

## Wyoming Administrative Rules

# Health, Department of

## Health Quality

### Chapter 6: Licensure of Birthing Centers

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# **RULES AND REGULATIONS FOR LICENSURE OF BIRTHING CENTERS**

## **CHAPTER 6**

Section 1. Authority. These rules are promulgated by the Department of Health pursuant to the Health Facilities Act at W.S. §35-2-901 et seq. and the Wyoming Administrative Procedures Act at W.S. §16-3-101 et seq.

Section 2. Purpose. These licensure rules have been adopted to protect the health, safety, and welfare of clients and employees of Birthing Centers.

Section 3. Severability. If any portion of these rules is found to be invalid or unenforceable, the remainder shall continue in effect.

Section 4. Definitions.

The following definitions shall apply in the interpretation and enforcement of these rules. Where the context in which words are used in these rules indicates that such is the intent, words in the singular number shall include the plural and vice versa. Throughout these rules gender pronouns are used interchangeable. The drafters have attempted to utilize each gender pronoun in equal numbers, in random distribution. Words in each gender shall include individuals of the other gender.

For purpose of these rules, the following shall apply:

(a) Administration of Drugs - the act in which a single dose of a prescribed drug or biological is given to a patient by a licensed person in accordance with all laws and regulations governing such acts.

(b) Administrator - the person who is delegated the responsibility for interpreting, implementing, and applying policies and procedures established by the governing authority. He/she is delegated responsibility for the establishment of safe and effective administrative management, and the control and operation of the services provided.

(c) Bathing Facility - a bathtub or shower.

(d) Birthing Center - any health facility, place, professional office or institution which is not a hospital or in a hospital and where births are planned to occur away from the mother's residence following normal uncomplicated pregnancy.

(e) Birthing Room - a room and environment designed, equipped and arranged to provide for the care of a woman and newborn and to accommodate her support person(s) during the process of vaginal birth, (the three stages of labor and recovery of a woman and newborn).

(f) Certified Nurse Midwife - a registered professional nurse who performs advanced nursing acts and who may perform medical acts in collaboration with a licensed physician in such manner to assure quality and appropriateness of services rendered. The advanced practitioner of nursing performs such acts by reason of postgraduate education and additional nursing preparation which provides for the knowledge, judgment and skill beyond that required of a registered professional nurse and who has completed a nationally accredited educational program for preparation as an advanced practitioner of nursing or who has passed a national certification examination of a nationally recognized accrediting agency accepted by the Wyoming State Board of Nursing.

(g) Clinical Staff - the physicians and certified nurse midwives appointed by the governing authority to practice within the birthing center, governed by rules approved by the governing body, and licensed by the state of Wyoming.

(h) Commissioner - the State Survey Agent of the Department of Health, Office of Health Quality.

(i) Collaboration - to labor together, to work jointly with others, especially in an institutional endeavor.

(j) Division - the Department of Health, Office of Health Quality.

(k) Governing Body - an individual or group which is legally responsible for the operation, control and maintenance of the birthing center.

(l) Hospital - means an institution or a unit in an institution providing one (1) or more of the following to patients by or under the supervision of an organized medical staff.

(m) Lavatory - a plumbing fixture designed and equipped for handwashing purposes.

(n) Licensing Agency - means the Department of Health, Office of Health Quality.

(o) Low Risk - normal, uncomplicated prenatal course as determined by adequate prenatal care and prospects for a normal, uncomplicated birth as defined by reasonable and generally accepted criteria of maternal and fetal health. These services shall be limited to mothers not falling in the categories of conditions and needs listed in Appendix 1, "Limitation of Services."

