6 CCR 1011-1, Chapter IX - Community Clinics

SUBCHAPTER IX.A - GENERAL REQUIREMENTS
SUBCHAPTER IX.B - ADDITIONAL REQUIREMENTS FOR CLINICS WITH INPATIENT BEDS AND COMMUNITY EMERGENCY CENTERS

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

Division Director

Colorado Department of Public Health and Environment

Health Facilities Division

4300 Cherry Creek Drive South

Denver, Colorado 80222-1530

Main switchboard: (303) 692-2800

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

Division Director

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

SUBCHAPTER IX.A - GENERAL REQUIREMENTS

Part 1. STATUTORY AUTHORITY

1.101 Statutory Authority. Authority to establish minimum standards through regulation and to administer and enforce such regulations is provided by Sections 25-1.5-103 and 25-3-101, 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 II.

(b) Subchapter IX.A.

(c) Subchapter IX.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 IX 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 under the auspices of 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 llcensed 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) "Plan review" means the review by the Department, or its designee, of new construction, previously unlicensed space, or remodeling to ensure compliance by the facility with the National Fire Protection Association (NFPA) Life Safety Code and with this Chapter IX. Plan review consists of the analysis of construction plans/documents and onsite inspections, where warranted. For the purposes of the NFPA requirements, the Department is the authority having jurisdiction for state licensure.

(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.

(13) "Structural element" for the purposes of plan review, means an element relating to load bearing or to the scheme (layout) of a building as opposed to a screening or ornamental element. Structural elements of a building include but are not limited to: floor joists, rafters, wall and partition studs, supporting columns and foundations.

Part 3. DEPARTMENT OVERSIGHT

3.100 APPLICATION FEES.

(1) A non-refundable fee shall be submitted with the license application as follows:

	Initial license	**Renewal license**	**Change of ownership**
Community emergency center	$3,100	$1,700	$3,100
Clinic operating inpatient beds	$3,100	$1,700	$3,100
Clinic operated under the auspices of the Department of Corrections	$2,500	$1,300	$2,500
Optional licensure pursuant to Section 2.101 (3)(a)(iv):			
clinic serving the uninsured or underinsured	$1,250	$650	$1,250
other clinic	$2,500	$1,300	$2,500

3.200 COMMERCIAL PROFESSIONAL LIABILITY INSURANCE

3.201 Community clinics shall submit evidence to the Colorado Department of Public Health and Environment that they maintain at least $300,000 professional liability insurance per incident and $900,000 annual aggregate per year in order to demonstrate compliance with the Health Care Availability Act of 1988.

Part 4. FIRE SAFETY AND PHYSICAL PLANT STANDARDS

4.101 PLAN REVIEW AND PLAN REVIEW FEES. This Section 4.101 applies to community clinics with the exception of clinics operated in prisons and school-based clinics subject to construction plan review by the Division of Fire Safety, pursuant to C.R.S. 24-33.5-1203 (1)(p) (2010). In addition, plan review is optional for clinics that opt to obtain licensure unless the services provided by the facility lead to a determination by the Department that the facility shall meet ambulatory health care occupancy or health care occupancy.

Plan review and plan review fees are required as listed below. If the facility has been approved by the Department to use more than one building for the direct care of patients on its campus, each building is subject to the applicable base fee plus square footage costs. Fees are nonrefundable and shall be submitted prior to the Department initiating a plan review for a facility.

(1) <u>Initial Licensure, Additions, Relocations</u>

(a) Plan review is applicable to the following, and includes new facility construction and new occupancy of existing structures:

(i) Applications for an initial license, when such initial license is not a change of ownership and the application is submitted on or after July 1, 2009.

(ii) Additions of previously uninspected or unlicensed square footage to an existing occupancy and the building permit for such addition is issued on or after July 1, 2009 or if no permit is required by the local jurisdiction, construction began on or after July 1, 2009.

(iii) Relocations of a currently licensed facility in whole or in part to another physical plant, where the occupancy date occurs on or after July 1, 2009.

(b) Initial licensure, addition, and relocation plan review fees:

(i) Base fee of $2,250, plus square footage costs as shown in the table below.

Square Footage	Cost per Square Foot	Note
0-25,000 sq ft	$0.10	This is the cost for the first 25,000 sq ft of any plan submitted.
25,001+ sq ft	$0.02	This cost is applicable to the additional square footage over 25,000 sq ft.

(2) <u>Remodeling</u>

(a) Plan review is applicable to remodeling for which the application for the building permit from the local authority having jurisdiction is dated on or after July 1, 2009, or if no permit is required by the local jurisdiction, construction began on or after July 1, 2009. Remodeling includes, but is not limited to:

(i) Alteration, in patient sleeping areas, of a structural element subject to Life Safety Code standards, such as egress door widths and smoke or fire resisting walls.

