COLORADO
Department of Public Health & Environment

To: Members of the State Board of Health

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

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

Date: April 21, 2021

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

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The Department will begin licensing Behavioral Health Entities (BHEs) and Freestanding Emergency Departments (FSEDs) on July 1, 2021, per House Bill (HB) 19-1237 and HB 19-1010, respectively. The two new rule chapters are being submitted to the Board of Health concurrently, and this third request is being submitted separately in order to integrate conforming amendments resulting from the creation of both new rule chapters into the general licensure chapter, 6 CCR 1011-1, Chapter 2, General Licensure Standards, and to harmonize the chapter to align with Colorado state law. Thus, the requested changes are contingent upon the adoption of the two new rule chapters, 6 CCR 1011-1, Chapter 3, Behavioral Health Entities, and Chapter 13, Freestanding Emergency Departments.

In addition to the proposed conforming amendments, the Division took the opportunity to make minor, non-substantive changes, such as correcting typographical errors.

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for Amendments to
6 CCR 1011-1 Chapter 2 - General Licensure Standards

Basis and Purpose.

Effective July 1, 2021, the Department will begin to license two new facility types: Behavioral Health Entities at 6 CCR 1011-1, Chapter 3 and Freestanding Emergency Departments at 6 CCR 1011-1, Chapter 13. Chapter 2 of 6 CCR 1011-1 contains the general licensing requirements for all facilities and agencies licensed by the Department. Proposed changes to Chapter 2 were brought about by the statutory changes that add Behavioral Health Entities (BHEs) and Freestanding Emergency Departments (FSEDs) to the list of health care facilities that the Department licenses, and whose rulemaking will take place concurrently.

With the addition of two new rule chapters, conforming amendments are needed in order to adequately integrate BHEs and FSEDs into Chapter 2. In addition to the conforming amendments required by the addition of licensing BHEs and FSEDs, the Division took the opportunity to make minor, non-substantive changes throughout the chapter. The following are the proposed changes:

1) Conforming Amendments
    - Part 2 – Licensure Process
        - At Part 2.2.2, BHEs have been added to the list of licensees exempt from the requirement of having a separate license for each physical location.
        - At Part 2.9.6(A)(4), BHEs have been added to the list of licensees that shall notify the Department if there is a change in the scope of services.
    - Part 3 – General Building and Fire Safety Provisions
        - At Part 3.2.3(A), FSEDs have been added to the list of licensees that follow the Guidelines for Design and Construction of Hospitals in the Facility Guidelines Institute (FGI), 2018 Edition.
        - At Part 3.2.3(B), BHEs have been added to the list of licensees that follow the Guidelines for Design and Construction of Outpatient Facilities in the Facility Guidelines Institute (FGI), 2018 Edition, and Community Clinics and Emergency Centers have been renamed to Community Clinics Providing Emergency Services, to align with changes being proposed to 6 CCR 1011-1, Chapter 9, Community Clinics.
        - At Part 3.2.3(C), BHEs have been added to the list of licensees that follow the Guidelines for Design and Construction of Residential Health, Care, and Support Facilities in the Facility Guidelines Institute (FGI), 2018 Edition.

2) Non-substantive changes
    - Typographic errors, statutory references, and other minor corrections have been made throughout the chapter, specifically at Parts 2.1.1, 2.3.3(F), 3.2.3, 3.2.4, 3.3.1, and 9.2.3.

Specific Statutory Authority.

Statutes that require or authorize rulemaking:

Section 25-1.5-103, C.R.S.
Section 25-3-100.5, et seq., C.R.S.

Other Relevant Statutes:
Section 25-1.5-114, C.R.S.
Section 25-3-119, C.R.S.
Section 25-27.6-101, et seq., C.R.S.

Is this rulemaking due to a change in state statute?

_X_ Yes, the bill number is _HB19-1237 and HB19-1010_. Rules are ___
authorized _X_ required.
_____ 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?

