

CHAPTER 26

BIRTHING CENTERS

Section 1. Authority. The Wyoming Department of Health (Department) promulgates this Chapter under Wyoming Statutes 35-2-904, -907, and -908.

Section 2. Purpose and Applicability.

- (a) This Chapter applies to the operation of a birthing center.
- (b) This Chapter does not apply to the operation of a birthing center that is exempt from licensure under Section 4(b) of this Chapter.
- (c) The Department may issue a provider manual, provider bulletin, or other guidance materials to interpret the provisions of this Chapter. Such guidance must be consistent with and reflect the policies contained in this rule.
- (d) If any portion of this Chapter is found to be invalid or unenforceable, the remainder shall continue in effect.

Section 3. Definitions.

- (a) The following definitions apply to this Chapter:
 - (i) “Administration of Drugs” means 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.
 - (ii) “Activity, Pulse, Grimace, Appearance, and Respiration” or “APGAR” means the overall assessment of the newborn.
 - (iii) “Bathing Facility” means a bathtub or shower.
 - (iv) “Birthing Center” means a facility which operates for the primary purpose of performing deliveries and is not part of a hospital.
 - (v) “Birthing Room” means 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 delivery.
 - (vi) “Certified Nurse Midwife” or “CNM” means a midwife who is licensed as an Advanced Practice Registered Nurse by the Wyoming State Board of Nursing and is certified by the American Midwifery Certification Board.

(vii) “Central Registry” means the registry operated by the Wyoming Department of Family Services to index individuals who have been substantiated for:

(A) Abuse or neglect of children under W.S. 14-3-213; or

(B) Abuse, neglect, exploitation, or abandonment of vulnerable adults under W.S. 35-20-115.

(viii) “Certified Professional Midwife” or “CPM” means a midwife who is certified by the North American Registry of Midwives (NARM) and currently licensed by the Wyoming Board of Midwifery.

(ix) “Clinical Staff” means the physicians, CNMs, or CPM’s hired to practice within the birthing center and licensed by the state of Wyoming.

(x) “Governing Body” means an individual or group which is legally responsible for the operation, control and maintenance of the birthing center.

(xi) “Immediate jeopardy” means a situation in which a center’s noncompliance with one or more requirements of these Rules has caused, or is likely to cause, serious injury, harm, impairment, or death to a patient.

(xii) “Low Risk” means normal, uncomplicated prenatal course as determined by adequate prenatal care and prospects for a normal, uncomplicated delivery 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 Section 11 of this Chapter.

(xiii) “Patient” means a pregnant woman or the newborn receiving care in a birthing center.

(xiv) “Personnel” mean individuals employed by the birthing center.

(xv) “Physician” means a person authorized by the Wyoming Board of Medicine to practice medicine pursuant to W.S. 33-26-301.

(xvi) “Plan of correction” means a center’s plan to correct the deficiencies identified during a survey conducted by the State Survey Agency.

(xvii) “Recovery” means that period or duration of time starting at birth and ending with the discharge of a patient from the birthing center.

(xviii) “State Survey Agency” means the Department of Health, Aging Division, Healthcare Licensing and Surveys, including its staff and designees.

(xix) “Support Person” means the individual(s) selected or chosen by a mother to provide emotional support and to assist her during the process of labor and childbirth.

(xx) “Survey” means an onsite or offsite inspection conducted by the State Survey Agency to determine compliance with these Rules. The term includes activities commonly referred to in the field as surveys, revisits, complaint investigations, periodic surveys, and other inspections deemed necessary by the State Survey Agency.

Section 4. Licensing.

(a) A birthing center may not operate in Wyoming unless the center is licensed by the State Survey Agency under this Chapter.

(b) Despite the licensure requirement under Subsection (a) of this Section, a center may operate without a license if the center:

(i) Consists of no more than one (1) birthing room; and

(ii) Is located within thirty (30) road miles of an acute care hospital.

(c) A center shall display its current license in a public area within the center.

