

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Health Facilities and Emergency Medical Services Division

STANDARDS FOR HOSPITALS AND HEALTH FACILITIES: CHAPTER 22 - BIRTH CENTERS

6 CCR 1011-1 Chap 22

[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.

DEFINITIONS

Birth Center – Any public or private health facility or institution which is not licensed as a hospital or as part of a hospital and provides care during delivery and immediately after delivery for generally less than twenty-four hours.

I. LICENSE

- A. Birth Center shall meet all the requirements specified in chapter II and this Chapter XXII of the Colorado Department of Health Standards for Hospitals and Health Facilities.

II. GOVERNING BODY

- A. Responsibility: A Governing Body shall provide facilities, personnel and services necessary for the welfare and safety of the patients.
- B. Duties: The Governing Body shall:
 - 1. adopt by-laws in accordance with legal requirements;
 - 2. meet regularly and maintain accurate records of such meetings;
 - 3. appoint a credentials committee, composed of clinical staff, which shall have the authority and responsibility for appointments and reappointments of clinical staff and ensure that only members of the clinical staff shall admit patients to the birth center;
 - 4. appoint and delineate clinical privileges of practitioners based upon recommendations by the clinical staff and other appropriate indicators of physicians and certified nurse mid-wife competence;
 - 5. establish a formal means of liaison with the clinical staff;
 - 6. approve by-laws, rules and regulations of the clinical staff;
 - 7. appoint committees consistent with the needs of the birth center.
- C. Quality of Care:
 - 1. Conduct, with the active participation of the clinical staff, an ongoing, comprehensive self-assessment of the quality of care provided, including the medical necessity of procedures performed, the appropriateness of care, and the appropriateness of utilization. This information shall provide a basis for the revision of facility policies and the granting or continuation of clinical privileges.
 - 2. Require that the facility's Quality Assurance Program ensures the adequate investigation, control and prevention of infections.
 - 3. Provide that there shall be on file in the center an agreement with an ambulance service (air or ground) for emergency transfer of patients to hospital.

III. ADMINISTRATOR

- A. Responsibility; The administrator shall be the official representative of the governing body and the chief executive officer of the birth center. The administrator shall be delegated responsibility and authority in writing by the governing body for the management of the birth center and shall provide liaison among the governing body, clinical staff and other departments of the birth center.
- B. Duties: The administrator shall be responsible for the development of Birth Center policies and procedures for employee and clinical staff use. All policies and procedures shall be reviewed and/or updated as necessary but at least annually.

IV. CLINICAL STAFF

- A. Organization: The birth center shall have an organized clinical staff restricted to physicians and certified nurse-midwives.
- B. Definition: Certified Nurse-Midwife (CNM) - a professional nurse licensed in the state of Colorado who is educated in the two disciplines of nursing and midwifery, who possesses evidence of certification according to the requirements of the American College of Nurse-Midwives.
- C. Duties: The clinical staff or a delegated committee shall:
 - 1. be responsible for the quality of all medical care provided patients in the facility;
 - 2. hold meetings regularly and maintain accurate records of such meetings;
 - 3. formulate, adopt and enforce by-laws, rules, regulations and policies for the proper conduct of its members;
 - 4. recommend staff privileges to the governing body;
 - 5. establish formal liaison with the governing body;
 - 6. participate actively in the quality assurance program;
 - 7. recommend admission and procedure policies to the governing body.
- D. Clinical Staff Requirements;
 - 1. Each staff physician shall be licensed to practice medicine in the state of Colorado and provide proof.
 - 2. Each certified nurse-midwife shall be licensed as a professional nurse and show proof.
 - 3. Any physician applying for privileges at the birthing center must demonstrate hospital admitting privileges for patients who develop complications.
 - 4. Any certified nurse-midwife applying for privileges must provide proof of a back-up agreement with a physician who will accept consultation calls and referrals from the CNM 24 hours a day. Proof of hospital admitting privileges of the back-up physicians must be submitted.
 - 5. A physician or certified nurse mid-wife shall be present at each birth and until the woman and newborn are stable postpartum. A second person in addition to the above, who is a registered nurse with adult and infant resuscitation skills, shall be present during the delivery.
 - 6. A certified nurse-midwife or registered nurse with adult and infant resuscitation skills shall be present at the birthing center at all times when a patient is present. Additional and sufficient personnel shall be provided when more than one woman is in active labor.

