

**R432. Health, Family Health and Preparedness, Licensing.**

**R432-550. Birthing Centers.**

**R432-550-1. Legal Authority.**

This rule is adopted pursuant to Title 26, Chapter 21.

**R432-550-2. Purpose.**

This rule provides health and safety standards for the organization, physical plant, maintenance and operation of birthing centers.

(1) Birthing centers shall consist of one to five birth rooms. Licensure is not required for birthing centers with only one birth room.

(2) Birthing centers provide quality care and services in a pleasing and safe environment to a select low risk population of healthy maternal patients who choose a safe and cost-effective alternative to the traditional hospital childbirth experience.

(3) Birthing center clinical staff assess the maternal patient's risk for obstetric complications through careful review of the patient's records for prenatal screening of potential problems.

(4) Birthing centers recognize the individual needs of, and provide service to, low risk maternal patients expected to have an uncomplicated labor and delivery.

**R432-550-3. Time for Compliance.**

Facilities governed by these rules shall be in full compliance with these rules at the time of licensure.

**R432-550-4. Definitions.**

(1) Common definitions Section R432-1-3.

(2) Special Definitions:

(a) "Alongside midwifery unit" means a birthing unit that may be licensed as a birthing center and is connected to a hospital facility, either through a bridge, ramp, or adjacent to the labor and delivery unit within the hospital with care provided with the midwifery model of care, where maternal patients are received and care provided during labor, delivery, and immediately after delivery.

(b) "Birth room" means a room and environment designed, equipped and arranged to provide for the care of a maternal patient and newborn and to accommodate a maternal patient's support person during the process of vaginal birth and recovery. "Birth room" does not include rooms intended for pre-admittance or post-discharge accommodations of maternal patients and their newborns.

(c) "Birthing center" means a facility, receiving maternal patients and providing care during labor, delivery and immediately after delivery; including an alongside midwifery unit.

(d) Certification in Cardiopulmonary Resuscitation (CPR) refers to certification issued after completion of a course that is consistent with the most current version of the American Heart Association Guidelines for Health Care Provider CPR.

(e) "Patient" means a woman or newborn receiving care and services provided by a birthing center during labor, childbirth and recovery.

(f) "Clinical staff" means a licensed maternity care practitioner appointed by the governing authority to practice within the birthing center and governed by rules approved by the governing body.

(g) "Support person" means the individual or individuals selected or chosen by a patient to provide emotional support and to assist her during the process of labor and childbirth.

(h) "Vaginal birth" means the three stages of labor.

(i) "Licensed maternity care practitioner" means a person licensed to provide maternity care services including physicians licensed under Title 58, Chapters 67 and 68, Certified Nurse-Midwives licensed under Title 58, Chapter 44a, Naturopathic Physicians licensed under Title 58, Chapter 71, Licensed Direct-Entry Midwives licensed under Title 58, chapter 77, and others licensed to provide maternity, midwifery, or obstetric care under Title 58.

**R432-550-5. General Construction Rules.**

See R432-14 Birthing Center Construction Rules.

**R432-550-6. Governing Body.**

(1) The licensee shall appoint in writing an individual or group to constitute the facility's governing body. The governing body shall:

(a) comply with federal, state and local laws, rules and regulations;

(b) adopt written policies and procedures which describe the functions and services of the birthing center and protect patient rights;

(c) adopt a policy prohibiting discrimination because of race, color, sex, religion, ancestry, or national origin in accordance with Title 13, Chapter 7, Sections 1 through 4.

(d) develop an organizational structure establishing lines of authority and responsibility;

(e) when the governing body is more than one individual, conduct meetings in accordance with facility policy, but at least annually, and maintain written minutes of the meetings;

(f) appoint by name and in writing a qualified administrator;

(g) appoint by name and in writing a qualified director of the clinical staff;

(h) appoint members of the clinical staff and delineate their clinical privileges;