(ii) Relocation, removal or installation of walls that results in alteration of 25% or more of the existing habitable square footage or 50% or more of a smoke compartment.

(iii) Conversion of existing space into rooms with inpatient beds.

(iv) Changes to egress components, specifically the alteration of a structural element, relocation, or addition of an egress component. Examples of egress components include, but are not limited to, corridors, stairwells, exit enclosures, and points of refuge.

(v) Installation of any new sprinkler systems or the addition, removal or relocation of 20 or more sprinkler heads.

(vi) Installation of any new fire alarm system, or addition, removal or relocation of 20 or more fire alarm system appliances including, but not limited to, pull stations, detectors and notification devices.

(vii) Installation, removal or renovation of any kitchen hood suppression system.

(viii) Essential electrical system: replacement or addition of a generator or transfer switch. However, replacement of either the generator or transfer switch with one having the same exact performance specifications is considered maintenance and not subject to plan review.

This draft assumes that the existing language of Chapter IX (shown on pages 22-34) will be struck in its entirety and replaced with the proposed language shown on pages 1-21).

(b) Remodeling plan review fees:

(i) Base fee of $1,750, plus square footage costs as shown in the table below.

Square Footage	Cost per Square Foot	Note
0-20,000 sq ft	$0.07	This is the cost for the first 20,000 sq ft of any plan submitted.
20,001+ sq ft	$0.02	This cost is applicable to the additional square footage over 20,000 sq ft.

4.102 COMPLIANCE WITH THE FIRE SAFETY REQUIREMENTS

(1) With the exception of school-based clinics subject to construction plan review by the Division of Fire Safety pursuant to C.R.S. 24-33.5-1203 (1)(p) (2010), community clinics shall be compliant with the applicable occupancy chapter of the National Fire Protection Association (NFPA) 101, Life Safety Code (2000), which is hereby incorporated by reference. Such incorporation by reference, as provided for in 6 CCR 1011-1, Chapter II, excludes later amendments to or editions of referenced material.

(a) Facilities licensed on or before April 30, 2012 shall meet the applicable "existing occupancy" requirements. Facilities licensed on or after May 1, 2012, or portions of facilities that undergo remodeling on or after May 1, 2012, shall meet the applicable "new occupancy" requirements. In addition, if the remodel represents a modification of more than 50 percent of the total interior licensed space, the entire licensed space shall be renovated to meet "new occupancy" requirements.

(b) Notwithstanding subsection (1)(a) above, primary care clinics that are in operation before May 1, 2012 and submit a license application before July 1, 2012 shall meet "existing occupancy" requirements.

(2) Notwithstanding NFPA 101 Life Safety Code (2000) provisions to the contrary:

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

(b) Any story containing an exterior door or an exterior window that opens to grade level shall be counted as a story.

(c) The occupancy requirement is based on the level of services provided to one or more persons in such occupancy.

(3) Exceptions to 2-Hour Firewall Requirements. Facilities that are not classified as either an ambulatory health care occupancy or a health care occupancy shall be exempt from the provisions set forth in Chapter II, Section 2.3.5 (A).

4.103 COMPLIANCE WITH AIA STANDARDS

(1) The “Guidelines for Design and Construction of Health Care Facilities” (2006 Edition), American Institute of Architects (AIA), may be used by the Department in resolving health, building, and life safety issues for construction initiated or systems installed on or after July 1, 2009. The AIA Guidelines are hereby

incorporated by reference. Such incorporation by reference, as provided for in 6 CCR 1011-1, Chapter II, excludes later amendments to or editions of referenced material.

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) Community clinics shall be in compliance with 6 CCR 1007-3, Colorado Hazardous Waste Regulations 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 ***{Explanatory note: The majority of provisions derived from the CDC's Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care.}***

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) 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. The community clinic shall be in compliance with 6 CCR 1011-1, Chapter II, Part 6.

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) Services shall be compliant with Clinical Laboratory Improvement Amendments (CLIA) standards.

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) Services shall be compliant with Colorado Department of Public Health and Environment standards pertaining to radiation control (6 CCR 1007-1).

SUBCHAPTER IX.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 IX.A, as well as the requirements in this Subchapter IX.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.

(E) fire drills, procedures in case of fire, evacuation and relocation procedures. Fire drills shall be conducted at least once per shift every three months that the facility is open in accordance with the Life Safety Code. In addition, prior to accepting patients or within 24 hours of resumption of services: all staff and all shifts shall participate in a fire drill; and all staff shall be oriented to the procedures in case of fire as well as their responsibilities during an evacuation and relocation emergency.