V. MEDICAL RECORDS

- A. Facilities: The center shall provide sufficient space and equipment for the processing and the safe storage of records.
- B. Personnel: A person knowledgeable in the management of Medical Records shall be responsible for the proper administration and functioning of the medical records section.
- C. Security: Medical records shall be protected from loss, damage and unauthorized use.
- D. Preservation: With the exception of medical records of minors (individuals under the age of 18 years) medical records shall be preserved as original records or on microfilm for no less than ten years after the most recent patient care usage, after which time records may be destroyed at the discretion of the facility.
 - 1. Medical records of minors shall be preserved for the period of minority plus 10 years.
 - 2. Facilities shall establish procedures for notification to patients whose records are to be destroyed prior to the destruction of such records.
 - 3. The sole responsibility for the destruction of all medical records shall be in the facility involved.
 - 4. Nothing in this section shall be construed to affect the requirements for the destruction of public records as set out in Part 1 of Article 80 of Title 24, C.R.S.
- E. Content: The medical records shall contain sufficient accurate information to justify the diagnosis and warrant the treatment and end results including, but not limited to:
 - 1. complete patient identification and a unique identification number;
 - 2. admission and discharge dates;
 - 3. chief complaint and admission diagnosis;
 - 4. medical history and physical examination completed prior to birth;
 - 5. diagnostic tests, laboratory and x-ray reports when appropriate;
 - 6. progress notes if appropriate;
 - 7. properly executed informed consent which shall be obtained prior to the onset of labor and shall include evidence of an explanation by personnel of the birth services offered and the potential risks;
 - 8. patient's condition on discharge, final diagnosis and instructions given patient for follow-up care of patient and child;
 - 9. obstetrical records shall include in addition to the requirements for medical records the following:
 - a. prenatal care record containing at least a hemoglobin or hematocrit, urine screening, prenatal blood serology, RH factor determination, rubella titre, past obstetrical history and physical examination;

- b. labor and delivery record, including reasons for induction and operative procedures if any;
 - c. records of anesthesia and analgesia and medication given in the course of labor, delivery and postpartum.
- 10. Records of newborn infants shall be maintained as separate records and shall include in addition to the requirements for medical records the following information:
 - a. date and hour of birth, birth weight and length, period of gestation, sex and condition of infant on delivery (including Apgar and any resuscitative measures taken);
 - b. mother's name and facility number, and/or similar identification. Type of ID placed on infant in delivery room;
 - c. record of ophthalmic prophylaxis;
 - d. record of administration of Rh immune globulin if any;
 - e. appropriate physical examination at birth and at discharge;
 - f. genetic screening, PKU or other metabolic disorders report;
 - g. fetal monitoring record;
 - h. copy of birth certificate.
- F. Nursing Records: Standard nursing practice and procedure shall be followed in the recording of medications and treatments, including operative and post-operative notes. Nursing notes shall include notation of the instructions given patients pre-operatively and at the time of discharge. All recordings shall be in ink and properly signed, including name and identifying title.
- G. Entries: All orders for diagnostic procedures, treatments and medications will conform to the requirements of Chapter IV, section 4.4, of Standards for Hospitals and Health Facilities.

VI. NURSING SERVICES

- A. Nursing Personnel; There shall be sufficient Registered Professional Nurses and auxiliary nursing personnel on duty to meet the total nursing needs of the patients.

VII. PERSONNEL

- A. Orientation; The purpose and objectives of the birth center shall be explained to all personnel as part of an overall orientation program.
- B. Policies: There shall be appropriate written personnel policies, rules and regulations governing the conditions of employment, the management of employees and the types of functions to be performed.

