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

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

Emergency rules adopted by the Board of Health on March 16, 2022. Effective March 16, 2022. [Emergency rules expired 07/14/2022]

Copies of these regulations may be obtained at cost by contacting:
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Colorado Department of Public Health and Environment
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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.

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PART 1. DEFINITIONS

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

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.

1.4 "Admission" means the acceptance of a person as a client of the facility or agency.

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.

1.6 "Board" means the State Board of Health.

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.

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

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.

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.

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.

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.

1.16 "Cost sharing" means the share of cost covered by a client's insurance that the client pays out of pocket. This term includes, but is not limited to deductibles, coinsurance, copayments, or other similar charges.

1.17 "Deficiency" means a failure to fully comply with any statutory and/or regulatory requirements applicable to a licensee.

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

1.19 "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.

1.20 "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 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.

1.21 "Direct Ownership" means the possession of stock, equity in capital, or any interest greater than 5 percent of the facility or agency.

1.22 "Emergency medical condition" means a medical condition that manifests itself by acute symptoms of sufficient severity, including severe pain, that a prudent layperson with an average knowledge of health and medicine could reasonably expect, in the absence of immediate medical attention, to result in: serious jeopardy to the health of the individual or, with respect to a pregnant woman, the health of the woman or her unborn child; or serious impairment to bodily functions; or serious dysfunction of any bodily organ or part.

1.23 "Emergency services," with respect to an emergency medical condition, means: a medical screening examination that is within the capability of the emergency department of a hospital, including ancillary services routinely available to the emergency department to evaluate the emergency medical condition; and within the capabilities of the staff and facilities available at the hospital, further medical examination and treatment as required to stabilize the patient to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a facility.

1.24 "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.

1.25 "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.

1.26 "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 Part 4.2 of these rules.

1.27 "Grievance mechanism" means the process whereby complaints by a client or the client's designated representative may be initiated and resolved by the facility or agency.

1.28 "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.

1.29 "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.

1.30 "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.

1.31 "Influenza Season" means November 1 through March 31 of the following year, or as otherwise defined by the Division of Disease Control and Public Health Response within the Department.

1.32 "Influenza Vaccine" means a currently licensed United States Food and Drug Administration approved vaccine product.

1.33 "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 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.

1.34 "In-network" means a facility or agency that is a participating provider, as defined at section 10-16-102(46), C.R.S., in an individual's health insurance plan.

1.35 "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.

1.36 “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.

1.37 “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.

1.38 “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.

1.39 “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.

1.40 “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.

1.41 "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.

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

1.43 “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.

1.44 “Neglect” means the failure to provide goods and services necessary to attain and maintain physical and mental well-being.

1.45 “Out-of-network” means a facility or agency that is not a participating provider, as defined at Section 10-16-102(46), C.R.S.

1.46 “New construction” means the construction of new buildings or newly constructed additions.

1.47 “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.

1.48 "Pharmacist" means a pharmacist licensed in the State of Colorado.

1.49 “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.

1.50 "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.

1.51 "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.

1.52 "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, ventilation, and electrical systems. It also means the changing of the functional operation of the space. Renovations do not include "minor alterations," as defined herein.

1.53 "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.

1.54 "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/or seclusion.

1.55 "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.

1.56 "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.

1.57 "Seclusion" means the involuntary placement of a person alone in a room from which egress is involuntarily prevented.

1.58 "Service Provider" means an individual who is responsible for a client's care in a facility or agency.

1.59 "Survey" means an inspection of a facility or agency for compliance with applicable state regulations or federal conditions of participation.

1.60 "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.

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 25-3-100.5, et seq., C.R.S.

2.1.2 A facility or agency licensed by the Department shall comply with all applicable federal and state statutes and regulations including this Chapter 2. In the event of a discrepancy between the Department's regulations, the more specific standards shall apply.

2.1.3 All licenses shall expire one year from the date of issuance, unless otherwise acted upon pursuant to Part 2.11 of this Chapter.

2.2 License Required

2.2.1 No person or business entity shall establish, maintain, or operate a facility or agency that is subject to section 25-3-101, C.R.S. without first having obtained a license or, in the case of governmental facilities, a certificate of compliance from the Department.

(A) A 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 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 facility or agency shall create the impression that it is licensed at any location unless it meets the legal definition of the facility or agency that it purports to be.

2.2.2 A separate license shall be required for each physical location or campus of a facility or agency, except as otherwise specified in Chapter 3, Behavioral Health Entities, Chapter 4, General Hospitals, and Chapter 26, Home Care Agencies.

2.2.3 Each licensee 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 offers services within the same building or on the same campus as another licensee, the client space of one licensee shall be separately identifiable from the client space of any other licensee.

(1) Client space shall include, but not be limited to, client bed wings, diagnostic, procedure, and operating rooms.