(3) establish a patient transfer plan that includes:

(a) agreements with hospital(s) that includes procedures for obtaining air or ground transportation, as appropriate. If a medically necessary transfer is needed, the patient shall be transferred to the closest acute care hospital with the capacity to meet the needs of the patient, unless regional trauma triage protocols dictate otherwise.

(b) 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) processing patients presenting for emergency services including procedures for initial assessment, prioritization for medical screening and treatment, and patient reassessment and monitoring.

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

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

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

(f) 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.

18.102 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 CO_2 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 XXII 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 Regulation Division~~

~~STANDARDS FOR HOSPITALS AND HEALTH FACILITIES~~

~~CHAPTER IX - COMMUNITY CLINICS AND COMMUNITY CLINICS AND EMERGENCY CENTERS~~

~~6 CCR 1011-1 Chap 09~~

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

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

~~Division Director~~

~~Colorado Department of Public Health and Environment~~

~~Health Facilities Division~~

~~4300 Cherry Creek Drive South~~

~~Denver, Colorado 80222-1530~~

~~Main switchboard: (303) 692-2800~~

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

~~Division Director~~

~~Colorado Department of Public Health and Environment~~

~~Health Facilities Division~~

~~4300 Cherry Creek Drive South~~

~~Denver, Colorado 80222-1530~~

~~Main switchboard: (303) 692-2800~~

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

~~Policy Statement : The following regulations are the minimum standards necessary, to operate a community clinic or a community clinic and emergency center. Facilities shall always operate by providing a level of care that meets the needs of the patients being served. This may necessitate standards that~~

~~exceed the minimum. Patient populations vary widely and the minimum standard may not be enough to meet the needs of patients being served and those needs must still be met.~~

~~Section 1. DEFINITIONS~~

~~1.1 Community Clinic or Community Clinic and Emergency Center. A "community clinic" or a "community clinic and emergency center" is defined as a comprehensive community-based medical facility which includes general or primary care services, preventive health services, diagnostic or therapeutic outpatient services, appropriate inpatient services, and/or emergent care services. The emergency center (emergency services available 24 hours) portion of the license shall be an optional component, and a community clinic may be licensed as a "community clinic" or as a "community clinic and emergency center." A "community clinic" or a "community clinic and emergency center" includes accommodations for inpatient stays, unless otherwise exempted by statutory provisions or by a waiver of the requirement by the Department under section 10.1. A "community clinic" or a "community clinic and emergency center" may include general and primary care providers participating in the medically indigent program pursuant to article 15 of title 26. No waiver of inpatient accommodation requirements as required under section 10.1 of these regulations shall be necessary for medically indigent program providers who provide only primary care and other outpatient services during normal business hours. No waiver of inpatient accommodation requirements as required under section 10.1 Of the regulations shall be necessary for a community clinic or a community clinic and emergency center located within a licensed hospital, but not licensed as part of the hospital, and has an admission or transfer agreement with that hospital.~~

~~1.2 Emergency or Emergent Care. Emergency or emergent care is defined as treatment for a medical condition manifesting itself by acute symptoms of a sufficiently severe nature that are life, limb, or disability threats requiring immediate attention, where any delay in treatment could be reasonably expected to place the health of the individual in serious jeopardy, or seriously impair bodily functions, or cause serious dysfunction of any bodily organ or part.~~

~~1.3 Inpatient Care. For the purposes in Chapter IX of these regulations, "inpatient care" shall be defined as extended care or stay in the facility beyond the primary care or general services normally rendered which would include an overnight stay or a continuous period of care exceeding twenty-four (24) hours, but not to exceed 72 hours.~~

~~1.4 Primary Care. Primary care is defined as a practice that deals with the individual rather than an organ system or an abnormal physiology and provides an array of services covering the preventive, diagnostic, and therapeutic needs of patients, including referral and coordination of care to the services.~~

~~1.5 Exclusions. The term community clinic or a community clinic and emergency center does not include the following:~~

~~(a) A facility that is licensed as part of or a department of a general hospital and is not freestanding;~~

~~(b) A facility which is used as an office for the private practice of a physician(s) except when:~~

~~I) it holds itself out to the public or other health care providers as a community clinic or a community clinic and emergency center or as a similar facility with a similar name or variation thereof which creates confusion in the mind of the public, indicating that it is capable of providing the same care as required by these regulations and or in fact provides the same level of care as required by these regulations, and in the case of an emergency center, of providing 24-hour emergency care;~~