VIII. ADMISSIONS

- A. Admissions: All persons admitted to a birth center shall be under the direct care of a member of the provider staff and agree to remain at the center not less than four hours postpartum.
- B. Disclosure Document: As a condition of acceptance for birth center care all persons shall sign prior to the onset of labor a disclosure document which shall contain:
 - 1. an explanation of the services available;
 - 2. an explanation of the services not available, including types of anesthesia;
 - 3. a statement of the time to and location of the nearest hospital facilities for care of mother and child;
 - 4. a statement of the additional risk involved in having a child at a birth center instead of a hospital;
 - 5. a statement of cost.
- C. Prohibitions from Birth Center Delivery:
 - 1. Medical limitations:
 - a. current drug or alcohol addiction;
 - b. paraplegia, quadraplegics;
 - c. hypertensives on medications;
 - d. hypertension over 140/90;
 - e. diabetes (insulin dependent or gestational);
 - f. history of significant deep vein thrombophlebitis or any thrombophlebitis with this pregnancy;
 - g. severe anemia (hct. below 30 at admission);
 - h. epileptics on medication;
 - i. mental impairment that would interfere with the ability to follow directions;
 - j. morbid obesity (100% over ideal body weight).
 - 2. Obstetrical Limitations:
 - a. grand multiparity (over five births);
 - b. previous birth of a baby with serious congenital anomaly of a probably repeating type that cannot be excluded through antenatal evaluation;
 - c. suspected congenital anomaly;
 - d. previous Cesarean delivery;

- e. preeclampsia;
- f. multiple gestation;
- g. intrauterine growth retardation or macrosomia;
- h. documented oligohydramnios or polyhydramnios;
- i. abnormal fetal surveillance studies;
- j. fetal presentation other than vertex;
- k. rising antibody titre of any type that is known to affect fetal well-being;
- l. all RH sensitizations;
- m. significant third trimester bleeding of unexplained cause;
- n. need for induction of labor (no induction allowed);
- o. need for general or conduction anesthesia;
- p. need for C-section (no C-sections allowed);
- q. placental abnormalities (previa or abruptio) which might threaten the neonate;
- r. known or suspected active genital herpes at the time of admission;
- s. premature labor (before 37 weeks) or postmaturity (after 42 weeks);
- t. any other condition or need which will adversely affect the health of the mother or infant during pregnancy, labor, birth, or the immediate postpartum period.

D. Conditions Requiring Intrapartum Transfer from Birth Center to a Hospital:

- 1. a desire for transfer from birth center care;
- 2. patient inadvertently admitted with any of the listed conditions which preclude birth center delivery;
- 3. excessive need for analgesia during labor, or for anesthesia other than pudendal or local;
- 4. failure of progressive cervical dilation or descent after trial of therapeutic steps capable of being applied at the center;
- 5. fetal distress without delivery imminent;
- 6. passage of any meconium when delivery is not imminent;
- 7. development of hypertension or preeclampsia;
- 8. intrapartum hemorrhage (placenta previa or abruptio placentae);
- 9. prolapsed cord;

10. change to non-vertex presentation;
11. evidence of amnionitis;
12. development of other severe medical or surgical problems.

E. Conditions Requiring for Post-partum Transfer from Birth Center to a Hospital

1. Maternal:
 - a. hemorrhage not responding to treatment;
 - b. need for transfusion;
 - c. retained placenta greater than 30 minutes;
 - d. need for extended observation that prevents discharge home;
 - e. any other significant morbidity.
2. Infant:
 - a. Apgar less than 7 at 5 minutes;
 - b. need for oxygen beyond 5 minutes;
 - c. signs of prematurity;
 - d. signs of respiratory distress;
 - e. jaundice, anemia, polycythemia, or hypoglycemia;
 - f. persistent hypothermia (less than 97° at 2 hours of life);
 - g. persistent hypotonia;
 - h. exaggerated tremors, seizures or irritability;
 - i. any significant congenital anomaly, seen or suspected;
 - j. sign of significant birth trauma;
 - k. feeding difficulty;
 - l. any other significant morbidity.

IX. EQUIPMENT AND SUPPLIES

- A. There shall be appropriate equipment and supplies maintained for the mother and newborn to include, but not be limited to:
1. a bed suitable for labor, birth and recovery;
 2. oxygen with flow meters and masks or equivalent;

3. mechanical suction and bulb suction (immediately available);
4. resuscitation equipment to include resuscitation bags, endotracheal tubes and oral airways for the mother and newborn;
5. firm surfaces suitable for resuscitation;
6. emergency medications, intravenous fluids, and related supplies and equipment for both mother and newborn;
7. fetoscope and doptone for fetal monitoring;
8. a means for monitoring and maintaining the optimum body temperature of the newborn;
9. infant scale;
10. a clock with a sweep second hand;
11. sterile suturing equipment and supplies;
12. adjustable examination light;
13. containers for soiled linen and waste materials which shall be closed or covered;
14. autoclave;
15. log book, for registration of birth which shall contain at least the following:
 - a. mother's name
 - b. mother's facility number
 - c. date of delivery
 - d. time of delivery
 - e. mother's age
 - f. Gravida, Para,
 - g. newborn weight
 - h. newborn sex
 - i. gestational age
 - j. transport:
 - (1) mother
 - (2) baby
 - (3) where
 - (4) when

- (5) by whom
- k. indication for hospital delivery
- l. maternal outcome after transfer
- m. indication for newborn transfer n. newborn outcome after transfer o. death:
 - (1) neonatal
 - (2) maternal
 - (3) stillbirth
- p. type of delivery
- q. condition of newborn at delivery/congenital anomalies
- r. delivering person
- s. Apgar
- t. any required resuscitation.