2.2.4 Each 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 Initial License Application Procedure

2.3.1 Any person or business entity seeking a license to operate a 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.

2.3.2 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 (12) 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.

2.3.3 Each applicant shall provide the following information:

(A) The legal name of the applicant and all other names used by it to provide services. The applicant has a continuing duty to submit a letter of intent to the Department 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.

(B) Contact information for the applicant shall include a mailing address, telephone number, and e-mail addresses. If applicable, the facility’s or agency’s website and facsimile number are to be provided.

(C) The identity, address, and telephone number of all persons and business entities with a controlling interest in the facility or agency, 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.

(6) 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) Proof of professional liability insurance obtained and held in the name of the 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.

(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.

(F) The address(es) of the physical location where services are delivered, as well as, if different, where records are stored for Department review.

(G) A map for each floor of the applicant's buildings indicating room layout, services to be provided in each of the rooms, 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.

(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.

(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 under the license, 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, on the applicant's letterhead, if available, signed and dated, submitted with the application stating whether 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) 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) A civil judgment or criminal conviction resulting from conduct or an offense in the operation, management or ownership of a facility or agency or other entity related to substandard care or health care fraud. A guilty verdict, a plea of guilty, or a plea of nolo contendere (no contest) accepted by the court is considered a conviction.

(c) A disciplinary action imposed upon the applicant by an agency in another jurisdiction that registers or licenses facilities or agencies including but not limited to, a sanction, probation, civil penalty, or a denial, suspension, revocation, or modification of a license or registration.

(d) Limitation, denial, revocation, or suspension by any federal, state, or local authorities of any health care related license.

(e) The refusal to grant or renew a license for operation of a facility or agency, or contract for participation or certification for Medicaid, Medicare, or other public health or social services payment program.

(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) 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) 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 facility or agency or other entity related to substandard care or health care fraud.

(c) Limitation, denial, revocation, or suspension of a state license or federal certification by another jurisdiction.

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

(1) If the event is an action by a governmental agency, as described in 2.3.3(J)(2): 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.

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

2.3.5 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 Provisional License

2.4.1 Where an applicant fails to fully conform to the applicable statutes and regulations but the Department determines the 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.

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

(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.

(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.

(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.

(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 Part 2.11 of this Chapter.

2.5 Renewal License Application Procedure

2.5.1 Except for those renewal applicants described in (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 Part 2.3.3, above, 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.

2.5.2 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.

2.5.4 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.

2.5.5 [Emergency rule expired 08/08/2020]

2.5.6 [Emergency rule expired 08/08/2020]

2.6 Change of Ownership/Management

2.6.1 When a currently licensed facility or agency anticipates a change of ownership, the current licensee shall submit a letter of intent to 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 within the same time frame. The time frame for submittal of the letter of intent and the application and supporting documentation shall be at least ninety (90) calendar days before a change of ownership involving any facility or agency except those specifically enumerated in (A) below.

(A) 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.

2.6.2 The Department shall consider the following criteria in determining whether there is a change of ownership of a 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 fifty percent (50%) of the ownership interest in a 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 fifty percent (50%) 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 fifty percent (50%) 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 fifty percent (50%) 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 fifty percent (50%) 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 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 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 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.

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

(1) If the licensee 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, 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.

2.6.3 Each applicant for a change of ownership shall submit an application as prescribed in 2.3.2 through 2.3.6 of this Chapter.

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.

2.6.5 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.

2.7 Fitness Review Process

2.7.1 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

(I) Other documents deemed appropriate by the Department.

2.7.2 The Department may conduct a fitness review of an existing owner of a licensed facility or agency 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.

2.8 Issuance of License

2.8.1 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 certifying that the building or structure of the 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 services on their own premises.

2.8.2 Each license shall contain the name of the facility or agency, license category, term of license, holder of license, and the licensed capacity.

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

(B) Except as specified below, no licensee shall admit a client if such admission would exceed the licensed capacity.

(1) If the facility or agency has the physical space and staff capacity to meet the needs of one additional client, the licensee may request from the Department a thirty (30) day exception from the licensed capacity if the client requires immediate admission and the Department determines that there is no convenient appropriate alternative source of admission.

(2) In the event of an emergency involving multiple ill or injured persons, hospitals and other licensees providing essential emergent or continued care services may admit clients that exceed their maximum bed capacity. The length of stay may be for up to thirty (30) consecutive days. One or more extensions of up to thirty (30) consecutive days may be requested based upon extenuating circumstances. Any 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 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.

2.8.3 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.

(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 Continuing Obligations of Licensee

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

2.9.2 The license shall be displayed in a conspicuous place readily visible to clients who enter at the address that appears on the license.

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

2.9.5 Where a facility or agency 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.

2.9.6 Each licensee shall submit to the Department a letter of intent of any change in the information required by Part 2.3.3 of this Chapter from what was contained in the last submitted license application.