(d) The State Survey Agency may issue a center a provisional license according to the following conditions:

(i) A provisional license provides a center with temporary authorization to operate while the center pursues compliance with these Rules. A provisional license is effective for no more than three (3) months. The State Survey Agency may extend the term of a provisional license for an additional three (3) months, as deemed necessary by the State Survey Agency.

(ii) To apply for a provisional license, a center shall submit the following to the State Survey Agency:

(A) A complete and accurate application form, available from the State Survey Agency upon request or at <http://health.wyo.gov/aging/hls>;

(B) A complete and accurate Freestanding Emergency Center Required Licensure Documentation Checklist, available from the State Survey Agency upon request or at <http://health.wyo.gov/aging/hls>; and

(C) The required licensure fee, in the form of a check or money order made payable to “Treasurer, State of Wyoming,” identified in *Rules, Wyoming Department of Health, Health Quality*, Chapter 1 (1998).

(iii) Upon receipt and review of the required application, checklist, and fee, the State Survey Agency may issue the center a provisional license if the State Survey Agency finds

the center has demonstrated a good faith effort to comply with these Rules. The State Survey Agency may also issue a provisional license to the center as the State Survey Agency deems necessary to allow the center to become compliant with these Rules.

(e) After the State Survey Agency completes a survey under Section 5(b)(i) of this Chapter, the State Survey Agency may issue a license to a provisionally-licensed center if the State Survey Agency determines the center has submitted an acceptable plan of correction, or corrected any deficiencies cited by the State Survey Agency.

(f) The renewal of a license is subject to the following:

(i) To apply for licensure renewal, a center shall submit the following to the State Survey Agency:

(A) A complete and accurate application form, available from the State Survey Agency upon request or at <http://health.wyo.gov/aging/hls>; and

(B) The required licensure fee, in the form of a check or money order made payable to “Treasurer, State of Wyoming,” identified in *Rules, Wyoming Department of Health, Health Quality*, Chapter 1 (1998).

(ii) Upon receipt of the required application and fee, the State Survey Agency may renew the center’s license if the State Survey Agency finds the center has demonstrated a good faith effort to comply with the regulatory requirements.

(g) A center may not transfer a license, even if the center changes ownership.

(i) If a center undergoes a change of ownership, the center shall:

(A) Provide written notice no later than sixty (60) days prior to the effective date of the change of ownership to the State Survey Agency that outlines the specific details of the change, parties involved, and proposed effective date;

(B) Within twenty-four (24) hours of the effective change of ownership date, submit a copy of the signed bill of sale and any lease agreements that reflects the effective date of the sale or lease; and

(C) Obtain a new license according to the provisions of this Section before the center may continue operations.

(ii) A change of ownership occurs when there is a change in the legal entity responsible for the operation of the center, whether by lease or by ownership.

(h) If a center changes the center’s name or address, the center shall submit the appropriate form and fee established by the State Survey Agency no later than sixty (60) days before the change in center name or address is effective.

(i) If a center voluntarily terminates operations, the center shall notify the State Survey Agency in writing within sixty (60) days before the voluntary termination of operations.

(i) A center voluntarily terminating operations shall provide for the continued storage of medical, financial, and personnel records for a period of six (6) years.

(ii) The notice provided to the State Survey Agency must include the name, address, email, and other contact information of the custodian of the center's medical, financial, and personnel records.

Section 5. Surveys.

(a) A center shall submit to and comply with a survey performed by the State Survey Agency.

(b) The State Survey Agency shall perform:

(i) A survey before the State Survey Agency may issue a license under Section 4(e) of this Chapter;

(ii) A survey as necessary to monitor or resolve previously-identified deficiencies;

(iii) A survey as necessary to periodically monitor compliance with these Rules;

(iv) A survey upon receipt of a complaint against a center for the alleged violation of these Rules or other applicable laws; and

(v) Any other surveys the State Survey Agency deems necessary to enforce the provisions of these Rules, to enforce other applicable law, or to protect the public health, safety, or welfare.