X. LABORATORY

- A. Services: Clinical pathology services shall be available as required by the needs of the patients as determined by the provider staff.
 - 1. Quality Control: Internal quality control shall be established to insure compliance with generally accepted standards of laboratory practice and procedure.

XI. PHARMACEUTICAL SERVICES

- A. There shall be methods, procedures and controls which ensure the appropriation, acquisition, storage, dispensing and administration of drugs and biologicals in accordance with acceptable pharmaceutical practice and applicable state and federal laws and regulations.
- B. When the facility maintains its own pharmaceutical services, it shall comply with applicable regulations of the Colorado State Board of Pharmacy.

XII. HOUSEKEEPING SERVICES

- A. Organization: Each facility shall provide housekeeping services which ensure a pleasant, safe and sanitary environment. The facility shall be kept clean and orderly.
- B. Written Policies and Procedures: Appropriate written policies and procedures shall be established and followed which ensure adequate cleaning and/or disinfection of the physical plant and equipment.
- C. Storage: All cleaning materials, solutions, cleaning compounds and hazardous substances shall be properly identified and stored in a safe place.
- D. Rubbish and Refuse Containers: All rubbish and refuse containers in treatment areas shall be impervious, lined and clean.

- E. Handwashing: All personnel shall wash their hands immediately after handling refuse.

XIII. LAUNDRY AND LINENS

Written provisions shall be made for the proper handling of linens and washable goods.

- A. Outside Laundry: Laundry that is sent out shall be sent to a commercial or hospital laundry. A contract for laundry services performed by commercial laundries for birth centers shall include these standards.
- B. Storage: If soiled linen is not processed on a daily basis, a separate, properly ventilated storage area shall be provided.
- C. Processing: The laundry processing area shall be arranged to allow for an orderly progressive flow of work from the soiled to the clean area.
- D. Washing Temperatures: The temperature of water during the washing process shall be controlled to provide a minimum temperature of 165° F. for 25 minutes or 130° F. if the soap/detergent supplier will verify that their products will work effectively at that lower temperature. A label indicating same shall be affixed to the laundry machine.
- E. Packaging: The linens to be returned from the outside laundry to the facility shall be completely wrapped or covered to protect against contamination.
- F. Soiled Linen Transportation; Soiled linen shall be enclosed in an impervious bag and removed from surgery units after each procedure.
- G. Soiled Linen Carts; Carts, if used to transport soiled linen, shall be constructed of impervious materials, cleaned and disinfected after each use.
- H. Clean Linen Storage: Adequate provisions shall be made for storage of clean linen.
- I. Contaminated Linens: Contaminated linens shall be afforded appropriate special treatment by the laundry.
- J. Procedures: Adequate procedures for the handling of all laundry and for the positive identification and proper packaging and storage of sterile linens must be developed and followed.

XIV. MAINTENANCE

- A. Written Policies and Procedures: There shall be written policies and procedures for a preventive maintenance program which is implemented to keep the entire facility and equipment in good repair and to provide for the safety, welfare and comfort of the occupants of the building(s).

XV. PEST CONTROL

- A. Pest Control: Adequate written policies and procedures shall be developed and implemented to provide for effective control and eradication of insects and rodents.
- B. Outer Air Openings: All openings to the outer air shall be effectively protected against the entrance of insects and rodents, etc., by self-closing doors, closed windows, screens, controlled air currents or other effective means.

XVI. WASTE STORAGE AND DISPOSAL

- A. Sewage and Sewer Systems: All sewage shall be discharged into a public sewer system, or if such is not available, shall be disposed of in a manner approved by the Colorado State Department of Health.