~~2) it is operated or used by a person or entity different than the physician(s).~~

~~3) patients are charged a fee for the use of the facility in addition to the physician(s) professional fee.~~

~~1.6 Plan Review – means the review by the Department, or its designee, of new construction, previously unlicensed space, or remodeling to ensure compliance by the facility with the National Fire Protection Association (NFPA) Life Safety Code and with this Chapter IX. Plan review consists of the analysis of construction plans/documents and onsite inspections, where warranted. For the purposes of the National Fire Protection Association requirements, the Department is the authority having jurisdiction for state licensure.~~

~~1.7 Qualifying Community Clinic - for the purposes of plan review, means a clinic with a total interior physical plant square footage of under 2,500 square feet where the services do not include treatment that renders patients incapable of self-preservation without the assistance of others during an emergency situation. (Qualifying community clinics do not include community clinics and emergency centers.)~~

~~1.8 Structural Element – for the purposes of plan review, means an element relating to load bearing or to the scheme (layout) of a building as opposed to a screening or ornamental element. Structural elements of a building include but are not limited to: floor joists, rafters, wall and partition studs, supporting columns and foundations.~~

~~1.9 Anesthetizing Location - means any area of a facility that has been designated to be used for the administration of nonflammable inhalation anesthetic agents in the course of examination or treatment, including the use of such agents for relative analgesia.~~

~~1.10 Relative Analgesia - means a state of sedation and partial block of pain perception produced in a patient by the inhalation of concentrations of nitrous oxide insufficient to produce loss of consciousness; i.e., conscious sedation.~~

~~**Section 2. LICENSE**~~

~~2.1 A community clinic or a community clinic and emergency center shall be licensed and meet all of the licensure requirements in chapter II and the requirements of this Chapter IX of the Colorado Department of Public Health and Environment's Standards for Hospitals and Health Facilities .~~

~~2.2 A community clinic or a community clinic and emergency center shall be in compliance with all other applicable state, local, and federal laws.~~

~~**Section 3. ORGANIZATIONAL STRUCTURE**~~

~~3.1 Governing Body . The community clinic or a community clinic and emergency center shall have a governing body which shall have responsibility for the oversight of the organization and the provider staff. The governing body shall meet as necessary. The governing body shall adopt the general bylaws or policies by which the community clinic or a community clinic and emergency center operates. These by-~~

~~3.2 Medical Director . The governing body of the community clinic or a community clinic and emergency center 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.~~

~~3.3 Provider Staff . The community clinic or a community clinic and emergency center shall have an organized provider staff under the direction of the medical director that shall be responsible for the quality of medical care provided to patients in the facility.~~

~~3.4 Administrator . The governing body of the community clinic or a community clinic and emergency center shall appoint an administrator or a designated person who is principally responsible for directing the daily operation of the community clinic or a community clinic and emergency center. The administrator shall develop clear lines of authority and responsibility for the provider staff. The administrator, in conjunction with the provider staff, or a representative committee from the provider staff, shall develop policies and procedures for the operation of the facility. The policies and procedures shall be approved by the governing body and reviewed periodically and revised as needed.~~

~~3.5 Government Entities . A community clinic or a community clinic and emergency center wholly owned and operated by the state or any of its political subdivisions shall be governed, directed, administered, and staffed according to the statutory provisions establishing such facilities.~~

~~3.6 Corporate Health Care Entities or Health Care Networks . A community clinic or a community clinic and emergency center that is part of a larger, corporate health care system or health care network may fulfill the administrative record requirements, the policies and procedures requirements, and the medical records requirements of this Chapter IX through a central system common to the entire organization, providing that the intent of the requirements of this Chapter is met.~~

~~Section 4. STAFFING~~

~~4.1 Provider Staff . There shall be adequate provider staff to meet the preventive, diagnostic, and therapeutic needs of the patient population being served. The provider staff shall participate in the quality management program; and, in coordination with the administrator/participate in the enforcement of policies and procedures or rules and regulations of the facility. If the facility is operating as an emergency center, at least one of the provider staff on duty at all times shall be qualified in basic cardiac life support and advanced cardiac life support.~~

~~4.2 Personnel . The administrator shall develop and maintain personnel policies and procedures. Personnel employed by the community clinic or a community clinic and emergency center shall have qualifications as met by education, training, and experience necessary to meet the medical needs of the patients. Personnel shall be oriented and trained upon employment and kept abreast of new health care services developments and new technology through in-services and other educational programs.~~

