COLORADO
Department of Public Health & Environment

To: Members of the State Board of Health

From: Jo Tansey, Acute Care and Nursing Facilities Branch Chief, Health Facilities and Emergency Medical Services Division

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

Date: February 17, 2021

Subject: Request for a Rulemaking Hearing concerning 6 CCR 1011-1, Standards for Hospitals and Health Facilities, Chapter 9 - Community Clinics and new Chapter 13 -Freestanding Emergency Departments, and conforming amendments, 6 CCR 1015-4, Statewide Emergency Medical and Trauma Care System, Chapters Two and Three

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The Department is requesting consideration of several sets of rules in the attached package.

Chapter 13 – Freestanding Emergency Departments is a new chapter added to 6 CCR 1011-1, Standards for Hospitals and Health Facilities. These new rules are the result of HB19-1010, a legislative mandate to create a new licensure category for Freestanding Emergency Departments (FSEDs). These facilities are currently licensed as Community Clinics but the new legislation dictates that these facilities must be re-licensed as FSEDs no later than June 30, 2022. Since licensure is annual, and because there is a statutory mandate, the Department is requesting that the rules be effective July 1, 2021, which is when existing clinics may begin the transition process to become FSEDs.

While these facilities are licensed as Community Clinics, that licensure category never really "fit" the business model. The passage of HB 19-1010 allows the department to better align the requirements for FSEDs with the requirements for hospital-based emergency departments. Approximately 40 of the 45 facilities currently licensed as Community Clinics and Emergency Centers will be required to convert to the new FSED licensure category.

In addition, Chapter 9 – Community Clinics and Community Clinics and Emergency Centers is being extensively revised. Much of the content is similar to the current Chapter 9. However, the language is updated, and the chapter is restructured for ease of use. Chapters 9 and 13 use identical or similar language where the regulatory requirements are comparable.

Finally, the proposed rules incorporate non-substantive revisions to certain existing rule sections in the trauma rules, 6 CCR 1015-4, Statewide Emergency Medical and Trauma Care System, Chapters Two and Three (The Trauma Registry and Designation of Trauma Facilities). In these chapters, current references to "Community Clinics and Emergency Centers" must be changed to include the newly re-licensed FSEDs, as they are also regulated for the purpose of trauma. (Please note that all references to these non-substantive revisions will be indicated with ** in the attached document.)

The Department is requesting a July 1, 2021 effective date for all of the proposed rule changes included in this hearing.

STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY
for Amendments to
6 CCR 1011-1, Chapter 9 - Community Clinics
And for New Rule
6 CCR 1011-1, Chapter 13 - Freestanding Emergency Departments
And for Conforming Amendments
6 CCR 1015-4, Statewide Emergency Medical and Trauma Care System,
Chapters Two and Three

Basis and Purpose.

In HB19-1010, the legislature directed the Department to create a new health facility licensure category for Freestanding Emergency Departments (FSEDs). These facilities are currently licensed as Community Clinics along with several other types of facilities, some of which provide emergency services and some of which do not. The legislation requires that all facilities eligible for this new licensure type must convert to an FSED license no later than June 30, 2022.

In addition, the legislation requires that the Board of Health adopt rules to take effect July 1, 2021, to guide the conversion process. The result will be approximately 40 +/- facilities transitioning to the new license type (FSED), while about five facilities will remain licensed Community Clinics, as permitted in statute. It is important to note that this count was completed prior to the COVID-19 pandemic during which some FSEDs closed to allow hospital systems to focus efforts on understaffed hospital emergency departments. It is unknown how many of the temporarily closed locations will re-open once the pandemic is over.

As a result of the legislative mandate, the major rule changes being submitted to the Board of Health will:

1) Create licensure requirements for the new FSED licensure category, and
2) Revise and clarify the requirements for the remaining Community Clinics.

These rules will be housed in 6 CCR 1011-1, Chapter 9 - Community Clinics, and the new Chapter 13 - Freestanding Emergency Departments. Please note: Chapter 9 looks like all new language as indicated by the red, small cap font; however, more than half of the language is original as indicated by comments in the margins.

Conforming amendments are also required in Chapter 2 - General Licensure Standards in order to integrate FSEDs into the general licensing requirements. Chapter 2 also has conforming amendments due to another new set of rules being submitted to the Board of Health concurrently (Chapter 3 - Behavioral Health Entities), and thus all amendments to Chapter 2 will be covered in a separate packet.

Chapter 13 also contains new rules permitted by the passage of SB18-146. These rules simply point FSEDs to notification/signage language requirements that must be presented to patients and posted in conspicuous locations. SB18-146 contained permissive, not mandatory, rulemaking authority; and since this is the initial rulemaking for FSED licensure, this is the first opportunity to create these rules.

**Finally, these proposed rules incorporate non-substantive revisions to certain sections in 6 CCR 1015-4, Statewide Emergency Medical and Trauma Care System. The trauma rules are

implicated in this rulemaking because Section 25-3.5-704(2)(d), C.R.S., requires every licensed facility "that receives ambulance patients" to participate in Colorado's trauma care system as either a designated or nondesignated trauma facility. The proposed rules impose that requirement on licensed FSEDs and Community Clinics that provide emergency services, two facility types that receive ambulance patients. Therefore, the proposed trauma rules incorporate non-substantive conforming amendments in two respects.

First, the trauma rules have been revised to define and reference "Community Clinics providing emergency services (CCs)," and to delete all trauma rule references to Community Clinic Emergency Centers (CCECs). These revisions are necessary because the trauma rules inaccurately refer to the term "community clinic and emergency centers," which is not adopted in the statute authorizing rulemaking. The proposed rules therefore delete those references and define and incorporate accurate terminology concerning the one category of licensed Community Clinics that is material to the trauma rules: a Community Clinic licensed under Section 25-3-101(2)(a)(I), C.R.S., which is defined as a health facility that "(B) provides emergency services at the facility ..."

Second, the trauma rules have been amended to reference the "Freestanding Emergency Department" licensure category that was enacted in SB18-146 and amended in HB 19-1010. *See* Section 25-1.5-114, C.R.S.; *see also* Section 25-3-101(2)(a)(I)(B), C.R.S. Consequently, conforming amendments have been made to the trauma rule sections that should refer or relate to this new licensure category.

The Department is requesting an effective date of July 1, 2020 for all of the proposed changes.

Specific Statutory Authority.

Statutes that require or authorize rulemaking:
Section 25-1.5-103, C.R.S.
Section 25-1.5-114, C.R.S.
Section 25-3-100.5, et seq., C.R.S.
Section 25-3-119, C.R.S.
Section 25-3.5-704(1), C.R.S.
Section 25-3.5-704(2)(d), C.R.S.
Section 25-3.5-704(2)(f), C.R.S.

Is this rulemaking due to a change in state statute?
_X_ Yes, the bill number is _HB19-1010_. Rules are ___ authorized _X_ required.

_X_ Yes, the bill number is _SB18-146_. Rules are _X_ authorized ___ required.

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_ Yes, but only in 6 CCR 1011-1, Chapter 13 _____ 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.

REGULATORY ANALYSIS
for Amendments to
6 CCR 1011-1, Chapter 9 - Community Clinics
And for New Rule
6 CCR 1011-1, Chapter 13 - Freestanding Emergency Departments
And for Conforming Amendments
6 CCR 1015-4, Statewide Emergency Medical and Trauma Care System,
Chapters Two and Three

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/CLG/S/B
Community Clinics Providing Emergency Services that will be required to become licensed as Freestanding Emergency Departments (FSEDs) no later than June 30, 2022	40 +/-	C
Community Clinics	1	C
Department of Corrections Community Clinics	22	C
Community Clinics Providing Emergency Services that meet the grandfathering clause and will remain Community Clinics	5	C
Healthcare Systems, Healthcare Management Companies, and Healthcare Associations such as the Colorado Hospital Association	Multiple	C/S
Clients receiving services at licensed facilities	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.

**The Division anticipates that the proposed conforming amendments to the trauma rules will not affect any class of persons.

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
Summarize the financial costs and benefits, include a description of costs that must be incurred, costs that may be incurred, any Department measures taken to reduce or eliminate these costs, any financial benefits.

C: The only facility type that will experience any fiscal impact will be those facilities currently licensed as Community Clinics that are required to convert to FSED licensing by June 30, 2022. There will be no change in economic impact to Community Clinics providing outpatient services, Community Clinics within the Colorado Department of Corrections, and Community Clinics providing emergency services that meet the definition in Section 25-1.5-114, C.R.S. (Those that were licensed as community clinics prior to July 1, 2010, and are located in rural or ski areas.)

The change in fees for newly licensed FSEDs is exactly as proposed in the fiscal note submitted during the legislative process. These fees are based on the actual costs of current on-site surveys plus anticipated costs of extra survey work required to verify compliance with additional FSED standards. The table below represents the current fees for Community Clinics providing emergency services and the new fees that these facilities will be required to pay.

The economic impact on facilities newly licensed as FSEDs, beginning July 1, 2021, is as follows:

License Category	Initial license	Renewal license	Change of ownership
Current Fees for Community Clinic Providing Emergency Services	$2,873.89	$1,410.82	$3,239.65
New FSED Fees, beginning July 1,2021	$6,150.00	$3,400.00	$3,300.00

S: There will only be an economic impact to entities in this group.

B: There should be little, if any, fiscal impact for those using the services of the newly licensed FSEDs. These facilities have always charged prices comparable to hospital-based emergency departments, and the increased annual licensure fee should not be a major driver of any cost increases.

In addition, the requirement to provide disclosures to patients of FSEDs has existed since the adoption of SB18-146 in 2018. So while the rules are new, the requirements are not, and thus should have no impact, positive or negative, on the cost of care provided to consumers.

**The proposed revisions to the trauma rules will not result in any qualitative impact to affected classes of persons. The proposed conforming amendments clarify that Community Clinics providing emergency services and FSEDs are two licensed facility types that must participate in the trauma system as designated or nondesignated facilities. Therefore, because the proposed amendments do not alter the substance of the trauma rules, no affected class of persons will incur new expenses or financially benefit from the conforming provisions.

Non-economic outcomes
Summarize the anticipated favorable and non-favorable non-economic outcomes (short-term and long-term), and, if known, the likelihood of the outcomes for each affected class of persons by the relationship category.

C: New and revised definitions should create improved clarity for the regulated community. Inclusion of references to national best practice guidelines also provides for the provision of up-to-date care while improving the flexibility of the rules based on the constant changes in current medical practice.

Each facility regulated under Chapter 9, Community Clinics will be required to have an explicit scope of care, providing better clarity for the facility and patients alike with regard to what services will be offered.

Each FSED regulated under Chapter 13 will have more explicit requirements regarding the required scope of emergency services, better aligning the scope with hospital-based emergency departments.

C and B: In both chapters, patients will benefit from the new regulations in that numerous rules have been rewritten to stress what resources are necessary to ensure the safe care of the patient. In addition, the proposed rules encourage rapid and appropriate transfer of patients, after stabilization, if the facility does not have the resources to meet all patient needs.

**The conforming trauma rule amendments will not result in any non-economic impacts. They merely clarify that the same entities that were subject to the trauma designation rules remain subject to those same rules, despite their new nomenclature.

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 Department expects that expenditures for implementing the FSED license process will be somewhat higher than the expenditures to support facilities currently licensed as Community Clinics providing emergency services. The new and more detailed requirements for the FSEDs will result in the following additional costs:

- One-time costs associated with an onsite inspection of each facility converting services to an FSED. This conversion process will require each facility to undergo an "initial" licensure inspection to ensure that it meets the new standards as described in Chapter 13.
- One-time costs associated with providing outreach to facilities required to convert to the new licensure type and education to those facilities regarding new standards and how those standards will be measured.
- One-time costs associated with revising the onsite inspection processes to assess regulatory compliance with new standards.
- Ongoing costs associated with additional staff hours required to assess compliance with additional standards.
- One-time costs associated with the addition of a new licensure type to the current process of licensure issuance including costs associated with potential software changes.

- One-time and ongoing costs associated with training staff on new licensure category requirements.

Anticipated CDPHE Revenues:

Staff calculated expected revenues based on the 40 +/- facilities currently licensed as Community Clinics providing emergency services that will transition to an FSED license. The expected net revenue gain in the first year is roughly $189,567 (due to the "initial" fee being charged for each FSED conversion). After the first year, the move from "initial" license fees to the lower "renewal" license fees is expected to decrease the net revenue gain to roughly $79,567 above current revenues.

**Implementation or enforcement of the conforming amendments in the trauma rules will not impose any additional costs, or result in any additional revenue, to the Department or any other agency.

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

Anticipated revenues/expenditures 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.

Rulemaking is required by HB19-1010; thus inaction is not an option.

The Department's goal is to provide the regulated community a set of standards that are simple, clear, and not redundant. This rule revision significantly clarifies the requirements while reducing redundancy. Furthermore, by allowing each facility to (within certain parameters) define its scope of care, the rules provide freedom to facilities that have additional resources while protecting the minimum standards upon which all facilities are measured.

**N/A to the conforming amendments to the trauma rules.

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.
_X_ Implement a Regulatory Efficiency Review (rule review) result
___ Improve public and environmental health practice.
_X_ 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)
___ 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.

Section 25-1.5-103, C.R.S., requires the Board of Health to promulgate rules providing minimum standards for the operation of FSEDs. Less costly or less intrusive methods do not fulfill this requirement. The new chapter proposed in this rulemaking was developed in conjunction with the facilities currently licensed under Chapter 9, Community Clinics and other stakeholders to provide consistent, appropriate regulations to achieve the maximum benefit at the minimum cost. Rules were consistently evaluated regarding whether they were the minimum necessary to fulfill the intent of, and achieve compliance with, HB19-1010 and to protect the health, safety, and welfare of individuals seeking services at FSEDs.

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

Rulemaking was required per statute to create a new health facility licensure category for FSEDs. The rules were drafted based on review of the statute, rules for similar facility types, and rules from other states. A work group, including members of the regulated community, participated in monthly work sessions and considered many alternative proposals for individual rules. They selected those elements that were deemed critical to public health and safety.

The consensus rules presented here were written with the goal of providing safe and appropriate care while minimizing regulation. Applicable regulations from other rule sets are cross-referenced rather than repeated to reduce duplication. The group also worked to modernize those areas of Chapter 9 that had somewhat dated language.

**Alternative trauma rules were not considered because the changes are non-substantive and simply update the appropriate facility nomenclature.

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 Department and work group did not utilize numerical data other than the numbers of affected facilities. Rather, they relied heavily on the expertise and experience of work group members as well as upon information and opinions provided by professional organizations when developing the proposed rules. The national organizations and resources include:

- Recommendations and practice guidelines published by the American College of Emergency Physicians (https://www.acep.org/);
- Recommendations and standards published by the American College of Surgeons; Committee on Trauma (https://www.facs.org/quality-programs/trauma/tqp/center-programs/vrc);
- Regulations from other states;
- Research in Colorado statutes to align all uses of similar terms with regard to licensure categories; and
- 42 C.F.R. § 482 (Federal Conditions of Participation).

In order to ensure that the Department received the broadest amount of expertise and experience, staff reached out to affected facilities, some of which were not able to attend work group meetings, to ensure that those facilities had the opportunity to attend meetings or provide written feedback.

**N/A to the conforming amendments to the trauma rules.

STAKEHOLDER ENGAGEMENT
for Amendments to
6 CCR 1011-1, Chapter 9 - Community Clinics
And for New Rule
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State law requires agencies to establish a representative group of participants when considering to adopt or modify new and existing rules. This is commonly referred to as a stakeholder group.

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

Organization	**Representative Name and Title (if known)**
Banner Health	Tania Hare
	Tara Guenzi
Beacon Home Health Care	Marina Gougoulian
Boulder Community Health	Holly Pederson
CO Department of Public Health and Environment	Jeff Beckman, Associate Division Director, HFEMSD
	Donnie Woodyard, Emergency Medical and Trauma Services Branch Chief, HFEMSD
	Martin Duffy, Trauma Section Manager, HFEMSD
Central Mountains RETAC	Sarah Weatherred, RETAC Coordinator
Centura Health	Debra Carpenter
	Erica MacDonald
	Kelly Gallant
	Michelle M Roque
	Aimee Johnson
	Heather Bashore
	Linda Hills *(Emergency and Urgent Care Centers)*
	Michele L Johler *(Parker Adventist Hospital)*
	Erin Upton *(Southlands ER, Parker Adventist Hospital)*
	Julie Lombard *(West Littleton Freestanding ER)*
Clear View Behavioral Health Services, LLC	Monica Tatum
Colorado Health Network	Lili Carrillo
Colorado Hospital Association	Amber Burkhart
	Kevin Caudill
Complete Care	Julie Radley
	Robert Morris
CO Department of Corrections	Randolph Maul, Chief Medical Officer
	Tina Cullyford, Clinical Manager

Organization	Representative Name and Title (if known)
Eating Recovery Center	Matthew Compton
Fountain Valley Regional Hospital and Medical Center	Adrian Miranda
CO Department of Health Care Policy and Financing	Janna Leo
	Justen Adams
	Matt Colussi
	Raine Henry
HealthOne	Lori McCormick
Keefe Memorial Hospital	Char Korrell
	Stella Worley
Littleton Adventist Hospital	Catherine Cordoue
Medical Center of Aurora	Eric Hill
National Association of Freestanding Emergency Centers (NAFEC)	Brad Shields
Orthopaedic & Spine Center of the Rockies	JoAne Ridgway
SCL Health	Jenessa Williams
	Kelli Lewis
St. Thomas More Hospital	Abigail Tate
Talem Home Care	Marcy Kowalski
Telluride Medical Center	Karen Winkelmann
The Medical Center of Aurora and Centennial Medical Plaza	Tracy Lauzon
UC Health	Cheri Krauss
	Patrick M Conroy
	Suzanne Golden
	Zach Conroy
	Mariann Benjamin *(Memorial Hospital, Southern Region)*
	Kathryn Trujillo *(North Region)*
	Mary Jo Hallaert *(Northern Region Hospitals)*
	Marcee Paul *(University of Colorado Hospital)*
	Sheryl Bardell *(University of Colorado Hospital)*
University of Colorado Hospital	Kelly Alexander
US Acute Care Solutions	Sean Bender
Vail Health	Jessica Peterson
	Joe Gonzales
	Lisa Arnett
	Lisa Herota
	A. Wilburn
	Ben Tice
	Cathy Quinn
	Jasmine Shea
	LeeAnne Faulkner
	Margaret Hunter

Organization	Representative Name and Title (if known)
	# of Unidentified Telephone Numbers and first names (all meetings combined) = 57 (Some may be duplicates of individuals identified above.)
EMTS on the Go (newsletter mailing list)	This weekly newsletter is emailed to a list of 700+ constituents from the EMS and trauma systems and provides details for all public meetings hosted by the EMTS Branch including the State Emergency Medical and Trauma Services Advisory Council and the Statewide Trauma Advisory Committee meetings. The newsletter also notified readers of the non-substantive changes being made to the Trauma Registry (Chapter 2) and Designation (Chapter 3) rules over the course of the stakeholder process.
State Emergency Medical and Trauma Services Advisory Council (SEMTAC)	The SEMTAC is a governor-appointed council consisting of 25 members and seven non-voting (ex-officio) members representing the interests of citizens and emergency medical service providers. The council advises the department in developing, implementing and improving emergency medical and trauma services statewide. The Division introduced SEMTAC to the final proposed conforming amendments to the trauma rules in its January 14, 2021, meeting. It will be voted on for a recommendation by April 8, 2021, and the SEMTAC chair will provide a letter of support for BOH consideration.

The Division held nine monthly meetings between February 2020 and January 2021. Three meetings were cancelled due to the Division's and stakeholders' response to the COVID-19 pandemic. 129 unique participants (including staff) attended the monthly meetings over the course of the process.

All stakeholder meetings were open to the public, and there was substantial interest and attendance, as shown in the above table. All licensed Community Clinics and interested stakeholders were provided notice of meetings, including alternate methods of providing feedback. The Division sent meeting information through its portal messaging system to impacted facilities and directly emailed 51 unique stakeholders that signed up to receive such emails as "interested parties." Meeting information and documents were posted to the Department google drive in advance of each meeting, including draft rules for discussion.

Stakeholder Group Notification

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

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

____ Yes.

Summarize Major Factual and Policy Issues Encountered and the Stakeholder Feedback Received. If there is a lack of consensus regarding the proposed rule, please also identify the

Department's efforts to address stakeholder feedback or why the Department was unable to accommodate the request.

No major factual or policy issues were encountered. There were discussions around many details in the rules; however, stakeholders were not opposed to any major concept since these are modifications of regulations that they already meet. In all cases where there was dissent about any detail of the proposed rule set, group discussion led to revised language that the group could gain consensus on. In some cases, staff was directed to do additional research and come back to the group with information that helped to clarify where there was consensus or where there were changes needed to achieve agreement.

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

This rulemaking creates more appropriate standards for Freestanding Emergency Departments (FSEDs) by seeking to align the FSED standards with hospital emergency department standards. Thus, when people seek emergency care at an "emergency department," whether located within or outside the walls of a hospital, they should experience a consistent level of care.

In addition, by putting FSEDs in their own licensing category, and then updating the current licensing category to more accurately reflect Community Clinics providing emergency care, populations that are served by these Community Clinics will have standards that better protect their health, safety, and welfare while reflecting the rural nature of the remaining Community Clinics providing emergency services.

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.	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:_____ _____

An Act

HOUSE BILL 19-1010

BY REPRESENTATIVE(S) Mullica and Landgraf, Buentello, Caraveo, Esgar, Exum, Garnett, Hansen, Herod, Jackson, Jaquez Lewis, Kennedy, Lontine, Roberts, Singer, Sirota, Snyder, Tipper, Titone, Valdez D., Weissman, Becker;
also SENATOR(S) Gardner and Pettersen, Bridges, Court, Danielson, Donovan, Fenberg, Fields, Ginal, Gonzales, Moreno, Rodriguez, Story, Todd, Williams A., Winter, Garcia.

CONCERNING THE LICENSING OF FREESTANDING EMERGENCY DEPARTMENTS, AND, IN CONNECTION THEREWITH, MAKING AN APPROPRIATION.

Be it enacted by the General Assembly of the State of Colorado:

SECTION 1. In Colorado Revised Statutes, **add** 25-1.5-114 as follows:

25-1.5-114. Freestanding emergency departments - licensure - requirements - rules - definition. (1) ON OR AFTER DECEMBER 1, 2021, A PERSON THAT WISHES TO OPERATE A FREESTANDING EMERGENCY DEPARTMENT MUST SUBMIT TO THE DEPARTMENT ON AN ANNUAL BASIS A COMPLETED APPLICATION FOR LICENSURE AS A FREESTANDING EMERGENCY DEPARTMENT. ON OR AFTER JULY 1, 2022, A PERSON SHALL NOT OPERATE A

Capital letters or bold & italic numbers indicate new material added to existing law; dashes through words or numbers indicate deletions from existing law and such material is not part of the act.

FREESTANDING EMERGENCY DEPARTMENT THAT IS REQUIRED TO BE LICENSED PURSUANT TO THIS SECTION WITHOUT A LICENSE ISSUED BY THE DEPARTMENT.

(2) THE DEPARTMENT MAY GRANT A WAIVER OF THE LICENSURE REQUIREMENTS SET FORTH IN THIS SECTION AND IN RULES ADOPTED BY THE BOARD FOR EITHER A LICENSED COMMUNITY CLINIC OR COMMUNITY CLINIC SEEKING LICENSURE THAT IS SERVING AN UNDERSERVED POPULATION IN THE STATE.

(3) (a) THE BOARD SHALL ADOPT RULES ESTABLISHING THE REQUIREMENTS FOR LICENSURE OF, WAIVER FROM THE REQUIREMENT FOR LICENSURE OF, SAFETY AND CARE STANDARDS FOR, AND FEES FOR LICENSING AND INSPECTING FREESTANDING EMERGENCY DEPARTMENTS. THE BOARD MUST SET THE FEES IN ACCORDANCE WITH SECTION 25-3-105.

(b) THE RULES ADOPTED BY THE BOARD SHALL INCLUDE A REQUIREMENT THAT EACH INDIVIDUAL SEEKING TREATMENT AT THE FREESTANDING EMERGENCY DEPARTMENT RECEIVE A MEDICAL SCREENING EXAMINATION AND A PROHIBITION AGAINST DELAYING A MEDICAL SCREENING EXAMINATION IN ORDER TO INQUIRE ABOUT THE INDIVIDUAL'S ABILITY TO PAY OR INSURANCE STATUS.

(c) THE RULES ADOPTED BY THE BOARD MUST TAKE EFFECT BY JULY 1, 2021, AND THEREAFTER THE BOARD SHALL AMEND THE RULES AS NECESSARY.

(4) A FREESTANDING EMERGENCY DEPARTMENT LICENSED PURSUANT TO THIS SECTION IS SUBJECT TO THE REQUIREMENTS IN SECTION 25-3-119.

(5) (a) AS USED IN THIS SECTION, "FREESTANDING EMERGENCY DEPARTMENT" MEANS A HEALTH FACILITY THAT OFFERS EMERGENCY CARE, THAT MAY OFFER PRIMARY AND URGENT CARE SERVICES, AND THAT IS EITHER:

(I) OWNED OR OPERATED BY, OR AFFILIATED WITH, A HOSPITAL OR HOSPITAL SYSTEM AND LOCATED MORE THAN TWO HUNDRED FIFTY YARDS FROM THE MAIN CAMPUS OF THE HOSPITAL; OR

(II) INDEPENDENT FROM AND NOT OPERATED BY OR AFFILIATED WITH

A HOSPITAL OR HOSPITAL SYSTEM AND NOT ATTACHED TO OR SITUATED WITHIN TWO HUNDRED FIFTY YARDS OF, OR CONTAINED WITHIN, A HOSPITAL.

