1, CHAPTER 2, UNLESS OTHERWISE SPECIFIED IN THIS CURRENT CHAPTER.

~~Effective July 1, 2013, all ambulatory surgical centers shall be constructed in conformity with the standards adopted by the Director of the Division of Fire Prevention and Control (DFPC) at the Colorado~~

~~Department of Public Safety. For construction initiated or systems installed on or after July 1, 2013, that affect patient health and safety and for which DFPC has no applicable standards, each center shall conform to the relevant section(s) of the Guidelines for Design and Construction of Health Care Facilities, (2010 Edition), Facilities Guidelines Institute. The Guidelines for Design and Construction of Health Care Facilities, (2010 Edition), Facilities Guidelines Institute (FGI), is hereby incorporated by reference and excludes any later amendments to or editions of the Guidelines. The 2010 FGI Guidelines are available at no cost in a read only version at: HTTP://FGIGUIDELINES.ORG/DIGITALCOPY.PHP~~

SECTION 24 - LICENSE FEES

24.1 As part of the licensing process described at 6 CCR 1011-1, Chapter 2, PART 2~~sections 2.4 through 2.7~~, an applicant for an ambulatory surgical center license shall submit, in the form and manner specified by the Department, a license application with the corresponding nonrefundable fee as set forth below:

****

SECTION 25 - AMBULATORY SURGICAL CENTER WITH A CONVALESCENT CENTER

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25.6 ANY CONSTRUCTION OR RENOVATION OF A CONVALESCENT CENTER INITIATED ON OR AFTER JULY 1, 2020, SHALL CONFORM TO PART 3 OF 6 CCR 1011-1, CHAPTER 2, UNLESS OTHERWISE SPECIFIED IN THIS CURRENT CHAPTER.

~~Compliance with FGI Guidelines: Effective July 1, 2013, all convalescent centers shall be constructed in conformity with the standards adopted by the Director of the Division of Fire Prevention and Control (DFPC) at the Colorado Department of Public Safety. For construction initiated or systems installed on or after July 1, 2013, that affect patient health and safety and for which DFPC has no applicable standards, each center shall conform to the relevant section(s) of the Guidelines for Design and Construction of Health Care Facilities, (2010 Edition), Facilities Guidelines Institute. The Guidelines for Design and Construction of Health Care Facilities, (2010 Edition), Facilities Guidelines Institute (FGI), is hereby incorporated by reference and excludes any later amendments to or editions of the Guidelines. The 2010 FGI Guidelines are available at no cost in a read only version at: HTTP://FGIGUIDELINES.ORG/DIGITALCOPY.PHP~~

25.7 License Fees: ~~For new license applications received or renewal licenses that expire on or after March 1, 2015, A~~AN applicant for an ambulatory surgical center with a convalescent center license shall comply with the licensing process described at 6 CCR 1011-1, Chapter 2, ~~sections 2.4 through 2.7~~PART 2, and submit, in the form and manner specified by the Department, a license application with the corresponding nonrefundable fee as set forth below:

****

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

STANDARDS FOR HOSPITALS AND HEALTH FACILITIES: CHAPTER 21 - HOSPICES

6 CCR 1011-1 Chap 21

Adopted by the Board of Health on_____, 2019. Effective _____, 2020.

SECTION 1 STATUTORY AUTHORITY AND APPLICABILITY

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~~1.3 These regulations incorporate by reference (as indicated within) materials originally published elsewhere. Such incorporation does not include later amendments to or editions of the referenced material. The Department of Public Health and Environment maintains copies of the complete text of the incorporated materials for public inspection during regular business hours, and shall provide certified copies of the incorporated material at cost upon request. Information regarding how the incorporated material may be obtained or examined is available from:~~

~~Division Director~~
~~Health Facilities and Emergency Medical Services Division~~
~~Colorado Department of Public Health and Environment~~
~~4300 Cherry Creek Drive South~~
~~Denver, CO 80246~~
~~Phone: 303-692-2800~~

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****

SECTION 4 ADMINISTRATION

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4.5 The hospice shall develop, implement, and maintain an effective, ongoing, hospice-wide data-driven quality assessment and performance improvement program that complies with 6 CCR 1011-1, Chapter II, Part ~~3~~4. In addition, the hospice's governing body shall ensure that the program:

****

SECTION 13 COMPLIANCE WITH FGI GUIDELINES

ANY CONSTRUCTION OR RENOVATION OF A HOSPICE INPATIENT FACILITY INITIATED ON OR AFTER JULY 1, 2020, SHALL CONFORM TO PART 3 OF 6 CCR 1011-1, CHAPTER 2, UNLESS OTHERWISE SPECIFIED IN THIS CURRENT CHAPTER.