(A) Changes to the operation of the facility or agency shall not be implemented without prior approval from the Department. A licensee shall, at least thirty (30) calendar days in advance, submit a letter of intent to the Department regarding any of the following proposed changes.

(1) Increase in licensed capacity.

(a) If a licensee requests an increase in 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 capacity if it determines that the increase poses a potential risk to the health, safety, or welfare of the licensee's clients based upon the licensee's compliance history, or because the 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.

(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.

(e) For behavioral health entities, the addition or removal of an endorsement, a service, or a physical location.

(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.

2.10 Department Oversight

2.10.1 The Department and any duly authorized representatives thereof shall have the right to enter upon and into the premises of any licensee or applicant in order to determine the state of compliance with the statutes and regulations, and shall initially identify themselves to the person in charge of the 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.

2.10.2 Licensure Surveys and Tiered Inspections

For each 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.

(A) In order to be eligible, the 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 clients of the 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 2.10.2 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 licensee meets the requirements for participation in the Medicare and Medicaid programs.

2.10.3 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's or licensee's 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.

2.10.4 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 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 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 included, 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 reoccur, and

(c) 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.

(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 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 time frame 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:

(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.

2.11 Enforcement and Disciplinary Sanctions

2.11.1 License Denials

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

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

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

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

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

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

(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 client(s) served,

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

(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 client(s) served.

(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.

(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

(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:

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

(2) Makes a false statement of material fact about 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,

(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,

(4) Falsely advertises or in any way misrepresents the licensee's ability to provide services for the clients served based on its license type or status,

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

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

(7) Falsifies records or documents.

(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.

(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

(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.

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

(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.

(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.

2.12 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	$376.22
Renewal license	$376.22
Conditional license	$1,567.57
First provisional license	$1,045.05
Second provisional license	$1,045.05
Change of ownership	$376.22
Change in licensed capacity	$376.22
Change of name	$78.38
Renewal application late fee	See Part 2.5.2, above.

2.13 Performance Incentive

2.13.1 Licensee shall be eligible for a performance incentive if the Department's on-site re-licensure inspection demonstrates that:

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

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

(C) The Department has found no documented actual or potential harm to clients; and

(D) If significant deficiencies are found that do not negatively affect the life, safety, or health of 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 The incentive payment shall be calculated at ten percent (10%) of the licensee's renewal license fee and shall apply when:

(A) The inspection is completed with the full and timely cooperation of the licensee,

(B) Inspection findings do not document harm or potential harm to clients, and

(C) Correction of the deficient practice is verified by the Department on or prior to the respective due dates.

(D) The incentive payment shall be paid to the licensee within sixty (60) days following the acceptance of the validation of correction of all cited deficiencies, or within sixty (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 thirty (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.

2.14.3 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.

2.14.4 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) Within 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.

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, Freestanding Emergency Departments, and Hospital Units: Guidelines for Design and Construction of Hospitals;

(B) for outpatient facilities, including but not limited to Ambulatory Surgery Centers, Behavioral Health Entities, Community Clinics, Community Clinics providing Emergency Services, 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, Behavioral Health Entities, 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 maintain the facility to 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 1.46 of these rules.

(C) A renovation of a licensed facility or agency, as defined at Part 1.52 of these rules.

(D) A guideline compliance review is not needed for minor alterations, as defined at Part 1.43 of these rules.

3.3.2 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 are undertaken.

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 4. QUALITY MANAGEMENT PROGRAM, OCCURRENCE REPORTING, PALLIATIVE CARE

4.1 Quality Management Program, Occurrence Reporting, Palliative Care

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.

4.1.3 If a 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.

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

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

4.2 Occurrence Reporting

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.

4.2.2 The following occurrences shall be reported to the Department within one business day after the occurrence or when the licensee becomes aware of the occurrence, in the format required by the Department:

(A) Any occurrence that results in the death of a client of the 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;

(B) Any occurrence that results in any of the following serious injuries to a client:

(1) Brain or spinal cord injuries;

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

(3) Second or third degree burns involving twenty percent (20%) or more of the body surface area of an adult client or fifteen percent (15%) or more of the body surface area of a child client;

(C) Any time that a client of the facility or agency cannot be located following a search of the facility or agency, its grounds, and the area surrounding facility or agency, and there are circumstances that place the client's health, safety, or welfare at risk or, regardless of whether such circumstances exist, the client has been missing for eight hours;

(D) Any occurrence involving physical, sexual, or verbal abuse of a 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 client, an employee of the licensee or a visitor to the facility or agency;

(E) Any occurrence involving neglect of a client, as described in section 26-3.1-101(2.3),(7)(b) C.R.S.

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

(G) Any occurrence in which drugs intended for use by 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

(H) Any occurrence involving the malfunction or intentional or accidental misuse of client equipment that occurs during treatment or diagnosis of a client and that significantly adversely affects or if not averted would have significantly adversely affected a client of the facility or agency.