(c) The State Survey Agency may conduct a survey off-site, or remotely, as the State Survey Agency deems necessary.

(d) While under survey, a center shall provide the State Survey Agency with immediate access to all center records.

(e) If immediate jeopardy is identified during a survey, the State Survey Agency shall verbally notify the administrator or the administrator's designee. The center shall:

(i) Immediately develop a written action plan to remove the immediate risk to the patient(s);

(ii) Provide the written action plan to the State Survey Agency for review and approval; and

(iii) Upon approval, implement the action plan.

(f) The State Survey Agency shall notify the administrator or administrator's designee when an immediate jeopardy situation has been removed.

Section 6. Deficiencies and Actions Against a License.

(a) If the State Survey Agency determines during a survey that a center is out of compliance with any provision of these Rules or other applicable law, the following conditions apply:

(i) The State Survey Agency shall provide the center a statement of deficiencies within ten (10) business days of the survey exit date.

(ii) If a center receives a statement of deficiencies, the center shall comply with the following provisions.

(A) The center shall submit an acceptable plan of correction to the State Survey Agency within ten (10) business days.

(B) The plan of correction must be a written document that provides the following information:

(I) Who will be charged with the responsibility to correct each deficiency;

(II) What will be done to correct each deficiency;

(III) How the plan of correction will be incorporated into the center's quality management program;

(IV) Who will be charged with monitoring the center to ensure each deficiency does not occur or develop again; and

(V) The date the center expects to correct all deficiencies, which may not exceed sixty (60) calendar days after the survey exit date.

(iii) If the State Survey Agency determines it will take the center longer than the sixty (60) days to implement the plan of correction and there is no threat to the health or safety of patients, the State Survey Agency may extend the sixty (60) day deadline.

(b) Pursuant to W.S. 35-2-905, the State Survey Agency may take action against a center according to the following conditions:

(i) The State Survey Agency may take action against a center if the State Survey Agency finds that the center:

(A) Violated a provision of these Rules or other applicable laws;

(B) Permitted, aided, or abetted the commission of any illegal act by a facility licensed by the State Survey Agency; or

(C) Conducted practices detrimental to the health, safety, or welfare of the patients of the center.

(ii) Action against a center may include:

(A) Placing conditions upon the center's license;

(B) Installing a monitor or manager, at the center's expense, that has been approved by the State Survey Agency;

(C) Suspending the admission of new patients at the center; or

(D) Denying, suspending, or revoking a center's license.

Section 7. Governing Body.

(a) The governing body of a center shall:

(i) Adopt and maintain bylaws that define, identify, and establish responsibilities for the operation and performance of the center,

(ii) Establish administrative policies including qualifications and responsibilities of the center administrator;

(iii) Provide the appropriate personnel, equipment, supplies and special services necessary to provide safe and effective care; and

(iv) Meet at least annually and keep minutes or other records necessary for the orderly conduct of the center. Meetings held by the center's governing body shall be separate meetings with separate minutes.

Section 8. Center Administrator.

(a) Prior to licensure, a center shall employ and designate a center administrator.

- (b) The center administrator shall:
 - (i) Oversee management and operation for the center;
 - (ii) Comply with policies, rules and regulations and statutory provisions pertaining to the health and safety of patients;
 - (iii) Serve as the liaison between the governing body and the staff;
 - (iv) Plan, organize and direct activities that may be delegated by the governing body;
 - (v) Control the purchase, maintenance, and distribution of the equipment, materials, and facilities of the center;
 - (vi) Establish lines of authority, accountability, and supervision of staff;
 - (vii) Establish controls related to the custody of the official documents of the center and to maintaining the confidentiality, security, and physical safety of data on patients and staff; and
 - (viii) Ensure personnel policies are adopted, implemented, and enforced to facilitate attainment of the mission, goals, and objectives of the center.

Section 9. Duties and Powers of a Birthing Center.