(b) "FREESTANDING EMERGENCY DEPARTMENT" DOES NOT INCLUDE A HEALTH FACILITY DESCRIBED IN SUBSECTION (5)(a) OF THIS SECTION THAT WAS LICENSED BY THE DEPARTMENT PURSUANT TO SECTION 25-1.5-103 AS A COMMUNITY CLINIC PRIOR TO JULY 1, 2010, IF THE FACILITY IS SERVING A RURAL COMMUNITY OR A SKI AREA, AS DEFINED IN BOARD RULES.

SECTION 2. In Colorado Revised Statutes, 25-1.5-103, **amend** (1)(a)(I)(A) and (2)(a.5)(II); and **add** (2)(a.5)(III) as follows:

25-1.5-103. Health facilities - powers and duties of department - limitations on rules promulgated by department - definitions. (1) The department has, in addition to all other powers and duties imposed upon it by law, the powers and duties provided in this section as follows:

(a) (I) (A) To annually license and to establish and enforce standards for the operation of general hospitals, hospital units as defined in section 25-3-101 (2), FREESTANDING EMERGENCY DEPARTMENTS AS DEFINED IN SECTION 25-1.5-114, psychiatric hospitals, community clinics, rehabilitation hospitals, convalescent centers, community mental health centers, acute treatment units, facilities for persons with intellectual and developmental disabilities, nursing care facilities, hospice care, assisted living residences, dialysis treatment clinics, ambulatory surgical centers, birthing centers, home care agencies, and other facilities of a like nature, except those wholly owned and operated by any governmental unit or agency.

(2) For purposes of this section, unless the context otherwise requires:

(a.5) "Community clinic" has the same meaning as set forth in section 25-3-101 and does not include:

(II) A rural health clinic, as defined in section 1861 (aa)(2) of the federal "Social Security Act", 42 U.S.C. sec. 1395x (aa)(2); OR

(III) A FREESTANDING EMERGENCY DEPARTMENT AS DEFINED IN AND REQUIRED TO BE LICENSED UNDER SECTION 25-1.5-114.

SECTION 3. In Colorado Revised Statutes, 25-3-101, **amend** (1), (2)(a)(I)(B), and (2)(a)(III)(C); and **add** (2)(a)(III)(D) as follows:

25-3-101. Hospitals - health facilities - licensed - definitions. (1) It is unlawful for any person, partnership, association, or corporation to open, conduct, or maintain any general hospital, hospital unit, FREESTANDING EMERGENCY DEPARTMENT AS DEFINED IN SECTION 25-1.5-114, psychiatric hospital, community clinic, rehabilitation hospital, convalescent center, community mental health center, acute treatment unit, facility for persons with developmental disabilities, as defined in section 25-1.5-103 (2)(c), nursing care facility, hospice care, assisted living residence, except an assisted living residence shall be assessed a license fee as set forth in section 25-27-107, dialysis treatment clinic, ambulatory surgical center, birthing center, home care agency, or other facility of a like nature, except those wholly owned and operated by any governmental unit or agency, without first having obtained a license from the department. ~~of public health and environment.~~

(2) As used in this section, unless the context otherwise requires:

(a) (I) "Community clinic" means a health care facility that provides health care services on an ambulatory basis, is neither licensed as an on-campus department or service of a hospital nor listed as an off-campus location under a hospital's license, and meets at least one of the following criteria:

(B) Provides emergency services at the facility AND IS NOT OTHERWISE REQUIRED TO OBTAIN LICENSURE AS A FREESTANDING EMERGENCY DEPARTMENT IN ACCORDANCE WITH SECTION 25-1.5-114; or

(III) "Community clinic" does not include:

(C) A facility that functions only as an office for the practice of medicine or the delivery of primary care services by other licensed or certified practitioners; OR

(D) A FREESTANDING EMERGENCY DEPARTMENT AS DEFINED IN AND REQUIRED TO BE LICENSED UNDER SECTION 25-1.5-114.

SECTION 4. In Colorado Revised Statutes, 25-3-119, **amend** (8)(c)

as follows:

25-3-119. Freestanding emergency departments - required notices - disclosures - rules - definitions. (8) As used in this section:

(c) ~~(I)~~ "Freestanding emergency department" ~~means a health facility that offers emergency care, that may offer primary and urgent care services, that is licensed by the department pursuant to section 25-1.5-103, and that is either:~~ HAS THE SAME MEANING AS SECTION 25-1.5-114 (5).

~~(A) Owned or operated by, or affiliated with, a hospital or hospital system and is located more than two hundred fifty yards from the main campus of the hospital; or~~

~~(B) Independent from and not operated by or affiliated with a hospital or hospital system and is not attached to or situated within two hundred fifty yards of, or contained within, a hospital.~~

~~(II) "Freestanding emergency department" does not include a health facility described in subsection (8)(c)(I) of this section that was licensed by the department pursuant to section 25-1.5-103 as a community clinic prior to July 1, 2010, if the facility is serving a rural community or a ski area, as defined in state board rules.~~

SECTION 5. Appropriation. For the 2019-20 state fiscal year, $43,248 is appropriated to the department of public health and environment for use by the health facilities and emergency medical services division. This appropriation is from the health facilities general licensure cash fund created in section 25-3-103.1 (1), C.R.S., and is based on an assumption that the division will require an additional 0.5 FTE. To implement this act, the division may use this appropriation for the nursing facility survey.

SECTION 6. Act subject to petition - effective date. This act takes effect at 12:01 a.m. on the day following the expiration of the ninety-day period after final adjournment of the general assembly (August 2, 2019, if adjournment sine die is on May 3, 2019); except that, if a referendum petition is filed pursuant to section 1 (3) of article V of the state constitution against this act or an item, section, or part of this act within such period, then the act, item, section, or part will not take effect unless

approved by the people at the general election to be held in November 2020 and, in such case, will take effect on the date of the official declaration of the vote thereon by the governor.

KC Becker
SPEAKER OF THE HOUSE
OF REPRESENTATIVES

Leroy M. Garcia
PRESIDENT OF
THE SENATE

Marilyn Eddins
CHIEF CLERK OF THE HOUSE
OF REPRESENTATIVES

Cindi L. Markwell
SECRETARY OF
THE SENATE

APPROVED May 29, 2019 at 9:20 A.M.
(Date and Time)

Jared S. Polis
GOVERNOR OF THE STATE OF COLORADO

An Act

SENATE BILL 18-146

BY SENATOR(S) Kefalas and Smallwood, Martinez Humenik, Aguilar, Coram, Crowder, Donovan, Garcia, Gardner, Jahn, Moreno, Tate, Todd, Williams A., Guzman, Jones, Kagan, Kerr, Lambert, Lundberg, Merrifield, Neville T.;
also REPRESENTATIVE(S) Sias and Singer, Hansen, Kennedy, Arndt, Becker K., Bridges, Buckner, Coleman, Esgar, Exum, Garnett, Ginal, Hamner, Herod, Hooton, Lee, Lontine, Melton, Michaelson Jenet, Pettersen, Roberts, Rosenthal, Saine, Valdez, Weissman, Winter, Young, Duran.

CONCERNING A REQUIREMENT THAT A FREESTANDING EMERGENCY DEPARTMENT INFORM A PERSON WHO IS SEEKING MEDICAL TREATMENT ABOUT THE HEALTH CARE OPTIONS THAT ARE AVAILABLE TO THE PERSON, AND, IN CONNECTION THEREWITH, MAKING AN APPROPRIATION.

Be it enacted by the General Assembly of the State of Colorado:

SECTION 1. Legislative declaration. (1) The general assembly hereby finds and declares that:

(a) Colorado struggles to control the cost of health care, which is consistent with national trends;

Capital letters or bold & italic numbers indicate new material added to existing statutes; dashes through words indicate deletions from existing statutes and such material not part of act.

(b) The cost of health care benefits, including health insurance policies and monthly premiums, is directly related to the costs of health care services, products, and medications used by Colorado residents to maintain their health, whether addressing acute health needs or managing chronic health conditions;

(c) The costs of receiving health care services for treating a specific condition vary significantly based on the setting or facility at which the health care services are delivered to the patient;

(d) Emergency departments, including freestanding emergency departments, which are often referred to as "FSEDs", have been widely recognized as the most expensive setting for receiving nonemergency health care services, and evidence shows that utilization of FSEDs for nonemergency health care services significantly drives up health care costs for Colorado residents;

(e) Data from the all payer claims database indicate that seven of the top ten reasons for visiting a FSED were for nonemergency services;

(f) FSEDs have proliferated, primarily along the Front Range, with thirty-seven FSEDs in operation in 2016, and Colorado is one of the top three states in terms of the number of FSEDs operating in the state;

(g) Colorado health care providers, facilities, and insurers have a shared responsibility to inform and educate Colorado health care consumers regarding their health care options and costs associated with those options so that consumers can make informed health care decisions regarding where they choose to receive their health care, what the costs will be, and the costs for which they will be responsible;

(h) While initially introduced in Colorado as facilities necessary to address critical health care coverage gaps existing across diverse geographic regions, particularly rural regions, FSEDs are increasingly located in more suburban and urban areas with adequate access to health care facilities;

(i) Significant differences also exist in terms of the costs patients incur for receiving nonemergency health care services at FSEDs compared to receiving similar care at urgent care centers or a primary care physician's

office;

(j) FSED facility fees significantly increase patients' costs compared to costs associated with receiving nonemergency care at an urgent care center or primary care physician's office;

(k) The price of hospital facility fees rose eighty-nine percent between 2009 and 2015, twice as much as the price of outpatient health care and four times as much as overall health care spending; and

(l) The intent of this bill is to:

(I) Require transparency and disclosure to consumers by FSEDs or off-campus emergency departments for the purpose of helping health care consumers make informed decisions; and

(II) Authorize the Colorado department of public health and environment to oversee and enforce a comprehensive set of consumer protections through the implementation of transparency and disclosure measures.

SECTION 2. In Colorado Revised Statutes, **add** 25-3-119 as follows:

25-3-119. Freestanding emergency departments - required notices - disclosures - rules - definitions. (1) (a) (I) A FREESTANDING EMERGENCY DEPARTMENT SHALL GIVE TO EVERY INDIVIDUAL SEEKING TREATMENT AT THE FACILITY A WRITTEN NOTICE CONTAINING THE FOLLOWING STATEMENTS IMMEDIATELY UPON REGISTRATION:

PATIENT INFORMATION

THIS IS AN EMERGENCY MEDICAL FACILITY THAT TREATS EMERGENCY MEDICAL CONDITIONS.

WE WILL SCREEN AND TREAT YOU REGARDLESS OF YOUR ABILITY TO PAY.

YOU HAVE A RIGHT TO ASK QUESTIONS REGARDING YOUR TREATMENT OPTIONS AND COSTS.

YOU HAVE A RIGHT TO RECEIVE PROMPT AND REASONABLE RESPONSES TO QUESTIONS AND REQUESTS.

YOU HAVE A RIGHT TO REJECT TREATMENT.

HOWEVER, WE ENCOURAGE YOU TO DEFER YOUR QUESTIONS UNTIL AFTER WE SCREEN YOU FOR AN EMERGENCY MEDICAL CONDITION.

THIS IS NOT A COMPLETE STATEMENT OF PATIENT INFORMATION OR RIGHTS. YOU WILL RECEIVE A MORE COMPREHENSIVE STATEMENT OF PATIENT'S RIGHTS UPON THE COMPLETION OF A MEDICAL SCREENING EXAMINATION THAT DOES NOT REVEAL AN EMERGENCY MEDICAL CONDITION OR AFTER TREATMENT HAS BEEN PROVIDED TO STABILIZE AN EMERGENCY MEDICAL CONDITION.

(II) (A) IF THE FREESTANDING EMERGENCY DEPARTMENT DOES NOT HAVE OR INCLUDE WITHIN ITS FACILITY AN URGENT CARE CENTER OR CLINIC, THE FREESTANDING EMERGENCY DEPARTMENT SHALL INCLUDE THE FOLLOWING STATEMENT IN THE NOTICE REQUIRED BY SUBSECTION (1)(a)(I) OF THIS SECTION, IMMEDIATELY FOLLOWING THE SENTENCE THAT READS "THIS IS AN EMERGENCY MEDICAL FACILITY THAT TREATS EMERGENCY MEDICAL CONDITIONS.":

THIS IS NOT AN URGENT CARE CENTER OR PRIMARY CARE PROVIDER.

(B) IF THE FREESTANDING EMERGENCY DEPARTMENT HAS OR INCLUDES WITHIN ITS FACILITY AN URGENT CARE CENTER OR CLINIC, THE FREESTANDING EMERGENCY DEPARTMENT SHALL INCLUDE THE FOLLOWING STATEMENT IN THE NOTICE REQUIRED BY SUBSECTION (1)(a)(I) OF THIS SECTION, IMMEDIATELY FOLLOWING THE SENTENCE THAT READS "THIS IS AN EMERGENCY MEDICAL FACILITY THAT TREATS EMERGENCY MEDICAL CONDITIONS.":

THIS FACILITY ALSO CONTAINS AN URGENT CARE CENTER THAT OPERATES FROM (INSERT TIME URGENT CARE CENTER OPENS) TO (INSERT TIME URGENT CARE CENTER CLOSES) AND PROVIDES PRIMARY CARE SERVICES (AND INSERT, IF

APPLICABLE, THAT THE URGENT CARE CENTER OFFERS PRIMARY CARE SERVICES BY APPOINTMENT).

(III) IF THE INDIVIDUAL SEEKING TREATMENT IS A MINOR WHO IS ACCOMPANIED BY AN ADULT, THE FREESTANDING EMERGENCY DEPARTMENT SHALL PROVIDE THE WRITTEN NOTICE REQUIRED BY THIS SUBSECTION (1)(a) TO THE ACCOMPANYING ADULT.

(b) IN ADDITION TO GIVING AN INDIVIDUAL THE WRITTEN NOTICE REQUIRED BY SUBSECTION (1)(a) OF THIS SECTION, A FREESTANDING EMERGENCY DEPARTMENT STAFF MEMBER OR HEALTH CARE PROVIDER SHALL PROVIDE THE INFORMATION SPECIFIED IN SUBSECTION (1)(a) OF THIS SECTION TO THE INDIVIDUAL ORALLY.

(c) AS NECESSARY, THE STATE BOARD OF HEALTH, BY RULE, MAY UPDATE THE INFORMATION REQUIRED TO BE INCLUDED IN THE WRITTEN NOTICE OF PATIENT INFORMATION SET FORTH IN THIS SUBSECTION (1).

(2) (a) A FREESTANDING EMERGENCY DEPARTMENT SHALL POST A SIGN THAT IS PLAINLY VISIBLE IN THE AREA WITHIN THE FACILITY WHERE AN INDIVIDUAL SEEKING CARE REGISTERS OR CHECKS IN AND THAT STATES:

THIS IS AN EMERGENCY MEDICAL FACILITY THAT TREATS EMERGENCY MEDICAL CONDITIONS.

(b) (I) IF THE FREESTANDING EMERGENCY DEPARTMENT DOES NOT HAVE OR INCLUDE WITHIN ITS FACILITY AN URGENT CARE CENTER OR CLINIC, THE FREESTANDING EMERGENCY DEPARTMENT SHALL INCLUDE THE FOLLOWING STATEMENT ON THE SIGN REQUIRED BY THIS SUBSECTION (2), IMMEDIATELY FOLLOWING THE STATEMENT SPECIFIED IN SUBSECTION (2)(a) OF THIS SECTION:

THIS IS NOT AN URGENT CARE CENTER OR PRIMARY CARE PROVIDER.

(II) IF THE FREESTANDING EMERGENCY DEPARTMENT HAS OR INCLUDES WITHIN ITS FACILITY AN URGENT CARE CENTER OR CLINIC, THE FREESTANDING EMERGENCY DEPARTMENT SHALL INCLUDE THE FOLLOWING STATEMENT ON THE SIGN REQUIRED BY THIS SUBSECTION (2), IMMEDIATELY FOLLOWING THE STATEMENT SPECIFIED IN SUBSECTION (2)(a) OF THIS

SECTION:

THIS FACILITY ALSO CONTAINS AN URGENT CARE CENTER THAT OPERATES FROM (INSERT TIME URGENT CARE CENTER OPENS) TO (INSERT TIME URGENT CARE CENTER CLOSES) AND PROVIDES PRIMARY CARE SERVICES (AND INSERT, IF APPLICABLE, THAT THE URGENT CARE CENTER OFFERS PRIMARY CARE SERVICES BY APPOINTMENT).

(3) (a) AFTER PERFORMING AN APPROPRIATE MEDICAL SCREENING EXAMINATION AND DETERMINING THAT A PATIENT DOES NOT HAVE AN EMERGENCY MEDICAL CONDITION OR AFTER TREATMENT HAS BEEN PROVIDED TO STABILIZE AN EMERGENCY MEDICAL CONDITION, THE FREESTANDING EMERGENCY DEPARTMENT SHALL PROVIDE TO THE PATIENT A WRITTEN DISCLOSURE THAT:

(I) SPECIFIES WHETHER THE FREESTANDING EMERGENCY DEPARTMENT ACCEPTS PATIENTS WHO ARE ENROLLED IN: THE STATE MEDICAL ASSISTANCE PROGRAM UNDER ARTICLES 4, 5, AND 6 OF TITLE 25.5; MEDICARE, AS AUTHORIZED IN TITLE XVIII OF THE FEDERAL "SOCIAL SECURITY ACT", AS AMENDED; THE CHILDREN'S BASIC HEALTH PLAN ESTABLISHED UNDER ARTICLE 8 OF TITLE 25.5; OR A HEALTH PLAN AUTHORIZED UNDER 10 U.S.C. SEC. 1071 ET SEQ.;

(II) LISTS THE SPECIFIC HEALTH INSURANCE PROVIDER NETWORKS AND CARRIERS WITH WHICH THE FREESTANDING EMERGENCY DEPARTMENT PARTICIPATES OR STATES THAT THE FREESTANDING EMERGENCY DEPARTMENT IS NOT A PARTICIPATING PROVIDER IN ANY HEALTH INSURANCE PROVIDER NETWORKS;

(III) STATES THAT THE FREESTANDING EMERGENCY DEPARTMENT OR A PHYSICIAN PROVIDING HEALTH CARE SERVICES AT THE FREESTANDING EMERGENCY DEPARTMENT MAY NOT BE A PARTICIPATING PROVIDER IN THE PATIENT'S HEALTH INSURANCE PROVIDER NETWORK;

(IV) STATES THAT A PHYSICIAN PROVIDING HEALTH CARE SERVICES AT THE FREESTANDING EMERGENCY DEPARTMENT MAY BILL SEPARATELY FROM THE FREESTANDING EMERGENCY DEPARTMENT FOR THE HEALTH CARE SERVICES PROVIDED TO THE PATIENT;

(V) SPECIFIES THE CHARGEMASTER OR FEE SCHEDULE PRICE FOR THE TWENTY-FIVE MOST COMMON HEALTH CARE SERVICES PROVIDED BY THE FREESTANDING EMERGENCY DEPARTMENT;

(VI) CONTAINS A STATEMENT SPECIFYING THAT THE PRICE LISTED ON THE FREESTANDING EMERGENCY DEPARTMENT'S CHARGEMASTER OR FEE SCHEDULE FOR ANY GIVEN HEALTH CARE SERVICE IS THE MAXIMUM CHARGE THAT ANY PATIENT WILL BE BILLED FOR THE SERVICE AND THAT THE ACTUAL CHARGE FOR ANY HEALTH CARE SERVICE RENDERED MAY BE LOWER DEPENDING ON APPLICABLE HEALTH INSURANCE BENEFITS AND THE AVAILABILITY OF DISCOUNTS OR FINANCIAL ASSISTANCE;

(VII) CONTAINS THE FOLLOWING STATEMENT OR A STATEMENT CONTAINING SUBSTANTIALLY SIMILAR INFORMATION:

> IF YOU ARE COVERED BY HEALTH INSURANCE, YOU ARE STRONGLY ENCOURAGED TO CONSULT WITH YOUR HEALTH INSURER TO DETERMINE ACCURATE INFORMATION ABOUT YOUR FINANCIAL RESPONSIBILITY FOR A PARTICULAR HEALTH CARE SERVICE PROVIDED AT THIS FREESTANDING EMERGENCY DEPARTMENT. IF YOU ARE NOT COVERED BY HEALTH INSURANCE, YOU ARE STRONGLY ENCOURAGED TO CONTACT (INSERT NAME AND TELEPHONE NUMBER FOR OFFICE RESPONSIBLE FOR FINANCIAL SERVICES) TO DISCUSS PAYMENT OPTIONS AND THE AVAILABILITY OF FINANCIAL ASSISTANCE PRIOR TO RECEIVING A HEALTH CARE SERVICE FROM THIS FREESTANDING EMERGENCY DEPARTMENT.

(VIII) CONTAINS INFORMATION ABOUT THE FACILITY FEES THAT THE FREESTANDING EMERGENCY DEPARTMENT CHARGES, INDICATING EITHER THE MAXIMUM FACILITY FEE THAT THE FREESTANDING EMERGENCY DEPARTMENT CHARGES OR THE RANGE OF THE MINIMUM TO MAXIMUM AMOUNT OF THE FACILITY FEES THAT THE FREESTANDING EMERGENCY DEPARTMENT CHARGES; AND

(IX) INCLUDES THE FREESTANDING EMERGENCY DEPARTMENT'S WEBSITE ADDRESS WHERE THE INFORMATION CONTAINED IN THE DISCLOSURE REQUIRED BY THIS SUBSECTION (3) MAY BE FOUND.

(b) A FREESTANDING EMERGENCY DEPARTMENT SHALL UPDATE THE

INFORMATION CONTAINED IN THE WRITTEN DISCLOSURE REQUIRED BY THIS SUBSECTION (3) AT LEAST ONCE EVERY SIX MONTHS.

(c) RECEIPT OF THE DISCLOSURE UNDER THIS SUBSECTION (3) DOES NOT WAIVE A COVERED PERSON'S PROTECTIONS UNDER SECTION 10-16-704 (3)(b).

(4) A FREESTANDING EMERGENCY DEPARTMENT SHALL POST THE DISCLOSURE REQUIRED BY SUBSECTION (3) OF THIS SECTION ON ITS WEBSITE AND UPDATE THE DISCLOSURE POSTED ON ITS WEBSITE AT LEAST ONCE EVERY SIX MONTHS.

(5) A FREESTANDING EMERGENCY DEPARTMENT SHALL PROVIDE THE INFORMATION REQUIRED BY THIS SECTION IN A CLEAR AND UNDERSTANDABLE MANNER AND IN LANGUAGES APPROPRIATE TO THE COMMUNITIES AND PATIENTS THE FREESTANDING EMERGENCY DEPARTMENT SERVES.

(6) NOTHING IN THIS SECTION AFFECTS OR OTHERWISE LIMITS A HOSPITAL'S OR OTHER HEALTH FACILITY'S OBLIGATIONS UNDER SECTION 6-20-101 OR ARTICLE 49 OF THIS TITLE 25.

(7) THE STATE BOARD OF HEALTH MAY ADOPT RULES AS NECESSARY TO IMPLEMENT AND ENFORCE THIS SECTION, INCLUDING RULES NECESSARY TO ENSURE THAT FREESTANDING EMERGENCY DEPARTMENTS ARE COMPLYING IN GOOD FAITH WITH THE INTENT OF THIS SECTION AND THE TRANSPARENCY AND DISCLOSURE REQUIREMENTS OF THIS SECTION.

(8) AS USED IN THIS SECTION:

(a) "CHARGEMASTER OR FEE SCHEDULE", WHICH IS OFTEN REFERRED TO AS "CHARGE DESCRIPTION MASTER" OR "CDM", MEANS A UNIFORM SCHEDULE OF CHARGES REPRESENTED BY A HEALTH FACILITY AS THE FACILITY'S GROSS BILLED CHARGE, OR MAXIMUM CHARGE THAT ANY PATIENT WILL BE BILLED, FOR A GIVEN HEALTH CARE SERVICE, REGARDLESS OF PAYER AND BEFORE ANY DISCOUNTS OR NEGOTIATIONS ARE APPLIED.

(b) "EMERGENCY MEDICAL CONDITION" HAS THE SAME MEANING AS SET FORTH IN 42 U.S.C. SEC. 1395dd (e)(1).

(c) (I) "FREESTANDING EMERGENCY DEPARTMENT" MEANS A HEALTH FACILITY THAT OFFERS EMERGENCY CARE, THAT MAY OFFER PRIMARY AND URGENT CARE SERVICES, THAT IS LICENSED BY THE DEPARTMENT PURSUANT TO SECTION 25-1.5-103, AND THAT IS EITHER:

(A) OWNED OR OPERATED BY, OR AFFILIATED WITH, A HOSPITAL OR HOSPITAL SYSTEM AND IS LOCATED MORE THAN TWO HUNDRED FIFTY YARDS FROM THE MAIN CAMPUS OF THE HOSPITAL; OR

(B) INDEPENDENT FROM AND NOT OPERATED BY OR AFFILIATED WITH A HOSPITAL OR HOSPITAL SYSTEM AND IS NOT ATTACHED TO OR SITUATED WITHIN TWO HUNDRED FIFTY YARDS OF, OR CONTAINED WITHIN, A HOSPITAL.

(II) "FREESTANDING EMERGENCY DEPARTMENT" DOES NOT INCLUDE A HEALTH FACILITY DESCRIBED IN SUBSECTION (8)(c)(I) OF THIS SECTION THAT WAS LICENSED BY THE DEPARTMENT PURSUANT TO SECTION 25-1.5-103 AS A COMMUNITY CLINIC PRIOR TO JULY 1, 2010, IF THE FACILITY IS SERVING A RURAL COMMUNITY OR A SKI AREA, AS DEFINED IN STATE BOARD RULES.

SECTION 3. Appropriation. For the 2018-19 state fiscal year, $34,725 is appropriated to the department of public health and environment for use by the health facilities and emergency medical services division. This appropriation is from the health facilities general licensure cash fund created in section 25-3-103.1 (1), C.R.S., and is based on an assumption that the division will require an additional 0.5 FTE. To implement this act, the division may use this appropriation for administration and operations.