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.

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

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

4.2.6 Every licensee shall have a policy for requiring its employees to report occurrences to it.

4.2.7 No licensee, nor any employee, officer, or any other person with controlling interest in the facility or agency, shall discharge, 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, 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.

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

(A) The report shall include:

(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.

(B) A summary report shall not identify a client or health care professional.

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

(d) Prior to releasing a summary report that identifies a facility or agency, the Department shall notify the licensee and provide it with a copy of the summary report. The licensee shall be allowed seven (7) days to review, comment, and verify the report. If immediate release of information is necessary and the Department cannot provide at least prior oral notice to the licensee, the Department shall provide notice as soon as reasonably possible with an explanation of why it could not provide prior notice.

4.2.9 Nothing in this Part 4 shall be construed to limit or modify any statutory or common law right, privilege, confidentiality, or immunity.

4.2.10 Nothing in this Part 4 shall affect a person's access to 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 client or the client's designated representative.

4.3 Palliative Care Standards

4.3.1 If palliative care is provided within or by a facility or agency, the licensee shall have written policies and procedures for the comprehensive delivery of these services. For each client receiving palliative care, there shall be documentation in the plan of care regarding evaluation of the 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:

(A) Assessment and management of the client's pain and other distressing symptoms,

(B) Goals of care and advance care planning,

(C) Provision of, or access to, services to meet the psychosocial and spiritual needs of the client and the individuals who are identified as the client's personal support system,

(D) Provision of, or access to, a support system to help the individuals who are identified as the client's personal support system cope during the client's illness, and

(E) As indicated, the need for bereavement support for individuals who are identified as the client's personal support system by providing resources or referrals.

PART 5. WAIVER OF REGULATIONS FOR FACILITIES AND AGENCIES

5.1 Statutory Authority, Applicability, and Scope

5.1.1 This Part 5 is promulgated by the State Board of Health pursuant to 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 25-1.5-103, C.R.S.

5.1.2 This Part 5 applies to facilities and agencies licensed by the Department and establishes procedures with respect to waiver of regulations relating to state licensing and federal certification of facilities and agencies. For waivers of the Facility Guidelines Institute (FGI) provisions, see Part 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.

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.

5.1.5 It is the policy of the State Board of Health and the Department that every licensed 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. Absent the existence of a current waiver issued pursuant to this Part, 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).”

5.2 Application Procedure

5.2.1 Waiver applications shall be submitted to the Department on the form and in the manner required by the Department.

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

(B) The waiver application shall provide the Department the information and documentation required to validate the conditions under which the waiver is being sought.

(C) The waiver application must be signed by an authorized representative of the facility or agency, who shall be the primary contact person and the individual responsible for ensuring that accurate and complete information is provided to the Department.

5.3 Notice and Opportunity to Comment

5.3.1 No later than the date of submitting the waiver application to the Department, written notice of the application shall be posted for thirty (30) days at all public entrances to the facility or agency, as well as in at least one area commonly used by clients, such as a waiting room, lounge, or dining room. If services are not provided on the premises, such as home care agencies and hospices, written notice shall instead be provided directly to 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 to clients upon request.

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:

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 80246-1530

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, 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.

5.4 Department Action Regarding Waiver Application

5.4.1 In making its determination, the Department may consider any information it deems relevant, including but not limited to, occurrence and complaint investigation reports, licensure or certification survey reports, and findings related to the facility or agency and/or the operator or owner thereof.

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.

5.4.3 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.

5.5 Termination, Expiration, and Revocation of Waiver

5.5.1 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) 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.

(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.

5.5.2 Change of Ownership. A waiver shall automatically terminate upon a change of ownership of the facility or agency, as defined in Part 2.6. 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.

5.5.3 Expiration

(A) Except as otherwise provided in this Part 5, a waiver shall not be granted for a term that exceeds the current license term.

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.

5.5.4 Revocation

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

(1) The waiver's continuation jeopardizes the health, safety, or welfare of clients of the facility or agency;

(2) The waiver application contained false or misleading information;

(3) The terms and conditions of the waiver have not been complied with;

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

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

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

5.6 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.

PART 6. ACCESS TO CLIENT RECORDS

6.1 Facility or Agency Records

6.1.1 Except as hereinafter provided, client records in the custody of a facility or agency required to be certified under section 25-1.5-103 (1)(II) or licensed under Part 1 of Article 3 of Title 25 of the C.R.S. shall be available to a client or their designated representative through the service provider or 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.

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.

6.1.3 A client, whether current or discharged, of a facility or agency may inspect their own record within a reasonable time.

(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.

(1) if the facility or agency is unable to make the records available for inspection within three (3) business days, the facility or agency will provide a written status update to the client explaining why the records are not available and an estimated date as to when the records will be made available.