(p) NEC - the National Electrical Code

(q) New Construction - any of the following started after promulgation of these rules and regulations:

(1) New buildings to be used as a birthing center;

- (2) Addition(s) to an existing birthing center;
- (3) Alteration(s) or modification(s) (other than strictly repairs for maintenance), costing more than \$3,000 or that affect the structure or mechanical system.
- (r) NFPA - the National Fire Protection Association.
- (s) Patient - a Pregnant woman admitted to a birthing center by, and/or under the order of a duly licensed clinical staff member.
- (t) Personnel - individuals employed by the birthing center.
- (u) Physician - doctors specializing in obstetrics and pediatrics.
- (v) Registered Nurse - a person licensed under the provision of the law regulating the practice of registered nursing in the state of Wyoming.
- (w) Recovery - that period or duration of time starting at birth and ending with the discharge of a patient from the birthing center or the period of time between the birth and the time a mother leaves the premises of the birthing center.
- (x) Shall - compliance is mandatory.
- (y) Should - a suggestion or recommendation, but not a requirement.
- (z) Support Person - the individuals selected or chosen by a mother to provide emotional support and to assist her during the process of labor and childbirth.

Section 5. Licensure. Applicants must demonstrate full compliance with paragraphs (a) and (b) of this section.

- (a) Licensing Procedure.
  - (i) For an initial license to be issued, the Licensing Division shall receive:
    - (A) A completed application form as supplied by the Licensing Division.
    - (B) Each completed application shall be accompanied by the required licensure fee identified in Chapter 1, Rules and Regulations for Health Care Facilities Licensure Fees. The check or money order shall be made payable to the Treasurer, State of Wyoming.
    - (C) Applicant shall demonstrate full compliance with the licensure requirements in paragraph (b) of this section.

(ii) For renewal of a full license for one (1) year beginning July 1<sup>st</sup>, and unless suspended or revoked, expiring on June 30<sup>th</sup> of the following year, the Licensing Division shall receive:

(A) A completed application form by the date stated in the application cover letter supplied by the Licensing Division; and

(B) The license fee as required in paragraph (a) (i) (B) of this section.

(b) Requirements for Licensure. The Licensing Division shall consider:

(i) Initial and annual renewal licensure survey deficiencies cited by the Survey Division;

(ii) Life Safety Code deficiencies cited by the Survey Division;

(iii) Complaint investigations and resolutions;

(iv) Compliance with all laws and standards relating to communicable and reportable diseases as required by the Department of Health, State Health Officer and Preventive Health and Safety Division; and

(v) The effectiveness of the quality management program to evaluate and improve patient care and services.

(c) Transfer of license.

(i) No license granted shall be assigned or transferred by the licensee without prior approval of the Licensing Division.

(A) Requests to assign or transfer a Birthing Center license shall be submitted in writing by the licensee to the Licensing Division at least thirty (30) days prior to the planned date of assignment or transfer.

(B) Any license approved for assignment or transfer by the Licensing Division shall be subject to the plan of correction for licensure submitted by the previous owner.

(ii) If the Birthing Center's name is changed, the Licensing Division shall be advised in writing before the name is changed, by the current licensee and a new license will be issued upon the receipt of an application and licensure fee.

(d) Conditions for Denying, Revoking, or Suspending a License.

(i) Denial, revocation, or suspension of a license may occur for noncompliance with any provisions of these licensure rules.

(e) Suspension of Admissions.

(i) The Licensing Division may suspend new admissions or re-admissions to the Birthing Center when conditions are such that patient needs cannot be met. Conditions in a Birthing Center shall not jeopardize the patient's health or safety.

(f) Monitor.

(i) The Licensing Division shall place a Department of Health approved monitor at the Birthing Center's expense when conditions are such that patients' needs are not being met by the Birthing Center. The monitor shall insure that neither the health nor the safety of the patients is jeopardized.

(g) Hearings.

(i) Any Birthing Center aggrieved by a decision of the Licensing Division may request a hearing by submitting a written request to the Licensing Division within ten (10) days of receipt of the adverse action.

(ii) Except in matters concerned with the spread of communicable disease, the Licensing Division (Nurse I or designated representative) shall present the preliminary decisions and reasons for the decision to the parties concerned and shall provide an opportunity for a hearing. Any request for hearing shall adhere to the time frames of (i) above.

(iii) In matters concerned with the spread of communicable disease, the Wyoming State Health Officer or designated representative shall present the preliminary decisions and reasons for the decision to the parties concerned and shall provide an opportunity for a hearing. Any request for a hearing shall adhere to the time frames in (i) above.