SECTION 4. Act subject to petition - effective date. This act takes effect January 1, 2019; except that, if a referendum petition is filed pursuant to section 1 (3) of article V of the state constitution against this act or an item, section, or part of this act within the ninety-day period after final adjournment of the general assembly, then the act, item, section, or part will not take effect unless approved by the people at the general election to be held in November 2018 and, in such case, will take effect on January 1,

2019, or on the date of the official declaration of the vote thereon by the governor, whichever is later.

Kevin J. Grantham
PRESIDENT OF
THE SENATE

Crisanta Duran
SPEAKER OF THE HOUSE
OF REPRESENTATIVES

Effie Ameen
SECRETARY OF
THE SENATE

Marilyn Eddins
CHIEF CLERK OF THE HOUSE
OF REPRESENTATIVES

APPROVED 3:05 PM 4/25/18

John W. Hickenlooper
GOVERNOR OF THE STATE OF COLORADO

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

STANDARDS FOR HOSPITALS AND HEALTH FACILITIES CHAPTER 9 - COMMUNITY CLINICS

6 CCR 1011-1 Chapter 9

Adopted by the Board of Health on_____. Effective _____.

INDEX

PART 1. STATUTORY AUTHORITY AND APPLICABILITY

Commented [SG1]: Part 1 almost all original language, except where noted

1.1 STATUTORY AUTHORITY

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.

1.2 APPLICABILITY

(A) COMMUNITY CLINICS (CCS) SHALL COMPLY WITH ALL APPLICABLE FEDERAL, STATE, AND LOCAL LAWS AND REGULATIONS, INCLUDING, BUT NOT LIMITED TO:

(1) 6 CCR 1011-1, CHAPTER 2.

(2) 6 CCR 1009-1 RULES AND REGULATIONS PERTAINING TO EPIDEMIC AND COMMUNICABLE DISEASE CONTROL.

(B) CONTRACTED SERVICES SHALL MEET THE STANDARDS ESTABLISHED HEREIN.

(C) A COMMUNITY CLINIC WHOSE OPERATIONS ARE DIRECTLY OR INDIRECTLY OWNED OR CONTROLLED BY, IN WHOLE OR IN PART, OR AFFILIATED WITH A LARGER, CORPORATE SYSTEM MAY FULFILL THE FOLLOWING REQUIREMENTS OF THIS CHAPTER 9 THROUGH A CENTRAL SYSTEM COMMON TO THE ENTIRE ORGANIZATION, PROVIDING THAT THE INTENT OF THE REQUIREMENTS OF THIS CHAPTER IS MET. THE SPECIFIC POLICIES APPLICABLE TO THE COMMUNITY CLINIC, THAT SHALL BE IDENTIFIED AND MADE ACCESSIBLE TO COMMUNITY CLINIC STAFF, INCLUDE:

(1) ADMINISTRATIVE RECORDS, INCLUDING, BUT NOT LIMITED TO, PERSONNEL FUNCTIONS;

(2) POLICIES AND PROCEDURES, INCLUDING INFECTION CONTROL AND ANTIBIOTIC STEWARDSHIP;

(3) GOVERNANCE AND LEADERSHIP;

(4) QUALITY MANAGEMENT PROGRAM; AND

(5) HEALTH INFORMATION MANAGEMENT SERVICES.

Commented [SG2]: All of D is similar to original language but revised to be consistent with Chapter 13

PART 2. DEFINITIONS

Commented [SG3]: Part 2 is original or slightly modified original language except where noted

2.1 "ANESTHESIA SERVICES" MEANS PROCEDURAL SEDATION OR REGIONAL ANESTHESIA USED DURING THE COURSE OF PROVIDING TREATMENT.

2.2 "CLINIC SERVING THE UNINSURED OR UNDERINSURED" MEANS A NONPROFIT FACILITY WHOSE SOLE MISSION IS THE DELIVERY OF PRIMARY CARE TO LOW-INCOME AND PUBLICLY INSURED PATIENTS REGARDLESS OF ABILITY TO PAY. ANY CHARGES ASSESSED, WHETHER A FLAT FEE OR ON A SLIDING FEE SCALE, SHALL BE BASED ON THE PATIENT'S INCOME AND ABILITY TO PAY.

2.3 "COMMUNITY CLINIC," REFERRED TO HEREIN AS CC, MEANS:

(A) A HEALTH CARE FACILITY THAT PROVIDES HEALTH CARE SERVICES ON AN AMBULATORY BASIS, IS NEITHER LICENSED AS AN ON-CAMPUS DEPARTMENT OR SERVICE OF A HOSPITAL NOR LISTED AS AN OFF-CAMPUS LOCATION UNDER A HOSPITAL'S LICENSE, AND MEETS AT LEAST ONE OF THE FOLLOWING CRITERIA:

(1) OPERATES INPATIENT BEDS AT THE FACILITY FOR THE PROVISION OF EXTENDED OBSERVATION AND OTHER RELATED SERVICES FOR NOT MORE THAN SEVENTY-TWO HOURS.

(2) PROVIDES EMERGENCY SERVICES AT THE FACILITY AND IS NOT OTHERWISE REQUIRED TO OBTAIN LICENSURE AS A FREESTANDING EMERGENCY DEPARTMENT.

(3) PROVIDES PRIMARY CARE SERVICES, INCLUDING HEALTH CARE SERVICES NOT OTHERWISE SUBJECT TO HEALTH FACILITY LICENSURE UNDER SECTION 25-3-101, C.R.S. OR SECTION 2-1.5-103, C.R.S., BUT OPTS TO OBTAIN LICENSURE IN ORDER TO RECEIVE PRIVATE DONATIONS, GRANTS, GOVERNMENT FUNDS, OR OTHER PUBLIC OR PRIVATE REIMBURSEMENT FOR SERVICES RENDERED.

(4) IS OPERATED OR CONTRACTED BY THE DEPARTMENT OF CORRECTIONS.

(B) THE TERM "COMMUNITY CLINIC" DOES NOT MEAN:

(1) A FEDERALLY QUALIFIED HEALTH CENTER WHICH IS A FACILITY THAT MEETS THE DEFINITION UNDER SECTION 1861 (AA)(4) OF THE FEDERAL "SOCIAL SECURITY ACT", 42 U.S.C. SECTION 1395X (AA)(4) WHICH PROVIDES FOR THE DELIVERY OF COMPREHENSIVE PRIMARY AND AFTER HOURS CARE IN UNDERSERVED AREAS.

(2) A RURAL HEALTH CLINIC WHICH IS A FACILITY THAT MEETS THE DEFINITION UNDER SECTION 1861 (AA)(2) OF THE FEDERAL "SOCIAL SECURITY ACT", 42 U.S.C. SECTION 1395X (AA)(2) WHICH PROVIDES FOR THE DELIVERY OF BASIC OUTPATIENT PRIMARY CARE IN UNDERSERVED, NON-URBAN AREAS.

(3) A FACILITY THAT FUNCTIONS ONLY AS AN OFFICE FOR THE PRACTICE OF MEDICINE OR THE DELIVERY OF PRIMARY CARE SERVICES BY OTHER LICENSED OR CERTIFIED PRACTITIONERS. A HEALTH CARE FACILITY IS NOT REQUIRED TO BE LICENSED AS A COMMUNITY CLINIC SOLELY DUE TO THE FACILITY'S OWNERSHIP STATUS, CORPORATE STRUCTURE, OR ENGAGEMENT OF OUTSIDE VENDORS TO PERFORM NONCLINICAL MANAGEMENT SERVICES. THIS SECTION PERMITS REGULATION OF A PHYSICIAN'S OFFICE ONLY TO THE EXTENT THE OFFICE IS A COMMUNITY CLINIC AS DEFINED IN THIS PART 2.3(A).

(4) A FACILITY THAT MEETS THE DEFINITION OF A FREESTANDING EMERGENCY DEPARTMENT AT SECTION 25-1.5-114, C.R.S.

Commented [SG4]: New statutory language from FSED licensing statute.

2.4 "EMERGENCY SERVICES" MEANS THE TREATMENT OF PATIENTS ARRIVING BY ANY MEANS WHO HAVE MEDICAL CONDITIONS, INCLUDING ACUTE ILLNESS OR TRAUMA THAT, IF NOT TREATED IMMEDIATELY, COULD RESULT IN LOSS OF LIFE, LOSS OF LIMB, OR PERMANENT DISABILITY.

2.5 "INPATIENT BEDS" FOR THE PURPOSE OF THIS CHAPTER 9. THE TERM INPATIENT BED IN A COMMUNITY CLINIC MEANS THE USE OF BEDS FOR THE MONITORING OR OBSERVATION OF PATIENTS WHO PRESENT FOR SERVICES AND WOULD BENEFIT FROM MONITORING BY HEALTH CARE PROVIDERS FOR A PERIOD OF NO MORE THAN 72 HOURS, EXCEPT THAT THE 72-HOUR LIMIT SHALL NOT APPLY TO DEPARTMENT OF CORRECTIONS CLINICS. SUCH BEDS ARE NOT MEANT TO BE USED FOR ROUTINE PREPARATION OR RECOVERY PRIOR TO OR FOLLOWING DIAGNOSTIC OR SURGICAL SERVICES OR TO ACCOMMODATE HOSPITAL OVERFLOW. IF THE PATIENT NEEDS CARE BEYOND 72 HOURS, THE PATIENT MUST BE TRANSFERRED.

2.6 "GOVERNING BODY" MEANS THE BOARD OF TRUSTEES, DIRECTORS, OR OTHER GOVERNING ENTITY IN WHOM THE ULTIMATE AUTHORITY AND RESPONSIBILITY FOR THE CONDUCT OF THE CLINIC IS VESTED.

2.7 "PATIENT" 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 "PATIENT" IS SYNONYMOUS WITH THE TERMS "CLIENT," "RESIDENT," OR "CONSUMER" AS USED ELSEWHERE IN 6 CCR 1011-1.

Commented [SG5]: New language consistent with Chap 2 def.

2.8 "PRIMARY CARE SERVICES" MEANS OUTPATIENT HEALTH CARE SERVICES THAT INCLUDE: COMPREHENSIVE ASSESSMENT AT FIRST CONTACT; EVALUATION AND TREATMENT OF HEALTH CARE CONCERNS; REFERRALS TO SPECIALISTS AS APPROPRIATE; AND PLANNED CONTINUING ROUTINE CARE INCLUDING COORDINATION WITH SPECIALISTS. PRIMARY CARE SERVICES ALSO ENCOMPASS PREVENTIVE HEALTH SERVICES, INCLUDING, BUT NOT LIMITED TO: HEALTH EDUCATION, BEHAVIORAL HEALTH, WELL CHILD SERVICES, IMMUNIZATIONS, ETC.

2.9 "PROVIDER," FOR THE PURPOSE OF THIS CHAPTER 9, MEANS A MEDICAL DOCTOR, DOCTOR OF OSTEOPATHY, NURSE PRACTITIONER, PHYSICIAN ASSISTANT, OR LICENSED INDEPENDENT PRACTITIONER.

Commented [SG6]: New language consistent with Chapter 13,

PART 3. LICENSING FEES

Commented [SG7]: Original language and fees

FOR NEW LICENSE APPLICATIONS RECEIVED OR RENEWAL LICENSES THAT EXPIRE ON OR AFTER JULY 1, 2021, A NON-REFUNDABLE FEE SHALL BE SUBMITTED WITH THE LICENSE APPLICATION AS FOLLOWS:

LICENSE CATEGORY	INITIAL LICENSE	RENEWAL LICENSE	CHANGE OF OWNERSHIP
COMMUNITY CLINIC PROVIDING EMERGENCY SERVICES AND/OR	$2,873.89	$1,410.82	$3,239.65

COMMUNITY CLINIC OPERATING INPATIENT BEDS			
COMMUNITY CLINIC OPERATED UNDER THE AUSPICES OF THE DEPARTMENT OF CORRECTIONS	$2,612.62	$1,358.57	$2,612.62
OPTIONAL LICENSURE PURSUANT TO PART 2, 2.3(A)(3) COMMUNITY CLINIC SERVING THE UNINSURED OR UNDERINSURED	$1,254.06	$627.03	$1,306.31
OTHER COMMUNITY CLINIC	$2,508.13	$1,254.06	$2,612.62

PART 4. GENERAL BUILDING AND FIRE SAFETY PROVISIONS

Commented [SG8]: Original language

4.1 ANY CONSTRUCTION OR RENOVATION OF A COMMUNITY CLINIC INITIATED ON OR AFTER JULY 1, 2020, SHALL CONFORM TO PART 3 OF 6 CCR 1011-1, CHAPTER 2, UNLESS OTHERWISE SPECIFIED IN THIS CHAPTER.

4.2 ANY COMMUNITY CLINIC OPERATING INPATIENT BEDS SHALL ALSO COMPLY WITH THE REQUIREMENTS AT PART 19.9 OF THIS CHAPTER.

PART 5. OPERATIONS

Commented [BM9]: Renamed to match Chapter 13 FSEDs

5.1 ENVIRONMENTAL SERVICES

(A) THE CC SHALL PROVIDE ENVIRONMENTAL SERVICES AND STAFF TO ENSURE THAT THE PREMISES ARE CLEAN AND SANITARY.

Commented [SG10]: A-C modified original concepts

(B) THE CC SHALL PROVIDE FOR EFFECTIVE CONTROL AND ERADICATION OF VERMIN. ALL OPENINGS TO THE OUTER AIR SHALL BE EFFECTIVELY PROTECTED AGAINST THE ENTRANCE OF VERMIN BY SELF-CLOSING DOORS, CLOSED WINDOWS, SCREENS, CONTROLLED AIR CURRENTS, OR OTHER EFFECTIVE MEANS.

(C) THERE SHALL BE SEPARATE CLEAN AND SOILED UTILITY ROOMS.

(D) PERSONNEL SHALL RECEIVE ADEQUATE SUPERVISION. INITIAL AND ANNUAL IN-SERVICE TRAINING PROGRAMS SHALL BE PROVIDED FOR ENVIRONMENTAL SERVICES PERSONNEL.

Commented [SG11]: D- H, New language consistent with Chap 13

(E) SUITABLE EQUIPMENT AND SUPPLIES SHALL BE PROVIDED FOR CLEANING OF ALL SURFACES. SUCH EQUIPMENT SHALL BE MAINTAINED IN A SAFE, SANITARY CONDITION.

(F) CLEANING COMPOUNDS AND OTHER HAZARDOUS SUBSTANCES (INCLUDING PRODUCTS LABELED "KEEP OUT OF REACH OF CHILDREN" ON THEIR ORIGINAL CONTAINERS) SHALL BE CLEARLY LABELED TO INDICATE CONTENTS AND (EXCEPT WHEN A STAFF MEMBER IS PRESENT) SHALL BE STORED IN A LOCATION SUFFICIENTLY SECURE TO DENY ACCESS TO PATIENTS.

(G) CLEANING SHALL BE PERFORMED IN A MANNER TO MINIMIZE THE SPREAD OF PATHOGENIC ORGANISMS. FLOORS SHALL BE CLEANED REGULARLY.

(H) CARTS USED TO TRANSPORT REFUSE SHALL BE CONSTRUCTED OF IMPERVIOUS MATERIALS, ENCLOSED, USED SOLELY FOR REFUSE, AND MAINTAINED IN A SANITARY MANNER.

5.2 MAINTENANCE SERVICES

(A) THE CC SHALL BE MAINTAINED TO ENSURE THE SAFETY OF PATIENTS, STAFF, AND VISITORS.

Commented [SG12]: A-B Modified original language

(B) A PREVENTIVE MAINTENANCE PROGRAM SHALL BE IMPLEMENTED TO ENSURE THAT ALL ESSENTIAL MECHANICAL, ELECTRICAL, AND PATIENT CARE EQUIPMENT IS PERIODICALLY MONITORED, CALIBRATED, AND MAINTAINED IN SAFE OPERATING CONDITION.

(1) PREVENTIVE MAINTENANCE INCLUDES, BUT IS NOT LIMITED TO: ROUTINE INSPECTIONS, CLEANING, TESTING, AND CALIBRATING IN ACCORDANCE WITH MANUFACTURERS' INSTRUCTIONS, OR IF THERE ARE NOT MANUFACTURERS' INSTRUCTIONS, AS SPECIFIED BY THE CC'S WRITTEN POLICIES AND PROCEDURES. A CC MAY, UNDER CERTAIN CONDITIONS, USE EQUIPMENT MAINTENANCE ACTIVITIES AND FREQUENCIES THAT DIFFER FROM THOSE RECOMMENDED BY THE MANUFACTURER. CCS THAT CHOOSE TO EMPLOY ALTERNATE MAINTENANCE ACTIVITIES AND/OR SCHEDULES MUST DEVELOP, IMPLEMENT, AND MAINTAIN A DOCUMENTED ALTERNATE EQUIPMENT MAINTENANCE PROGRAM TO MINIMIZE RISKS ASSOCIATED WITH THE USE OF MEDICAL EQUIPMENT.

Commented [SG13]: 1-3, New language consistent with Chap 13

(2) PREVENTIVE MAINTENANCE SHALL BE CONDUCTED IN ACCORDANCE WITH WRITTEN MAINTENANCE SCHEDULES.

(3) RECORDS SHALL BE MAINTAINED SHOWING THE DATE OF MAINTENANCE AND ACTION TAKEN TO CORRECT ANY DEFICIENCIES.

5.3 WASTE DISPOSAL SERVICES

(A) ALL WASTE SHALL BE DISPOSED IN COMPLIANCE WITH LOCAL, STATE, AND FEDERAL LAWS.

Commented [SG14]: A-B Original language

(B) MEDICAL WASTE SHALL BE DISPOSED OF IN ACCORDANCE WITH THE DEPARTMENT'S REGULATIONS PERTAINING TO SOLID WASTE DISPOSAL SITES AND FACILITIES AT 6 CCR 1007-2, PART 1, SECTION 13, MEDICAL WASTE.

(C) THE CC SHALL HAVE POLICIES AND PROCEDURES ADDRESSING THE PROPER:

Commented [SG15]: C-I, New language consistent with Chap 13

(1) DISCHARGE OF SEWAGE INTO A PUBLIC SEWER SYSTEM.

(2) COLLECTION, STORAGE IN COVERED CONTAINERS, AND TIMELY REMOVAL OF GARBAGE AND REFUSE NOT TREATED AS SEWAGE.

(3) HANDLING AND DISPOSAL OF INFECTIOUS WASTE IN ACCORDANCE WITH THE REQUIREMENTS OF SECTION 25-15-401, ET SEQ., C.R.S. AND PART 11 OF THESE RULES.

(4) DISPOSAL OF BIOLOGICAL NON-INFECTIOUS WASTE.

(D) EACH CC SHALL HAVE A SUFFICIENT NUMBER OF WATER-TIGHT CONTAINERS WITH TIGHT FITTING LIDS TO HOLD ALL REFUSE THAT ACCUMULATES BETWEEN COLLECTIONS.

(E) CONTAINERS USED FOR STORING OR HOLDING REFUSE WAITING FOR COLLECTION MUST BE ENCLOSED.

(F) REFUSE CONTAINERS SHALL BE CLEANED EACH TIME THEY ARE EMPTIED.

(G) SINGLE SERVICE CONTAINER LINERS ARE REQUIRED.

(H) ACCUMULATED WASTE MATERIAL SHALL BE REMOVED FROM THE FACILITY AT LEAST DAILY.

(I) ALL EXTERNAL RUBBISH AND REFUSE CONTAINERS SHALL BE IMPERVIOUS AND TIGHTLY COVERED.

5.4 LINEN AND LAUNDRY SERVICES

Commented [SG16]: A-B Original language, C new language, Chapter 13

(A) LINEN AND LAUNDRY SERVICES SHALL BE PROVIDED IN-HOUSE OR BY CONTRACT WITH A COMMERCIAL LAUNDRY SERVICE.

(B) SEPARATE CLEAN AND SOILED LINEN AREAS SHALL BE PROVIDED AND MAINTAINED.

(C) FOR SERVICES PROVIDED IN-HOUSE, THE WATER TEMPERATURE AND DURATION OF WASHING CYCLE SHALL BE CONSISTENT WITH THE TEMPERATURE AND DURATION RECOMMENDED BY THE MANUFACTURERS OF THE LAUNDRY CHEMICALS AND EQUIPMENT BEING USED.

PART 6. GOVERNANCE AND LEADERSHIP

6.1 APPLICABILITY

Commented [SG17]: Consistent with previous requirements, but including new clarifying language.

(A) ALL COMMUNITY CLINICS SHALL MEET THE STANDARDS IN THIS PART 6.2.

(B) ALL COMMUNITY CLINICS OPERATING INPATIENT BEDS SHALL ADDITIONALLY MEET THE STANDARDS IN THIS PART 6.3 AND 6.4.

(C) ALL COMMUNITY CLINICS PROVIDING EMERGENCY SERVICES SHALL ADDITIONALLY MEET THE STANDARDS IN THIS PART 6.3, 6.4, AND 6.5.

6.2 ADMINISTRATOR

(A) THE CLINIC SHALL HAVE AN ADMINISTRATOR OR A DESIGNATED PERSON WHO IS PRINCIPALLY RESPONSIBLE FOR DIRECTING THE DAILY OPERATION OF THE CLINIC.

Commented [SG18]: Original language

(B) THE ADMINISTRATOR SHALL BE RESPONSIBLE FOR THE DEVELOPMENT AND IMPLEMENTATION OF POLICIES AND PROCEDURES FOR ALL FACILITY OPERATIONS. THE POLICIES AND PROCEDURES SHALL BE REVIEWED AND UPDATED AS NEEDED BUT NO LESS THAN EVERY THREE YEARS. POLICIES SHALL INCLUDE:

Commented [SG19]: Modified original language

(1) A WRITTEN ORGANIZATIONAL PLAN DEFINING THE AUTHORITY, RESPONSIBILITY, AND FUNCTION OF EACH CATEGORY OF PERSONNEL.

(2) A POLICY REGARDING THE FACILITY'S HOURS OF OPERATION. THE FACILITY'S HOURS OF OPERATION SHALL BE POSTED ON ENTRY DOORS AND THE FACILITY'S WEBSITE, IF APPLICABLE.

(3) A WRITTEN EMERGENCY EVACUATION PLAN, INCLUDING:

Commented [SG20]: Original language

(A) ROLES AND RESPONSIBILITIES OF EMPLOYEES IN THE EVENT OF AN EMERGENCY.

(B) TRAINING REQUIREMENTS FOR EMPLOYEES REGARDING RESPONSIBILITIES IN THE EVENT OF AN EMERGENCY EVACUATION.

(C) THE PROMINENT POSTING OF EVACUATION ROUTES AND EXITS.

(C) THE ADMINISTRATOR SHALL DEVELOP A WRITTEN POLICY DEFINING THE SCOPE OF CARE AND SERVICES OFFERED. THE FACILITY SHALL DEFINE THE SCOPE OF PREVENTIVE, DIAGNOSTIC, AND TREATMENT SERVICES IN WRITING. THE SCOPE SHALL INCLUDE A DESCRIPTION OF THOSE SERVICES FURNISHED DIRECTLY AND THROUGH AGREEMENTS WITH OR REFERRALS TO OTHER HEALTH CARE SERVICE PROVIDERS.

Commented [SG21]: Original language

6.3 ADDITIONAL REQUIREMENTS FOR THE ADMINISTRATOR OR GOVERNING BODY FOR COMMUNITY CLINICS OPERATING INPATIENT BEDS OR COMMUNITY CLINICS PROVIDING EMERGENCY SERVICES

Commented [SG22]: 6.3 Original or modified original language

(A) THE COMMUNITY CLINIC OPERATING INPATIENT BEDS OR PROVIDING EMERGENCY SERVICES MAY CHOOSE TO CONVENE A GOVERNING BODY. IF A COMMUNITY CLINIC OPERATING INPATIENT BEDS OR PROVIDING EMERGENCY SERVICES DOES NOT CONVENE A GOVERNING BODY, THE CLINIC ADMINISTRATOR SHALL HAVE RESPONSIBILITY FOR ALL TASKS AS SET FORTH IN THIS PART 6.3(B).

(1) IF A GOVERNING BODY IS CONVENED, IT SHALL BE RESPONSIBLE FOR THE OVERSIGHT OF THE ORGANIZATION AND THE PROVIDERS.

(2) THE GOVERNING BODY SHALL MEET AT LEAST ANNUALLY AND MAINTAIN ACCURATE RECORDS OF SUCH MEETINGS.

Commented [BM23]: Language from Birth Centers

(3) THE GOVERNING BODY SHALL ADOPT THE GENERAL BYLAWS BY WHICH THE GOVERNING BODY OPERATES.

(B) THE GOVERNING BODY OR THE ADMINISTRATOR SHALL:

(1) ENSURE THAT THE PATIENTS RECEIVE CARE IN A SAFE SETTING, INCLUDING PROVIDING THE EQUIPMENT, SUPPLIES, AND FACILITIES NECESSARY FOR THE WELFARE AND SAFETY OF PATIENTS.

Commented [SG24]: Similar to Chapter 9, but new wording consistent with Chap 13

(2) ESTABLISH THE HOURS OF OPERATION AND FACILITATE ACCESSIBILITY IF THE FACILITY IS CLOSED, AS SPECIFIED BELOW.

(A) THE CLINIC SHALL MAINTAIN REGULAR HOURS FOR SERVICES.

(B) THE CLINIC SHALL POST SIGNAGE ON OR NEAR THE FRONT ENTRANCE INDICATING: HOURS OF OPERATION AND AN EMERGENCY REFERRAL NUMBER AND/OR A PROCEDURE FOR OBTAINING MEDICAL SERVICES WHEN THE CLINIC IS NOT OPEN.

(3) ESTABLISH A PATIENT TRANSFER PLAN THAT INCLUDES:

(A) AGREEMENTS WITH A HOSPITAL(S) THAT INCLUDE PROCEDURES FOR OBTAINING AIR OR GROUND TRANSPORTATION, AS APPROPRIATE.