- (i) review and approve at least annually a quality assurance program for birthing center operation and patient care provided.
- (j) establish a system for financial management and accountability;
- (k) provide for resources and equipment to provide a safe working environment for personnel;
- (l) act on findings and recommendations of facility-created committees relevant to compliance with these birthing center rules;
- (m) ensure that facility patient admission eligibility criteria are strictly applied by clinical staff and are evaluated through quality assurance review in accordance with R432-550-11.
  - (2) Written policies and procedures shall:
    - (a) clearly, accurately and comprehensively define the methods by which the facility will be operated to protect the health and safety of patients;
    - (b) provide for meeting the patient's needs;
    - (c) provide for continuous compliance with federal, state and local laws, rules and regulations.
    - (d) Written policies and procedures shall include:
      - (i) defining the term "low risk maternal patient" which shall include eligibility criteria for birth services offered in the birthing center;
      - (ii) defining specific criteria, which shall in normally anticipated circumstances render a maternal patient ineligible for birth services or continued care at the birthing center;
      - (iii) identifying and outlining methods for transferring patients who, during the course of labor or recovery, are determined to be ineligible for birthing center services or continued care at the birthing center, including:
        - (A) information required for proper care and treatment of the individual(s) transferred, including patient records; and
        - (B) security and accountability of the personal effects of the individual being transferred.
      - (iv) planning for consultation, back-up services, transfer and transport of a newborn and maternal patient to a hospital where necessary care is available;
      - (v) documenting the maternal patient has been informed of the eligibility requirements of an out-of-hospital birthing center labor and birth;
      - (vi) providing instructions in postpartum and newborn care to the patient and any other family or support person designated by the patient;
      - (vii) registering birth, fetal death or death certificates in accordance with Title 26, Chapter 2, Sections 5, 13, 14, 23 and rules promulgated pursuant thereto in R436.
      - (viii) prescribing and instilling a prophylactic solution approved by the Department of Health in the eyes of the newborn in accordance with R386-702-8, Special Measures for the Control of Ophthalmia Neonatorum;
      - (ix) performing phenylketonuria (PKU) and other disease tests in accordance with Department of Health Laboratory rules developed pursuant to Section 6;
      - (x) verifying prenatal laboratory screening to include:
        - (A) blood type and Rh Factor and provision for appropriate use of Rh immunoglobulin;
        - (B) hematocrit or hemoglobin;
        - (C) antibody screen;
        - (D) rubella; and
        - (E) syphilis;
      - (xi) providing for infection control to include:
        - (A) housekeeping;
        - (B) cleaning, sterilization, sanitization and storage of supplies and equipment; and
        - (C) prevention of transmission of infection in personnel, patients and visitors.

**R432-550-7. Administrator.**

- (1) Direction.
  - (a) The administrator shall be responsible for the overall management and operation of the birthing center.
  - (b) The administrator shall designate in writing a competent employee to act as administrator in the temporary absence of the administrator.
    - (c) The administrator's designee shall have authority and responsibility to:
      - (i) act in the best interests of patient safety and well-being;
      - (ii) operate the facility in a manner which ensures compliance with these birthing center rules.
  - (2) Qualifications.
    - The administrator and administrator's designee shall be knowledgeable:
      - (a) by education, training or experience in administration and supervision of personnel and qualified as required by facility policy;
      - (b) in birthing center protocols;
      - (c) in applicable federal, state and local laws, rules and regulations.
    - (3) The administrator's responsibilities shall be included in a written job description available for Department review. The administrator shall:
      - (a) complete, submit and file records and reports required by the Department;
      - (b) develop and implement facility policies and procedures;

- (c) review facility policies and procedures at least annually and report to the governing body on the review;
- (d) employ or contract with competent personnel whose qualifications are commensurate with job responsibilities and authority and who have the appropriate Utah license or certificate of completion;
- (e) develop, for all employee positions, job descriptions that delineate functional responsibilities and authority; and
- (f) review and act on incident or accident reports.

**R432-550-8. Clinical Director.**

- (1) The clinical director shall be responsible for implementing, coordinating and assuring the quality of patient care services.
- (2) The clinical director shall:
  - (a) be currently licensed to practice medicine or midwifery in Utah;
  - (b) have training and expertise in obstetric and newborn services offered to ensure adequate supervision of patient care services; and
  - (c) for an alongside midwifery unit, the clinical director shall be a physician as defined in Section 58-67-102 or a certified nurse midwife under Title 58, Chapter 44a, Nurse Midwife Practice Act.

(3) The clinical director's responsibilities shall be included in a written job description available for Department review. The clinical director shall:

- (a) review and update facility protocols;
- (b) review and evaluate clinical staff privileges and revise them as necessary;
- (c) recommend, to the governing body, names of qualified licensed health care practitioners to perform approved procedures and the corresponding clinical staff privileges to be granted;
- (d) coordinate, direct and evaluate clinical operations of the facility;
- (e) evaluate and recommend to the administrator the type and amount of equipment needed in the facility;
- (f) ensure that qualified staff are on the premises while patients are admitted to the facility;
- (g) ensure clinical staff documentation is recorded immediately and reflects a description of care given;
- (h) ensure that planned birthing center services are within the scope of privileges granted to the clinical staff; and
- (i) recommend to the administrator appropriate remedial action and disciplinary action, when necessary, to correct violations of clinical protocols.