XVII. PHYSICAL PLANT STANDARDS

- A. Reserved
- B. Each birthing room shall be maintained in a condition which is adequate and appropriate to provide for the equipment, staff, supplies and emergency procedures required for the physical and emotional care of a mother, her support person(s), and the newborn during birth, labor and the recovery period.
1. Birthing rooms shall have at least 120 square feet with a minimum room dimension of 10 feet.
 2. Birthing rooms shall be located to provide unimpeded, rapid access to an exit of the building which will accommodate emergency transportation vehicles and equipment.
- C. Patient toilet and bathing facilities.
1. A toilet and lavatory shall be maintained in or adjacent to the vicinity of the birthing room.
 2. A shower shall be available for mother's use.
 3. All wall, ceiling, floor surfaces, toilets, lavatories, tubs and showers shall be kept clean and in good repair.
- D. Hallways and doors providing entry/exit and access into the birthing center and birth room(s) shall be of adequate width and/or configuration to accommodate maneuvering of ambulance stretchers and wheelchairs and other emergency equipment.
- E. Water Supply: There shall be an adequate supply of hot and cold running water under pressure for human consumption and other purposes which shall be approved by the Colorado Department of Health as meeting the Colorado Primary Drinking Water Regulations, 1981.
- F. Heating and Ventilation:
1. A safe and adequate source of heat capable of maintaining a room temperature of at least 72°F. shall be provided and maintained.
 2. Ventilation shall remove objectionable odors, excessive heat and condensations.
 3. Mechanically operated systems shall be used to supply air to and/or exhaust air from soiled workrooms or soiled holding rooms, janitor's closets, soiled storage areas, toilet rooms, and from spaces which are not provided with openable windows or outside doors. All fans serving exhaust systems shall be located at the discharge end of the system.
- G. Food Services:
1. When birth center policy provides for allowing the preparation and/or storage of personal food brought in by the patient or families of patients for consumption of that family, there shall be an adequate electric or gas refrigerator and dishwashing facilities.

- H. Safety and Accident Prevention:
1. Emergency numbers shall be located near the telephone.
 2. There shall be a written evacuation and fire plan for the removal of patients in case of fire and other emergencies. The plan shall be posted in a conspicuous place in the building.
 3. A simulated drill shall be performed every quarter per work shift. A written record of each drill shall be kept on file.
- I. Every bathroom door lock shall be designed to permit the opening of the locked door from the outside in an emergency.
- J. There shall be no pets on the premises.
- K. Each birthing room shall be equipped with a nurse call system.
- L. Grab bars and a nurse call system shall be installed in each patient bathing and toilet area.
- M. Automatic regulation of water supply temperature not to exceed 110 F. at shower, bathing and handwashing facilities. Control devices shall be inaccessible to unauthorized personnel.
- N. The birth center shall be maintained to provide a safe, clean sanitary environment.
- O. Effective July 1, 2013, all birth centers shall be constructed in conformity with the standards adopted by the Director of the Division of Fire Prevention and Control (DFPC) at the Colorado Department of Public Safety. For construction initiated or systems installed on or after July 1, 2013, that affect patient health and safety and for which DFPC has no applicable standards, each facility shall conform to the relevant section(s) of the Guidelines for Design and Construction of Health Care Facilities, (2010 Edition), Facilities Guidelines Institute. The Guidelines for Design and Construction of Health Care Facilities, (2010 Edition), Facilities Guidelines Institute (FGI), is hereby incorporated by reference and excludes any later amendments to or editions of the Guidelines. The 2010 FGI Guidelines are available at no cost in a read only version at: http://openpub.realread.com/rrserver/browser?title=/FGI/2010_Guidelines

SPECIFIC STATUTORY AUTHORITY

These Standards were developed under the statutory authority found at 25-1-107(1)(L)I and II and 25-3-101 which requires the Department of Health to annually license and to establish and enforce standards for the operation of hospitals and other institutions of a like nature.

Editor's Notes

6 CCR 1011-1 has been divided into separate chapters for ease of use. Versions prior to 05/01/2009 are located in the main section, 6 CCR 1011-1. Prior versions can be accessed from the All Versions list on the rule's current version page. To view versions effective on or after 05/01/2009, select the desired chapter, for example 6 CCR 1011-1 Chap 04 or 6 CCR 1011-1 Chap 18.

History

Chapter 22 Title, Definitions, Section 27 eff. 06/30/2009.

Chapter 22 Definitions, Section 17 eff. 08/14/2013.