(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.

(1) if the facility or agency is unable to make the records available for inspection within ten (10) business days, the facility or agency will provide a written status update to the client explaining why the records are not available and an estimated date as to when the records will be made available.

6.1.4 The client or designated representative shall sign and date the request. The service provider or their designated representative shall acknowledge in writing the client's or representative's request. After inspection, the client or designated representative shall sign and date the record to acknowledge inspection.

6.1.5 The 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.

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.

6.2 Nothing in this 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.

6.3 If any changes/corrections, deletions, or other modifications are made to any portion of a client record, the person who is making the changes must note in the record the date, time, nature, reason, correction, deletion, or other modification, and their name, to the change, correction, deletion, or other modification.

6.4 Effect of this Part 6 on Similar Rights of a Client

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

6.4.2 Nothing in this Part 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.

6.4.3 Nothing in this Part 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.

6.4.4 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 7. CLIENT RIGHTS

7.1 Client Rights Policy

7.1.1 The facility or agency shall develop and implement a policy regarding client rights. The policy shall ensure that each client or, where appropriate, the client's designated representative, has the right to:

(A) Participate in all decisions involving the client's care or treatment.

(B) Be informed about whether the facility or agency is participating in teaching programs, and to provide informed consent prior to being included in any clinical trials relating to the client's care.

(C) Refuse any drug, test, procedure, or treatment and to be informed of risks and benefits of this action.

(D) 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) Be informed of, at a minimum, 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.

(F) Receive, upon request:

(1) Prior to initiation of non-emergent care or treatment, the estimated average charge to the client. This information shall be presented to the client in a manner that is consistent with all state and federal laws and regulations.

(2) The facility's or agency's general billing procedures.

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

(G) Give informed consent for all treatment and procedures. It is the responsibility of the licensed independent practitioner and other service providers to obtain informed consent for procedures that they provide to the client.

(H) Register complaints with the facility or agency and the Department and to be informed of the procedures for registering complaints including contact information.

(I) Be free of abuse and neglect.

(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) Be free from the improper application of restraints or seclusion. Restraints or seclusion shall be used only in a manner consistent with Part 8 of these rules.

(K) 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) Care delivered by the facility or agency in accordance with the needs of the client.

(M) Confidentiality of all client records.

(N) Receive care in a safe setting.

(O) Disclosure as to whether referrals to other providers are to entities in which the facility or agency has a financial interest.

(P) Formulate advance directives and have the facility or agency comply with such directives, as applicable, and in compliance with applicable state statute.

(Q) Request that an in-network healthcare provider provide services at an in-network facility or agency if available.

7.1.2 The facility or agency shall disclose the policy regarding client rights to the client or the client's designated representative prior to treatment or upon admission, where possible. For any services requiring multiple client encounters, disclosure provided at the beginning of such care or treatment course shall meet the intent of the regulations.

7.1.3 Pursuant to Section 25-3-121, C.R.S., facilities and agencies shall provide the disclosure contained in Appendix A, at a minimum, to all clients whose comprehensive major medical health plans are regulated by the Colorado Division of Insurance, about the potential effects of receiving emergency or nonemergency services from an out-of-network facility or agency or an out-of-network provider who provides services at an in-network facility or agency.

Required disclosures by carriers and healthcare providers may be found in rules promulgated by the Department of Regulatory Agencies, Division of Insurance and Division of Occupations and Professions.

(A) The facility or agency shall provide the disclosure contained in Appendix A on the following occasions:

(1) For emergency services: After performing an appropriate medical screening examination and determining that a client does not have an emergency medical condition or after treatment has been provided to stabilize an emergency medical condition. The disclosure shall be provided to the client or their designated representative for signature prior to discharge or at the time of admission for continuing nonemergency services;

(2) For nonemergency services: prior to the provision of any services, the disclosure shall be provided to the client or their designated representative for signature.

(B) The facility or agency shall provide the disclosure contained in Appendix A minus the signature block on the following occasions:

(1) With billing statements and billing notices issued by the facility or agency; and

(2) With other forms or communications related to the services being provided pursuant to insurance coverage.

7.1.4 Each facility or agency shall post a clear and unambiguous notice in a public location in the facility or agency specifying that complaints may be registered with the facility or agency, the Department, and with the appropriate oversight board at the Department of Regulatory Agencies (DORA). Upon request, the facility or agency shall provide the client and any interested person with contact information for registering complaints.

7.2 Client Grievance Mechanism

7.2.1 All facilities or agencies that have a client capacity of fifty-one (51) 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.

7.2.2 **Client Grievance Plan and Procedure**

(A) The facility or agency shall develop and implement a written client grievance mechanism plan that shall include, but not be limited, to the following:

(1) A client care advocate that serves as a liaison between the client and the facility or agency. The plan shall describe:

(a) The qualifications, job description, and level of decision-making authority of the client care advocate.