- (a) A center shall provide:
 - (i) Anesthetic agents according to Section 10 of this Chapter;
 - (ii) Provision of services according to Section 11 of this Chapter; and
 - (iii) Pharmaceutical services according to Section 12 of this Chapter.
- (b) A center shall adopt, implement, and enforce:
 - (i) An emergency preparedness plan according to Section 13 of this Chapter;
 - (ii) A patient rights policy according to Section 14 of this Chapter;
 - (iii) A quality management program according to Section 15 of this Chapter;
 - (iv) A records policy according to Section 16 of this Chapter; and
 - (v) A staffing policy according to Section 17 of this Chapter.

(c) A center shall purchase and maintain equipment and supplies according to Section 18 of this Chapter.

(d) A center shall maintain a physical environment according to the following conditions:

(i) A facility must be designed, constructed, arranged, equipped and maintained, including the provision of fire safety, in accordance with Chapter 3 of these Rules.

(ii) If a facility constructs, remodels, or changes the use of facility space, the facility shall comply with Chapter 3 of these Rules.

(e) A center shall provide, disclose, or otherwise make available medical records, personnel records, incident reports, and other documents related to compliance with these Rules upon the written request of the State Survey Agency.

Section 10. Anesthetic Agents.

(a) A center may not administer general or conduction anesthesia.

(b) A center may administer:

(i) Systemic analgesia for pain control; and

(ii) Local anesthesia for perineal repair if indicated.

(c) A center shall adopt, implement, and enforce policies and procedures for the proper use of anesthetic agents, including relevant techniques, at the center.

Section 11. Provision of Services.

(a) A center may not accept a pregnant woman under sixteen (16) years of age for care.

(b) A center may not perform a delivery if the pregnant woman exhibits medical evidence of the following conditions:

(i) Hypertension, pre-eclampsia, or eclampsia;

(ii) Multiple gestation (i.e. twins);

(iii) Placental abnormalities, including previa or abruptio, which may threaten the neonate;

(iv) Premature labor, post-maturity labor, or medically-induced labor;

(v) More than one (1) prior cesarean section with no history of a vaginal delivery; a cesarean section within eighteen (18) months of the current delivery; or, any cesarean section that was surgically closed with a classical or vertical uterine incision; or

(vi) Known breech or other abnormal, non-vertex, presentation.

(c) If a center accepts a pregnant woman, the center shall provide services according to the following standards:

(i) A physician, CNM, or CPM shall attend each delivery at the center. A second staff member shall also attend the delivery.

(ii) If more than one patient is in labor at a center, a minimum of one staff member per a patient must be present at the center.

(iii) After a delivery, a CNM, CPM, or RN shall be present in the center at all times until the mother and newborn are stable and discharged from care.

(d) A center shall develop, implement, and enforce written operational policies for:

(i) Informed consent that is obtained prior to the onset of labor and shall include evidence of an explanation by personnel of the services offered and potential risks;

(ii) Orientation and education of patients, family, and support persons regarding childbirth and newborn care;

(iii) Consultation, back-up services, transfer, and transport of the patient(s) to the hospital where appropriate care is available;

(iv) Emergency transport of the patient(s) if indicated, including method of providing pertinent medical information to the receiving hospital;

(v) Discharge of the mothers and newborns within 24 hours after delivery;

(vi) A program for prompt follow-up care and postpartum evaluation after discharge; and

(vii) Registration of birth and reporting of complications, anomalies, and stillbirths.

Section 12. Pharmaceutical Services.

(a) A center shall provide pharmaceutical services necessary to meet the needs of patients and to adequately support the center's clinical capabilities.

(b) A center shall:

- (i) Maintain the pharmacy or drug storage area according to relevant federal and state law;
 - (ii) Package and dispense drugs and biologicals according to relevant federal and state law;
 - (iii) Keep drugs and biologicals in a locked storage area; and
 - (iv) Destroy drugs and biologicals as necessary according to accepted medical practices. If the drug is a controlled substance, a RN shall destroy the drug in the presence of another qualified professional and shall document the destruction in the patient's medical record.
- (c) A staff member shall immediately report a drug administration error, adverse drug reaction, or incompatibility to the clinical staff.