**R432-550-9. Personnel.**

- (1) The administrator shall employ a sufficient number of qualified professional and support staff who are competent to perform their respective duties, services and functions.
- (2) The facility shall maintain written personnel policies and procedures which shall be available to personnel and shall address the following:
  - (a) content of personnel records;
  - (b) job descriptions, qualifications and validation of licensure or certificates of completion as appropriate for the position held;
  - (c) conditions of employment; and
  - (d) management of employees.
- (3) The facility shall maintain personnel records for employees and shall retain personnel records for terminated employees for a minimum of one year following termination of employment.
- (4) The facility shall establish a personnel health program through written personnel health policies and procedures which shall protect the health and safety of personnel and patients commensurate with the services offered.
- (5) An employee placement health evaluation shall include at a health inventory which shall be completed when an employee is hired. The health inventory shall obtain the employee's history of the following:
  - (a) conditions that predispose the employee to acquiring or transmitting infectious diseases; and
  - (b) conditions which may prevent the employee from performing certain assigned duties satisfactorily.
- (6) Employee health screening and immunization components of personnel health programs shall be developed in accordance with R386-702, Code of Communicable Disease Rules.
- (7) Employee skin testing by the Mantoux method or other FDA approved in-vitro serologic test and follow-up for tuberculosis shall be done in accordance with R388-804, Special Measures for the Control of Tuberculosis.
  - (a) The licensee shall ensure that all employees are skin-tested for tuberculosis within two weeks of:
    - (i) initial hiring;
    - (ii) suspected exposure to a person with active tuberculosis; and
    - (iii) development of symptoms of tuberculosis.
  - (b) Skin testing shall be exempted for all employees with known positive reaction to skin tests.
- (8) The birthing center personnel must receive documented orientation to the facility and the job for which they are hired.
- (9) The birthing center personnel must receive documented ongoing in-service training to include:
  - (a) an annual review of facility policies and procedures; and
  - (b) infection control, personal hygiene and each employee's responsibility in the personnel health program.
- (10) The birthing center Personnel shall have access to the facility's policy and procedure manuals when on duty.
- (11) Personnel shall maintain current licensing, certification or registration appropriate for the work performed and as required by the Utah Department of Commerce.

- (a) Personnel shall provide evidence of current licensure, registration or certification to the Department upon request.
- (b) Failure to ensure personnel are licensed, certified or registered may result in sanctions to the facility license.

**R432-550-10. Contracts.**

(1) The licensee shall provide a written contract for any birthing center services that are not provided directly by the facility. The licensee shall ensure that the contracted entity:

- (a) performs according to facility policies and procedures;
- (b) conforms to standards required by laws, rules and regulations; and
- (c) provides services that meet professional standards and are timely.

(2) Contracts shall be available for Department review.

(3) An alongside midwifery unit shall have a transfer agreement in place with the adjoining hospital to transfer a patient to the adjacent hospital's labor and delivery unit if a higher level of care is needed, and for services that are provided by the adjacent hospital's staff in collaboration with the alongside midwifery unit staff.

(4) An alongside midwifery unit may contract with staff from the adjoining hospital to assist with newborn care or resuscitation of a patient in an emergency.

**R432-550-11. Quality Assurance.**

(1) The administrator shall establish a quality assurance committee and program. This committee shall review regularly clinic operations, protocols, policies and procedures, incident reports, infection control, patient care policies and safety.

(2) The quality assurance committee shall initiate action to resolve identified quality assurance problems by filing a written report of findings and recommendations with the licensee.

(3) The quality assurance committee shall meet as prescribed in facility policy or at least quarterly and shall keep written minutes available for department review.

(4) The quality assurance program shall include surveillance, prevention and control of infection.

**R432-550-12. Emergency and Disaster.**

(1) The facility shall assure the safety and well-being of patients in the event of an emergency or disaster. An emergency or disaster may include but is not limited to interruption of public utilities, explosion, fire, earthquake, bomb threat, flood, windstorm, epidemic and injury.

(2) The administrator shall educate, train and drill staff to respond appropriately in an emergency in accordance with NFPA 101, Life Safety Code.