(b) How each client will be made aware of the client grievance mechanism and how the 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.

(2) The facility or agency shall implement a grievance procedure with, at minimum, the following components:

(a) The ability for clients to submit grievances, either orally or in writing, to a facility or agency staff member. If the grievance is submitted to a staff member other than the client care advocate, the staff member shall submit the grievance to the client care advocate by the next working day.

(b) Prior to initiating an investigation, the client care advocate shall contact the client within three (3) working days of receipt of the grievance to acknowledge receipt of such grievance.

(c) The client care advocate shall investigate the grievance and respond to the client in writing within fifteen (15) business days of 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 thirty (30) calendar days following the client care advocate's receipt of the grievance.

(3) A means to inform the client regarding how to lodge a grievance and that the facility or agency encourages clients to speak out and to present grievances without fear of retribution.

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

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

PART 8. PROTECTION OF CLIENTS FROM INVOLUNTARY RESTRAINT OR SECLUSION

8.1 Statutory Authority and Applicability.

8.1.1 The statutory authority for the promulgation of these rules is set forth pursuant to section 26-20-101, et. seq., C.R.S.

8.1.2 This Part applies to the use of involuntary restraint and seclusion in all licensed health care facilities, except for:

(A) Hospitals as provided for in Part 8.2.1(A)(1); and

(B) Medicare/Medicaid certified nursing homes as provided for in Part 8.2.1(A)(2).

8.1.3 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.

8.2 Exemptions

8.2.1 "Restraint" does not include:

(A) The use of any form of restraint in a licensed or certified hospital when such use:

(1) Is in the context of providing medical or dental services that are provided with the consent of the client or the client's guardian. For the purposes of this Part (A)(1) 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

(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.

(C) The use of protective devices or adaptive devices for providing physical support, prevention of injury, or voluntary or life-saving medical procedures.

(D) The holding of an individual for less than five (5) minutes by a staff person for protection of the individual or other persons.

(E) Placement of a client in their room for the night in an inpatient or residential setting.

8.2.2 This Part 8 does not apply to a facility or agency 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.

8.2.3 A facility, as defined in 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 27-65-105 through 27-65-107, C.R.S., to any person with a mental illness, as defined in section 27-65-102(14), C.R.S., may use seclusion to restrain a person with a mental illness when the seclusion is necessary to eliminate a continuous and serious disruption of the treatment environment.

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.

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.

8.3 Basis for Use of Restraint or Seclusion

8.3.1 A facility may only use restraint or seclusion:

(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

(1) After the failure of less restrictive alternatives; or

(2) After a determination that such alternatives would be inappropriate or ineffective under the circumstances.

(B) A facility or agency that uses restraint or seclusion pursuant to the provisions of (A), above, shall use such restraint or seclusion:

(1) Only for the purpose of preventing the continuation or renewal of an emergency;

(2) Only for the period of time necessary to accomplish its purpose; and

(3) In the case of physical restraint, using no more force than is necessary to limit the 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.

8.4 Duties Relating to Use of Restraint or Seclusion

8.4.1 A facility or agency that uses restraint shall ensure that:

(A) At least every fifteen (15) minutes, staff shall monitor any client held in mechanical restraints to assure that the client is properly positioned, that the client's blood circulation is not restricted, that the client's airway is not obstructed, and that the client's other physical needs are met;

(B) No physical or mechanical restraint of a client shall place excess pressure on the chest or back of that client or inhibit or impede the client's ability to breathe;

(C) During physical restraint of a client, an agent or employee of the facility or agency shall check to ensure that the breathing of the client in such physical restraint is not compromised;

(D) A chemical restraint shall be given only on the order of a physician who has determined, either while present during the course of the emergency justifying the use of the chemical restraint or after telephone consultation with a registered nurse, certified physician assistant, or other authorized staff person who is present at the time and site of the emergency and who has participated in the evaluation of the client, that such form of restraint is the least restrictive, most appropriate alternative available;

(E) An order for a chemical restraint, along with the reasons for its issuance, shall be recorded in writing at the time of its issuance;

(F) An order for a chemical restraint shall be signed at the time of its issuance by such physician, if present at the time of the emergency;

(G) An order for a chemical restraint, if authorized by telephone, shall be transcribed and signed at the time of its issuance by an individual with the authority to accept telephone medication orders who is present at the time of the emergency; and

(H) Staff trained in the administration of medication shall make notations in the record of the client as to the effect of the chemical restraint and the client's response to the chemical restraint.

8.4.2 For clients in mechanical restraints, staff shall provide relief periods, except when the client is sleeping, of at least ten (10) minutes as often as every two (2) 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 client and provide movement of limbs, as necessary. In addition, during such relief periods, staff shall provide assistance for use of appropriate toileting methods, as necessary. The 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.