(iv) Hearings requested under the terms of these licensure rules shall be held in accordance with the provisions of the Wyoming Administrative Procedures Act.

(h) Posting of License.

(i) The current license issued by the Licensing Division shall be displayed in a public area within the Birthing center.

(i) Surveys for Licensure.

(i) The Survey Division or its designated representative shall perform initial and periodic surveys for the renewal of licensure.

(A) These surveys shall be based on the current Licensure Rules and Regulations for Birthing Centers as promulgated by the Wyoming Department of Health.

(B) The Survey Division shall provide, within ten (10) working days after the last day of survey, copies of its cited deficiencies to the Birthing Center.

(C) The Birthing Center shall provide an acceptable plan of correction for all cited deficiencies, within ten (10) working days after receipt of the deficiencies, to the Licensing Division.

(ii) At the time of survey, all records, including patient medical records, pertaining to matters involved in the survey shall be made available to members of the survey team in their assigned disciplines.

(j) Voluntary Closure.

(i) If a Birthing Center voluntarily ceases to operate, it shall notify the Licensing Division in writing at least thirty (30) working days prior to closure.

(ii) The first working day after closure, the Birthing Center's license shall be hand carried to or sent by certified mail to the Office of Health Quality; 2020 Carey Avenue, Eighth Floor; Cheyenne, WY 82002.

#### Section 6. Governing Body and Administration.

(a) The birthing center shall have a governing body which is legally responsible for overall operation and maintenance of the birthing center.

(b) The governing body shall be responsible for provision of personnel, facilities, equipment, supplies and special services needed to meet the needs of the mother/child admitted to the birthing center.

(c) The governing body shall appoint an administrator or director who shall be responsible for implementing the policies adopted by the governing body.

(d) The governing body and administrator shall establish and maintain a current written organizational plan which includes all positions and delineates responsibilities, authority, and relationship of positions within the birthing center.

(e) The governing body shall have the authority and responsibility for appointments of the clinical staff and ensure that only members of the clinical staff shall admit patients to the birthing center.

(i) Each birthing center shall have a written policy and procedure which shall set forth the extent of physician supervision in the services offered.

(2) The governing body shall develop and adopt bylaws, rules, and regulations which shall include requirements for clinical staff membership; delineation of clinical privileges and the organization of clinical staff.

(f) The governing body and administrator/physician director shall be responsible for documenting and implementing a program to review the care of patients within the birthing center.

(g) There shall be separate agreements on file in the birthing center with an obstetrician and a pediatrician or group of such practitioners who shall be responsible in the event of emergency transfer of a patient to a hospital.

(1) The obstetrician and pediatrician or group of such practitioners who shall be responsible in the event of an emergency transfer shall have admitting privileges at a hospital where the mother or newborn can receive appropriate levels of care.

#### Section 7. Staffing.

(a) A physician or certified nurse midwife shall be present at each birth. A second person in addition to the above, who is a registered nurse with adult and infant resuscitation skills shall be present during each birth.

(b) A certified nurse midwife or registered nurse shall be present in the birthing center at all times when mother(s) are in the postpartum period, and a second registered nurse shall be present if more than one patient is in labor.

(c) Meetings of the professional staff shall be held at least monthly to discuss, review and evaluate patient care. Written minutes of these meetings shall be maintained and distributed to the staff.

(d) All personnel shall receive inservice education at least semi-annually which shall include, but not be limited to, infection control, fire and safety procedures. Written minutes of these meetings shall be maintained and distributed to the staff.

(e) Physicians certified by the American Board of Obstetrics and Gynecology and American Academy of Pediatrics or other physicians who are qualified and recognized by peers in the community as experienced, competent practitioners in obstetrics and gynecology, and pediatrics, shall be immediately available by telephone every twenty-four (24) hours a day. A listing of such services kept and updated and maintained at the birthing center.

#### Section 8. Policies and Procedures.

(a) Personnel policies.

(1) There shall be on file in the birthing center written personnel policies and operating practices which define the services of the birthing center.



(a) There shall be written job descriptions for each position in the birthing center including at least the title, authority, specific responsibilities and minimum qualifications. Each employee shall be provided a copy of his or her job description.