~~Section 5. MEDICAL RECORDS~~

~~5.1 All community clinics or community clinic and emergency centers shall maintain a clinical medical record system as established by the facility's written patient care policies. A designated member of the staff shall be responsible for maintaining medical records and for ensuring that they are completely and accurately documented. Medical records shall be systematically organized and easily accessible. All necessary precautions shall be taken to protect the confidentiality of the information contained within.~~

~~5.2 An individual medical record for each patient that receives services from any community clinic or a community clinic and emergency center shall contain, but not necessarily be limited to, the following:~~

~~(a) identification and social data, evidence of consent forms, relevant medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient per visit;~~

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

~~(c) all physician's orders, reports of treatments and medications, and other information necessary to monitor the patient's progress;~~

~~(d) signatures of the physician or other health care professionals making entries into the medical record.~~

~~5.2 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. Medical records for minors must be retained for the period of minority plus 10 years after the last patient usage.~~

~~**Section 6. SERVICE PROVISION**~~

~~6.1 Care From Licensed Practitioner . The policies of the community clinic or community clinic and emergency center shall ensure that every patient is under the care of a physician or, if applicable, a physician assistant or advanced practice nurse with appropriate specialization and registered pursuant to 12-38-111.5.~~

~~6.2 Patient Care Policy . The facility shall have written patient care policies. The policies shall include but are not limited to the following:~~

~~(a) a description of the services furnished directly and those furnished through agreements, arrangements with, or referrals to other facilities or other health care service providers;~~

~~(b) protocols for the medical management of health problems, including the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for periodic review and evaluation of the services furnished by the facility;~~

~~(1) protocols shall include:~~

~~(A) a description of the scope of medical acts that may be undertaken by the physician assistant, or advanced practice nurse, or other provider staff under the supervision of a physician or other authorized licensed practitioner; and~~

~~(B) protocols to be followed for acts of medical diagnosis and treatment that may be undertaken without direct, over the shoulder physician supervision.~~

~~(2) Protocols are not intended to mandate the development of practice guidelines for physicians or other licensed provider staff practicing in the facility.~~

~~6.3 Outpatient Surgery . Outpatient surgical procedures commonly performed in a physician's office may be performed in any community clinic or a community clinic and emergency center if adequate staffing, equipment, and supplies are available.~~

~~**Section 7. EMERGENCY SERVICES PROVISIONS**~~

~~7.1 Services and Equipment . Emergency centers shall provide at a minimum the following services and equipment, both adult and pediatric as applicable:~~

~~(a) an emergency call system;~~

~~(b) oxygen;~~

~~(c) ventilation assistance equipment, including airways, manual breathing bag;~~

~~(d) continuous electrocardiogram monitoring with cardiac defibrillator;~~

~~(e) intravenous therapy supplies;~~

~~(f) laryngoscope and endotracheal tubes;~~

~~(g) suction equipment;~~

~~(h) indwelling urinary catheters; and~~

~~(i) drugs and other emergency medical equipment and supplies, including basic obstetric supplies, necessary for the level of services to stabilize the patient as specified by the provider staff and by the specific needs of the community being served.~~

~~7.2 Triage Protocols . A community clinic or a community clinic and emergency center shall have in place emergency medical protocols to provide triage and stabilization procedures to be initiated by on-duty staff; and to provide air or ground transportation with pre-arranged destinations, including transfer agreements with a hospital(s).~~

~~**Section 8. ANCILLARY SERVICES**~~

~~8.1 Obstetrics . A community clinic or a community clinic and emergency center may provide for routine pre-natal care and for necessary emergency obstetrical services according to emergency triage protocols of the facility. 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 XXII of the regulations.~~

~~8.2 Laboratory Services . Laboratory services essential to the treatment and diagnosis of the patient (both primary care and emergency patients) shall be available. Laboratory services shall be provided directly or by contract. Services provided directly shall be provided pursuant to the "Clinical Laboratory Improvement Amendments of 1988," and the corresponding regulations (42 USC 263a and 42 CFR 493).~~

~~8.3 Radiological Services . Radiological services essential to the treatment and diagnosis of the patient shall be available. Radiological services shall be provided directly or by contract or plan. 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. Services provided directly shall be provided pursuant to the regulations of the Department of Public Health and Environment pertaining to radiation control (6 CCR 1007-1).~~

~~8.4 Pharmacy . Pharmaceutical methods, procedures, and controls which ensure the appropriation, acquisition, storage, dispensing, administration, and control of pharmaceuticals shall be developed in accordance with applicable state and federal laws regulating the practice of pharmacy.~~

This draft assumes that the existing language of Chapter IX (shown on pages 22-34) will be struck in its entirety and replaced with the proposed language shown on pages 1-21).