8.4.3 Relief periods from seclusion shall be provided for reasonable access to toilet facilities.

8.4.4 A client in physical restraint shall be released from such restraint within fifteen (15) minutes after the initiation of physical restraint, except when precluded for safety reasons.

8.5 Staff Training Concerning the Use of Restraint and Seclusion

8.5.1 All facilities and agencies shall ensure that all staff involved in utilizing restraint or seclusion are trained in the appropriate use of restraint and seclusion.

(A) All facilities and agencies shall ensure that staff are trained to explain, where possible, the use of restraint or seclusion to the client who is to be restrained or secluded and to the client's designated representative, if appropriate.

8.6 Documentation Requirements Related to the Use of Restraint and Seclusion

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:

(A) Type of restraint and length of time in the restraint or seclusion;

(B) Identification of staff involved in the initiation and application of the restraint or seclusion;

(C) Care provided while in the restraint or seclusion, including monitoring conducted and relief periods granted; and

(D) The effect of the restraint or seclusion on the client.

8.7 Review Process

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

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.

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 12-280-135, 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 10. HEALTHCARE-ASSOCIATED INFECTION REPORTING

10.1 Statutory Authority and Applicability

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.

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.

10.2 Enforcement Activities

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.

PART 11. INFLUENZA IMMUNIZATION OF EMPLOYEES AND DIRECT CONTRATORS

11.1 Statutory Authority and Applicability

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.

11.1.2 The requirements of this Part 11 shall be overseen and enforced by the Department in a manner consistent with Parts 2.10 and 2.11 of this Chapter.

11.2 General Provisions

11.2.1 Licensees and facility or agency employees and direct contractors have a shared responsibility to prevent the spread of infection and avoid causing harm to 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) [Emergency rule expired 12/28/2021}

(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 FDA.

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.

(A) All other facilities and agencies shall ensure that employees and direct contractors are offered the opportunity to receive an annual influenza immunization.

11.3 Requirements for Hospitals, Hospital Units, Ambulatory Surgical Centers, and Nursing Facilities that Fail to Meet Vaccination Rate

11.3.1 Each licensed hospital, hospital unit, ambulatory surgical center, and nursing facility that fails to meet the ninety percent (90%) vaccination rate for any given influenza season shall 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:

(A) Ensuring that the facility or agency has either of the following for employees and direct contractors:

(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 FDA.

(B) Ensuring that 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 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 employees and direct contractors and

(2) Inform other 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 employees and direct contractors;

(b) The licensee requires each employee and direct contractor who has not been immunized to wear a mask during influenza season when in direct contact with clients and in common areas specified by the licensee; and

(c) The licensee has masks available for those who have not been immunized.

11.4 Requirements for All Other Licensed Facilities and Agencies that Fail to Meet Vaccination Rate

11.4.1 Each licensee, other than those identified in Part 11.3, above, that fails to meet the ninety percent (90%) vaccination rate for any given influenza season shall perform an assessment of the facility or agency to assist in the development of a written policy regarding influenza transmission from its employees and direct contractors to clients. The assessment shall, at a minimum, consider the following criteria:

(A) The number of employees and direct contractors at the facility or agency;

(B) The number of clients served by the facility or agency;

(C) Whether the facility or agency has an ongoing wellness program that offers annual influenza vaccinations;

(D) Whether influenza transmission from employees or direct contractors is addressed in the 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; and

(F) What type of educational material is utilized by the facility or agency to promote influenza immunization.

11.4.2 Each licensee that fails to meet the ninety percent (90%) vaccination rate, other than those identified in 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 written policy, if none exists, that is based on that facility's or agency's attributes and resources. The policy shall, at a minimum, address the following criteria:

(A) Maintaining records of employees' and direct contractors' proof of immunization, or medical exemption from immunization; and

(B) 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.

Part 12. COVID-19 IMMUNIZATION OF EMPLOYEES, DIRECT CONTRACTORS, AND SUPPORT STAFF [Emergency rule expired 07/14/2022]

Appendix A: Surprise Billing Disclosure

Surprise Billing -- Know Your Rights

What is surprise billing?

If you are seen by a provider or use services in a facility or agency that is not in your health insurance plan's provider network, referred to as "out-of-network," you may receive a bill for additional costs associated with that care. Out-of-network facilities or agencies often bill you the difference between what your insurer decides is the eligible charge and what the out-of-network provider bills as the total charge. Under Colorado law this is defined as balanced billing and is commonly called surprise billing.

On Jan. 1, 2020, a new state law went into effect to protect you from surprise billing. These protections apply when:

- You receive covered emergency services, other than ambulance services, from an out-of-network provider in Colorado.

- You unintentionally receive covered services from an out-of-network provider at an in-network facility in Colorado.