(2) All staff shall be informed of and have access to the written policies.

(3) Personnel records shall be maintained for each person employed in the birthing center which include at least:

(a) An employment application;

(b) verification of references and/or credentials as required;

(c) incident and/or accident reports;

(d) results of medical examinations required as a part of employment.

(b) Birthing Center Policies and Procedures. These shall include, but not be limited to:

(1) Definition of a low-risk pregnant patient who shall be eligible for birth services offered by the birth center.

(2) Definition of a high risk patient who shall be ineligible for birth services at the birth center. (See Appendix 1)

(3) Written policies for consultation, backup services, transfer and transport of a newborn and/or mother to a hospital where appropriate care is available.

(4) Written policy and procedure with the ambulance service for emergency transport of a newborn and/or mother.

(5) Written 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 potential risks.

(6) Provision for orientation and education of patients, family, and support persons in childbirth and newborn care. The birth center shall include a program of education which prepares women and their families for self-care and self-help, for psychoprophylaxis of pain, and which outlines the importance of good nutrition and prenatal care in pregnancy outcome. In addition, the adverse effects of smoking, alcohol, drugs, and poor nutrition shall be explained. Plans for medical evaluation, feeding, and care of the newborn shall be made.

(7) Postpartum care. Mothers and infants shall be discharged within 24 hours after birth in accordance with standards set by the clinical staff and specified in the policy and procedures

manual. A program for prompt follow-up care and postpartum evaluation after discharge shall be ensured and outlined in the manual of policies and procedures. This program shall include assessment of infant health including physical examination, laboratory screening tests at the appropriate times, maternal postpartum status, instruction in child care including immunization, referral to sources of pediatric care, provision of family planning services, and assessment of mother-child relationship including breast feeding.

(8) Registration of birth and reporting of complications and anomalies.

(9) Policy on fetal deaths.

(c) Infection Control. This shall include development and implementation of specific patient care and administrative policies aimed at investigating, controlling and prevention infections in the birthing center. Procedures shall be enforced to prevent the exposure of the woman and/or newborn to siblings, visitors and staff personnel with communicable disease.

(d) Arrangements shall be made for all mothers to be screened for blood -type and Rh Factor. Those determined to be Rh negative shall have provision for appropriate follow-up studies both prenatally and at time of delivery in order to determine the need for anti D Immune Globulin (Human) to prevent sensitization by the postpartum mother. There shall be evidence of a plan for the appropriate use of Rh immune globulin.

(e) Patients shall remain at the birthing center not less than six (6) hours not more than twenty-four (24) hours following delivery.

#### Section 9. Equipment and Supplies.

(a) There shall be appropriate equipment and supplies maintained 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.

(4) Cardio pulmonary resuscitation cart shall include:

(a) Resuscitation bags;

(b) Endotracheal tubes;

(c) Oral airways;

- (d) Needles;
  - (e) Syringes;
  - (f) Emergency drugs;
  - (g) Laryngoscope;
  - (h) Equipment for delivering positive pressure oxygen;
  - (i) Cardiac monitor/defibrillator unit.
- (5) Firm surfaces suitable for resuscitation.
- (6) Emergency medications, intravenous fluids, and related supplies and equipment for both mother and newborn.
- (7) Electronic fetal monitoring equipment.
- (8) Transfer isolette with a temperature control and oxygen capabilities.
- (9) Infant scale.
- (10) A clock with a sweep second hand.
- (11) Sterile suturing equipment and supplies.
- (12) Adjustable lighting that is pleasant for the patient and adequate for examinations.
- (13) Containers for soiled linen which shall be closed or covered.
- (14) Heavy duty plastic bags shall be used for double bagging of patient wastes, as well as sanitary disposal of all wastes.
- (15) Log book for registration of birth which shall contain at least the following:
- (a) Mother's name;
  - (b) Patient medical record 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:
  - (i) mother
  - (ii) baby
  - (iii) where
  - (iv) when
  - (v) by whom
- (k) Death:
  - (i) neonatal
  - (ii) maternal
  - (iii) stillbirth
- (l) Type of delivery;
- (m) Condition of newborn at delivery/congenital anomalies;
- (n) Delivering person;
- (o) APGARS.