(B) IF AN EMERGENCY MEDICAL CONDITION NECESSITATES PATIENT TRANSFER, THE PATIENT SHALL BE TRANSFERRED, AVOIDING DELAY IN CARE AND WITH CONSIDERATION OF TRANSPORT TIME, TO THE CLOSEST, MOST APPROPRIATE ACUTE CARE HOSPITAL WITH THE RESOURCES NECESSARY TO MEET THE NEEDS OF THE PATIENT.

Commented [BM25]: Reworded to match Chapter 13

(C) TRANSFER PROTOCOLS TO INCLUDE:

(I) COORDINATION WITH THE LOCAL EMERGENCY MEDICAL SERVICES SYSTEM AND LICENSED AMBULANCE SERVICES.

(II) TRIAGE AND STABILIZATION TO BE INITIATED BY ON-DUTY STAFF.

(III) TRANSFER OF RELEVANT PATIENT INFORMATION WITH THE PATIENT.

(IV) COMPLIANCE WITH ALL REQUIREMENTS AS A DESIGNATED OR NON-DESIGNATED TRAUMA CENTER PER REGULATION, 6 CCR 1015-4, CHAPTER THREE, IF APPLICABLE.

Commented [SG26]: New language, conforming to requirements of 6 CCR 1015-4, Chapter Three, Designation of Trauma Facilities

(V) COMPLIANCE WITH REGIONAL TRAUMA TRIAGE PROTOCOLS, IF APPLICABLE.

(4) ENSURE THAT THERE ARE WRITTEN PROCEDURES FOR:

(A) LINES OF AUTHORITY AND ACCOUNTABILITY, AND

(B) THE QUALIFICATIONS OF THE PERSONNEL PERFORMING CARE.

(5) ENSURE THE APPROVAL AND IMPLEMENTATION OF WRITTEN POLICIES AND PROCEDURES IN COOPERATION WITH THE ADMINISTRATOR AND MEDICAL DIRECTOR.

Commented [SG27]: 5-8 new language consistent with Chap 13

(6) ENSURE THAT THERE IS SUFFICIENT STAFF TO MEET THE DEMANDS FOR SERVICES ROUTINELY PROVIDED AND COVERAGE DURING PERIODS OF HIGH DEMAND OR EMERGENCY.

(7) ENSURE ANY DISCIPLINARY ACTION THAT RESULTS IN A SUSPENSION, REVOCATION, OR LIMITATION OF THE PRIVILEGES OF A MEMBER OF THE PROVIDER, NURSING, OR ANCILLARY STAFF IS REPORTED TO THE APPROPRIATE LICENSING OR CERTIFICATION AUTHORITY.

(8) ENSURE THAT THE COMMUNITY CLINIC OPERATING INPATIENT BEDS OR PROVIDING EMERGENCY SERVICES MEETS ALL OF THE QUALITY MANAGEMENT PROGRAM REQUIREMENTS OF PART 8.

6.4 MEDICAL DIRECTOR (REQUIRED ONLY FOR COMMUNITY CLINICS OPERATING INPATIENT BEDS OR COMMUNITY CLINICS PROVIDING EMERGENCY SERVICES)

Commented [SG28]: A-B Original language

(A) THE GOVERNING BODY OF THE COMMUNITY CLINIC OPERATING INPATIENT BEDS OR PROVIDING EMERGENCY SERVICES, OR THE CLINIC ADMINISTRATOR IF THERE IS NO GOVERNING BODY, SHALL APPOINT A MEDICAL DIRECTOR FOR THE FACILITY. SUCH MEDICAL DIRECTOR SHALL BE A PHYSICIAN, LICENSED UNDER THE LAWS OF THE STATE OF COLORADO, WHO IS A MEMBER OF THE CC'S STAFF. THE MEDICAL DIRECTOR SHALL BE RESPONSIBLE FOR THE QUALITY OF MEDICAL CARE PROVIDED TO PATIENTS IN THE FACILITY.

(B) THE MEDICAL DIRECTOR SHALL BE RESPONSIBLE FOR THE DEVELOPMENT OF POLICIES AND PROCEDURES RELATED TO THE MEDICAL CARE PROVIDED. THE POLICIES AND PROCEDURES SHALL BE APPROVED BY THE APPROPRIATE MEMBERS OF THE PROVIDER STAFF AND REVIEWED AND UPDATED AS NEEDED, BUT NO LESS THAN EVERY THREE YEARS.

(C) THE MEDICAL DIRECTOR SHALL SERVE AS THE FORMAL CLINICAL LIAISON WITH THE GOVERNING BODY AND ADMINISTRATOR.

Commented [SG29]: C-D, New language consistent with Chap 13

(D) THE MEDICAL DIRECTOR SHALL ENSURE THAT SERVICES ARE PROVIDED IN ACCORDANCE WITH CURRENT STANDARDS OF PRACTICE AND ARE CONSISTENT WITH STANDARDS ESTABLISHED THROUGH THE QUALITY MANAGEMENT PROGRAM AS DEFINED IN PART 8.

6.5 HOURS OF OPERATION (REQUIRED ONLY FOR COMMUNITY CLINICS PROVIDING EMERGENCY SERVICES)

Commented [SG30]: Original language

(A) COMMUNITY CLINICS PROVIDING EMERGENCY SERVICES SHALL MAINTAIN OPERATIONS ON A 24-HOUR BASIS, EVERY DAY OF THE YEAR, EXCEPT AS AUTHORIZED BELOW.

(1) SERVICE INTERRUPTION DURING A 24-HOUR PERIOD: COMMUNITY CLINICS PROVIDING EMERGENCY SERVICES IN NON-METROPOLITAN AREAS THAT DO NOT HAVE THE DEMAND TO SUPPORT 24-HOUR SERVICES MAY INTERRUPT OPERATIONS FOR A PART OF THE 24-HOUR PERIOD ON A ROUTINELY SCHEDULED BASIS. THE GOVERNING BODY OR ADMINISTRATOR OF A FACILITY THAT CONDUCTS SUCH SERVICE INTERRUPTIONS SHALL DEVELOP AND IMPLEMENT A WRITTEN PLAN THAT ADDRESSES:

(A) REPORTING TO THE DEPARTMENT ANY CHANGES IN HOURSOF OPERATION.

(B) ACCESS TO ALTERNATIVE EMERGENCY SERVICES DURING THE SERVICE INTERRUPTION. THE FACILITY SHALL ESTABLISH A PROCESS FOR MAKING SERVICES AVAILABLE WITHIN 30 MINUTES OR SOONER IF MEDICALLY NECESSARY FOR PERSONS WHO PRESENT AT A CLOSED FACILITY. CLEAR DIRECTIONS AT THE FRONT AND/OR EMERGENCY ENTRANCE TO THE FACILITY THAT CAN BE EASILY UNDERSTOOD BY PERSONS APPROACHING THE ENTRANCE(S) SHALL BE POSTED IN A CONSPICUOUS LOCATION WITH AN APPROPRIATE COMMUNICATIONS DEVICE, SUCH AS A "HOT PHONE" OR "TIP AND RING PHONE" SO THAT CARE CAN BE SUMMONED IMMEDIATELY AND AN APPROPRIATE EMERGENCY RESPONSE OCCURS.

(C) HOW LICENSED AMBULANCE SERVICES AND OTHER APPROPRIATE EMERGENCY RESPONSE ORGANIZATIONS WILL BE ALERTED ABOUT THE PERIODS DURING WHICH THE FACILITY IS CLOSED.

(2) SEASONAL CLOSURES. A COMMUNITY CLINIC PROVIDING EMERGENCY SERVICES IN A NON-METROPOLITAN AREA THAT EXPERIENCES SEASONAL POPULATION INFLUX MAY CHOOSE TO ONLY OPERATE EACH YEAR DURING SPECIFIED TIMES.THE GOVERNING BODY OR ADMINISTRATOR OF A FACILITY THAT CONDUCTS SEASONAL CLOSURES SHALL DEVELOP AND IMPLEMENT A WRITTEN PLAN THAT ADDRESSES:

(A) REPORTING THE SEASONAL CLOSURE TO THE DEPARTMENT AT LEAST 30 DAYS PRIOR TO SUCH CLOSURE AND THE RESUMPTION OF SERVICES AT LEAST 30 DAYS PRIOR TO SUCH RESUMPTION.

(B) COMPLIANCE WITH 6.5(A)(1) (B) AND (C) FOR THE PURPOSE OF THE SEASONAL CLOSURE.

PART 7. EMERGENCY PREPAREDNESS

Commented [SG31]: Mostly new language from Chap 13, but current regulations require an emergency plan

7.1 EMERGENCY MANAGEMENT PLAN

EACH CC SHALL DEVELOP AND IMPLEMENT A COMPREHENSIVE EMERGENCY MANAGEMENT PLAN THAT MEETS THE REQUIREMENTS OF THIS PART, UTILIZING AN ALL-HAZARDS APPROACH. THIS PLAN SHALL TAKE INTO CONSIDERATION PREPAREDNESS FOR NATURAL EMERGENCIES, MAN-MADE EMERGENCIES, FACILITY EMERGENCIES, BIOTERRORISM EVENTS, PANDEMIC, OR AN OUTBREAK BY A HIGHLY INFECTIOUS AGENT OR BIOLOGICAL TOXIN.

Commented [SG32]: Previously an administrator role

7.2 THE PLAN SHALL INCLUDE, BUT IS NOT LIMITED TO, THE FOLLOWING TYPES OF EMERGENCIES:

(A) CARE-RELATED EMERGENCIES;

(B) INTERRUPTIONS IN THE NORMAL SUPPLY OF UTILITIES OR ESSENTIALS, SUCH AS WATER, HEAT, ELECTRICITY, FOOD, PHARMACEUTICALS, PERSONAL PROTECTIVE EQUIPMENT (PPE), AND OTHER ESSENTIALS;

(C) EQUIPMENT FAILURES;

(D) INTERRUPTIONS IN COMMUNICATIONS, INCLUDING CYBER-ATTACKS;

(E) FIRE, EXPLOSION, OR OTHER PHYSICAL DAMAGE TO THE FACILITY;

Commented [SG33]: E-G original language

(F) LOCAL OR WIDESPREAD WEATHER EMERGENCIES OR NATURAL DISASTERS ENDEMIC TO THE REGION.

(G) ITS ROLE IN PANDEMICS OR OTHER EMERGENCY SITUATIONS WHERE THE COMMUNITY'S NEED FOR SERVICES EXCEEDS THE AVAILABILITY OF BEDS AND SERVICES REGULARLY OFFERED BY AREA HOSPITALS.

7.3 THE EMERGENCY MANAGEMENT PLAN MUST ALSO MEET THE FOLLOWING REQUIREMENTS:

(A) THE PLAN MUST BE:

(1) SPECIFIC TO THE CC;

(2) RELEVANT TO THE GEOGRAPHIC AREA;

(3) READILY PUT INTO ACTION, TWENTY-FOUR (24) HOURS A DAY, SEVEN (7) DAYS A WEEK OR DURING THE HOURS OF OPERATION FOR CCS NOT OPEN AT ALL TIMES; AND

(4) REVIEWED AND REVISED PERIODICALLY.

(B) THE PLAN MUST IDENTIFY:

(1) WHO IS RESPONSIBLE FOR EACH ASPECT OF THE PLAN; AND

(2) ESSENTIAL AND KEY PERSONNEL RESPONDING TO A DISASTER.

(C) THE PLAN SHALL INCLUDE:

(1) A STAFF EDUCATION AND TRAINING COMPONENT;

(2) A PROCESS FOR TESTING EACH ASPECT OF THE PLAN AT LEAST EVERY TWO (2) YEARS OR AS DETERMINED BY CHANGES IN THE AVAILABILITY OF CC RESOURCES;

(3) A COMPONENT FOR DEBRIEFING AND EVALUATION AFTER EACH DISASTER, INCIDENT, OR DRILL; AND

(4) THE PROMINENT POSTING OF EVACUATION ROUTES AND EXITS.

PART 8. QUALITY MANAGEMENT PROGRAM

Commented [SG34]: Language from Chapter 13, but the requirement to comply has always applied. This just points the user to Chapter 2.

8.1 EACH CC SHALL COMPLY WITH THE REQUIREMENTS OF 6 CCR 1011-1, CHAPTER 2, PART 4.1.

8.2 IF A CC IS PART OF A LARGER SYSTEM CONSISTING OF MULTIPLE HOSPITALS/CCS USING A SYSTEM GOVERNING BODY THAT IS LEGALLY RESPONSIBLE FOR THE CONDUCT OF TWO OR MORE HOSPITALS/CCS, THE SYSTEM GOVERNING BODY MAY HAVE A UNIFIED QUALITY MANAGEMENT PROGRAM (QMP) PROVIDED THE QMP DOES THE FOLLOWING:

(A) TAKES INTO ACCOUNT EACH CC'S UNIQUE CIRCUMSTANCES AND ANY SIGNIFICANT DIFFERENCES IN PATIENT POPULATIONS AND SERVICES OFFERED IN EACH CC; AND

(B) ESTABLISHES AND IMPLEMENTS POLICIES AND PROCEDURES TO ENSURE THE NEEDS AND CONCERNS OF EACH CC, REGARDLESS OF PRACTICE OR LOCATION, ARE GIVEN DUE

CONSIDERATION, AND THAT THE UNIFIED QUALITY MANAGEMENT PROGRAM HAS MECHANISMS IN PLACE TO ENSURE THAT ISSUES LOCALIZED TO PARTICULAR CCS ARE DULY CONSIDERED AND ADDRESSED.

PART 9. PERSONNEL

Commented [SG35]: Mixture of modified original language and new language

9.1 ORGANIZATION AND STAFFING

(A) THERE SHALL BE SUFFICIENT AVAILABLE PROVIDER, NURSING, AND ANCILLARY STAFF WITH THE APPROPRIATE EDUCATION, TRAINING, COMPETENCIES, AND EXPERIENCE TO MEET THE NEEDS OF THE PATIENT, IN ACCORDANCE WITH THE SCOPE OF THE SERVICES PROVIDED BY THE CC.

(B) THE CC SHALL MAINTAIN POSITION DESCRIPTIONS FOR ALL CATEGORIES OF PERSONNEL THAT CLEARLY STATE THEIR QUALIFICATIONS AND EXPECTED DUTIES.

(C) STAFF SHALL BE LICENSED, CERTIFIED, OR REGISTERED IN ACCORDANCE WITH APPLICABLE STATE LAWS AND REGULATIONS AND SHALL PROVIDE SERVICES WITHIN THEIR SCOPE OF PRACTICE, FACILITY POLICY, AND PROFESSIONAL STANDARDS OF PRACTICE.

(D) THE CC SHALL MAINTAIN PERSONNEL RECORDS ON EACH MEMBER OF THE CC STAFF INCLUDING VERIFICATION OF LICENSURE, CERTIFICATION, OR REGISTRATION. IN ADDITION, THE CC SHALL MAINTAIN PROCEDURES TO ENSURE THAT STAFF FOR WHOM STATE LICENSES, REGISTRATIONS, OR CERTIFICATES ARE REQUIRED HAVE A CURRENT LICENSE, REGISTRATION, OR CERTIFICATION.

(E) STAFF SHALL RECEIVE ORIENTATION INCLUDING, BUT NOT LIMITED TO, THE PATIENT CARE ENVIRONMENT, INFECTION CONTROL, AND RELEVANT POLICIES AND PROCEDURES.

Commented [SG36]: E, G, H, New language consistent with Chap 13.

(F) STAFF SHALL RECEIVE ANNUAL TRAINING ON INFECTION CONTROL PRACTICES AS REQUIRED IN PART 11.3 (A).

(G) THE CC SHALL ENSURE THAT POLICIES AND PROCEDURES ARE AVAILABLE TO EMPLOYEES AT ALL TIMES.

(H) CCS THAT UTILIZE EMERGENCY MEDICAL SERVICE (EMS) PROVIDERS SHALL, IN COLLABORATION WITH THE PROVIDER STAFF, ESTABLISH OPERATING POLICIES AND PROCEDURES THAT ENSURE EMS PROVIDERS PERFORM TASKS AND PROCEDURES AND ADMINISTER MEDICATIONS WITHIN THEIR SCOPE OF PRACTICE PURSUANT TO SECTION 25-3.5-207, C.R.S.

9.2 NURSING SERVICES

Commented [SG37]: Modified original language

(A) THE CC SHALL PROVIDE NURSING SERVICES SUFFICIENT TO MEET THE SCOPE OF CARE AND SERVICES AS DEFINED IN CLINIC POLICY.

(B) THERE SHALL BE WRITTEN NURSING POLICIES AND PROCEDURES THAT ESTABLISH THE STANDARDS FOR PERFORMANCE FOR SAFE, EFFECTIVE NURSING CARE OF PATIENTS. THESE PROCEDURES SHALL BE REVIEWED PERIODICALLY AND REVISED AS NECESSARY, NO LESS THAN EVERY THREE (3) YEARS.

(C) NURSING SERVICES SHALL BE OVERSEEN BY A REGISTERED NURSE QUALIFIED BY TRAINING AND EXPERIENCE.

9.3 PROVIDER STAFF

(A) THE COMMUNITY CLINIC SHALL HAVE AN ORGANIZED PROVIDER STAFF WHICH SHALL PROVIDE CLINICAL SERVICES SUFFICIENT TO MEET THE SCOPE OF CARE AS DEFINED IN POLICY.

(B) Care shall be provided by providers qualified by education, training, and experience to deliver such care.

(C) Medications and treatments shall be administered only on the order of a provider authorized by law.

(D) The CC's provider staff shall develop and implement written patient care policies that are reviewed and updated on a routine basis and no less than every three (3) years. The policies and procedures shall address:

(1) Primary care services.

(2) Coordination of care with other facilities or health care service providers, including, but not limited to, the transfer of records to facilitate continuity of care.

(3) Continuing care by the same health care provider whenever possible.

(4) If the CC does not provide emergency services, the facility response to an individual who presents with or declares the need for emergency services, including when it is appropriate to:

(A) Treat the patient within the clinic;

(B) Advise the individual to go to an emergency room; or

(C) Call 9-1-1 for the individual.

Part 10. HEALTH INFORMATION MANAGEMENT

10.1 Each CC shall comply with the requirements of 6 CCR 1011-1, Chapter 2, Part 6, regarding patient access to medical records.

Commented [SG38]: 10.1-10.3 are new language from Chap 13.
10.1 has always been accurate, just not expressly stated.

10.2 The CC shall provide sufficient space and equipment for the processing and the safe storage of medical records. Records shall be maintained and stored out of direct access of water, fire, and other hazards to protect them from damage and loss. A records recovery or backup system shall be utilized to ensure that there is no loss of medical records.

10.3 A person knowledgeable in health information management shall be responsible for the proper administration and protection of health information.

10.4 The facility shall store health information in a manner that protects patient privacy and confidentiality and allows for retrieval of records in a timely manner.

Commented [SG39]: Original language

10.5 Medical records shall be preserved as original records, in a manner determined by the CC:

Commented [SG40]: Modified original Language

(A) For minors, for the period of minority plus ten (10) years (i.e., until the patient is age 28) or ten (10) years after the most recent patient encounter, whichever is later.

(B) For adults, ages eighteen (18) and older, for no less than seven (7) years after the most recent patient care encounter.

10.6 If a CC ceases operation, the CC shall make provision for secure, safe storage and prompt retrieval of all medical records for the period specified in this Part 10.5 (A) and (B).

Commented [SG41]: 10.6-10.8 new language from Chap 13

10.7 A CC that ceases operation must comply with the provisions of 6 CCR 1011-1, Chapter 2, Part 2.14.4.

Commented [SG42]: Newly stated here but has always been true.

10.8 After the required time of record preservation, records may be destroyed at the discretion of the CC, in accordance with the CC's record retention policy. The CC shall establish procedures for notification to patients whose records are to be destroyed prior to the destruction of such records.

10.9 General Content of Medical Records

(A) Complete medical records shall be maintained on every patient from the time of registration for services through discharge. All entries into the record shall be dated, timed, and authorized by appropriate personnel.

(B) All diagnostic procedures, treatments, and medications shall be ordered by the provider staff or other authorized licensed practitioners and entered in the medical record. The prompt completion of the medical record shall be the responsibility of the provider staff.

(C) Authorization may be by written signature, identifiable initials, or computer key.

Commented [SG43]: C and D are new language from Chap 13

(D) The record shall contain accurate documentation of significant clinical information pertaining to the patient sufficiently detailed and organized in such a manner to enable:

(1) Another provider to assume care of the patient at any time.

(2) Sufficient information for the evaluation of the quality of patient care by the quality management program.

(3) The provider staff to utilize the record to instruct the patient and family members.

10.10 The records of individual patients shall contain, but not be limited to:

(A) A unique medical record identification number, identification data including medical history, physical examination, and risk assessments, including psychosocial information.

(B) Properly executed consent to treat forms, informed consent(s), and advance directives, when applicable.

Commented [SG44]: Language Chapter 13

(C) Reports of physical examinations, vital signs, diagnostic and laboratory test results, reports of all imaging, and consultative reports and findings, if any.

(D) A brief summary of the care encounter and a record of patient education, medications, treatments, procedures, and any other information necessary to monitor the patient's progress. Documentation shall include notation of the instructions given to patients on the date of service.

(E) Documentation of complications, adverse reactions to drugs and anesthesia, referrals, and transfers.

Commented [SG45]: New language from Chap 13

(F) FINAL DIAGNOSIS WITH COMPLETION OF MEDICAL RECORDS WITHIN (THIRTY) 30 DAYS FOLLOWING THE CC VISIT.

PART 11. INFECTION PREVENTION AND CONTROL AND ANTIBIOTIC STEWARDSHIP PROGRAM

11.1 APPLICABILITY

(A) ALL COMMUNITY CLINICS SHALL MEET THE STANDARDS IN THIS PART 11.2, 11.3, AND 11.4.

(B) ALL COMMUNITY CLINICS OPERATING INPATIENT BEDS SHALL ADDITIONALLY MEET THE STANDARDS IN THIS PART 11.5.

(C) ALL COMMUNITY CLINICS PROVIDING EMERGENCY SERVICES SHALL ADDITIONALLY MEET THE STANDARDS IN THIS PART 11.5 AND 11.6.

11.2 THE CC SHALL HAVE AN INFECTION PREVENTION AND CONTROL PROGRAM THAT REFLECTS THE SCOPE AND COMPLEXITY OF SERVICES PROVIDED BY THE CC. THE PROGRAM SHALL BE BASED ON NATIONAL STANDARDS FOR INFECTION CONTROL AND SHALL ENSURE THE ADEQUATE INVESTIGATION, CONTROL, AND PREVENTION OF INFECTIONS.

Commented [SG46]: 11.2 and 11.3 Modified original language

11.3 THE CC SHALL DEVELOP AND IMPLEMENT POLICIES AND PROCEDURES REGARDING:

(A) TRAINING OF PROVIDER, NURSING, ANCILLARY, AND ALL OTHER STAFF ON INFECTION CONTROL PRACTICES. THE POLICY SHALL ADDRESS TRAINING PROVIDED UPON ORIENTATION TO THE CC AS WELL AS ONGOING ANNUAL TRAINING.

(B) PATIENT ISOLATION PRECAUTIONS IN RESPONSE TO COMMUNICABLE DISEASE.

(C) HAND HYGIENE, WHICH SHALL BE PERFORMED AS OFTEN AS NECESSARY USING SOAP AND WATER OR ALCOHOL-BASED HAND SANITIZER AND SHALL BE PERFORMED ACCORDING TO NATIONALLY RECOGNIZED GUIDELINES.

Commented [SG47]: C-F Language from Chapter 13

(D) MAINTENANCE OF A SANITARY ENVIRONMENT.

(E) MITIGATION OF RISKS ASSOCIATED WITH PATIENT INFECTIONS PRESENT UPON ARRIVAL.

(F) COORDINATION WITH OTHER FEDERAL, STATE, AND LOCAL AGENCIES, AS NECESSARY.

11.4 AS A CONDITION OF LICENSURE, THE COMMUNITY CLINIC SHALL CONDUCT DISEASE REPORTING IN ACCORDANCE WITH 6 CCR 1009-1 RULES AND REGULATIONS PERTAINING TO EPIDEMIC AND COMMUNICABLE DISEASE CONTROL.

Commented [SG48]: 11.4-11.6 original language

11.5 ADDITIONAL INFECTION CONTROL REQUIREMENTS (REQUIRED ONLY FOR COMMUNITY CLINICS OPERATING INPATIENT BEDS OR COMMUNITY CLINICS PROVIDING EMERGENCY SERVICES)

Commented [SG49]: Original language

(A) THE PROGRAM SHALL BE OVERSEEN BY AT LEAST ONE INDIVIDUAL TRAINED IN INFECTION PREVENTION AND CONTROL WHO SHALL BE EMPLOYED BY OR REGULARLY AVAILABLE TO THE CC.

11.6 ANTIBIOTIC STEWARDSHIP PROGRAM (REQUIRED ONLY FOR COMMUNITY CLINICS PROVIDING EMERGENCY SERVICES)

Commented [SG50]: New Language from Chap 13

(A) THE CC SHALL HAVE AN ANTIBIOTIC STEWARDSHIP PROGRAM RESPONSIBLE FOR THE OPTIMIZATION OF ANTIBIOTIC USE THROUGH STEWARDSHIP.

(B) THE PROGRAM SHALL BE OVERSEEN BY AN INDIVIDUAL WHO IS QUALIFIED THROUGH EDUCATION, TRAINING, OR EXPERIENCE IN INFECTIOUS DISEASE, INFECTION PREVENTION AND CONTROL, PHARMACY, AND/OR ANTIBIOTIC STEWARDSHIP.

(C) THE PROGRAM SHALL DOCUMENT THE EVIDENCE-BASED USE OF ANTIBIOTICS IN ALL SERVICES OF THE CC AND ANY IMPROVEMENTS IN PROPER ANTIBIOTIC USE.

(D) THE PROGRAM SHALL ADHERE TO NATIONALLY RECOGNIZED GUIDELINES, AS WELL AS BEST PRACTICES, FOR IMPROVING ANTIBIOTIC USE.

(E) THE PROGRAM SHALL REFLECT THE SCOPE AND COMPLEXITY OF THE SERVICES PROVIDED AT THE CC.