~~Effective July 1, 2013, all hospice inpatient facilities shall be constructed in conformity with the standards adopted by the Director of the Division of Fire Prevention and Control (DFPC) at the Colorado Department of Public Safety. For construction initiated or systems installed on or after July 1, 2013, that affect patient health and safety and for which DFPC has no applicable standards, each facility shall conform to the relevant section(s) of the Guidelines for Design and Construction of Health Care Facilities, (2010 Edition), Facilities Guidelines Institute. The Guidelines for Design and Construction of Health Care Facilities, (2010 Edition), Facilities Guidelines Institute (FGI), is hereby incorporated by reference and excludes any later amendments to or editions of the Guidelines. The 2010 FGI Guidelines are available at no cost in a read only version at:~~
~~http://openpub.realread.com/rrserver/browser?title=/FGI/2010_Guidelines~~

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DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

STANDARDS FOR HOSPITALS AND HEALTH FACILITIES: CHAPTER 22 – BIRTH CENTERS

6 CCR 1011-1 Chapter 22

Adopted by the Board of Health on_____, 2019. Effective _____, 2020.

SECTION 1 – STATUTORY AUTHORITY AND APPLICABILITY

1.1 The statutory authority for the promulgation of these rules is set forth in section 25-1.5-103 and 25-3-~~101~~100.5, *et seq.*, C.R.S.

****

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****

SECTION 4 – GOVERNING BODY

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4.2 The governing body shall:

****

(J) maintain an effective quality management program in accordance with 6 CCR 1011-1, Chapter 2, PART 4 ~~Section 3.1~~.

****

SECTION 15 – CLIENT CARE

15.1 Client Rights. The facility shall be compliant with 6 CCR 1011.1, Chapter 2, Part ~~6~~7.

****

SECTION 21 – PHYSICAL PLANT STANDARDS

21.1 ANY CONSTRUCTION OR RENOVATION OF A BIRTH CENTER INITIATED ON OR AFTER JULY 1, 2020, SHALL CONFORM TO PART 3 OF 6 CCR 1011-1, CHAPTER 2, UNLESS OTHERWISE SPECIFIED IN THIS CURRENT CHAPTER. ~~Effective July 1, 2013, all birth centers shall be constructed in conformity with the standards adopted by the Director of the Division of Fire Prevention and Control (DFPC) at the Colorado Department of Public Safety. For construction initiated or systems installed on or after July 1, 2013, that affect patient health and safety and for which DFPC has no applicable standards, each facility shall conform to the relevant section(s) of the Guidelines for Design and Construction of Health Care Facilities, (2010 Edition), Facilities Guidelines Institute. The Guidelines for Design and Construction of Health Care Facilities, (2010 Edition), Facilities Guidelines Institute (FGI), is hereby incorporated by reference and excludes any later amendments to or editions of the Guidelines. The 2010 FGI Guidelines are available at no cost in a read only version at: https://www.fgiguidelines.org/guidelines/2010-edition/read-only-copy/.~~

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DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

STANDARDS FOR HOSPITALS AND HEALTH FACILITIES: CHAPTER 26 - HOME CARE AGENCIES

6 CCR 1011-1 Chap 26

Adopted by the Board of Health on _____, 2019. Effective _____, 2020.

~~**Adopted by the Board of Health on November 16, 2016. Effective January 14, 2017**~~

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

~~**Division Director**~~
~~**Colorado Department of Public Health and Environment**~~
~~**Health Facilities Division**~~
~~**4300 Cherry Creek Drive South**~~
~~Denver, Colorado 80222-1530~~
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5.4 License fees

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5.4.6 Change of ownership fee

(A) Any agency meeting the criteria set forth in 6 CCR 1011-1, Chapter II, ~~section~~PART 2.6~~7.2~~ shall pay a change of ownership fee. The fee shall be determined according to the license classifications set forth in section 5.1 of this chapter and submitted with the change of ownership notice. The fee shall be:

****

5.4.7 Change of name and change of address fees

(A) A licensed HCA shall conform with the notification requirements of 6 CCR 1011-1, Chapter II, ~~section~~PART 2.~~10.5~~9.6 regarding any change in the agency name or business address.

****

Section 6. GENERAL REQUIREMENTS FOR ALL LICENSE CATEGORIES

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6.10 Agency reporting requirements

(A) Each HCA shall comply with the occurrence reporting requirements set forth in 6 CCR 1011, Chapter II, ~~section 3.2~~PART 4.2.

****

6.14 Quality management program

(A) Every HCA shall establish a quality management program appropriate to the size and type of agency that evaluates the quality of consumer services, care and safety, and that complies with the requirements set forth in 6 CCR 1011, Chapter II, ~~section 3.1~~PART 4.1.

****