This law only applies if you have a "CO-DOI" on your health insurance ID card and you are receiving care and services provided at a regulated facility in Colorado.

When you cannot be surprise billed:

Emergency Services
If you are receiving emergency services, you can only be billed for your plan's in-network cost-sharing amounts, which are copayments, deductibles, and/or coinsurance. You cannot be billed for anything else. This applies only to services related to and billed as an "emergency service."

Non-Emergency Services at an In-Network Facility by an Out-of-Network Provider
Facility or agency staff must tell you if you are at an out-of-network location or if they are using out-of-network providers, when known. Staff must also tell you what types of services you will be using that might be provided by an out-of-network provider.

You have the right to request that in-network providers perform all covered medical services. However, you may have to receive medical services from an out-of-network provider if an in-network provider is unavailable. If your insurer covers the service, you can only be billed for your in-network cost-sharing amount, which are copayments, deductibles, and/or coinsurance.

Additional Protections

- Your insurer will pay out-of-network providers and facilities directly.

- Your insurer must count any amount you pay for emergency services or certain out-of-network services toward your in-network deductible and out-of-pocket limit.

- The provider, facility, hospital, or agency must refund any amount you overpay within 60 days of being notified.

- No one, including a provider, hospital, or insurer, can ask you to limit or give up these rights.

If you receive services from an out-of-network provider or facility or agency in any other situation, you may still be surprise billed, or you may be responsible for the entire bill. If you intentionally receive non-emergency services from an out-of-network provider or facility, you may also be surprise billed.

If you think you have received a bill for amounts other than your copayments, deductible, and/or coinsurance, please contact the facility's or agency's billing department or the Colorado Division of Insurance at 303-894-7499 or 1-800-930-3745.

_____DATE _____
My signature acknowledges receiving this notice and does not waive my rights under the law.

Editor's Notes

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

History

Rule 2.20 eff. 05/21/2007.

Rule 2.20 eff. 08/30/2007.

Rule 5.2 eff. 03/01/2008.

Parts 1, 2, rules 3.2.1, 3.2.5-3.2.7, 3.2.9, 4.101, 4.102, 4.103, 4.104, 4.105, 4.106, 5.2, 5.2.1, 5.4.1-5.4.3, Parts 6-7; Part 9 eff. 04/30/2010. Rule 5.4.4 repealed eff. 04/30/2010.

Rules 1.100-1.101, 1.200 emer. rules eff. 09/15/2010.

Rules 1.100-1.101, 1.200, 2.105(A), 2.3.5(A)(1), 2.3.5(C)(1), 6.104 (1)(b), 6.104 (1)(f)-(f)(iii), 6.201(2) eff. 12/30/2010.

Part 7 eff. 04/30/2011.

Rules 2.3.6, 2.10.5(B)(2), 2.13 eff. 09/30/2011.

Part 10 eff. 03/30/2012.

Rules 2.2.7-2.2.15, 2.7, 2.8.2, 2.10.3-2.10.6, 2.11.2-2.11.4, 4.105(1)(c) eff. 03/17/2013.

Part 1, rules 2.3.1, 2.3.5, 2.4.2, 2.9.1(A), 2.9.6, 2.10.6(A)(1)(b), 3.2.1(5), 4.101(3), 4.103-4.106 eff. 08/14/2013.

Rules 2.2.12-2.2.16, 2.14, 3.3-3.3.1, 5.2.3.4, 5.2.5-5.3, 5.4.2 eff. 03/02/2014.

Rules 3.1, 5.2.3.4 eff. 12/15/2014.

Rules 4.103(4)(b), 7.200-7.203, 8.102(1), 8.103(2)-(4), 10.5(J) eff. 06/01/2016.

Rule 2.13 eff. 07/01/2019.

Rules 1.16, 1.22, 1.23, 1.34, 1.45, 7.1.1(Q), 7.1.3, Appendix A emer. rules eff. 01/01/2020.

Entire rule eff. 01/14/2020.

Rules 2.5.5, 2.5.6 emer. rules eff. 04/10/2020; expired 08/08/2020.

Rules 1.16, 1.22, 1.23, 1.34, 1.45, 7.1.1(Q), 7.1.3, Appendix A eff. 04/14/2020.

Rule 2.12 eff. 07/01/2020.

Rules 2.6.2, 7.2.1, 9.2.1(A) eff. 02/14/2021.

Rules 2.1.1, 2.2.2, 2.3.3(F), 2.9.6(A)(4), 3.2.3, 3.2.4, 3.3.1, 9.2.2, 9.2.3 eff. 06/14/2021.

Rules 11.2.3(C)(1), Part 12 emer. rules eff. 08/30/2021. Rule 11.2.3(C)(1) expired 12/28/2021.

Part 12 emer. rule eff. 12/15/2021.

Part 12 emer. rule eff. 03/16/2022; expired 07/14/2022.