_____ Yes
_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 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
Community Clinics Providing Emergency Services that will be required to become licensed as Freestanding Emergency Departments (FSEDs) beginning July 1, 2021	40 +/-	C
Current licensees holding an Acute Treatment Unit License that will be required to become licensed as a Behavioral Health Entity (BHE) beginning July 1, 2021	5	C
Current licensees holding a Crisis Stabilization Unit License that will be required to become licensed as a BHE beginning July 1, 2021	4	C
Current Licensees holding a Community Mental Health Center License that will be required to become licensed as a BHE beginning July 1, 2021	17	C
Current Licensees holding a Community Mental Health Clinic License that will be required to become licensed as a BHE beginning July 1, 2021	7	C
Agencies that are currently unlicensed and are eligible, but not required, to be licensed as a Community Mental Health Clinic, and that will be required to become licensed as a BHE beginning July 1, 2021	25	C
Licensed facilities that must comply with Chapter 2, not listed above	Unknown	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.

   Economic outcomes
   The Department does not foresee an economic impact to any licensee due to the requested changes. The economic impacts of licensing BHEs and FSEDs are discussed in-depth in their relevant Regulatory Analysis documentation.

   Non-economic outcomes
   The non-economic impact of the proposed conforming amendments is that these changes ensure that the facility-specific chapters and the general licensure standards are consistent. Otherwise, without the proposed conforming amendments, it may be unclear to the providers (C) which standards within the general licensure chapter apply to them. Additionally, the proposed changes to Chapter 2 make the chapter clearer for both providers (C) and clients receiving services (B).

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:

   _X_ Comply with a statutory mandate to promulgate rules.
   ___ 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
   _X_ Improve public and environmental health practice.
   ___ Implement stakeholder feedback.
   _X_ Advance the following CDPHE Strategic Plan priorities:

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)
_X_ 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)
_X_ 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:

N/A

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 was considered.

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

Chapter 2 contains the general licensing requirements for all healthcare facilities across the spectrum of services. With the creation of Chapter 3 for Behavioral Health Entities and Chapter 13 for Freestanding Emergency Departments, references need to be added to Chapter 2 to maintain constancy.

No alternatives to this rulemaking were considered.

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 changes did not require a data based evaluation or analysis. The data used in determining how best to license BHEs and FSEDs is documented in their relevant Regulatory Analysis documentation. These changes are being proposed for conforming purposes.

STAKEHOLDER ENGAGEMENT
for Amendments to
6 CCR 1011-1 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 are contingent upon the adoption of two new licensing categories being requested concurrently to the Board of Health, Behavioral Health Entities (BHEs) and Freestanding Emergency Departments (FSEDs). Extensive early stakeholder engagement was conducted for both of the proposed new rule chapters, and information is provided in those related packages for review by the Board of Health at the same time as this request.

For the purposes of the request for hearing, no stakeholder processes or stakeholder meetings were conducted prior to the request for rulemaking. Stakeholders were notified of the proposed changes prior to the rulemaking hearing.

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.
_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.

X	Improves behavioral health and mental health; or, reduces substance abuse or suicide risk.	X	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 _____. Effective _____

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.

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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.*~~ ET SEQ., C.R.S.

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2.2 License Required

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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.

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2.3 Initial License Application Procedure

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2.3.3 Each applicant shall provide the following information:

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

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2.9 Continuing Obligations of Licensee

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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.

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PART 3. GENERAL BUILDING AND FIRE SAFETY PROVISIONS

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3.2 Physical Plant Standards

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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 ~~and~~PROVIDING Emergency SERVICES~~Centers~~, Dialysis Treatment Clinics, and Birth Centers: Guidelines for Design and Construction of Outpatient Facilities; and

(C) for residential facilities, including but not limited to Assisted Living Residences, 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 ~~meet~~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.

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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 1.4~~1~~6 of these rules.

(C) A renovation of a licensed facility or agency, as defined at Part 1.4~~7~~52 of these rules.

(D) A guideline compliance review is not needed for minor alterations, as defined at Part 1.3~~9~~43 of these rules.

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PART 9. MEDICATIONS, MEDICAL DEVICES, AND MEDICAL SUPPLIES

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

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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:~~

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.

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Commented [BM1]: The purpose of striking the language at line 136 is to correct the font and spacing of this language as they are incorrect in the current published version.