~~Section 9. AVAILABILITY OF SERVICES~~

~~9.1 The Community Clinic . The community clinic shall maintain regular hours for services. The community clinic shall provide an emergency referral number and/or a procedure for the provision of medical services when the clinic is not open for regular service.~~

~~9.2 The Community Clinic and Emergency Center . The community clinic and emergency center shall maintain operations on a 24-hour basis, every day of the year. If a community clinic and emergency center chooses to temporarily interrupt operations or access to services for any part of the 24-hour period, a means of making services available within 30 minutes or sooner if medically necessary shall be instituted. Any seasonal interruption in services, such as seasonal closures, shall be reported to the Department prior to such closure, and all signage that would indicate that services are available shall be removed. 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. Clear directions at the front and/or emergency entrance to the facility that can be easily understood by persons approaching the 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 response by the facility can be made.~~

~~Section 10. INPATIENT SERVICES~~

~~10.1 Limited Stay. A community clinic or a community clinic and emergency center may provide inpatient services to ill or injured persons where a determination has been made that transportation to a hospital or other appropriate facility when a higher level of care is not immediately necessary provided that the needs of such patients can be met by the facility during a short stay not to exceed 72 hours. "Meeting the needs of patients" shall include, appropriate licensed provider staff, patient care services, equipment and supplies, and physical plant. *[Eff. 06/30/2009]*~~

~~(a) The Department may waive the requirement for inpatient services after a review of applicant materials for licensure provided that the facility demonstrates that it meets the definition of a facility under this Chapter IX of the regulations, with the exception of the inpatient component, and is not the private practice of an independent, licensed physician.~~

~~(b) The 72-hour limit on inpatient stays shall not apply to the Department of Corrections providing medical services pursuant to article I of title 17.~~

~~10.2 Patient Care Unit . A community clinic or a community clinic and emergency center providing inpatient care shall establish and maintain a patient care unit. Each patient shall have a visible means of identification placed securely on his or her person until discharge. Each patient room shall have adequate space to meet the needs of the patient. In general, the standard shall be 100 square feet for each single patient room or 80 square feet per bed for multiple bedrooms and include sufficient illumination to meet patient needs for treatment. Each patient shall have direct access to a call system which signals the provider staff on duty. The facility shall provide patient bathing facilities for patients staying overnight.~~

~~10.3 Admissions . Any community clinic or a community clinic and emergency center providing inpatient services shall develop admissions policies and procedures, which include but shall not be limited to appropriateness of admissions, and the necessary staffing to provide those services,~~

~~(a) Necessary staffing includes the licensed staff with the ability to meet the needs of the patient and the regulatory requirements imposed by other state laws on the use of such licensed staff.~~

~~10.4 Nutrition . Dietary services shall be provided in the following manner:~~

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

~~(b) All food shall be pre-packaged and require microwave heating only and disposable products for preparation and service shall be used unless the facility meets the requirements of the Rules and Regulations Governing the Sanitation of Food Service Establishments in the State of Colorado, Colorado Department of Health. 1990 or the intent of such regulations as applicable and appropriate.~~

~~(c) A person shall be assigned the responsibility for food preparation and service and shall have no other assigned duties during such assignment.~~

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

~~(e) Food shall, at all times, be prepared, stored, and served properly so as to prevent the development and spread of food borne disease.~~

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

~~(g) There shall be food service available to serve adequate meals to patients "required to stay" in any community clinic or a community clinic and emergency center for more than six hours, if necessary or consistent with medical treatment or evaluation needed. Being "required to stay" is defined as a condition which requires the patient to stay in the facility for extended treatment or until transportation to another facility can be arranged. It does not apply to outpatient visits that may require extensive waiting before receiving services if the patient is able to leave after services are rendered or is able to reschedule a visit if service cannot be provided in a timely manner.~~

~~10.5 Discharge Planning . For those community clinics or community clinic and emergency centers that offer inpatient care, documentation of discharge and follow-up shall be included in the patient record to ensure the provision of post-discharge care.~~

~~Section 11. INFECTION CONTROL~~

~~11.1 All community clinics or community clinic and emergency centers shall develop a plan for infection control that is adequate to avoid the sources of and prevent the transmission of infections and communicable diseases. The facility shall develop a system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel. Sterilization procedures shall be developed and implemented in necessary service areas.~~

~~Section 12. LIABILITY~~

~~12.1 Community clinics or community clinic and emergency centers shall submit evidence to the Colorado Department of Public Health and Environment that they maintain at least $300,000 professional liability insurance per incident and $900,000 annual aggregate per year in order to demonstrate compliance with the Health Care Availability Act of 1988.~~