PART 12. PATIENT RIGHTS

Commented [SG51]: Original language

AS A CONDITION OF LICENSURE, THE CC SHALL BE IN COMPLIANCE WITH 6 CCR 1011-1, CHAPTER 2, PART 7.

PART 13. PHARMACY

Commented [SG52]: Content from Chap 13. Existing language stricken.

13.1 THE CC SHALL MAINTAIN AN INVENTORY OF MEDICATIONS SUFFICIENT TO CARE FOR THE NUMBER AND TYPES OF PATIENTS COVERED IN THE SCOPE OF SERVICES.

13.2 THE CC SHALL IMPLEMENT METHODS, PROCEDURES, AND CONTROLS WHICH ENSURE THE APPROPRIATION, ACQUISITION, STORAGE, DISPENSING, AND ADMINISTRATION OF MEDICATION ARE IN ACCORDANCE WITH APPLICABLE STATE AND FEDERAL LAWS AND REGULATIONS, WHETHER IT PROVIDES ITS OWN PHARMACEUTICAL SERVICES OR MAKES OTHER LEGAL AND APPROPRIATE ARRANGEMENTS FOR OBTAINING NECESSARY PHARMACEUTICALS.

13.3 MEDICATIONS SHALL NOT BE ADMINISTERED TO PATIENTS UNLESS ORDERED BY A LEGALLY AUTHORIZED PROVIDER.

13.4 MEDICATIONS MAINTAINED IN THE CC SHALL BE APPROPRIATELY STORED AND SAFEGUARDED AGAINST DIVERSION OR ACCESS BY UNAUTHORIZED PERSONS. APPROPRIATE RECORDS SHALL BE KEPT REGARDING THE DISPOSITION OF ALL MEDICATIONS.

13.5 EACH CC SHALL MAINTAIN REFERENCE SOURCES FOR IDENTIFYING AND DESCRIBING MEDICATIONS. SOURCES MAY BE IN PRINT, ELECTRONIC FORMAT, OR WEB-BASED.

13.6 MEDICATION SHALL BE ADMINISTERED ONLY BY A PERSON LEGALLY AUTHORIZED PER THEIR SCOPE OF PRACTICE.

13.7 ADVERSE MEDICATION REACTIONS SHALL BE REPORTED IMMEDIATELY TO THE PROVIDER RESPONSIBLE FOR THE PATIENT AND DOCUMENTED IN THE MEDICAL RECORD.

PART 14. LABORATORY SERVICES

14.1 LABORATORY SERVICES SHALL BE MADE AVAILABLE ON-SITE OR THROUGH CONTRACT.

Commented [SG53]: 14.1 and 14.2 Modified original language

14.2 CLINICAL LABORATORY SERVICES SHALL BE AVAILABLE AS REQUIRED BY THE NEEDS OF THE CLIENTS AS DETERMINED BY THE CLINICAL STAFF. THE LABORATORY SHALL MEET THE REQUIREMENTS OF THE "CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988," 42 USC § 263A, AND THE CORRESPONDING REGULATIONS AT 42 CFR PART 493.

14.3 THE CC SHALL PROVIDE PROMPT FOLLOW-UP FOR LABORATORY RESULTS OUTSIDE THE NORMAL VALUE RANGE.

Commented [SG54]: 14.3-14.5 from Chapter 13

14.4 IF UTILIZED AT THE FACILITY, THE CC SHALL DEVELOP AND IMPLEMENT POLICIES AND PROCEDURES REGARDING POINT OF CARE TESTING.

14.5 IF BLOOD OR BLOOD PRODUCTS ARE MAINTAINED AT THE FACILITY, THE CC SHALL MEET THE REQUIREMENTS OF 6 CCR 1011-1, CHAPTER 4, PART 14.2.

PART 15. RADIOLOGICAL SERVICES

15.1 RADIOLOGICAL SERVICES ESSENTIAL TO THE TREATMENT AND DIAGNOSIS OF THE PATIENT SHALL BE AVAILABLE DIRECTLY OR THROUGH REFERRAL.

Commented [SG55]: 15.1 and 15.2 original language

15.2 AS A CONDITION OF LICENSURE, SERVICES SHALL BE COMPLIANT WITH COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT STANDARDS PERTAINING TO RADIATION CONTROL (6 CCR 1007-1).

15.3 DIAGNOSTIC IMAGING SERVICES SHALL BE ORDERED BY A PHYSICIAN OR OTHER PROVIDER AUTHORIZED BY LAW.

15.4 THE CC SHALL PROVIDE PROMPT NOTIFICATION ON ALL CRITICAL AND/OR ABNORMAL IMAGING FINDINGS. FOR ALL CRITICAL ABNORMAL FINDINGS, THE CC SHALL IMMEDIATELY NOTIFY THE PATIENT REGARDING THE COURSE OF CARE.

Commented [SG56]: 15.3 and 15.4 From Chap 13

PART 16. DIETARY SERVICES (REQUIRED ONLY FOR COMMUNITY CLINICS OPERATING INPATIENT BEDS)

Commented [SG57]: Part 16 all original language and original applicability.

16.1 THERE SHALL BE FOOD SERVICE AVAILABLE TO SERVE ADEQUATE MEALS TO PATIENTS ADMITTED TO INPATIENT BEDS.

16. 2 CATERING AND ALTERNATIVE METHODS OF MEAL PROVISION SHALL BE ALLOWED IF PATIENT NEEDS AND THE INTENT OF THIS PART OF THE REGULATIONS ARE MET.

16.3 PERSONS ASSIGNED TO FOOD PREPARATION AND SERVICE SHALL HAVE THE APPROPRIATE TRAINING NECESSARY TO STORE, PREPARE, AND SERVE FOOD IN A MANNER THAT PREVENTS FOODBORNE ILLNESS.

16.4 DIETARY OR NUTRITION CONSULTATION SHALL BE PROVIDED BY A QUALIFIED PERSON FOR ROUTINE DIETARY NEEDS AND ON-CALL CONSULTATION AVAILABLE FOR SPECIAL DIETARY NEEDS.

16.5 MEALS SHALL BE STORED, PREPARED, AND SERVED IN A MANNER THAT PREVENTS FOODBORNE ILLNESS. ALL FOOD SHALL BE PRE-PACKAGED AND REQUIRE MICROWAVE HEATING ONLY, AND DISPOSABLE PRODUCTS FOR PREPARATION AND SERVICE SHALL BE USED UNLESS THE FACILITY DEVELOPS AND IMPLEMENTS POLICIES AND PROCEDURES FOR THE SAFE STORAGE, PREPARATION, AND SERVING OF FOODS.

16.6 THE FOOD SERVICE AREA SHALL BE AN AREA SEPARATE FROM THE EMPLOYEE LOUNGE OR OTHER AREAS USED BY FACILITY PERSONNEL OR THE PUBLIC.

PART 17. ANESTHESIA SERVICES

Commented [SG58]: Mostly original language and original applicability

17.1 APPLICABILITY

(A) ANESTHESIA SERVICES ARE OPTIONAL FOR COMMUNITY CLINICS AND COMMUNITY CLINICS WITH INPATIENT BEDS. IF ANESTHESIA SERVICES ARE PROVIDED AT THE FACILITY, THE CC SHALL MEET THE REQUIREMENTS OF THIS PART 17.

(B) ALL COMMUNITY CLINICS PROVIDING EMERGENCY SERVICES SHALL MEET THE REQUIREMENTS OF THIS PART 17.

17.2 PROCEDURAL SEDATION OR REGIONAL ANESTHESIA SHALL ONLY BE ADMINISTERED BY QUALIFIED PROVIDERS IN ACCORDANCE WITH THEIR SCOPE OF PRACTICE, NATIONALLY RECOGNIZED PRACTICE STANDARDS, STATE PRACTICE ACTS AND REGULATIONS, AND CLINICAL PRIVILEGES GRANTED BY THE FACILITY.

17.3 ALL COMMUNITY CLINICS OFFERING ANESTHESIA SERVICES SHALL DEVELOP AND IMPLEMENT POLICIES AND PROCEDURES REGARDING:

(A) THE QUALIFICATIONS AND RESPONSIBILITIES OF PERSONS ADMINISTERING PROCEDURAL SEDATION OR REGIONAL ANESTHESIA, INCLUDING THE LEVEL OF SUPERVISION REQUIRED.

(B) PATIENT EDUCATION AND INFORMED CONSENT.

(C) PATIENT ASSESSMENT AS APPROPRIATE TO THE PATIENT AND THE LEVEL OF SEDATION/ANESTHESIA BEING USED.

(D) PATIENT MONITORING DURING THE PROVISION OF PROCEDURAL SEDATION OR REGIONAL ANESTHESIA.

(E) THE SAFE DISCHARGE OF PATIENTS WHO HAVE UNDERGONE SEDATION OR ANESTHESIA.

Commented [SG59]: From Chap 13

PART 18. EMERGENCY SERVICES (REQUIRED ONLY FOR COMMUNITY CLINICS PROVIDING EMERGENCY SERVICES)

18.1 ORGANIZATION

(A) THE COMMUNITY CLINIC PROVIDING EMERGENCY SERVICES SHALL DEVELOP AND IMPLEMENT POLICIES AND PROCEDURES OUTLINING THE SCOPE OF SERVICES PROVIDED.

(B) EACH PATIENT SHALL BE DISCHARGED ONLY UPON A PROVIDER'S RECORDED AUTHORIZATION INCLUDING INSTRUCTIONS GIVEN TO THE PATIENT FOR FOLLOW-UP CARE, MODIFIED DIET, MEDICATIONS, AND SIGNS AND SYMPTOMS TO BE REPORTED TO A PROVIDER, IF RELEVANT, AND A CONTACT TO CALL IN CASE THE PATIENT HAS QUESTIONS AFTER DISCHARGE.

Commented [SG60]: Original language from original Part 11 (General Patient Care Services), merged with new language. Should this language be added to Chapter 13 also?

(C) THE LOCATION AND TELEPHONE NUMBER OF A POISON CONTROL CENTER SHALL BE POSTED PROMINENTLY IN THE FACILITY.

Commented [BM61]: Proposed Ch 4 and 13 language

18.2 EMERGENCY SERVICES PERSONNEL

Commented [SG62]: Original language except where marked.

(A) AN APPROPRIATELY QUALIFIED PHYSICIAN SHALL BE AVAILABLE TO COVER EMERGENCY SERVICES ON-SITE OR BY TELEPHONE. WHERE COVERAGE IS PROVIDED BY PHONE, THE PHYSICIAN MUST BE ABLE TO ARRIVE IN THE EMERGENCY SERVICES AREA WITHIN THIRTY (30) MINUTES OF THE NEED FOR PHYSICIAN SERVICES HAVING BEEN DETERMINED.

(B) NURSING CARE SHALL BE SUPERVISED BY A REGISTERED NURSE QUALIFIED BY TRAINING AND EXPERIENCE IN EMERGENCY SERVICES.

(C) THERE SHALL BE SUFFICIENT REGISTERED NURSES WITH THE ADEQUATE TRAINING AND EXPERIENCE TO MEET THE NEEDS OF THE PATIENT CENSUS. AT MINIMUM, THERE SHALL BE ONE REGISTERED NURSE ON-SITE DURING THE HOURS OF OPERATION.

(D) REGISTERED NURSE TRAINING SHALL INCLUDE, AT A MINIMUM, ADVANCED CARDIOVASCULAR LIFE SUPPORT (ACLS) AND PEDIATRIC ADVANCED LIFE SUPPORT (PALS), OR COMPARABLE CERTIFICATIONS, TO ASSURE COMPETENCY IN ADULT AND PEDIATRIC EMERGENCY CARE.

Commented [SG63]: New language from Chapter 13

(E) THE CLINIC SHALL HAVE AT LEAST ONE OF THE PROVIDER STAFF ON DUTY AT ALL TIMES DURING OPERATING HOURS WHO IS QUALIFIED IN ACLS OR BOARD CERTIFIED IN EMERGENCY MEDICINE.

(F) EVERY PATIENT SHALL BE UNDER THE CARE OF A PROVIDER WITH APPROPRIATE SPECIALIZATION.

Commented [SG64]: E-H Original language moved and modified to include the more generic term provider.

(G) THERE SHALL BE PROCEDURES FOR ACCESSING ADDITIONAL STAFF TO MEET UNANTICIPATED NEEDS.

(H) A CURRENT ROSTER OF ON-CALL PROVIDERS, INCLUDING ALTERNATES, SHALL BE MADE AVAILABLE AT ALL TIMES.

18.3 MINIMUM SERVICES

Commented [SG65]: Mostly new language from Chapter 13, Although most concepts were in the original language.

(A) EMERGENCY SERVICES SHALL BE PROVIDED DURING ALL HOURS OF OPERATION, AS SPECIFIED IN PART 6.5.

(B) THE CLINIC SHALL PROVIDE, AT A MINIMUM, BASIC AND ADVANCED LIFE SUPPORT FOR BOTH ADULT AND PEDIATRIC PATIENTS DURING ALL OPERATING HOURS.

Commented [BM66]: Existing language

(C) THE CLINIC SHALL PROVIDE, AT A MINIMUM, THE FOLLOWING SERVICES ON-SITE COMMENSURATE TO THE SCOPE OF SERVICES PROVIDED:

(1) INITIAL STABILIZATION AND TREATMENT FOR ANY ACUTE MEDICAL, TRAUMATIC, AND/OR BEHAVIORAL HEALTH PATIENT, INCLUDING, BUT NOT LIMITED TO: IV THERAPY, OXYGEN THERAPY, RESPIRATORY ASSISTANCE, AND EMERGENCY OBSTETRICS.

(2) RADIOLOGICAL SERVICES, INCLUDING THOSE SERVICES NECESSARY TO RULE OUT EMERGENCY CONDITIONS.

(3) LABORATORY, TO INCLUDE THOSE SERVICES NECESSARY TO RULE OUT EMERGENCY CONDITIONS.

(4) PHARMACY SERVICES, TO INCLUDE THOSE SERVICES NECESSARY TO MANAGE EMERGENCY CONDITIONS.

(5) PROCEDURAL SEDATION OR REGIONAL ANESTHESIA USED DURING THE COURSE OF PROVIDING TREATMENT.

(D) ALL PATIENTS PRESENTING FOR EMERGENCY SERVICES SHALL BE OFFERED A MEDICAL SCREENING EXAM, REGARDLESS OF AN INDIVIDUAL'S ABILITY TO PAY, METHOD OF PAYMENT, OR INSURANCE STATUS. THE PROVISION OF MEDICAL SCREENING SHALL NOT BE DELAYED IN ORDER TO INQUIRE ABOUT THE INDIVIDUAL'S METHOD OF PAYMENT OR INSURANCE STATUS.

18.4 POLICIES AND PROCEDURES

Commented [SG67]: Mostly original language except where noted

THE FACILITY SHALL DEVELOP AND IMPLEMENT POLICIES, PROCEDURES, AND/OR GUIDELINES FOR THE FOLLOWING:

(A) CLINICAL CARE GUIDELINES THAT SHALL BE BASED ON NATIONALLY-RECOGNIZED GUIDELINES, PROCEDURE MANUALS, AND REFERENCE MATERIALS.

Commented [BM68]: Modified from Ch 4

(B) EMERGENCY TRIAGE POLICIES AND PROCEDURES FOR OBSTETRICAL EMERGENCIES.

Commented [SG69]: Moved from Part 20 below.

(C) DUTIES AND RESPONSIBILITIES OF HEALTH CARE PERSONNEL DELIVERING CARE, TO INCLUDE THE TRAINING AND EXPERIENCE REQUIRED FOR ASSIGNED RESPONSIBILITIES AND CLEARLY DEFINED LINES OF AUTHORITY.

(D) AN EASILY ACCESSIBLE CENTRALIZED RECORD ON EACH INDIVIDUAL PRESENTING WHO IS IN NEED OF EMERGENCY SERVICES AND WHETHER HE OR SHE REFUSED TREATMENT, WAS REFUSED TREATMENT, OR WHETHER THE INDIVIDUAL WAS TRANSFERRED, ADMITTED AND TREATED, DIED, STABILIZED AND TRANSFERRED, OR DISCHARGED.

(E) PROCESSING PATIENTS PRESENTING FOR EMERGENCY SERVICES INCLUDING PROCEDURES FOR INITIAL ASSESSMENT, PRIORITIZATION FOR MEDICAL SCREENING AND TREATMENT, AND PATIENT REASSESSMENT AND MONITORING.

(F) PROVISION OF FURTHER MEDICAL EXAMINATION AND SUCH TREATMENT AS MAY BE REQUIRED TO STABILIZE OR TRANSFER THE INDIVIDUAL WITHIN THE STAFF AND FACILITY'S CAPABILITIES AVAILABLE AT THE CLINIC.

(1) THE CLINIC SHALL TRANSFER PATIENTS TO A HIGHER LEVEL OF CARE WHEN THEIR NEEDS EXCEED THE CLINIC'S SCOPE OF SERVICES.

Commented [BM70]: From Chapter 4

(2) THE TRANSFERRING CLINIC MUST PROVIDE THE MEDICAL TREATMENT, WITHIN ITS CAPACITY, WHICH MINIMIZES THE RISK TO THE INDIVIDUAL; SEND ALL PERTINENT MEDICAL RECORDS AVAILABLE AT THE TIME OF TRANSFER; EFFECT THE TRANSFER THROUGH QUALIFIED PERSONS AND TRANSPORTATION EQUIPMENT; AND OBTAIN THE CONSENT OF THE RECEIVING FACILITY.

18.5 MINIMUM EQUIPMENT

Commented [SG71]: Original language

COMMUNITY CLINICS PROVIDING EMERGENCY SERVICES SHALL PROVIDE, AT A MINIMUM, THE FOLLOWING EQUIPMENT, FOR BOTH ADULT AND PEDIATRIC PATIENTS:

(A) AIRWAY CONTROL AND VENTILATION EQUIPMENT INCLUDING LARYNGOSCOPES AND ENDOTRACHEAL TUBES OF ALL SIZES, BAG MASK RESUSCITATORS, AND OXYGEN.

(B) PULSE OXIMETRY.

(C) END TIDAL CO2 DETERMINATION.

(D) SUCTION DEVICES.

(E) 12-LEAD ELECTROCARDIOGRAM MONITORING WITH CARDIAC DEFIBRILLATOR OR AUTOMATED EXTERNAL DEFIBRILLATOR.

(F) STANDARD INTRAVENOUS FLUIDS AND ADMINISTRATION DEVICES; INCLUDING LARGE BORE INTRAVENOUS CATHETERS.

(G) STERILE SURGICAL SETS FOR:

(1) AIRWAY CONTROL/CRICOTHYROTOMY.

(2) VASCULAR ACCESS TO INCLUDE CENTRAL LINE INSERTION AND INTRAOSSEOUS ACCESS.

(3) THORACOSTOMY-NEEDLE AND TUBE.

(H) GASTRIC DECOMPRESSION.

(I) DRUGS FOR EMERGENCY SERVICES, INCLUDING BUT NOT LIMITED TO DRUGS THAT SUPPORT CARDIAC RESUSCITATION, RESPIRATORY RESUSCITATION, AND THOSE THAT SUPPORT HEMODYNAMIC STABILITY.

(J) X-RAY AVAILABILITY.

(K) SPINAL IMMOBILIZATION EQUIPMENT.

(L) THERMAL CONTROL EQUIPMENT FOR PATIENT/FLUIDS.

(M) MEDICATION CHART, TAPE, OR OTHER SYSTEM TO ASSURE READY ACCESS TO INFORMATION ON PROPER DOSE-PER-KILOGRAM FOR RESUSCITATION DRUGS AND EQUIPMENT SIZES FOR PEDIATRIC PATIENTS.

PART 19. INPATIENT BEDS (REQUIRED ONLY FOR COMMUNITY CLINICS OPERATING INPATIENT BEDS)

19.1 FOR THE PURPOSE OF THIS CHAPTER 9, THE TERM INPATIENT BED IN COMMUNITY CLINICS MEANS THE USE OF BEDS FOR THE MONITORING OR OBSERVATION OF PATIENTS WHO PRESENT FOR SERVICES AND WOULD BENEFIT FROM MONITORING BY HEALTH CARE PROVIDERS FOR A PERIOD OF NO MORE THAN 72 HOURS, EXCEPT THAT THE 72-HOUR LIMIT SHALL NOT APPLY TO DEPARTMENT OF CORRECTIONS CLINICS. SUCH BEDS ARE NOT MEANT TO BE USED FOR ROUTINE PREPARATION OR RECOVERY PRIOR TO OR FOLLOWING DIAGNOSTIC OR SURGICAL SERVICES; OR TO ACCOMMODATE HOSPITAL OVERFLOW. IF THE PATIENT NEEDS CARE BEYOND 72 HOURS, THE PATIENT MUST BE TRANSFERRED.

Commented [SG72]: The definition of inpatient bed is repeated here to direct the user to this unique definition. This is very different from the meaning of inpatient bed in other settings and is largely defined in statute.

19.2 EACH COMMUNITY CLINIC OFFERING INPATIENT SERVICES SHALL HAVE POLICIES REGARDING THE USE OF APPROPRIATE LICENSED PROVIDER STAFF, PATIENT CARE SERVICES OFFERED, AND THE EQUIPMENT, SUPPLIES, AND PHYSICAL PLANT NECESSARY TO MEET THE SCOPE OF SERVICES PROVIDED.

19.3 AN APPROPRIATELY QUALIFIED PROVIDER SHALL BE AVAILABLE TO COVER INPATIENT SERVICES ON-SITE OR BY TELEPHONE. WHERE COVERAGE IS PROVIDED BY PHONE, THE PROVIDER MUST BE ABLE TO ARRIVE WITHIN THIRTY (30) MINUTES OF THE NEED FOR PROVIDER SERVICES HAVING BEEN DETERMINED, OR THE PATIENT MUST BE IMMEDIATELY TRANSFERRED TO A HOSPITAL

19.4 EVERY PATIENT SHALL BE UNDER THE CARE OF A PROVIDER WITH APPROPRIATE SPECIALIZATION.

Commented [SG73]: Original language moved and modified to include the more generic term provider.

19.5 AT ALL TIMES WHILE PROVIDING INPATIENT CARE, THERE SHALL BE A REGISTERED NURSE AVAILABLE ON-SITE, DEDICATED TO THE INPATIENT UNIT.

19.6 ADMISSIONS

Commented [SG74]: 19.6-19.9 original language

(A) THE COMMUNITY CLINIC OPERATING INPATIENT BEDS SHALL DEVELOP ADMISSIONS POLICIES AND PROCEDURES, INCLUDING, BUT NOT BE LIMITED TO, APPROPRIATENESS OF ADMISSIONS BASED ON PATIENT ACUITY.

(B) EACH PATIENT SHALL HAVE A VISIBLE MEANS OF IDENTIFICATION PLACED SECURELY ON HIS OR HER PERSON UNTIL DISCHARGE.

19.7 CARE PLANNING: AN INDIVIDUALIZED CARE PLAN SHALL BE PREPARED FOR EACH PATIENT, REVIEWED, AND REVISED AS NEEDED.

19.8 DISCHARGE PLANNING: THE CC OPERATING INPATIENT BEDS SHALL DEVELOP A DISCHARGE PLAN FOR EACH PATIENT THAT IS ADMITTED TO AN INPATIENT BED.

19.9 FACILITIES

(A) A CC OPERATING INPATIENT BEDS SHALL ESTABLISH AND MAINTAIN A PATIENT CARE UNIT.

(B) PATIENT ROOMS

(1) EACH PATIENT ROOM SHALL HAVE ADEQUATE SPACE TO MEET THE NEEDS OF THE PATIENT. THE STANDARD SHALL BE 100 SQUARE FEET FOR EACH SINGLE PATIENT ROOM OR 80 SQUARE FEET PER BED FOR MULTIPLE-BED ROOMS.

(2) EACH PATIENT ROOM SHALL INCLUDE SUFFICIENT ILLUMINATION TO MEET PATIENT NEEDS FOR TREATMENT.

(3) EACH PATIENT SHALL HAVE DIRECT ACCESS TO A CALL SYSTEM WHICH SIGNALS THE PROVIDER STAFF ON DUTY.

(C) BATHING FACILITIES. THE FACILITY SHALL PROVIDE PATIENT BATHING FACILITIES FOR PATIENTS STAYING OVERNIGHT.

~~**SUBCHAPTER 9.A - GENERAL REQUIREMENTS**~~

~~**SUBCHAPTER 9.B - ADDITIONAL REQUIREMENTS FOR CLINICS WITH INPATIENT BEDS AND COMMUNITY EMERGENCY CENTERS**~~

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

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

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

~~**SUBCHAPTER 9.A - GENERAL REQUIREMENTS**~~
~~Part 1. STATUTORY AUTHORITY~~

~~1.101 Statutory Authority. Authority to establish minimum standards through regulation and to administer and enforce such regulations is provided by Sections 25-1.5-103 and 25-3-100.5, C.R.S., et seq.~~

~~1.102 APPLICABILITY~~

~~(1) Community clinics shall meet applicable federal and state statutes and regulations, including but not limited to:~~

~~(a) 6 CCR 1011-1, Chapter 2.~~

~~(b) 6 CCR 1011-1, Chapter 9, Subchapter 9.A.~~

~~(c) 6 CCR 1011-1, Chapter 9, Subchapter 9.B, if the facility operates inpatient beds or is a community emergency center.~~

~~(2) Contracted services shall meet the standards established herein.~~

(3) When differing standards are imposed by federal, state, or local jurisdictions, the most stringent standard shall apply.

(4) A community clinic that is part of a larger, corporate health care system may fulfill the administrative record requirements, the policies and procedures requirements, and the medical records requirements of this Chapter 9 through a central system common to the entire organization, providing that the intent of the requirements of this Chapter is met and the specific policies applicable to the facility have been identified and made accessible to community clinic staff.

Part 2. DEFINITIONS

2.101

(1) "Anesthetizing services" means conscious sedation, deep sedation, regional anesthesia, and general anesthesia used during the course of providing treatment.

