COLORADO
Department of Public Health & Environment

To: Members of the State Board of Health

From: Elaine McManis, Deputy Director, Health Facilities & Emergency Medical Services Division

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

Date: Dec. 16, 2020

Subject: Rulemaking Hearing concerning 6 CCR 1011-1, Chapter 2 – General Licensure Standards

---

On November 20, 2019, the Board adopted updates to 6 CCR 1011-1, Chapter 2, General Licensure Standards. The updates presented to the Board at that time were developed over a year-long stakeholder process, started in response to issues identified through the regular rule reviews required by Section 24-4-103.3, C.R.S., to ensure the rules continue to be efficient, effective, and essential.

Post-adoption, the Office of Legislative Legal Services (OLLS), reviewed the rules pursuant to Section 24-4-103(8), C.R.S., identifying three minor changes that are necessary to ensure these regulations are consistent with Colorado State Law: 1. Eliminating the treatment of a non-profit to for-profit business structure (or vice versa) as a change of ownership, 2. Increasing specificity regarding the number of beds required related to the client grievance mechanisms, and 3. Updating a statutory reference in response to the re-numbering of Title 12.

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

Basis and Purpose.

Chapter 2 of 6 CCR 1011-1 contains the general licensing requirements for all facilities and agencies licensed by the Department pursuant to Section 25-3-101, C.R.S. The proposed changes to Chapter 2 were brought about by a review of the chapter by the Office of Legislative Legal Services (OLLS), as mandated by statute at Section 24-4-103(8), C.R.S., following the Board's adoption of revisions in November 2020. Three areas were identified by OLLS as needing revision to ensure these regulations are consistent with current state law. These changes are as follows:

1) Part 2.6.2(E) – Change of Ownership/Management for Non-Profit Corporations

In the most recent revisions, language was added to Chapter 2 to specify that the conversion of a non-profit to a for-profit corporation, or vice versa, is an event that triggers a change of ownership, requiring a new license be issued. However, Section 25-3-102(1)(e)(IV), C.R.S. states that a conversion of a health facility's legal structure does not constitute a change of ownership unless there is also a transfer of at least 50% ownership to one or more new owners. The proposed revisions remove the mere conversion of legal structure from the list of circumstances that constitute a change of ownership for a non-profit corporation.

2) Part 7.2.1 – Client Grievance Mechanism

Section 25-1-121, C.R.S. requires that facilities and agencies with greater than 50 beds/clients establish a grievance mechanism. The current Chapter 2 language imposes this requirement on facilities and agencies with 50 or more beds/clients, instead of greater than 50. The proposed revision increases the bed/client requirement to 51 or more to be consistent with statute.

3) Part 9.2.1(A) – Donation of Unused Medications, Medical Devices, and Medical Supplies

Subsequent to the revised regulations becoming effective on Jan. 14, 2020, the legislature reorganized Title 12, Professions and Occupations, of the Colorado Revised Statutes. Because of this, the statutory reference in this part is out-of-date and inaccurate. The proposed revision updates this reference to the accurate statutory citation.

Specific Statutory Authority.
Statutes that require or authorize rulemaking:

Section 25-1-108, C.R.S.
Section 25-1.5-101, C.R.S.

Section 25-1.5-103, C.R.S.
Section 25-1.5-108, C.R.S.
Section 25-3-101, C.R.S. *et seq.*
Section 25-27-101, C.R.S., *et seq.*
Section 25-27.5-101, C.R.S. *et seq.*

Other relevant statutes:
Section 24-4-103(8), C.R.S.
Section 25-1-121, C.R.S.

Is this rulemaking due to a change in state statute?

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

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

_____ Yes ___ URL
___X___ No

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

_____
___X___ No

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

___X__ No.

- The proposed rule does not require a local government to perform or increase a specific activity for which the local government will not be reimbursed;
- The proposed rule requires a local government to perform or increase a specific activity because the local government has opted to perform an activity, or;
- The proposed rule reduces or eliminates a state mandate on local government.

REGULATORY ANALYSIS
For Amendments to
6 CCR 1011-1, Standards for Hospitals and Health Facilities
Chapter 2 – General Licensure Standards

1. A description of the classes of persons affected by the proposed rule, including the classes that will bear the costs and the classes that will benefit from the proposed rule.

Group of persons/entities Affected by the Proposed Rule	Size of the Group	Relationship to the Proposed Rule Select category: C/S/B
All facilities or agencies licensed by the Department: hospitals, nursing care facilities, acute treatment units, home care agencies, dialysis treatment clinics, ambulatory surgical centers, hospice, community mental health centers, community clinics, convalescent centers, assisted living residences, birth centers, acute treatment units, home care placement agencies, and facilities for persons with intellectual and developmental disabilities.	3,684	C
Clients receiving services at licensed facilities and agencies.	Unknown	B

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

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

More than one category may be appropriate for some stakeholders.

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

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

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

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

The proposed amendments are cost neutral.

