

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:

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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.

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:
 - 1) 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.

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.

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 provider staff consistent with the licensure requirements relating to such staff.

(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

13.1 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.

- (a) Life Safety Code . All community clinics or community clinics and emergency centers shall comply with the Life Safety Code, National Fire Protection Association 101, 1991 for new and existing ambulatory health care facilities. A community clinic or a community clinic and emergency center that is currently licensed and was lawfully constructed and found to be in compliance at the time of initial licensure and during any subsequent surveys may continue to utilize existing, approved life safety systems provided that they present no hazard to the life, health, and safety of patients. The community clinic or the community clinic and emergency center shall, in the event of any renovation to the facility of 50 percent or greater of the total interior of the physical plant, after the effective date of these regulations, comply with the requirements of the Life Safety Code, National Fire Protection Association 101, 1991.
- (1) Other Building Requirements . The community clinic or the community clinic and emergency center shall also demonstrate compliance with all other building and fire safety requirements of local governments and other state agencies, including but not limited to structural, mechanical, plumbing, and electrical requirements.
- (b) Pest Control . Policies shall be developed and procedures implemented for the effective control of insects, rodents, and other pests.
- (c) Waste disposal . All wastes shall be disposed in compliance with local, state and federal laws.
- (d) 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.
- (e) 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.
- (f) 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.

Editor's Notes

6 CCR 1011-1 has been divided into separate chapters for ease of use. Versions prior to 05/01/2009 and rule history are located in the main section, 6 CCR 1011-1. Prior versions can be accessed from the History link that appears above the text in 6 CCR 1011-1. To view versions effective on or after 05/01/2009, select the desired chapter, for example 6 CCR 1011-1 Chap IV or 6 CCR 1011-1 Chap XVIII.

History