(2) "Clinic serving the uninsured or underinsured" means a nonprofit facility whose sole mission is the delivery of primary care to low-income and publicly insured patients regardless of ability to pay. Any charges assessed, whether a flat fee or on a sliding fee scale, shall be based on the patient's income and ability to pay.

(3) "Community clinic" means:

(a) a health care facility that provides health care services on an ambulatory basis, is neither licensed as an on-campus department or service of a hospital nor listed as an off-campus location under a hospital's license, and meets at least one of the following criteria:

(i) operates inpatient beds at the facility for the provision of extended observation and other related services for not more than seventy-two hours.

(ii) provides emergency services at the facility.

(iii) is operated or contracted by the Department of Corrections.

(iv) provides primary care services, is not otherwise subject to health facility licensure under Section 25-3-101, C.R.S. or Section 2-1.5-103, C.R.S., but opts to obtain licensure in order to receive private donations, grants, government funds, or other public or private reimbursement for services rendered.

(b) The term "community clinic" does not mean:

(i) a federally qualified health center.

(ii) a rural health clinic.

(iii) a facility that functions only as an office for the practice of medicine or the delivery of primary care services by other licensed or certified practitioners. A health care facility is not required to be licensed as a community clinic solely due to the facility's ownership status, corporate structure, or engagement of outside vendors to perform nonclinical management services. This section permits regulation of a physician's

office only to the extent the office is a community clinic as defined in this Section 2.101 (3)(a).

(4) "Community emergency center" means a community clinic that delivers emergency services. The care shall be provided 24 hours per day, 7 days per week every day of the year, unless otherwise authorized herein. A community emergency center may provide primary care services and operate inpatient beds.

(5) "Emergency services" means the treatment of patients arriving by any means who have medical conditions, including acute illness or trauma, that if not treated immediately could result in loss of life, loss of limb, or permanent disability.

(6) "Inpatient beds" means the use of beds for the care of medically stable patients who present for primary care services but would benefit from monitoring by nurses and physicians for a period between 12 and 72 hours, except that the 72-hour limit shall not apply to prison clinics. Such inpatient beds are not meant to be used for routine preparation or recovery prior to or following diagnostic or surgical services; or to accommodate inpatient overflow from another facility.

(7) "Federally qualified health center (FQHC)" means a facility that meets the definition under Section 1861 (aa)(4) of the federal "Social Security Act", 42 U.S.C. Section 1395x (aa)(4) which provides for the delivery of comprehensive primary and after hours care in underserved areas.

(8) "Governing body" means the board of trustees, directors, or other governing entity in whom the ultimate authority and responsibility for the conduct of the clinic is vested.

(9) Reserved

(10) "Preventive health services" means services provided to patients to prevent disease and interventions in patient behaviors designed to avert or ameliorate negative health consequences. Preventive health services may include, but are not limited to, nutritional assessment and referral, preventive health education, pre-natal care, well child services (including periodic screening), and immunizations.

(11) "Primary care services" means outpatient health care provided for the entire body rather than a specific organ system that includes: comprehensive assessment at first contact; preventive health services; evaluation and treatment of health care concerns; referrals to specialists as appropriate; and planned continuing routine care including coordination with specialists.

(12) "Rural health clinic" means a facility that meets the definition under Section 1861 (aa)(2) of the federal "Social Security Act", 42 U.S.C. Section 1395x (aa)(2) which provides for the delivery of basic outpatient primary care in underserved, non-urban areas.

Part 3. DEPARTMENT OVERSIGHT

3.100 APPLICATION FEES.

(1) For new license applications received or renewal licenses that expire on or after July 1, 2020, a non-refundable fee shall be submitted with the license application as follows:

License Category	Initial license	Renewal license	Change of ownership
Community emergency center	$2,873.89	$1,410.82	$3,239.65
Clinic operating inpatient beds	$2,873.89	$1,410.82	$3,239.65
Clinic operated under the	$2,612.62	$1,358.57	$2,612.62

~~auspices of the Department of Corrections~~			
~~Optional licensure pursuant to Section 2.101 (3)(a)(iv).~~ ~~Clinic serving the uninsured or underinsured:~~ ~~Other clinic:~~	~~$1,254.06~~ ~~$2,508.13~~	~~$627.03~~ ~~$1,254.06~~	~~$1,306.31~~ ~~$2,612.62~~

~~3.200 COMMERCIAL PROFESSIONAL LIABILITY INSURANCE~~

~~3.201 Community clinics shall comply with the liability insurance requirements set forth in 6 CCR 1011-1, Chapter 2, Part 2.3.3(D).~~

~~Part 4. PHYSICAL PLANT STANDARDS~~

~~4.101 COMPLIANCE WITH FGI STANDARDS~~

~~Any construction or renovation of a community clinic initiated on or after July 1, 2020, shall conform to Part 3 of 6 CCR 1011-1, Chapter 2, unless otherwise specified in this current Chapter.~~

~~Part 5. FACILITY OPERATIONS~~

~~5.100 Reserved.~~

~~5.200 HOUSEKEEPING SERVICES~~

~~5.201 ORGANIZATION AND STAFFING~~

~~(1) Housekeeping services to ensure that the premises are clean and orderly at all times shall be provided.~~

~~(2) Measures shall be in place to keep the facility free of insects, rodents, and other pests.~~

~~5.203 EQUIPMENT AND SUPPLIES. Reserved.~~

~~5.204 FACILITIES~~

~~(1) There shall be separate clean and soiled utility rooms. Alternatively, clean and soiled equipment and supplies may be in the same area if they are separated in such a way as to prevent cross-contamination.~~

~~5.300 MAINTENANCE SERVICES~~

~~5.301 ORGANIZATION AND STAFFING~~

~~(1) The community clinic shall be maintained to ensure the safety of patients, staff and visitors.~~

~~5.302 PROGRAMMATIC FUNCTIONS~~

~~(1) A preventive maintenance program shall be implemented to ensure that all essential mechanical, electrical and patient care equipment is maintained in safe operating condition.~~

5.400 WASTE DISPOSAL

5.401 ORGANIZATION AND STAFFING

(1) All wastes shall be disposed in compliance with local, state and federal laws.

(2) As a condition of licensure, community clinics shall be in compliance with 6 CCR 1007-3, Colorado Hazardous Waste Regulations and 6 CCR 1007-2, Section 13 Medical Waste Regulations.

Part 6. GOVERNANCE AND LEADERSHIP

6.100 Reserved.

6.200 ADMINISTRATOR

6.201 ORGANIZATION AND STAFFING

(1) The clinic shall have an administrator or a designated person who is principally responsible for directing the daily operation of the clinic.

6.202 PROGRAMMATIC FUNCTIONS

(1) Policies and Procedures. The administrator shall be responsible for the development of policies and procedures for the operation of the facility. The policies and procedures shall be developed in conjunction with the provider staff, or a representative committee from the provider staff, as appropriate. The policies and procedures shall be reviewed periodically and revised as needed.

(2) The administrator shall develop clear lines of authority and responsibility for the staff.

(3) Emergency Evacuation Plan

(a) The community clinic shall have a written evacuation plan to be activated in the event of an emergency, such as fire, that indicates individual roles and responsibilities of employees.

(b) Employees shall be trained as to their responsibilities in the event of an emergency evacuation.

(c) Evacuation routes and exits shall be prominently posted.

(4) The facility's hours of operation shall be posted in a manner clearly visible to the public.

Part 7. PERSONNEL

7.101 ORGANIZATION AND STAFFING

(1) Personnel shall have qualifications as met by professional licensure, education, training, and experience necessary to meet the clinical needs of the patients. Licensed personnel shall have an active license in the state of Colorado and shall provide services within their scope of practice.

(2) Services shall be provided in accordance with facility policy, state practice acts, and professional standards of practice.

~~7.102 PROGRAMMATIC FUNCTIONS~~

~~(1) Personnel shall be oriented, trained and competent to provide the services they are assigned to do. Personnel shall be kept abreast of new health care services developments and new technology through in-services and other educational programs.~~

~~Part 8. MEDICAL RECORDS~~

~~8.101 ORGANIZATION AND STAFFING~~

~~(1) The community clinic shall maintain a clinical medical record system as established by the facility's written policies and procedures. Medical records shall be systematically organized and easily accessible.~~

~~(2) A designated member of the staff shall be responsible for maintaining medical records and for ensuring that they are complete.~~

~~8.102 PROGRAMMATIC FUNCTIONS~~

~~(1) Content. Each patient's medical record shall contain the following:~~

~~(a) identification and social data.~~

~~(b) consent forms, when applicable.~~

~~(c) relevant medical history.~~

~~(d) assessment of the health status and health care needs of the patient.~~

~~(e) a brief summary of the episode, disposition, and instructions to the patient per visit.~~

~~(f) reports of physical examinations, diagnostic and laboratory test results, reports of x-rays, scans, and other radiological imaging studies, and consultative findings.~~

~~(g) all orders, reports of treatments and medications administered, and other information necessary to monitor the patient's progress.~~

~~(h) signatures, with dates and times, of the physician or other health care professionals making entries into the medical record.~~

~~(i) all medications ordered including the name; strength; dose; mode of administration; and date, time and signature of the practitioner that ordered.~~

~~(2) Patient records shall be readily accessible.~~

~~(3) Record Retention~~

~~(a) Medical records for adults (persons 18 years of age or over) shall be retained for no less than 10 years after the last patient usage. X-rays, films, scans, and other imaging records shall be maintained by the facility for a period of five years, if services are provided directly.~~

~~(b) Medical records for minors must be retained for the period of minority plus 10 years after the last patient usage.~~

(4) Confidentiality. All necessary precautions shall be taken to protect the confidentiality of the information contained within.

Part 9. INFECTION CONTROL

9.101 ORGANIZATION AND STAFFING

(1) The facility shall have an infection control program responsible for reducing the risk of acquiring or transmitting infections and infectious diseases in the facility.

9.102 PROGRAMMATIC FUNCTIONS

(1) The facility shall develop and implement policies and procedures regarding:

(a) training of clinical and non-clinical staff on infection control practices. The policy shall address training provided upon orientation to the facility as well as ongoing annual training.

(b) clean environment. The clinical environment shall be clean and free of clutter. Toys shall be visibly clean and wipeable or machine washable. Furnishings shall be in good repair and visibly clean with no evidence of soiling.

(c) hand hygiene. Hands shall be decontaminated before and after every patient contact.

(d) decontamination of equipment and exam tables. Equipment and exam tables used for more than one patient shall be decontaminated between patients. Decontamination includes cleaning and, as appropriate, disinfection and sterilization. Decontamination shall be conducted in accordance with manufacturer's instructions or national guidelines. Equipment that enters sterile tissue or the vascular system shall be subject to sterilization or disposed of after single use.

(e) safe injection practices and the management of injuries from sharps. Disposable needles and other sharps shall be discarded in a sharps container at the point of use by the user. Sharps containers must not be filled above the mark indicating they are full and then appropriately disposed.

(f) the prevention of communicable disease through respiratory hygiene/cough etiquette for patients and staff.

(2) As a condition of licensure, the community clinic shall conduct disease reporting in accordance with 6 CCR 1009-1 Rules and Regulations Pertaining to Epidemic and Communicable Disease Control.

9.103 EQUIPMENT AND SUPPLIES

(1) Adequate equipment and supplies for hand decontamination shall be accessible.

Part 10. PATIENT RIGHTS

As a condition of licensure, the community clinic shall be in compliance with 6 CCR 1011-1, Chapter 2, Part 7.

Part 11. GENERAL PATIENT SERVICES

11.101 ORGANIZATION AND STAFFING

(1) The community clinic shall have an organized provider staff.

(2) There shall be sufficient available medical, nursing and ancillary staff with the appropriate training and experience to meet the needs of the patient, in accordance with the scope of the services provided by the facility.

11.102 PROGRAMMATIC FUNCTIONS

(1) Scope of Services. The facility shall define the scope of preventive, diagnostic and treatment services in writing. The scope shall include a description of those services furnished directly and through agreements with, or referrals to other health care service providers.

(2) Care From Practitioners. Care shall be provided by practitioners qualified by education, training and experience to deliver such care.

(3) Policies and Procedures. The facility's provider staff shall develop and implement written patient care policies that are reviewed and updated on a routine basis. The policies and procedures shall address:

(a) preventive health services.

(b) coordination of care with other facilities or health care service providers, including but not limited to the transfer of records to facilitate continuity of care.

(c) continuing care by the same health care practitioner, whenever possible.

(d) prompt follow-up of abnormal laboratory and physical findings.

(e) if the facility does not provide emergency services, the facility response to an individual who presents with or declares the need for emergency services to include when it is appropriate to:

(i) treat the patient within the clinic,

(ii) advise the individual to go to an emergency room, or

(iii) call 9-1-1 for the individual.

Part 12. Reserved.

Part 13. PHARMACY

13.101 ORGANIZATION AND STAFFING. Reserved.

13.102 PROGRAMMATIC FUNCTIONS

(1) Where pharmaceuticals are dispensed other than by a licensed practitioner authorized to prescribe medications, the facility shall have a pharmacy or other outlet license in accordance with Board of Pharmacy regulations.

Part 14. LABORATORY SERVICES

14.101 ORGANIZATION AND STAFFING

(1) Laboratory services shall be made available through referral or directly.

14.102 PROGRAMMATIC FUNCTIONS

(1) As a condition of licensure, services shall be compliant with Clinical Laboratory Improvement Amendments (CLIA) standards (2012). The CLIA standards are hereby

~~incorporated by reference in accordance with the provisions regarding incorporation by reference at the beginning of this chapter.~~

~~Part 15. RADIOLOGICAL SERVICES~~

~~15.101 ORGANIZATION AND STAFFING~~

~~(1) Radiological services essential to the treatment and diagnosis of the patient shall be available directly or through referral.~~

~~15.102 PROGRAMMATIC FUNCTIONS~~

~~(1) As a condition of licensure, services shall be compliant with Colorado Department of Public Health and Environment standards pertaining to radiation control (6 CCR 1007-1).~~

~~SUBCHAPTER 9.B - ADDITIONAL REQUIREMENTS FOR CLINICS WITH INPATIENT BEDS AND COMMUNITY EMERGENCY CENTERS~~

~~Part 1. STATUTORY AUTHORITY AND APPLICABILITY~~

~~1.101 STATUTORY AUTHORITY. Reserved.~~

~~1.102 APPLICABILITY~~

~~(1) Clinics that operate inpatient beds and community emergency centers shall meet the requirements established in Subchapter 9.A, as well as the requirements in this Subchapter 9.B. To the extent that these subchapters conflict, the more stringent requirements shall apply.~~

~~Parts 2-4 Reserved.~~

~~Part 5. FACILITY OPERATIONS~~

~~5.100 CENTRAL MEDICAL SURGICAL SUPPLY SERVICES. Reserved.~~

~~5.200 HOUSEKEEPING SERVICES. Reserved.~~

~~5.300 MAINTENANCE SERVICES. Reserved.~~

~~5.400 WASTE DISPOSAL. Reserved.~~

~~5.500 LINEN AND LAUNDRY.~~

~~This section 5.500 is applicable only if the community clinic uses linen during the provision of patient care services.~~

~~5.501 ORGANIZATION AND STAFFING~~

~~(1) Laundry and linen services shall be provided by in-house staff or by contract.~~

~~5.502 PROGRAMMATIC FUNCTIONS. Reserved.~~

~~5.503 EQUIPMENT AND SUPPLIES. Reserved.~~

~~5.504 FACILITIES~~

~~(1) Separate clean and soiled linen areas shall be provided and maintained.~~

~~Part 6. GOVERNANCE AND LEADERSHIP~~

~~6.100 GOVERNING BODY~~

~~6.101 ORGANIZATION AND STAFFING~~

~~(1) The facility shall have a governing body that is responsible for the oversight of the organization and the provider staff.~~

~~(2) The governing body shall meet as necessary.~~

~~(3) The governing body shall adopt the general bylaws by which the clinic operates.~~

~~6.102 PROGRAMMATIC FUNCTIONS. The governing body shall:~~

~~(1) define the scope of care and services in writing.~~

~~(2) establish the community clinic's hours of operation and facilitate accessibility if the facility is closed, as specified below.~~

~~(a) General~~

~~(i) The clinic shall maintain regular hours for services.~~

~~(ii) The clinic shall post signage, on or near the front entrance indicating: hours of operation and an emergency referral number and/or a procedure for obtaining medical services when the clinic is not open.~~

~~(b) Community Emergency Center. The community emergency center shall maintain operations on a 24-hour basis, every day of the year, except as authorized below.~~

~~(i) Service Interruption during a 24-hour Period. Community emergency centers in non-metropolitan areas that do not have the demand to support 24-hour services may interrupt operations for a part of the 24-hour period on a routinely scheduled basis. A facility that conducts such service interruptions shall develop and implement a written plan that addresses:~~

~~(A) reporting to the Department any changes in hours of operation.~~

~~(B) signage. The facility shall post signage visible from adjacent major roadways indicating the hours of operation.~~

~~(C) access to alternative emergency services during the service interruption. The facility shall establish a process for making services available within 30 minutes or sooner if medically necessary for persons who present at a closed facility. Clear directions at the front and/or emergency entrance to the facility that can be easily understood by persons approaching the community emergency center shall be posted in a conspicuous location with an appropriate communications device, such as a “hot phone” or “tip and ring phone” so that~~

~~care can be summoned immediately and an appropriate emergency response occurs.~~

~~(D) how licensed ambulance services and other appropriate emergency response organizations will be alerted about the periods during which the facility is closed.~~

~~(ii) Seasonal Closures. a community emergency center in a non-metropolitan area that experiences seasonal population influx may choose to only operate each year during specified times. A facility that conducts seasonal closures shall develop and implement a written plan that addresses:~~

~~(A) reporting the seasonal closure to the Department at least 30 days prior to such closure and the resumption of services at least 30 days prior to such resumption.~~

~~(B) signage during the closure. The facility shall post signage visible from adjacent major roadways indicating that the facility is closed for the season. The facility shall remove any other signage that indicates that emergency services are available at the facility.~~

~~(C) access to alternative emergency services during the closure. The facility shall establish a process for making services available within 30 minutes or sooner if medically necessary for persons who present at a closed facility. Clear directions at the front and/or emergency entrance to the facility that can be easily understood by persons approaching the community emergency center shall be posted in a conspicuous location with an appropriate communications device, such as a "hot phone" or "tip and ring phone" so that care can be summoned immediately and an appropriate emergency response occurs.~~

~~(D) how licensed ambulance services and other appropriate emergency response organizations will be alerted about the periods during which the facility is closed.~~

~~(3) establish a patient transfer plan that includes:~~

~~(a) agreements with hospital(s) that includes procedures for obtaining air or ground transportation, as appropriate.~~

~~(b) If a medically necessary transfer is needed, the patient shall be transferred to the most appropriate acute care hospital with the capacity to meet the needs of the patient and with consideration for transport time, unless either of the following dictate otherwise:~~

~~(i) regional trauma triage protocols; or~~

~~(ii) the federal Emergency Medical Treatment and Active Labor Act (EMTALA) requirements codified at §1867 of the Social Security Act.~~

(c) transfer protocols to include:

(i) coordination with the local emergency medical services system and licensed ambulance services.

(ii) triage and stabilization to be initiated by on-duty staff.

(iii) transfer of relevant patient information with the patient.

6.200 ADMINISTRATOR

(1) Emergency Management Plan. The community clinic shall adopt a written emergency management plan that addresses:

(a) unanticipated interruption of utilities, including water and electricity within the facility.

(b) fire, explosion or other physical damage to the facility.

(c) local and widespread weather emergencies or natural disasters endemic to the region.

(d) its role in pandemics or other emergency situations where the community's need for services exceeds the availability of beds and services regularly offered by area hospitals.

6.300 MEDICAL STAFF

6.301 ORGANIZATION AND STAFFING

(1) Medical Director. The governing body of the clinic shall appoint a medical director for the facility. Such medical director shall be a physician, licensed under the laws of the state of Colorado, who is a member of the facility's staff. The medical director shall be responsible for the quality of medical care provided to patients in the facility.

Parts 7-8. Reserved.

Part 9. INFECTION CONTROL

9.101 ORGANIZATION AND STAFFING

(1) At least one individual trained in infection control shall be employed by or regularly available to the facility.

9.102 PROGRAMMATIC FUNCTIONS

(1) The facility shall develop written infection prevention policies and procedures appropriate to the services provided by the facility.

Part 10. Reserved.

Part 11. GENERAL PATIENT CARE SERVICES

11.101 ORGANIZATION AND STAFFING

(1) Clinical services shall be under the medical direction of a physician who is a member of the facility's medical staff and who is qualified by education and experience to oversee the services provided by the facility.

11.102 PROGRAMMATIC FUNCTIONS

(1) Care From Licensed Practitioner. Every patient shall be under the care of a physician, an advanced practice nurse with appropriate specialization, or a physician assistant with appropriate specialization.

(2) The facility shall develop and implement policies and procedures that address:

(a) patient assessment, evaluation and treatment, and monitoring.

(b) patient isolation in response to communicable disease.

(3) Unless transferred to another facility, the patient who receives anesthetizing or emergency services shall receive prior to discharge:

(a) a contact to call in case the patient has questions after discharge.

(b) written instructions about self-care, follow up care, modified diet, medications, and signs and symptoms to be reported a practitioner, if relevant.

Part 12. NURSING SERVICES

12.101 ORGANIZATION AND STAFFING

(1) The facility shall provide nursing services sufficient to meet the scope of services provided.

12.102 PROGRAMMATIC FUNCTIONS

(1) There shall be written nursing procedures that establish the standards for performance for safe, effective nursing care of patients.

Parts 13-15 Reserved.

Part 16. DIETARY SERVICES

16.101 ORGANIZATION AND STAFFING

(1) There shall be food service available to serve adequate meals to patients admitted to inpatient beds.

(2) Persons assigned to food preparation and service shall have the appropriate training necessary to store, prepare and serve food in a manner that prevents foodborne illness.

(3) Dietary or nutrition consultation shall be provided by a qualified person for routine dietary needs and on-call consultation available for special dietary needs.

16.102 PROGRAMMATIC FUNCTIONS

(1) Meals shall be stored, prepared and served in a manner that prevents foodborne illness. All food shall be pre-packaged and require microwave heating only and disposable products for preparation and service shall be used unless the facility develops and implements policies and procedures for the safe storage, preparation and serving of foods.

(2) Catering and alternative methods of meal provision shall be allowed if patient needs and the intent of this part of the regulations are met.

16.103 EQUIPMENT AND SUPPLIES. Reserved.

~~16.104 FACILITIES~~

~~(1) The food service area shall be an area separate from the employee lounge or other areas used by facility personnel or the public.~~

~~Part 17. ANESTHESIA SERVICES~~

~~17.101 ORGANIZATION AND STAFFING~~

~~(1) Sedation/anesthesia shall only be administered by qualified practitioners in accordance with their scope of practice, nationally recognized practice standards, state practice acts and regulations, and clinical privileges granted by the facility. The qualifications and responsibilities of persons administering sedation/anesthesia, including the level of supervision required shall be delineated in writing.~~

~~17.102 PROGRAMMATIC FUNCTIONS~~

~~(1) The facility shall develop and implement policies and procedures regarding:~~

~~(a) patient education and consent.~~

~~(b) patient assessment as appropriate to the patient and the level of sedation/anesthesia being used.~~

~~(c) patient monitoring during the provision of sedation/anesthesia.~~

~~(d) patient monitoring until the patient is stable.~~

~~Part 18. EMERGENCY SERVICES~~

~~18.101 ORGANIZATION AND STAFFING~~

~~(1) At minimum, the following services for both adult and children shall be available at all times during operating hours: basic and advanced life support, IV therapy, oxygen therapy, respiratory assistance, and emergency obstetrics. At minimum, the following services shall be available onsite commensurate to scope of services provided: radiology, laboratory services, pharmacy, anesthesia, blood transfusion.~~

~~(2) A physician shall be available to cover emergency services on-site or by telephone. Where coverage is provided by phone, the physician must be able to arrive in the emergency services area within 30 minutes of the need for physician services having been determined.~~

~~(3) Nursing care shall be supervised by a registered nurse qualified by training and experience in emergency services. There shall be sufficient registered nurses with the adequate training and experience to meet the needs of the current patient census and acuity. At minimum, there shall be at least one registered nurse onsite during the hours of operation.~~

~~(4) The clinic shall have at least one of the provider staff on duty at all times during operating hours who is qualified in basic cardiac life support and advanced cardiac life support.~~

~~(5) There shall be procedures for accessing additional staff to meet unanticipated needs.~~

~~18.102 PROGRAMMATIC FUNCTIONS~~

(1) The medical director shall be responsible for the development of policies and procedures related to the medical care provided. The policies and procedures shall be approved by the appropriate members of the medical staff and reviewed and updated as necessary.

(2) The facility shall develop and implement policies and procedures for the following:

(a) duties and responsibilities of health care personnel delivering care, to include the training and experience required for assigned responsibilities and clearly defined lines of authority.

(b) an easily accessible centralized record on each individual presenting who is in need of emergency services and whether he or she refused treatment, was refused treatment, or whether the individual was transferred, admitted and treated, died, stabilized and transferred, or discharged.

(c) processing patients presenting for emergency services including procedures for initial assessment, prioritization for medical screening and treatment, and patient reassessment and monitoring. All patients presenting for emergency services shall receive medical screening. The provision of medical screening shall not be delayed in order to inquire about the individual's method of payment or insurance status.

(d) Provision of further medical examination and such treatment as may be required to stabilize or transfer the individual within the staff and facility's capabilities available at the clinic. The transferring clinic must provide the medical treatment, within its' capacity, which minimizes the risk to the individual; send all pertinent medical records available at the time of transfer; effect the transfer through qualified persons and transportation equipment; and obtain the consent of the receiving facility.

(e) notification of patient's personal physician and transmission of relevant reports.

(f) handling of patients who have mental illness, to include the procedures used to de-escalate agitation.

(g) handling of patients under the influence of drugs or alcohol.