~~Section 13. PHYSICAL PLANT AND ENVIRONMENT [Eff. 06/30/2009]~~

~~13.1 Pest Control. Policies shall be developed and procedures implemented for the effective control of insects, rodents, and other pests.~~

~~13.2 Waste Disposal. All wastes shall be disposed in compliance with local, state and federal laws.~~

~~13.3 Preventive Maintenance. A preventive maintenance program to ensure that all essential mechanical, electrical and patient care equipment is maintained in safe operating condition shall be provided. Emergency systems, and all essential equipment and supplies shall be inspected and maintained on a frequent or as needed basis.~~

~~13.4 Housekeeping. Housekeeping services to ensure that the premises are clean and orderly at all times shall be provided and maintained. Appropriate janitorial storage shall be maintained.~~

~~13.5 Laundry and Linens. Laundry and linen services shall be provided by in-house staff or by contract. Separate clean and soiled linen areas shall be provided and maintained.~~

~~13.6 The community clinic or and the community clinic and emergency center shall be constructed and maintained to ensure access to all patients and to ensure the safety of patients.~~

~~13.7 Building Requirements. The community clinic or the community clinic and emergency center shall demonstrate compliance with the building and fire safety requirements of local governments and other state agencies.~~

~~13.8 Compliance with the Life Safety Code. Applicable facilities shall be compliant with the National Fire Protection Association (NFPA) 101, Life Safety Code (2000), which is hereby incorporated by reference. Such incorporation by reference, as provided for in 6 CCR 1011-1, Chapter II, excludes later amendments to or editions of referenced material.~~

~~(a) Facilities licensed on or before March 11, 2003 shall meet Chapter 21, Existing Ambulatory Health Care Occupancies, NFPA 101. However, a qualifying community clinic shall meet Chapter 39, Existing Business occupancies, NFPA 101.~~

~~(b) Facilities licensed on or after March 12, 2003 or portions of facilities that undergo remodeling on or after March 12, 2003 shall meet Chapter 20, New Ambulatory Health Care Occupancies, NFPA 101. In addition, if the remodel represents a modification of more than 50 percent of the total interior of the physical plant, the entire facility shall be renovated to meet Chapter 20, NFPA 101. However, a qualifying community clinic shall meet Chapter 38, New Business occupancies, NFPA 101. In addition, if the remodel represents a modification of more than 50 percent of the total interior of the physical plant, the entire facility shall be renovated to meet Chapter 38, NFPA 101.~~

~~(c) Notwithstanding NFPA 101 Life Safety Code (2000) provisions to the contrary:~~

~~(1) When differing fire safety standards are imposed by federal, state or local jurisdictions, the most stringent shall apply.~~

~~(2) Any story containing an exterior door or an exterior window that opens to grade level shall be counted as a story.~~

~~(d) This paragraph applies to community clinics and not to community clinics and emergency centers.~~

~~(1) Notwithstanding 6 CCR 1011-1, Chapter II, Section 2.3.5 (A), only community clinics that contain an anesthetizing location shall be required to have an intact, two-~~

~~hour fire rated separation wall, floor or ceiling assembly between the facility and all adjacent occupancies under the following circumstances:~~

~~(i) For each applicant seeking an initial license on or after January 1, 2011, except for an applicant that has submitted building plans to the Department and obtained a building permit prior to January 1, 2011 from the local authority having jurisdiction.~~

~~(ii) For each licensee that submits building plans to the Department or obtains a building permit on or after January 1, 2011 for relocations in whole or in part to another physical structure.~~

~~(iii) For each licensee that submits building plans to the Department or obtains a building permit on or after January 1, 2011 to add previously un-inspected or unlicensed square footage to an existing license. For the purposes of compliance with this section, the two-hour fire rated separation shall be around either the entire perimeter of the added square footage or the entire perimeter of the facility.~~

~~(iv) For each licensee that creates a new anesthetizing location on or after January 1, 2011, within an existing community clinic.~~

~~(2) The alternatives authorized under 6 CCR 1011-1, Chapter II, Section 2.3.5 (B) are applicable to community clinics subject to Section 13.8 (d) (1).~~

~~13.9 Plan Review and Plan Review Fees. This Section 13.9 applies to community clinics and community clinics and emergency centers with the exception of facilities operated in prisons under the auspices of the Department of Corrections.~~

~~Plan review and plan review fees are required as listed below. If the facility has been approved by the Department to use more than one building for the direct care of patients on its campus, each building is subject to the applicable base fee plus square footage costs, or in the case of a qualifying community clinic, to the set fee. Fees are nonrefundable and shall be submitted prior to the Department initiating a plan review for a facility.~~