(16) Access to a toilet, lavatory and shower which is not used by visitors or staff.

(17) One (1) or more comfortable chair(s) or recliner.

(18) Scrub sink with elbow, knee or foot control.

- (19) Emergency signal and/or communication system.
- (20) Adequate ventilation and temperature control.
- (21) Sphygmomanometer, stethoscope and fetoscope.
- (22) Microscope for routine examinations such as urine and hematocrit.
- (23) Any other equipment necessary to provide full scope of services and to ensure safety of mother and newborn.

Section 10. Medical Records. The birthing center shall maintain a separate medical record for each patient in accordance accepted professional standards for the purpose of continuity and evaluation of care, preservation as a legal document and as an aid in teaching and training. The birthing center shall maintain written policies and procedures for the preparation, completion, confidentiality, accessibility and preservation of medical records to include but not be limited to the following standards:

- (a) Staffing.
  - (1) The administrator shall designate in writing an employee who is responsible for medical record functions.
  - (2) Services of a qualified medical record consultant, who is a Registered Record Administrator (RRA) or Accredited Record Technician (ART), shall be provided at least twice a year and shall document all consultant activities.
- (b) Protection of Medical Record Information.
  - (1) The medical record, either in original or microfilm form, shall not be removed from the control of the birthing center except upon receipt of a subpoena duces tecum or the specific written authorization of the administration. Medical records are the property of the birthing center.
  - (2) The birthing center shall have written policies and procedures regarding access to medical records and release of information.
  - (3) Written consent of the patient (or the responsible person acting in her behalf) shall be required for release of information not authorized by law.
  - (4) Authorized personnel of the Division shall be permitted to review medical records as necessary to determine compliance with these rules.
- (c) Content of Medical Record. All entries shall be dated and signed and shall be made legibly in ink or typescript.

- (1) The medical record shall include at least the following:
- (a) Admitting identification data including patient history and physical examination;
  - (b) Signed consent;
  - (c) Medication orders counter-signed by physician;
  - (d) Laboratory tests;
  - (e) Anesthesia record;
  - (f) Recovery and other progress notes;
  - (g) Record of all medications and treatments ordered and administered;
  - (h) Condition and referral on discharge;
  - (i) Records of home visits following discharge.

(2) Obstetrical records shall include in addition to the requirements for medical records the following:

- (a) Prenatal record containing at least a CBC, UA, prenatal blood serology, Rh factor determination, past obstetrical history, physical examination and a rubella titer;
- (b) Labor and delivery record;
- (c) Records of anesthesia and analgesia and medication given in the course of labor, delivery, and postpartum;
- (d) Record of administration of RH immune globulin if any.

(3) Records of newborn infants 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)
- (b) Mother's name and birthing center number, and/or similar identification;
- (c) Record of ophthalmic prophylaxis;

physician/midwife;

- (d) Appropriate physical examination at birth and at discharge by

- (e) Genetic screening, PKU or other metabolic disorders report;

- (f) Fetal monitoring record;

- (g) Hospital copy of birth certificate.

- (d) Completion of Records and Centralization of Reports.

- (1) The medical records shall be completed and filed within 30 days of the patient's discharge.

- (2) All information pertaining to a patient's stay shall be centralized in the patient's medical record.

- (3) An original birth certificate shall be deleted and sent to the local registrar. A hospital copy is preserved in the newborn's record.

- (4) A copy of the patient's medical record, an abstract thereof, or a referral form shall accompany the patient transferring to another health care facility.

- (e) Retention of Records.

- (1) Records of private birthing centers shall be preserved permanently in the original or microfilm form. Public birthing centers shall refer to the Archives and Records Management Division, Wyoming State Archives, Museum and Historical Department; Barrett Building; Cheyenne, WY; for retention directives.

- (2) In the event of dissolution of the birthing center, the administrator shall notify the Division as to the location of medical records.

- (f) Index. A system of identification and filing to ensure the rapid retrieval of medical records shall be maintained.

- (1) Patient index shall include at least: full name of patient, date of birth, medical record number, date of admission and discharge, length of stay; other information necessary by the birthing center.