(h) handling of patients in the aftermath of a hazardous materials incident.

(3) Protocols shall be developed by the medical director to establish appropriate response times for on-call staff for differing emergent situations that would present themselves at the facility.

(4) A current roster of physicians on emergency call, including alternates shall be kept posted in the emergency services area at all times.

18.103 EQUIPMENT AND SUPPLIES

(1) Community emergency centers shall provide at a minimum the following equipment, both adult and pediatric as applicable:

(a) airway control and ventilation equipment including laryngoscopes and endotracheal tubes of all sizes, bag mask resuscitators, and oxygen.

(b) pulse oximetry.

(c) end tidal CO2 determination.

(d) suction devices.

(e) 12-lead electrocardiogram monitoring with cardiac defribrillator or automated external defibrillator.

(f) standard intravenous fluids and administration devices; including large bore intravenous catheters.

(g) sterile surgical sets for:

(i) airway control/crycothryrotomy.

(ii) vascular access to include central line insertion and intraosseous access.

(iii) thoracostomy-needle and tube.

(h) gastric decompression.

(i) drugs for emergency services, including but not limited to drugs that support cardiac resuscitation, respiratory resuscitation, and those that support hemodynamic stability.

(j) x-ray availability.

(k) spinal immobilization equipment.

(l) thermal control equipment for patient/fluids.

(m) medication chart, tape or other system to assure ready access to information on proper dose-per-kilogram for resuscitation drugs and equipment sizes for pediatric patients.

Part 19. INPATIENT BEDS

19.101 ORGANIZATION AND STAFFING

(1) The following standards only apply to facilities that operate inpatient beds. A facility may provide services to patients for whom a determination has been made that transfer to another facility with a higher level of care is not immediately necessary because the needs of such patients can be met at the facility. "Meeting the needs of patients" shall include the provision of appropriate licensed provider staff, patient care services, equipment and supplies, and physical plant.

(2) There shall be a physician onsite 24 hours per day, 7 days a week.

(3) There shall be a registered nurse onsite 24 hours per day, 7 days a week.

19.102 PROGRAMMATIC FUNCTIONS

(1) Admissions

(a) The community clinic shall develop admissions policies and procedures, to include but not be limited to appropriateness of admissions based on patient acuity.

(b) Each patient shall have a visible means of identification placed securely on his or her person until discharge.

(2) Care planning

(a) An individualized care plan shall be prepared for each patient, reviewed, and revised as needed.

(3) Discharge Planning . The community clinic shall develop a discharge plan for each patient that is admitted to an inpatient bed.

19.103 EQUIPMENT AND SUPPLIES. Reserved.

19.104 FACILITIES

(1) A community clinic that operates inpatient beds shall establish and maintain a patient care unit.

(2) Patient Rooms

(a) Each patient room shall have adequate space to meet the needs of the patient. The standard shall be 100 square feet for each single patient room or 80 square feet per bed for multiple-bed rooms.

(b) Each patient room shall include sufficient illumination to meet patient needs for treatment.

(c) Each patient shall have direct access to a call system which signals the provider staff on duty.

(3) Bathing Facilities. The facility shall provide patient bathing facilities for patients staying overnight.

Part 20. OBSTETRICS

20.101 ORGANIZATION AND STAFFING

(1) A community clinic may provide for routine pre-natal care and for necessary emergency obstetrical services. However, the facility shall not provide services for the routine delivery of newborn infants and care of obstetrical patients and newborn infants unless the facility can meet the requirements for a birthing center in Chapter 22 of the regulations.

20.102 PROGRAMMATIC FUNCTIONS.

(1) If emergency obstetrical services are provided, the facility shall develop and implement emergency triage policies and procedures.

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

STANDARDS FOR HOSPITALS AND HEALTH FACILITIES CHAPTER 13 - FREESTANDING EMERGENCY DEPARTMENTS (FSEDs)

6 CCR 1011-1 Chapter 13

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

Adopted by the Board of Health on_____. Effective _____

INDEX

PART 1. STATUTORY AUTHORITY AND APPLICABILITY

Commented [SG75]: Note As of Dec 2020, all references have been checked unless otherwise indicated

1.1 STATUTORY AUTHORITY

THE STATUTORY AUTHORITY FOR THE PROMULGATION OF THESE REGULATIONS IS SET FORTH IN SECTIONS 25-1.5-103, 25-1.5-114, 25-3-101, AND 25-3-119, ET SEQ., C.R.S.

1.2 APPLICABILITY

(A) FREESTANDING EMERGENCY DEPARTMENTS (FSEDS) SHALL COMPLY WITH ALL APPLICABLE FEDERAL, STATE, AND LOCAL LAWS AND REGULATIONS, INCLUDING, BUT NOT LIMITED TO:

(1) 6 CCR 1011-1, CHAPTER 2.

(2) RADIOLOGICAL SERVICES INVOLVING THE USE OF MACHINES THAT PRODUCE IONIZING RADIATION OR THE USE OF RADIOACTIVE MATERIALS FOR DIAGNOSTIC PURPOSES SHALL BE IN COMPLIANCE WITH 6 CCR 1007-1, RULES AND REGULATIONS PERTAINING TO RADIATION CONTROL.

(B) CONTRACTED SERVICES SHALL MEET THE STANDARDS ESTABLISHED HEREIN.

(C) A FREESTANDING EMERGENCY DEPARTMENT FOR WHICH OPERATIONS ARE DIRECTLY OR INDIRECTLY OWNED OR CONTROLLED BY, IN WHOLE OR IN PART, OR AFFILIATED WITH A LARGER, CORPORATE SYSTEM MAY FULFILL THE FOLLOWING REQUIREMENTS OF THIS CHAPTER 13 THROUGH A CENTRAL SYSTEM COMMON TO THE ENTIRE ORGANIZATION, PROVIDING THAT THE INTENT OF THE REQUIREMENTS OF THIS CHAPTER IS MET. THE SPECIFIC POLICIES APPLICABLE TO THE FSED, THAT SHALL BE IDENTIFIED AND MADE ACCESSIBLE TO FSED STAFF, INCLUDE:

(1) ADMINISTRATIVE RECORDS, INCLUDING, BUT NOT LIMITED TO, PERSONNEL FUNCTIONS;

(2) POLICIES AND PROCEDURES, INCLUDING INFECTION PREVENTION AND CONTROL AND ANTIBIOTIC STEWARDSHIP;

(3) GOVERNANCE AND LEADERSHIP;

(4) QUALITY MANAGEMENT PROGRAM; AND

(5) HEALTH INFORMATION MANAGEMENT SERVICES.

PART 2. DEFINITIONS

2.1 "ANCILLARY STAFF" MEANS ALL OTHER CLINICAL STAFF NOT ELSEWHERE DEFINED WHO ARE INVOLVED IN THE CARE OF THE PATIENT.

2.2 "ANESTHESIA SERVICES" MEANS PROCEDURAL SEDATION OR REGIONAL ANESTHESIA USED DURING THE COURSE OF PROVIDING TREATMENT.

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

2.4 "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.

Commented [76]: From statute CRS 10-16-704 (5.5) (e) (I)

2.5 "EMERGENCY SERVICES" MEANS THE TREATMENT OF PATIENTS ARRIVING BY ANY MEANS WHO HAVE BEHAVIORAL HEALTH OR MEDICAL CONDITIONS, TRAUMATIC INJURY, OR ACUTE ILLNESS THAT IF NOT TREATED IMMEDIATELY COULD RESULT IN LOSS OF LIFE, LOSS OF LIMB, OR PERMANENT DISABILITY.

2.6 "EMS PROVIDER" MEANS AN INDIVIDUAL WHO HOLDS A VALID EMERGENCY MEDICAL SERVICE PROVIDER CERTIFICATE OR LICENSE ISSUED BY THE DEPARTMENT AND INCLUDES EMERGENCY MEDICAL TECHNICIAN, ADVANCED EMERGENCY MEDICAL TECHNICIAN, EMERGENCY MEDICAL TECHNICIAN INTERMEDIATE, AND PARAMEDIC.

Commented [77]: Consistent with definition from 6 CCR 1015-3, Chapter One

2.7 "FREESTANDING EMERGENCY DEPARTMENT," REFERRED TO HEREIN AS FSED, MEANS:

Commented [78]: Definition from statute 25.1.5.114

(A) A HEALTH FACILITY THAT OFFERS EMERGENCY CARE AND THAT MAY OFFER PRIMARY AND URGENT CARE SERVICES AND THAT IS EITHER:

(1) OWNED OR OPERATED BY, OR AFFILIATED WITH, A HOSPITAL OR HOSPITAL SYSTEM AND LOCATED MORE THAN TWO HUNDRED FIFTY YARDS FROM THE MAIN CAMPUS OF THE HOSPITAL; OR

(2) INDEPENDENT FROM AND NOT OPERATED BY OR AFFILIATED WITH A HOSPITAL OR HOSPITAL SYSTEM AND NOT ATTACHED TO OR SITUATED WITHIN TWO HUNDRED FIFTY YARDS OF, OR CONTAINED WITHIN, A HOSPITAL.

(B) THE TERM "FREESTANDING EMERGENCY DEPARTMENT" DOES NOT INCLUDE A HEALTH FACILITY THAT WAS LICENSED BY THE DEPARTMENT PURSUANT TO SECTION 25-1.5-103 C.R.S. AS A COMMUNITY CLINIC PRIOR TO JULY 1, 2010, IF THE FACILITY IS SERVING A RURAL COMMUNITY OR A SKI AREA, AS DEFINED IN 6 CCR 1011-1, CHAPTER 9 – COMMUNITY CLINICS.

2.8 "GOVERNING BODY" MEANS THE BOARD OF TRUSTEES, DIRECTORS, OR OTHER GOVERNING ENTITY IN WHOM THE ULTIMATE AUTHORITY AND RESPONSIBILITY FOR THE CONDUCT OF THE FSED IS VESTED.

Commented [79]: From Chap 9

2.9 "PATIENT" MEANS ANY PERSON RECEIVING SERVICES FROM THE FSED.

2.10 "PRIMARY CARE SERVICES" MEANS OUTPATIENT HEALTH CARE SERVICES THAT INCLUDE: COMPREHENSIVE ASSESSMENT AT FIRST CONTACT; EVALUATION AND TREATMENT OF HEALTH CARE CONCERNS; REFERRALS TO SPECIALISTS AS APPROPRIATE; AND PLANNED CONTINUING ROUTINE CARE INCLUDING COORDINATION WITH SPECIALISTS. PRIMARY CARE SERVICES INCLUDE PREVENTIVE HEALTH SERVICES, INCLUDING, BUT NOT LIMITED TO: HEALTH EDUCATION, BEHAVIORAL HEALTH, WELL CHILD SERVICES, AND IMMUNIZATIONS.

Commented [80]: From Chap 9

2.11 "PROVIDER" IN THIS CHAPTER 13, MEANS A MEDICAL DOCTOR, DOCTOR OF OSTEOPATHY, ADVANCED PRACTICE NURSE, OR PHYSICIAN ASSISTANT.

Commented [81]: Consistent with proposed Chap 9

PART 3. LICENSING FEES

FOR NEW LICENSE APPLICATIONS RECEIVED OR RENEWAL LICENSES THAT EXPIRE ON OR AFTER JULY 1, 2021, A NON-REFUNDABLE FEE SHALL BE SUBMITTED WITH THE LICENSE APPLICATION AS FOLLOWS:

LICENSE CATEGORY	INITIAL LICENSE	RENEWAL LICENSE	CHANGE OF OWNERSHIP
FREESTANDING EMERGENCY DEPARTMENT	$6,150	$3,400	$3,300

PART 4. GENERAL BUILDING AND FIRE SAFETY PROVISIONS

4.1 ANY CONSTRUCTION OR RENOVATION OF AN FSED INITIATED ON OR AFTER JULY 1, 2021, SHALL CONFORM TO 6 CCR 1011-1, CHAPTER 2, PART 3, UNLESS OTHERWISE SPECIFIED IN THIS CHAPTER.

4.2 FROM JULY 1, 2021 THROUGH JUNE 30, 2022, THE TRANSITION TO AN FSED LICENSE BY AN ENTITY LICENSED PURSUANT TO 6 CCR 1011-1, CHAPTER 9 AS A COMMUNITY CLINIC, SHALL NOT TRIGGER A FACILITY GUIDELINES INSTITUTE (FGI) COMPLIANCE REVIEW.

4.3 NEW CONSTRUCTION OR RENOVATION, IN ACCORDANCE WITH 6 CCR 1011-1, CHAPTER 2, PART 3.3, SHALL TRIGGER AN FGI COMPLIANCE REVIEW OF THE RELEVANT BUILDING OR SPACE.

PART 5. OPERATIONS

5.1 ENVIRONMENTAL SERVICES

(A) EACH FSED SHALL PROVIDE ENVIRONMENTAL SERVICES AND STAFF TO ENSURE THAT THE PREMISES ARE CLEAN AND SANITARY.

(B) PERSONNEL SHALL RECEIVE ADEQUATE SUPERVISION. INITIAL AND ANNUAL IN-SERVICE TRAINING PROGRAMS SHALL BE PROVIDED FOR ENVIRONMENTAL SERVICES PERSONNEL.

(C) Suitable equipment and supplies shall be provided for cleaning of all surfaces. Such equipment shall be maintained in a safe, sanitary condition.

(D) Cleaning compounds and other hazardous substances (including products labeled "Keep out of reach of children" on their original containers) shall be clearly labeled to indicate contents and (except when a staff member is present) shall be stored in a location sufficiently secure to deny access to patients.

(E) Cleaning shall be performed in a manner to minimize the spread of pathogenic organisms. Floors shall be cleaned regularly.

(F) The FSED shall provide for effective control and eradication of vermin. All openings to the outer air shall be effectively protected against the entrance of vermin by self-closing doors, closed windows, screens, controlled air currents, or other effective means.

(G) There shall be separate clean and soiled utility rooms.

(H) Carts used to transport refuse shall be constructed of impervious materials, enclosed, used solely for refuse, and maintained in a sanitary manner.

5.2 Maintenance Services

(A) The FSED shall be maintained to ensure the safety of patients, staff, and visitors.

(B) A preventive maintenance program shall be implemented to ensure that all essential mechanical, electrical, and patient care equipment is periodically monitored, calibrated, and maintained in safe operating condition.

(1) Preventive maintenance includes, but is not limited to: routine inspections, cleaning, testing, and calibrating in accordance with manufacturers' instructions, or if there are not manufacturers' instructions, as specified by the FSED's written policies and procedures. An FSED may, under certain conditions, use equipment maintenance activities and frequencies that differ from those recommended by the manufacturer. FSEDs that choose to employ alternate maintenance activities and/or schedules must develop, implement, and maintain a documented alternate equipment maintenance program to minimize risks associated with the use of medical equipment.

(2) Preventive maintenance shall be conducted in accordance with written maintenance schedules.

(3) Records shall be maintained showing the date of maintenance and action taken to correct any deficiencies.

5.3 Waste Disposal Services

(A) All waste shall be disposed in compliance with local, state, and federal laws.

(B) Medical waste shall be disposed of in accordance with the Department's regulations pertaining to solid waste disposal sites and facilities at 6 CCR 1007-2, Part 1, Section 13, Medical Waste.

(C) The FSED shall have policies and procedures addressing the proper:

(1) Discharge of sewage into a public sewer system.

(2) Collection, storage in covered containers, and timely removal of garbage and refuse not treated as sewage.

(3) Handling and disposal of infectious waste in accordance with the requirements of Section 25-15-401, et seq., C.R.S. and Part 11 of these rules.

(4) Disposal of biological non-infectious waste.

(D) Each FSED shall have a sufficient number of water-tight containers with tight fitting lids to hold all refuse that accumulates between collections.

(E) Containers used for storing or holding refuse waiting for collection must be enclosed.

(F) Refuse containers shall be cleaned each time they are emptied.

(G) Single service container liners are required.

(H) Accumulated waste material shall be removed from the building at least daily.

(I) All external rubbish and refuse containers shall be impervious and tightly covered.

5.4 Linen and Laundry Services

(A) Linen and laundry services shall be provided in-house or by contract with a commercial laundry service.

(B) Separate clean and soiled linen areas shall be provided and maintained.

(C) For services provided in-house, the water temperature and duration of washing cycle shall be consistent with the temperature and duration recommended by the manufacturers of the laundry chemicals and equipment being used.

Part 6. GOVERNANCE AND LEADERSHIP

6.1 Administrator

(A) The FSED shall have an administrator or a designated person who is principally responsible for directing the daily operation of the FSED and acts as an administrative liaison with the governing body and medical director.

(B) The administrator shall be responsible for the development and implementation of:

(1) Policies and procedures for all FSED operations. The policies and procedures shall be reviewed and updated as needed, but no less than every three years.

(2) A written organizational plan defining the authority, responsibility, and function of each category of personnel.

(3) A written policy or plan defining the scope of care and services offered, which shall include emergency services, as required in Part 18, and optional primary care services as defined in Part 2.10, if provided.

(4) If primary care services are offered, the FSED administrator, in conjunction with the governing body and medical director, shall ensure that policies, procedures, and clinical guidelines are developed, implemented, and maintained for any primary care services included in the scope of care.

6.2 Governing Body

(A) An FSED shall have a governing body that is legally responsible for the conduct of the FSED.

(B) The governing body shall:

(1) Meet at least annually and maintain accurate records of such meetings.

(2) Adopt the general bylaws by which the governing body operates.

(3) Ensure that patients receive care in a safe setting, including providing the equipment, supplies, and facilities necessary for the welfare and safety of patients.

(4) Ensure that there are written procedures for:

(a) Lines of authority and accountability, and

(b) The qualifications of the personnel performing care.

(5) Ensure the approval and implementation of written policies and procedures in cooperation with the administrator and medical director.

(6) Ensure that there is sufficient staff to meet the demands for services routinely provided and coverage during periods of high demand or emergency.

(7) Ensure any disciplinary action that results in a suspension, revocation, or limitation of the privileges of a member of the provider, nursing, or ancillary staff is reported to the appropriate licensing or certification authority.

(8) Ensure that the FSED meets all of the Quality Management Program requirements of Part 8.

(9) Establish a patient transfer plan that includes:

(a) Agreements with a hospital(s) that include procedures for obtaining air or ground transportation, as appropriate.

(b) If an emergency medical condition necessitates patient transfer, the patient shall be transferred, avoiding delay in care and with consideration of transport time, to the closest, most appropriate acute care hospital with the capacity to meet the needs of the patient, unless either of the following dictates otherwise:

(I) THE FEDERAL EMERGENCY MEDICAL TREATMENT AND ACTIVE LABOR ACT (EMTALA) REQUIREMENTS CODIFIED AT 42 U.S.C. 1395DD, OR

(II) REGIONAL TRAUMA TRIAGE PROTOCOLS.

(C) TRANSFER PROTOCOLS TO INCLUDE:

(I) COORDINATION WITH THE LOCAL EMERGENCY MEDICAL SERVICES SYSTEM AND LICENSED AMBULANCE SERVICES.

(II) TRIAGE AND STABILIZATION TO BE INITIATED BY ON-DUTY STAFF.

(III) TRANSFER OF RELEVANT PATIENT INFORMATION WITH THE PATIENT.

(IV) COMPLIANCE WITH ALL REQUIREMENTS AS A DESIGNATED OR NON-DESIGNATED TRAUMA CENTER PER REGULATION, 6 CCR 1015-4, CHAPTER THREE, 301.3.

6.3 MEDICAL DIRECTOR

(A) A MEDICAL DIRECTOR SHALL BE A PHYSICIAN, LICENSED UNDER THE LAWS OF THE STATE OF COLORADO, WHO IS A MEMBER OF THE FSED'S STAFF AND WHO IS QUALIFIED BY EDUCATION AND EXPERIENCE TO OVERSEE THE SERVICES PROVIDED BY THE FSED. THE MEDICAL DIRECTOR SHALL BE RESPONSIBLE FOR THE QUALITY OF MEDICAL CARE PROVIDED TO PATIENTS IN THE FACILITY.

Commented [SG82]: Modified from the language approved by work group but made more consistent with Chapter 9.

(B) THE MEDICAL DIRECTOR SHALL BE RESPONSIBLE FOR THE DEVELOPMENT OF POLICIES AND PROCEDURES RELATED TO THE MEDICAL CARE PROVIDED. THE POLICIES AND PROCEDURES SHALL BE APPROVED BY THE APPROPRIATE MEMBERS OF THE PROVIDER STAFF AND REVIEWED AND UPDATED AS NEEDED, BUT NO LESS THAN EVERY THREE YEARS.

(C) THE MEDICAL DIRECTOR SHALL SERVE AS THE FORMAL CLINICAL LIAISON WITH THE GOVERNING BODY.

(D) THE MEDICAL DIRECTOR SHALL ENSURE THAT SERVICES ARE PROVIDED IN ACCORDANCE WITH CURRENT STANDARDS OF PRACTICE AND ARE CONSISTENT WITH STANDARDS ESTABLISHED THROUGH THE QUALITY MANAGEMENT PROGRAM AS DEFINED IN PART 8.

(E) THE MEDICAL DIRECTOR SHALL BE RESPONSIBLE FOR THE COORDINATION OF ALL THE PROFESSIONAL MEDICAL CONSULTANTS TO THE FSED, IF ANY.

PART 7. EMERGENCY PREPAREDNESS

7.1 EMERGENCY MANAGEMENT PLAN

(A) EACH FSED SHALL DEVELOP AND IMPLEMENT A COMPREHENSIVE EMERGENCY MANAGEMENT PLAN THAT MEETS THE REQUIREMENTS OF THIS SECTION, UTILIZING AN ALL-HAZARDS APPROACH. THIS PLAN SHALL TAKE INTO CONSIDERATION PREPAREDNESS FOR NATURAL EMERGENCIES, MAN-MADE EMERGENCIES, FACILITY EMERGENCIES, BIOTERRORISM EVENTS, PANDEMIC, OR AN OUTBREAK CAUSED BY AN INFECTIOUS AGENT OR BIOLOGICAL TOXIN. THE PLAN SHALL INCLUDE, BUT IS NOT LIMITED TO:

(1) CARE-RELATED EMERGENCIES;

(2) EQUIPMENT AND POWER FAILURES;

(3) Interruptions in communications, including cyber-attacks;

(4) Loss of a portion or all of a facility; and

(5) Interruptions in the normal supply of essentials, such as water, food, pharmaceuticals, personal protective equipment (PPE), and other essentials.

(B) The Emergency Management Plan components must include, but not be limited to, the following elements:

(1) The plan must be:

(A) Specific to the FSED;

(B) Relevant to the geographic area;

(C) Readily put into action, twenty-four (24) hours a day, seven (7) days a week; and

(D) Reviewed and revised periodically.

(2) The plan must identify:

(A) Who is responsible for each aspect of the plan; and

(B) Essential and key personnel responding to a disaster.

(3) The plan shall include:

(A) A staff education and training component;

(B) A process for testing each aspect of the plan at least every two (2) years or as determined by changes in the availability of FSED resources;

(C) A component for debriefing and evaluation after each disaster, incident, or drill; and

(D) The prominent posting of evacuation routes and exits.

PART 8. QUALITY MANAGEMENT PROGRAM

8.1 Each FSED shall comply with the requirements of 6 CCR 1011-1, Chapter 2, Part 4.1.

8.2 If an FSED is part of a larger system consisting of multiple hospitals/FSEDs using a system governing body that is legally responsible for the conduct of two or more hospitals/FSEDs, the system governing body may have a unified quality management program (QMP) provided the QMP does the following:

(A) Takes into account each FSED's unique circumstances and any significant differences in patient populations and services offered in each FSED; and

(B) Establishes and implements policies and procedures to ensure the needs and concerns of each FSED, regardless of practice or location, are given due consideration, and that the unified quality management program has mechanisms in

PLACE TO ENSURE THAT ISSUES LOCALIZED TO PARTICULAR FSEDS ARE DULY CONSIDERED AND ADDRESSED.

PART 9. PERSONNEL

9.1 ORGANIZATION AND STAFFING

(A) THERE SHALL BE SUFFICIENT PROVIDER, NURSING, AND ANCILLARY STAFF WITH THE APPROPRIATE TRAINING AND EXPERIENCE AVAILABLE TO MEET THE NEEDS OF THE PATIENT, IN ACCORDANCE WITH THE SCOPE OF THE SERVICES PROVIDED BY THE FSED.

(B) FSED STAFF SHALL BE LICENSED, CERTIFIED, OR REGISTERED IN ACCORDANCE WITH APPLICABLE COLORADO LAWS AND REGULATIONS AND SHALL PROVIDE SERVICES WITHIN THEIR SCOPE OF PRACTICE, PROFESSIONAL STANDARDS, AND, AS APPROPRIATE, IN ACCORDANCE WITH CREDENTIALING.

(C) PERSONNEL SHALL BE ORIENTED, TRAINED, AND COMPETENT TO PROVIDE THE SERVICES THEY ARE ASSIGNED TO DO. NEW STAFF SHALL RECEIVE ORIENTATION INCLUDING, BUT NOT LIMITED TO, THE PATIENT CARE ENVIRONMENT, INFECTION CONTROL, AND RELEVANT POLICIES AND PROCEDURES.

(D) THE FSED SHALL ENSURE THAT POLICIES AND PROCEDURES ARE AVAILABLE TO EMPLOYEES AT ALL TIMES.

(E) FSEDS THAT UTILIZE EMERGENCY MEDICAL SERVICE (EMS) PROVIDERS SHALL, IN COLLABORATION WITH THE PROVIDER STAFF, ESTABLISH OPERATING POLICIES AND PROCEDURES THAT ENSURE EMS PROVIDERS PERFORM TASKS AND PROCEDURES AND ADMINISTER MEDICATIONS WITHIN THEIR SCOPE OF PRACTICE PURSUANT TO SECTION 25-3.5-207, C.R.S.

(F) THE FSED SHALL MAINTAIN POSITION DESCRIPTIONS FOR ALL CATEGORIES OF PERSONNEL THAT CLEARLY STATE THE QUALIFICATIONS AND EXPECTED DUTIES OF THE POSITION.