Section 13. Emergency Preparedness.

- (a) A center shall develop and maintain an emergency preparedness plan according to Chapter 3 of these Rules.
- (b) A center shall:
 - (i) Ensure the plan includes ongoing coordination with community agencies and other local health care facilities;
 - (ii) Review the plan annually; and
 - (iii) Update the plan as necessary.

Section 14. Patient Rights.

- (a) A center shall promote and protect patient rights.
- (b) A center shall:
 - (i) Treat a patient with respect, consideration, and dignity;
 - (ii) Provide a patient appropriate privacy;
 - (iii) Provide a patient, to the degree known by the center, appropriate information concerning the patient's diagnosis, treatment, and prognosis. When it is medically inadvisable to give such information to a patient, the center shall provide the information to a person designated by the patient or to a legally authorized person;

(iv) Provide a patient the opportunity to participate in decisions involving the patient's health care, except when the patient's participation is contraindicated for medical reasons; and

(v) Provide the patient written information regarding the patient's rights including the following subjects:

(A) Patient conduct and responsibilities;

(B) Services available at the center;

(C) The center's transfer policy and procedures;

(D) Fees for services provided at the center;

(E) The center's payment policies; and

(F) The center's procedure for filing and pursuing a grievance, including all relevant steps from filing the initial grievance to achieving a resolution.

Section 15. Quality Management.

(a) A center shall implement a quality management function under W.S. 35-2-910.

(b) A center's quality management program must:

(i) Ensure and evaluate the quality of patient care provided at the center; and

(ii) Provide for the annual review of:

(A) The utilization of the center's services, including the number of patients served and volume of services;

(B) The center's health care policies;

(C) The center's infection control program including antibiotic stewardship; and

(D) The initiation and documentation of appropriate remedial action to address deficiencies found through the quality management program, as well as documentation of the outcome of remedial action.

Section 16. Records.

(a) If a patient receives services at a center, the center shall maintain a patient medical record. As applicable, a patient medical record must include:

(i) Regarding a pregnant woman or mother:

(A) Documentation of prenatal care, including:

(I) A complete blood count;

(II) Urinalysis;

(III) Prenatal blood serology;

(IV) Rhesus factor (Rh) determination and evidence of a plan for the appropriate use of Rh immune globulin;

(V) Past obstetrical history;

(VI) Physical examination;

(VII) Rubella titer;

(VIII) Identification data including patient history and physical examination;

(IX) Signed consent;

(X) Medication orders signed by licensed provider (Physician, CNM or CPM); and

(XI) Other laboratory test results.

(ii) Regarding the labor and delivery:

(A) Documentation of the labor and delivery:

(I) Anesthesia and analgesia and medication given in the course of labor, delivery, and postpartum;

(II) Administration of rhesus (Rh) immune globulin, if any;

(III) Recovery and other progress notes;

(IV) Medications administered;

(V) Condition and referral on discharge; and

(VI) Home visits following discharge.

(iii) Regarding a newborn:

(A) Documentation of newborn care, including:

(I) Date and hour of birth;

(II) Birth weight;

(III) Length;

(IV) Estimation of gestational age;

(V) Gender;

(VI) Condition of infant on delivery including APGAR;

(VII) Record of ophthalmic prophylaxis and Vitamin K, or refusal thereof;

(VIII) Appropriate physical examination at birth and at discharge by physician or midwife;

(IX) Genetic screening, phenylketonuria (PKU) or other metabolic disorders report or refusal thereof; and

(X) Fetal monitoring record.

(b) A center shall register a birth according to W.S. 35-1-410 and *Rules, Wyoming Department of Health, Vital Records Services, Chapter 3 (2008)*. A center shall include the birth registration information as part of the medical record.