~~(a) Initial Licensure, Additions, Relocations~~

~~1) Plan review is applicable to the following, and includes new facility construction and new occupancy of existing structures:~~

~~(i) Applications for an initial license, when such initial license is not a change of ownership and the application is submitted on or after July 1, 2009.~~

~~(ii) Additions of previously uninspected or unlicensed square footage to an existing occupancy and the building permit for such addition is issued on or after July 1, 2009 or if no permit is required by the local jurisdiction, construction began on or after July 1, 2009.~~

~~(iii) Relocations of a currently licensed facility in whole or in part to another physical plant, where the occupancy date occurs on or after July 1, 2009.~~

~~2) Initial licensure, addition, and relocation plan review fees:~~

~~(i) Base fee of $2,250, plus square footage costs as shown in the table below.~~

~~Square Footage~~	~~Cost per Square Foot~~	~~Explanatory Note~~
~~0-25,000 sq ft~~	~~$0.10~~	~~This is the cost for the first 25,000 sq ft of any plan submitted.~~
~~25,001+ sq ft~~	~~$0.02~~	~~This cost is applicable to the additional square footage over 25,000 sq ft.~~

~~(ii) Notwithstanding paragraph 13.9, (a) (2) (i) above, the fee for a qualifying community clinics is: $1,250.~~

~~(b) Remodeling~~

~~1) Plan review is applicable to remodeling for which the application for the building permit from the local authority having jurisdiction is dated on or after July 1, 2009, or if no permit is required by the local jurisdiction, construction began on or after July 1, 2009. Remodeling includes, but is not limited to:~~

~~(i) Alteration, in patient sleeping areas, of a structural element subject to Life Safety Code standards, such as egress door widths and smoke or fire resisting walls.~~

~~(ii) Relocation, removal or installation of walls that results in alteration of 25% or more of the existing habitable square footage or 50% or more of a smoke compartment.~~

~~(iii) Conversion of existing space into rooms with inpatient or observation beds.~~

~~(iv) Changes to egress components, specifically the alteration of a structural element, relocation, or addition of an egress component. Examples of egress components include, but are not limited to, corridors, stairwells, exit enclosures, and points of refuge.~~

~~(v) Installation of any new sprinkler systems or the addition, removal or relocation of 20 or more sprinkler heads.~~

~~(vi) Installation of any new fire alarm system, or addition, removal or relocation of 20 or more fire alarm system appliances including, but not limited to, pull stations, detectors and notification devices.~~

~~(vii) Installation, removal or renovation of any kitchen hood suppression system.~~

~~(viii) Essential electrical system: replacement or addition of a generator or transfer switch. However, replacement of either the generator or transfer switch with one having the same exact performance specifications is considered maintenance and not subject to plan review.~~

~~2) Remodeling plan review fees:~~

~~(i) Base fee of $1,750, plus square footage costs as shown in the table below.~~

~~**Square Footage**~~	~~**Cost per Square Foot**~~	~~**Explanatory Note**~~
~~0-20,000 sq ft~~	~~$0.07~~	~~This is the cost for the first 20,000 sq ft of any plan submitted.~~
~~20,001+ sq ft~~	~~$0.02~~	~~This cost is applicable to the additional square footage over 20,000 sq ft.~~

~~(ii) Notwithstanding paragraph 13.10, (b) (2) (i) above, the fee for a qualifying community clinic is: $750.~~

~~13.10 The "Guidelines for Design and Construction of Health Care Facilities" (2006 Edition), American Institute of Architects (AIA), may be used by the Department in resolving health, building, and life safety issues for construction initiated or systems installed on or after July 1, 2009. The AIA Guidelines are hereby incorporated by reference. Such incorporation by reference, as provided for in 6 CCR 1011-1, Chapter II, excludes later amendments to or editions of referenced material.~~

~~13.10 Application Fees~~

~~(1) A non-refundable fee shall be submitted with the license application as follows:~~

	~~**Initial License**~~	~~**Renewal License**~~	~~**Change of Ownership**~~
~~**Community Clinic**~~			
~~Clinic serving the uninsured or underinsured~~	~~$1,250~~	~~$650~~	~~$1,250~~
~~Other~~	~~$2,500~~	~~$1,300~~	~~$2,500~~
~~**Community Clinic with Inpatient Care**~~	~~$3,100~~	~~$1,700~~	~~$3,100~~
~~**Community Emergency Center**~~	~~$3,100~~	~~$1,700~~	~~$3,100~~