(G) THE FSED SHALL MAINTAIN PERSONNEL RECORDS ON EACH MEMBER OF THE FSED STAFF INCLUDING AND VERIFICATION OF LICENSURE, CERTIFICATION, OR REGISTRATION. IN ADDITION, THE FSED SHALL MAINTAIN PROCEDURES TO ENSURE THAT STAFF FOR WHOM STATE LICENSES, REGISTRATIONS, OR CERTIFICATES ARE REQUIRED HAVE A CURRENT LICENSE, REGISTRATION, OR CERTIFICATION.

9.2 NURSING SERVICES

(A) THE FSED SHALL PROVIDE NURSING SERVICES SUFFICIENT TO MEET THE SCOPE OF CARE AND SERVICES AS DEFINED IN FSED POLICY.

(B) NURSING SERVICES SHALL BE OVERSEEN BY A REGISTERED NURSE QUALIFIED BY TRAINING AND EXPERIENCE IN EMERGENCY SERVICES.

(C) THERE SHALL BE WRITTEN NURSING POLICIES AND PROCEDURES THAT ESTABLISH THE STANDARDS FOR PERFORMANCE FOR SAFE, EFFECTIVE NURSING CARE OF PATIENTS. THESE PROCEDURES SHALL BE REVIEWED PERIODICALLY AND REVISED AS NECESSARY, BUT NO LESS THAN EVERY THREE (3) YEARS.

(D) TO ASSURE COMPETENCY IN ADULT AND PEDIATRIC EMERGENCY CARE, REGISTERED NURSE TRAINING SHALL INCLUDE, AT A MINIMUM:

(1) ADVANCED CARDIOVASCULAR LIFE SUPPORT (ACLS) AND

(2) Pediatric Advanced Life Support (PALS) or Emergency Nursing Pediatric Course (ENPC).

9.3 Provider Staff

(A) The FSED shall provide clinical services sufficient to meet the scope of care and services as defined in FSED policy.

(B) Clinical services shall be overseen by the medical director, as detailed in Part 6.3.

(C) Every patient shall be under the care of a provider with appropriate training and education.

(D) Medications and treatments shall be given only on the order of a provider authorized by law.

Part 10. HEALTH INFORMATION MANAGEMENT

10.1 Each FSED shall comply with the requirements of 6 CCR 1011-1, Chapter 2, Part 6, regarding patient access to medical records.

10.2 The FSED shall provide sufficient space and equipment for the processing and safe storage of medical records. Records shall be maintained and stored out of direct access of water, fire, and other hazards to protect them from damage and loss. A records recovery or backup system shall be utilized to ensure that there is no loss of medical records.

10.3 A person knowledgeable in health information management shall be responsible for the proper administration and protection of medical records.

10.4 The FSED shall store medical records in a manner that protects patient privacy and confidentiality and allows for retrieval of records in a timely manner.

10.5 Medical records shall be preserved as original records, in a manner determined by the FSED:

(A) For minors, for the period of minority plus 10 years (i.e., until the patient is age 28) or 10 years after the most recent patient encounter, whichever is later.

(B) For adults, ages 18 and older, for no less than seven years after the most recent patient care encounter.

10.6 If an FSED ceases operation, the FSED shall make provision for secure, safe storage, and prompt retrieval of all medical records for the period specified in 10.5.

10.7 An FSED that ceases operation must comply with the provisions of 6 CCR 1011-1, Chapter 2, Part 2.14.4.

10.8 After the required time of record preservation, records may be destroyed at the discretion of the FSED, in accordance with the FSED's record retention policy. The FSED shall establish procedures for notification to patients whose records are to be destroyed prior to the destruction of such records.

10.9 All orders for diagnostic procedures, treatments, and medications shall be authorized by the provider and entered into the medical record. The prompt completion of a medical record shall be the responsibility of the attending provider.

10.10 AUTHORIZATION MAY BE BY WRITTEN SIGNATURE, IDENTIFIABLE INITIALS, OR COMPUTER KEY.

10.11 COMPLETE MEDICAL RECORDS SHALL BE MAINTAINED ON EVERY PATIENT FROM THE TIME OF REGISTRATION FOR SERVICES THROUGH DISCHARGE. ALL ENTRIES INTO THE RECORD SHALL BE DATED, TIMED, AND AUTHORIZED BY THE APPROPRIATE PERSONNEL.

10.12 ALL MEDICAL RECORDS SHALL INCLUDE, AT A MINIMUM, THE FOLLOWING, IF APPLICABLE:

(A) A UNIQUE MEDICAL RECORD IDENTIFICATION NUMBER, IDENTIFICATION DATA INCLUDING MEDICAL HISTORY, PHYSICAL EXAMINATION, AND RISK ASSESSMENTS, INCLUDING PSYCHOSOCIAL INFORMATION.

(B) PROPERLY EXECUTED CONSENT TO TREAT FORMS, INFORMED CONSENT(S), AND ADVANCE DIRECTIVES, WHEN APPLICABLE.

(C) REPORTS OF PHYSICAL EXAMINATIONS, VITAL SIGNS, DIAGNOSTIC AND LABORATORY TEST RESULTS, REPORTS OF ELECTROMAGNETIC RADIATIONS (X-RAYS), COMPUTED TOMOGRAPHY (CT) SCANS, AND OTHER RADIOLOGICAL IMAGING STUDIES, AND CONSULTATIVE REPORTS AND FINDINGS, IF ANY.

(D) A RECORD OF PATIENT EDUCATION, MEDICATIONS, TREATMENTS, AND PROCEDURES. DOCUMENTATION SHALL INCLUDE NOTATION OF THE INSTRUCTIONS GIVEN TO PATIENTS ON THE DATE OF SERVICE.

(E) DOCUMENTATION OF COMPLICATIONS, ADVERSE REACTIONS TO DRUGS AND ANESTHESIA, REFERRALS, AND TRANSFERS.

(F) A BRIEF SUMMARY OF THE CARE ENCOUNTER, PATIENT DISPOSITION, AND PROVISIONS FOR FOLLOW-UP CARE.

(G) FINAL DIAGNOSIS WITH COMPLETION OF MEDICAL RECORDS WITHIN (THIRTY) 30 DAYS FOLLOWING DISCHARGE.

PART 11. INFECTION PREVENTION AND CONTROL AND ANTIBIOTIC STEWARDSHIP PROGRAMS

11.1 INFECTION PREVENTION AND CONTROL PROGRAM

(A) THE FSED SHALL HAVE AN INFECTION CONTROL PROGRAM BASED ON NATIONAL STANDARDS FOR INFECTION CONTROL AND SHALL ENSURE THE ADEQUATE INVESTIGATION, CONTROL, AND PREVENTION OF INFECTIONS.

(B) THE INFECTION PREVENTION AND CONTROL PROGRAM SHALL REFLECT THE SCOPE AND COMPLEXITY OF THE SERVICES PROVIDED BY THE FSED.

(C) THE PROGRAM SHALL BE OVERSEEN BY AT LEAST ONE INDIVIDUAL TRAINED IN INFECTION PREVENTION AND CONTROL WHO SHALL BE EMPLOYED BY OR REGULARLY AVAILABLE TO THE FSED.

(D) THE FSED SHALL DEVELOP AND IMPLEMENT WRITTEN POLICIES REGARDING:

(1) TRAINING OF PROVIDER, NURSING, ANCILLARY, AND ALL OTHER STAFF ON INFECTION CONTROL PRACTICES. THE POLICY SHALL ADDRESS TRAINING PROVIDED UPON ORIENTATION TO THE FSED AS WELL AS ONGOING ANNUAL TRAINING.

(2) PATIENT ISOLATION PRECAUTIONS IN RESPONSE TO COMMUNICABLE DISEASE.

(3) Hand hygiene, which shall be performed as often as necessary using soap and water or alcohol-based hand sanitizer and shall be performed according to nationally recognized guidelines.

(4) Maintenance of a sanitary environment.

(5) Mitigation of risks associated with patient infections present upon arrival.

(6) Coordination with other federal, state, and local agencies, as necessary.

11.2 Antibiotic Stewardship Program

(A) The FSED shall have an antibiotic stewardship program responsible for the optimization of antibiotic use through stewardship.

(B) The program shall be overseen by an individual who is qualified through education, training, or experience in infectious disease, infection prevention and control, pharmacy, and/or antibiotic stewardship.

(C) The program shall document the evidence-based use of antibiotics in all services of the FSED and any improvements in proper antibiotic use.

(D) The program shall adhere to nationally recognized guidelines, as well as best practices, for improving antibiotic use.

(E) The program shall reflect the scope and complexity of the services provided at the FSED.

Part 12. PATIENT RIGHTS

As a condition of licensure, the FSED shall be in compliance with 6 CCR 1011-1, Chapter 2, Part 7.

Part 13. PHARMACY SERVICES

13.1 The FSED shall maintain an inventory of medications sufficient to care for the number and types of patients covered in the scope of services.

13.2 The FSED shall implement methods, procedures, and controls which ensure the appropriation, acquisition, storage, dispensing, and administration of medication are in accordance with applicable state and federal laws and regulations, whether it provides its own pharmaceutical services or makes other legal and appropriate arrangements for obtaining necessary pharmaceuticals.

13.3 Medications shall not be administered to patients unless ordered by a legally authorized provider.

13.4 Medications maintained in the FSED shall be appropriately stored and safeguarded against diversion or access by unauthorized persons. Appropriate records shall be kept regarding the disposition of all medications.

13.5 Each FSED shall maintain reference sources for identifying and describing medications. Sources may be in print, electronic format, or web-based.

13.6 Medication shall be administered only by a person legally authorized per their scope of practice.

13.7 Adverse medication reactions shall be reported immediately to the provider

RESPONSIBLE FOR THE PATIENT AND DOCUMENTED IN THE MEDICAL RECORD.

PART 14. LABORATORY SERVICES

14.1 CLINICAL LABORATORY SERVICES SHALL BE AVAILABLE AS REQUIRED BY THE NEEDS OF THE CLIENTS AS DETERMINED BY THE CLINICAL STAFF. THE LABORATORY SHALL MEET THE REQUIREMENTS OF THE "CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988," 42 USC § 263A, AND THE CORRESPONDING REGULATIONS AT 42 CFR PART 493.

14.2 THE FSED SHALL PROVIDE PROMPT FOLLOW-UP FOR LABORATORY RESULTS OUTSIDE THE NORMAL VALUE RANGE.

14.3 IF UTILIZED AT THE FACILITY, THE FSED SHALL DEVELOP AND IMPLEMENT POLICIES AND PROCEDURES REGARDING POINT OF CARE TESTING.

14.4 IF BLOOD OR BLOOD PRODUCTS ARE MAINTAINED AT THE FACILITY, THE FSED SHALL MEET THE REQUIREMENTS OF 6 CCR 1011-1, CHAPTER 4, PART 14.2.

PART 15. DIAGNOSTIC IMAGING SERVICES

15.1 DIAGNOSTIC IMAGING SERVICES ESSENTIAL TO THE TREATMENT AND DIAGNOSIS OF THE PATIENT SHALL BE AVAILABLE ON SITE FOR SERVICES SPECIFIED IN PART 18.3(C)(2). OTHER IMAGING SERVICES MAY BE AVAILABLE DIRECTLY OR THROUGH REFERRAL. THE SCOPE AND COMPLEXITY OF DIAGNOSTIC IMAGING SERVICES MUST BE SPECIFIED IN WRITING.

15.2 DIAGNOSTIC IMAGING SERVICES SHALL BE ORDERED BY A PHYSICIAN OR OTHER PROVIDER AUTHORIZED BY LAW.

15.3 ALL RADIOLOGICAL SERVICES SHALL MEET COLORADO REGULATIONS PERTAINING TO "RADIATION CONTROL," 6 CCR 1007-1. THE RADIOLOGICAL SERVICE SHALL BE DIRECTED BY A LICENSED RADIOLOGIST OR OVERSEEN BY A QUALIFIED INDIVIDUAL WITH APPROPRIATE EDUCATION AND EXPERIENCE WHO IS APPOINTED BY THE GOVERNING BODY.

15.4 THE FSED SHALL PROVIDE PROMPT NOTIFICATION ON ALL CRITICAL AND/OR ABNORMAL IMAGING FINDINGS. FOR ALL CRITICAL ABNORMAL FINDINGS, THE FSED SHALL IMMEDIATELY NOTIFY THE PATIENT REGARDING THE COURSE OF CARE.

PART 16. DIETARY SERVICES

IF DIETARY SERVICES ARE OFFERED AT THE FSED, SAFE FOOD STORAGE AND PREPARATION PRACTICES SHALL BE FOLLOWED, IN ACCORDANCE WITH POLICIES AND PROCEDURES, BY THE FSED.

PART 17. ANESTHESIA SERVICES

17.1 PROCEDURAL SEDATION OR REGIONAL ANESTHESIA SHALL ONLY BE ADMINISTERED BY QUALIFIED PROVIDERS IN ACCORDANCE WITH THEIR SCOPE OF PRACTICE, NATIONALLY RECOGNIZED PRACTICE STANDARDS, STATE PRACTICE ACTS AND REGULATIONS, AND CLINICAL PRIVILEGES GRANTED BY THE FSED.

17.2 THE FSED SHALL CREATE POLICIES REGARDING:

(A) THE QUALIFICATIONS AND RESPONSIBILITIES OF PERSONS ADMINISTERING PROCEDURAL SEDATION OR REGIONAL ANESTHESIA, INCLUDING THE LEVEL OF SUPERVISION REQUIRED.

(B) PATIENT EDUCATION AND INFORMED CONSENT.

(C) PATIENT ASSESSMENT APPROPRIATE TO THE LEVEL OF PROCEDURAL SEDATION OR REGIONAL

ANESTHESIA BEING USED.

(D) PATIENT MONITORING DURING THE PROVISION OF PROCEDURAL SEDATION OR REGIONAL ANESTHESIA AND UNTIL THE PATIENT IS STABLE.

(E) THE SAFE DISCHARGE OF PATIENTS WHO HAVE UNDERGONE SEDATION OR ANESTHESIA.

PART 18. EMERGENCY SERVICES

18.1 ORGANIZATION

(A) THE FSED SHALL DEVELOP AND IMPLEMENT POLICIES AND PROCEDURES OUTLINING THE SCOPE OF SERVICES PROVIDED.

(B) EACH PATIENT SHALL BE DISCHARGED ONLY UPON A PROVIDER'S RECORDED AUTHORIZATION INCLUDING INSTRUCTIONS GIVEN TO THE PATIENT FOR FOLLOW-UP CARE, MODIFIED DIET, MEDICATIONS, AND SIGNS AND SYMPTOMS TO BE REPORTED TO A PROVIDER, IF RELEVANT, AND A CONTACT TO CALL IN CASE THE PATIENT HAS QUESTIONS AFTER DISCHARGE.

(C) THE LOCATION AND TELEPHONE NUMBER OF A POISON CONTROL CENTER SHALL BE POSTED PROMINENTLY IN THE FSED.

18.2 EMERGENCY SERVICES PERSONNEL

(A) AN APPROPRIATELY EDUCATED AND QUALIFIED EMERGENCY PHYSICIAN SHALL BE ON-SITE AT ALL TIMES.

(B) AT A MINIMUM, THERE SHALL BE AT LEAST ONE REGISTERED NURSE ON-SITE AT ALL TIMES. THERE SHALL BE SUFFICIENT REGISTERED NURSES WITH ADEQUATE TRAINING AND EXPERIENCE TO MEET THE NEEDS OF PATIENT CENSUS.

(C) THERE SHALL BE PROCEDURES FOR ACCESSING ADDITIONAL STAFF TO MEET UNANTICIPATED NEEDS.

18.3 SERVICES

(A) EMERGENCY SERVICES SHALL BE PROVIDED 24 HOURS PER DAY, 7 DAYS PER WEEK, INCLUDING PROVIDING EVALUATION AND STABILIZATION OF BOTH ADULT AND PEDIATRIC PATIENTS WHO PRESENT FOR CARE.

(B) AT A MINIMUM, THE FSED SHALL PROVIDE THE NECESSARY RESOURCES TO ADDRESS EMERGENCIES FOR BOTH ADULT AND PEDIATRIC PATIENTS, INCLUDING, BUT NOT LIMITED TO: AIRWAY, CARDIAC, CIRCULATORY, NEUROLOGIC, OBSTETRIC, ORTHOPEDIC, PULMONARY, AND BEHAVIORAL HEALTH.

(C) THE FSED SHALL PROVIDE, AT A MINIMUM, THE FOLLOWING SERVICES ON-SITE:

(1) INITIAL STABILIZATION AND TREATMENT FOR ANY ACUTE MEDICAL, TRAUMATIC, AND/OR BEHAVIORAL HEALTH PATIENT.

(2) RADIOLOGY, IMAGING, AND OTHER DIAGNOSTIC SERVICES TO INCLUDE X-RAY, CT SCAN, AND ULTRASOUND SERVICES.

(3) LABORATORY, TO INCLUDE THOSE SERVICES NECESSARY TO EVALUATE AND TREAT PATIENTS WITHIN THE FACILITY'S SCOPE OF SERVICES.

(4) PHARMACY SERVICES, TO INCLUDE THE DRUGS NECESSARY FOR THE SERVICES PROVIDED WITHIN THE FACILITY'S SCOPE OF CARE.

(5) PROCEDURAL SEDATION OR REGIONAL ANESTHESIA USED DURING THE COURSE OF PROVIDING TREATMENT.

(D) ALL PATIENTS PRESENTING FOR EMERGENCY SERVICES SHALL BE OFFERED A MEDICAL SCREENING EXAM AND STABILIZING TREATMENT WITHIN THE CAPABILITY OF THE FSED FOR EMERGENCY MEDICAL CONDITIONS IDENTIFIED BY A MEDICAL SCREENING EXAM, REGARDLESS OF AN INDIVIDUAL'S ABILITY TO PAY, METHOD OF PAYMENT, OR INSURANCE STATUS.

18.4 POLICIES AND PROCEDURES

THE FSED SHALL DEVELOP AND IMPLEMENT POLICIES, PROCEDURES, AND/OR GUIDELINES FOR THE FOLLOWING:

(A) CLINICAL CARE THAT SHALL BE BASED ON NATIONALLY-RECOGNIZED GUIDELINES, PROCEDURE MANUALS, AND REFERENCE MATERIALS.

(B) AN EASILY ACCESSIBLE CENTRALIZED LOG OF EACH INDIVIDUAL PRESENTING WHO IS IN NEED OF EMERGENCY SERVICES AND WHETHER THE INDIVIDUAL REFUSED TREATMENT, LEFT WITHOUT BEING SEEN, ELOPED, WAS TRANSFERRED, WAS ADMITTED, DIED, OR WAS DISCHARGED.

(C) PROCESSING PATIENTS PRESENTING FOR EMERGENCY SERVICES INCLUDING PROCEDURES FOR INITIAL ASSESSMENT, PRIORITIZATION FOR MEDICAL SCREENING AND TREATMENT, AND PATIENT REASSESSMENT AND MONITORING.

(D) PROVISION OF FURTHER MEDICAL EXAMINATION AND SUCH TREATMENT AS MAY BE REQUIRED TO STABILIZE OR TRANSFER THE INDIVIDUAL WITHIN THE STAFF AND FSED'S CAPABILITIES.

(E) TRANSFER OF PATIENTS TO A HIGHER LEVEL OF CARE WHEN THEIR NEEDS EXCEED THE FSED'S CAPABILITIES. THE TRANSFERRING FSED MUST SEND ALL PERTINENT MEDICAL RECORDS AVAILABLE AT THE TIME OF TRANSFER, EFFECT THE TRANSFER THROUGH QUALIFIED PERSONS AND TRANSPORTATION EQUIPMENT, AND OBTAIN THE CONSENT OF THE RECEIVING FACILITY.

18.5 EQUIPMENT

THE FSED SHALL HAVE THE INSTRUMENTS, EQUIPMENT, AND OTHER RESOURCES TO DELIVER SERVICES TO ADULT AND PEDIATRIC PATIENTS COMMENSURATE WITH THE REQUIRED SERVICES DESCRIBED IN PART 18.3. THE FSED MAY LOOK TO NATIONAL GUIDELINES AND EVIDENCE-BASED MEDICAL PRACTICE TO INFORM DECISION-MAKING ON NECESSARY RESOURCES.

PART 19. REQUIRED CONSUMER NOTICES AND DISCLOSURES

19.1 ALL FSEDS ARE REQUIRED TO PROVIDE OUT-OF-NETWORK DISCLOSURES TO CLIENTS AS DESCRIBED IN 6 CCR 1011-1, CHAPTER 2, PART 7.1.3.

19.2 IN ADDITION, FSEDS ARE REQUIRED, PURSUANT TO SECTION 25-3-119, C.R.S., TO PROVIDE WRITTEN AND ORAL NOTICES, SIGNAGE, AND DISCLOSURES TO ALL PRESENTING PATIENTS.

19.3 INITIAL DISCLOSURE

(A) ALL FSEDS SHALL GIVE WRITTEN NOTICE TO EVERY INDIVIDUAL SEEKING TREATMENT AT THE FACILITY. THIS NOTICE SHALL BE PROVIDED IMMEDIATELY UPON REGISTRATION. THE NOTICE MUST COMPLY WITH THE LANGUAGE AT SECTION 25-3-119(1), C.R.S. THE FSED SHALL SELECT THE STATEMENT(S) APPROPRIATE TO THE SERVICES OFFERED.

(B) If the individual seeking care is a minor who is accompanied by an adult, the FSED shall provide the written notice to the accompanying adult.

(C) In addition to the written notice, a member of the FSED staff or a health care provider shall verbally provide the same required information to the individual.

19.4 Signage

All FSEDs must post a sign that is plainly visible in the area where an individual seeking care checks in or registers. The sign must comply with the required language at Section 25-3-119(2), C.R.S. The FSED shall select the statement(s) appropriate to the services offered.

19.5 Medical Screening Exam

All patients presenting for emergency services shall be offered a medical screening exam, regardless of an individual's ability to pay, method of payment, or insurance status.

19.6 Second Disclosure

(A) After performing a medical screening exam and determining that a patient does not have an emergency medical condition, or after treatment has been provided to stabilize an emergency medical condition, the FSED shall provide a written disclosure to the patient. The notice must comply with the language at Section 25-3-119(3), C.R.S.

(B) The FSED shall update the information contained in this second required disclosure at least once every six months.

(C) The FSED shall post this second required disclosure and any updates on its website at least once every six months.

(D) The FSED shall provide the required information in a clear and understandable manner and in languages appropriate to the communities and patients served by the FSED.

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DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

STATEWIDE EMERGENCY MEDICAL AND TRAUMA CARE SYSTEM

6 CCR 1015-4

_____

Adopted by the Board of Health on _____. Effective _____.

CHAPTER TWO – THE TRAUMA REGISTRY

200. Definitions

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3. Community Clinic ~~and~~PROVIDING Emergency SERVICES~~Centers (CCEC)~~ – Facilities as licensed by the Department under 6 CCR 1011-1, Chapter 9.

4. Department – The Colorado Department of Public Health and Environment.

5. Facility – A health facility licensed by the Department that receives ambulances such as a hospital, hospital unit, Critical Access Hospital (CAH), FREESTANDING EMERGENCY DEPARTMENT (FSED), or COMMUNITY CLINIC PROVIDING EMERGENCY SERVICES~~CCEC caring for trauma patients~~.

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DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

STATEWIDE EMERGENCY MEDICAL AND TRAUMA CARE SYSTEM

6 CCR 1015-4

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CHAPTER THREE – DESIGNATION OF TRAUMA FACILITIES

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301. Nondesignation and Designation Processes

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2. Process to be Applied

A. The current operational status of the facility will determine the designation process to be applied. The four types of operational statuses are:

(1) Nondesignated facility – A hospital, FREESTANDING EMERGENCY DEPARTMENT (FSED), community clinic ~~and~~PROVIDING emergency SERVICES~~center (CCEC)~~, or other licensed facility that receives and is accountable for injured persons, but chooses not to seek trauma center designation.

(2) New facility – A hospital, FSED, COMMUNITY CLINIC PROVIDING EMERGENCY SERVICES~~CCEC~~, or other licensed facility that is seeking trauma center designation for the first time or seeking to change to a different level of designation.

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5. Replacement Facility

A. Application Procedure

(1) A trauma designation review is required when the Department issues a new hospital, FSED, OR COMMUNITY CLINIC PROVIDING EMERGENCY SERVICES ~~CCEC~~ license based upon a change of location.

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307. Trauma Facility Designation Criteria – Level IV and V

Level IV trauma centers must be licensed as: a general hospital, FSED, a COMMUNITY CLINIC PROVIDING EMERGENCY SERVICES,~~and Emergency Center (CCEC), as defined in 6 CCR 1011-1 Chapter 9A,~~ or a Critical Access Hospital per 42 CFR 485.601, et seq., and be open 24 hours a day, 365 days a year with physician coverage for trauma patients arriving by ambulance.

Level V trauma centers must be licensed as: a general hospital, FSED, a COMMUNITY CLINIC PROVIDING EMERGENCY SERVICES,~~a CCEC,~~ or a Critical Access Hospital, per 42 CFR 485.601, et seq., and have a policy about hours of operation as described below:

1. A Level IV or V trauma center shall have:

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C. A trauma program with policies that identify and establish the scope of care for both adult and pediatric patients including, but not limited to:

(1) Initial resuscitation and stabilization;

(2) Rehabilitation capabilities if available;

(3) Written procedure for transfer of patients by fixed and rotary wing aircraft;

(4) Hospitals only (not applicable to ~~CCECs~~COMMUNITY CLINICS PROVIDING EMERGENCY SERVICES OR FSEDS) admission criteria;

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O. If licensed as a Community Clinic PROVIDING EMERGENCY SERVICES OR FSED~~and Emergency Center~~:

(1) A central log on each trauma patient/individual presenting with an emergency condition who comes seeking assistance and whether he or she refused

treatment, was refused treatment, or whether the individual was transferred, admitted and treated, died, stabilized and transferred, or discharged.

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