Anticipated CDPHE Revenues:

The proposed amendments are revenue neutral.

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

N/A

Anticipated Revenues for another state agency:

N/A

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

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

___ Comply with a statutory mandate to promulgate rules.
_X_ Comply with federal or state statutory mandates, federal or state regulations, and department funding obligations.
__ Maintain alignment with other states or national standards.
__ Implement a Regulatory Efficiency Review (rule review) result
___ Improve public and environmental health practice.
_X_ Implement stakeholder feedback.
___ Advance the following CDPHE Strategic Plan priorities (select all that apply):

Goal 1, Implement public health and environmental priorities
Goal 2, Increase Efficiency, Effectiveness and Elegance
Goal 3, Improve Employee Engagement
Goal 4, Promote health equity and environmental justice
Goal 5, Prepare and respond to emerging issues, and
Comply with statutory mandates and funding obligations

Strategies to support these goals:
___ Substance Abuse (Goal 1)
___ Mental Health (Goal 1, 2, 3 and 4)
___ Obesity (Goal 1)
___ Immunization (Goal 1)
___ Air Quality (Goal 1)
___ Water Quality (Goal 1)
___ Data collection and dissemination (Goal 1, 2, 3, 4, 5)
___ Implement quality improvement/a quality improvement project (Goal 1, 2, 3, 5)
___ Employee Engagement (Goal 1, 2, 3)
___ Decisions incorporate health equity and environmental justice (Goal 1, 3, 4)
___ Detect, prepare and respond to emerging issues (Goal 1, 2, 3, 4, 5)

__x_ Advance CDPHE Division-level strategic priorities.

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

Inaction has neither monetary cost nor benefit; however, inaction results in non-compliance with statute, and potential to invalidate all licensing requirements within Chapter 2.

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

The proposed changes are neither costly nor intrusive, and, as the purpose is compliance with statute, no alternative method was considered.

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

No alternatives to this rulemaking were considered. Failure to implement requirements that are consistent with Colorado state law, as identified by OLLS, may result in the rule being negated or invalidated by the legislature.

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

The proposed change did not require a data based evaluation or analysis.

STAKEHOLDER ENGAGEMENT
for Amendments to
6 CCR 1011-1, Standards for Hospitals and Health Facilities
Chapter 2 – General Licensure Standards

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

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

The proposed revisions correct technical deficiencies to ensure compliance with the Colorado Revised Statutes. Due to the minor nature of the changes, no stakeholder processes or stakeholder meetings were conducted prior to the request for rulemaking. Stakeholders will be notified of the proposed changes prior to the rulemaking hearing, if scheduled.

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

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

__X__ Yes.

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

No major factual or policy issues were encountered. The proposed changes are minor and are proposed to ensure the regulations are consistent with Colorado state law.

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

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

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

Select all that apply.

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

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

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

6 CCR 1011-1 Chapter 2

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

Adopted by the Board of Health on _____, 2020. Effective, _____, 2021.

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

Division Director
Colorado Department of Public Health and Environment
Health Facilities and Emergency Medical Services Division
4300 Cherry Creek Drive South
Denver, Colorado 80246-1530
Main switchboard: (303) 692-2800

Pursuant to section 24-4-103(12.5), C.R.S., the Health Facilities and Emergency Medical Services Division of the Colorado Department of Public Health and Environment maintains copies of the incorporated materials for public inspection during regular business hours. The requirements in Part 3.2.3 do not include any amendments, editions, or changes published after November 1, 2019. Interested persons may obtain certified copies of any non-copyrighted material from the Department at cost upon request. Information regarding how incorporated material may be obtained or examined is available by contacting:

Division Director
Colorado Department of Public Health and Environment
Health Facilities and Emergency Medical Services Division
4300 Cherry Creek Drive South
Denver, Colorado 80246-1530
Main switchboard: (303) 692-2800

Additionally, materials incorporated by reference have been submitted to the state publications depository and distribution center, and are available for interlibrary loans and through the state librarian.

INDEX

****

PART 2. LICENSURE PROCESS

****

2.6 Change of Ownership/Management

****

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.

~~(2) The conversion of a non-profit to a for-profit organization is considered a change of ownership.~~

~~(3) The conversion of a for-profit organization to a non-profit is considered a change 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.

****

PART 7. CLIENT RIGHTS

****

7.2 Client Grievance Mechanism

7.2.1 All facilities or agencies that have a client capacity of fifty-ONE (5~~0~~1) 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.

****

PART 9. MEDICATIONS, MEDICAL DEVICES, AND MEDICAL SUPPLIES

****

9.2 Donation of Unused Medications, Medical Devices, and Medical Supplies

9.2.1 A facility or agency may accept unused medications or medical supplies, and used or unused medical devices from a client or a client's personal representative.

(A) In accordance with ~~section 12-42.5-133, C.R.S.,~~ SECTION 12-280-135, C.R.S., the facility or agency may choose to either:

****