- (g) Maintenance and Storage.

- (1) There shall be adequate space and operable equipment to provide efficient systematic processing of medical records.

(2) Storage space shall be easily accessible and secure from unauthorized access or damage by water, fire, or hazards.

#### Section 11. Pharmaceuticals.

(a) There shall be written orders signed by a physician legally authorized to prescribe for all drugs administered to mother and infant within the birthing center.

(b) There shall be policies and procedures addressing the receiving, transcribing, and implementing of orders for administration, storage and disposing of drugs.

(c) Drugs, medications, and chemicals kept in the birthing center shall be clearly labeled with drug name, strength, and expiration date.

(d) Drugs, medications, and chemicals shall be stored in locked cabinets, closets, drawers, or storerooms and made accessible only to authorized persons.

(e) Controlled substances.

(1) Birthing Centers having narcotics shall maintain a narcotic administration record so that the disposition of any particular controlled substance can be readily traced. The date, time administered, name of administering nurse, the name and strength of the narcotic, the name of the patient and the balance remaining shall be documented in the record.

(2) Controlled substance shall be destroyed by the Board of Pharmacy according to State Statutes and rules and regulations.

#### Section 12. Anesthetic Agents.

(a) Anesthetic agents and techniques to be used in any given birthing center shall be determined by its governing board.

(b) Analgesia and anesthesia - general and conduction anesthesia shall not be administered at birthing centers. Local anesthesia for pudendal block and episiotomy repair may be performed if procedures are outlined by the clinical staff. Systemic analgesia may be administered but pain control should depend primarily on close emotional support and adequate preparation for the birth experience.

Section 13. Construction and Remodeling. Department of Health Rules and Regulations for Construction Rules for Health Care Facilities.

#### Section 14. Physical Environment



(a) The Birthing Center shall be constructed, arranged, and maintained to ensure health and safety of the patient.

(i) The building interior and exterior shall be clean, orderly, sanitary, and free of odors.

(b) Any renovations of the licensed birthing center, shall, after the effective date of these regulations, comply with the requirements as outlined in Section 11. Construction/Remodeling.

Section 15. Life Safety and Electrical Safety. Department of Health Rules and Regulations for Construction Rules for Health Care Facilities.

(a) Facilities licensed prior to the effective date of these rules, shall meet the Life Safety Code of the National Fire Protection Association that was in effect at the time the facility was licensed as a Birthing Center.

## APPENDIX I

### LIMITATION OF SERVICES

In order to be delivered in a birthing center the woman shall exhibit no medical evidence of:

- (a) Severe anemia (hgb. less than 9.5) or blood disease;
- (b) Diabetes mellitus (insulin dependent or diet controlled);
- (c) Symptomatic heart disease;
- (d) Hypertension, pre-eclampsia or eclampsia;
- (e) Renal disease;
- (f) Thrombophlebitis;
- (g) Multiple gestation (i.e. twins);
- (h) Sexually transmitted diseases;
- (i) Viral infection during pregnancy which will adversely affect the infant at birth;
- (j) Chronic urinary tract infections;
- (k) Placental abnormalities (such as previa or abruptio) which might threaten the neonate;
- (l) Premature labor (37 weeks or less) or postmaturity (42 weeks without labor) or chemical stimulation at labor, i.e. pitocin;
- (m) Prolonged rupture of membranes;
- (n) The need for multiple doses of analgesia or anesthesia other than pudendal or local while in labor;
- (o) Intrauterine growth retardation;
- (p) Fetal distress which will adversely affect the infant in labor or at birth;
- (q) Previous Caesarean delivery;

- (r) A desire for transfer from birthing center care;
- (s) Anticipated macrosomia which will adversely affect mother or baby in labor or at birth;
- (t) Breech or other abnormal (non-vertex) presentation;
- (u) Six or more (non-miscarriage or non-abortion) pregnancies;
- (v) 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;
- (w) Toxemia, hydramnios or chorioamnionitis;
- (x) Malformed fetus;
- (y) Prolonged labor.

Only pregnant women who are at least 16 years of age and under 36 years of age shall be accepted for care.