(c) A center shall comply with the Health Insurance Portability and Accountability Act (HIPAA) of 1996, the implementing regulations of HIPAA, and any other applicable law relating to the maintenance or disclosure of health information.

(d) A center shall maintain all records according to professional standards of practice, including storage of records in a secure and designated area.

(e) A center's medical records policy must:

- (i) Ensure the confidentiality of medical records and safeguard against loss, destruction, or unauthorized use, in accordance with applicable law;
 - (ii) Govern the use and removal of records from the record storage area;
 - (iii) Specify the conditions under which record information may be released and to whom;
 - (iv) Specify when the patient's written consent is required for release of information;
 - (v) Ensure all entries are dated, signed, and legible;
 - (vi) Ensure all information to a patient's care and stay is documented in the patient's medical record; and
 - (vii) Ensure that medical records are preserved in physical or electronic form.
- (f) A center shall maintain personnel records for each individual employed at the center that include:
- (i) An employment application;
 - (ii) Verification of criminal background check and Central Registry check;
 - (iii) Licensure verification;
 - (iv) Copies of certifications required under Section 17;
 - (v) Immunizations and other medical tests; and
 - (vi) Results of medical examinations required as a part of employment.
- (g) A center shall maintain equipment records per the manufacturer's recommendations.

Section 17. Staff.

- (a) A center may not permit a staff member to provide a service unless:
- (i) The staff member possesses the necessary education, training, experience, licensure, and certifications; and
 - (ii) The staff member is certified in Basic Life Support (BLS) and has required training in bloodborne pathogens.

- (b) A center shall employ sufficient staff to allow for:
 - (i) A practitioner, CNM or CPM to be on-site at the center when patients are present;
 - (ii) A practitioner to be on-call and immediately available by telephone or radio if there is no practitioner on-site at the center; and
 - (iii) An adequate number of practitioners, RNs or CPMs to be available on-call to meet the emergency needs of patients in a timely manner.
- (c) A center shall require all direct care center staff to submit to a Child & Adult Abuse/Neglect Central Registry Screen, through the Wyoming Department of Family Services, and a full fingerprint-based national criminal background check.
 - (i) If a direct care staff member is found to have previously committed abuse/neglect or a criminal offence, the center must not allow the staff member to work independently and unsupervised unless the center:
 - (A) Investigates the conduct at issue in a thorough manner;
 - (B) Determines, based on the findings of its investigation, that the direct care staff member may be allowed to have unsupervised access to patients and the center's operational systems; and
 - (C) Maintains documentation of its investigation and determination in the direct care staff member's subsequent personnel file.

Section 18. Equipment and Supplies.

- (a) A center shall maintain appropriate equipment and supplies, including:
 - (i) A bed suitable for labor, delivery, and recovery;
 - (ii) Oxygen with flow meters and masks or equivalent;
 - (iii) Mechanical suction or bulb suction;
 - (iv) Endotracheal tubes;
 - (v) Oral airways;
 - (vi) Needles;
 - (vii) Syringes;

- (viii) Emergency drugs;
- (ix) A laryngoscope;
- (x) An automated external defibrillator;
- (xi) Emergency medications, intravenous fluids, and related supplies and equipment for both mother and newborn;
- (xii) Equipment for monitoring fetal heartrate;
- (xiii) Equipment specifically designed for thermal regulation and transport of newborns, and regular training and review in proper use of equipment;
- (xiv) An infant scale;
- (xv) A clock;
- (xvi) Sterile suturing equipment and supplies;
- (xvii) Adjustable lighting that is adequate for examinations;
- (xviii) Containers for soiled linen which shall be closed or covered;
- (xix) Infection control supplies for the sanitary disposal of all wastes;
- (xx) An emergency communication system;
- (xxi) A sphygmomanometer, stethoscope and fetoscope;
- (xxii) Supplies for routine laboratory testing; and
- (xxiii) Any other equipment necessary to ensure the safety of pregnant women, mothers, and children.