(3) The administrator shall be responsible for the development of an emergency and disaster plan, coordinated with state and local emergency or disaster authorities, to respond to emergencies and disasters as appropriate. The plan shall:

- (a) be in writing and personnel shall have ready access when on duty;
  - (b) be reviewed and updated at least annually by the administrator and the licensee; and
  - (c) address evacuation of occupants to a safe place within the facility or to another location.
- (4) The facility must maintain safe ambient air temperatures within the facility.

(a) Emergency heating must have the approval of the local fire department.

(b) The facility shall have, and be capable of implementing contingency plans regarding excessively high or low ambient air temperatures within the facility that may affect the health and safety of the patients.

**R432-550-13. Patients' Rights.**

(1) Written patients' rights shall be established and made available to the patient as determined by facility policy which shall include the following:

(a) to be fully informed, prior to or at the time of admission, and during stay, of these rights and of facility rules that pertain to the patient;

(b) to be fully informed, prior to admission, of the treatment to be received, potential complications and expected outcomes;

(c) to refuse treatment to the extent permitted by law and to be informed of the medical consequences of such refusal;

(d) to be informed, prior to or at the time of admission and during stay, of services available in the facility and of any expected charges for which the patient may be liable;

(e) to be afforded the opportunity to participate in decisions involving personal health care, except when contraindicated;

(f) to refuse to participate in experimental research;

(g) to be ensured confidential treatment of personal and medical records and to approve or refuse release to any individual outside the facility, except in the case of transfer to another health facility, or as required by law or third party payment contract;

(h) to be treated with consideration, respect and full recognition of personal dignity and individuality, including privacy in treatment and in care for personal needs.

**R432-550-14. Clinical Staff and Personnel.**

(1) Information identifying current clinical staff and on-call and emergency telephone numbers shall be readily available to birthing center personnel.

(2) Clinical staff and licensed personnel of the birthing center shall be trained in emergency and resuscitation measures for infants and adults, including but not limited to, cardiopulmonary resuscitation certification.

(3) A licensed maternity care practitioner shall be present at each birth and remain until the maternal patient and newborn are stable postpartum.

(4) A second member of the birthing center staff who is licensed or certified to give cardiopulmonary resuscitation shall be present at each birth.

(5) Clinical staff, licensed personnel and support staff shall be provided to meet patients' needs, to ensure patients' safety and to ensure that patients in active labor are attended.

(6) A midwife practicing in an alongside midwifery unit shall be a certified nurse midwife under Title 58, Chapter 44a, Nurse Midwife Practice Act.

**R432-550-15. Clinical Staff.**

(1) The attending member of the clinical staff shall ensure the supervision of, and quality of, care delivered to the patient admitted to the facility.

(2) Each patient shall be under the care of a member of the clinical staff.

(3) Clinical staff members shall comply with applicable professional practice laws and written birthing center protocols approved by the clinical director.

(4) The attending member of the clinical staff shall verify in writing that the patient conforms to facility eligibility criteria.

(5) The attending member of the clinical staff shall decide when transfer of a patient to a hospital is necessary and document in writing the conditions warranting the decision.

**R432-550-16. Equipment and Supplies.**

(1) The administrator shall provide necessary equipment in good working order to meet the patient's needs.

(2) The type and amount of equipment shall be indicated in facility policy and approved by the clinical director.

(3) An emergency cart or tray equipped to allow completion of emergency procedures defined by facility policy shall be readily available.

(a) The facility shall safely store the emergency cart or tray in a designated area that is accessible to authorized personnel.

(b) The facility shall maintain a written log of all upkeep of the emergency cart or tray.

(4) The inventory of supplies shall be sufficient to care for the number of patients registered for care.

(5) Properly maintained equipment and supplies for the maternal patient and the newborn shall include at least the following:

(a) furnishings suitable for labor, birth and recovery;

(b) oxygen with flow meters and masks or equivalent;

(c) bulb suction;

(d) resuscitation equipment to include resuscitation bags, laryngeal mask airways and oral airways;

(e) firm surfaces suitable for use in resuscitating patients;

(f) emergency medications and related supplies and equipment;

(g) fetal monitoring equipment, minimally to include a fetoscope or doppler;

(h) equipment to monitor and maintain the optimum body temperature of the newborn;

(i) a clock indicating hours, minutes and seconds;

(j) sterile suturing equipment and supplies;

(k) adjustable examination light;

(l) infant scale;

(m) a telephone or equivalent two-way communication device capable of reaching other facilities or emergency agencies;

and

(n) a delivery log for recording birth data.

**R432-550-17. Medications.**

(1) Licensed personnel shall prescribe, order and administer medication in accordance with applicable professional practice acts, pharmacy and controlled substances laws.

**R432-550-18. Anesthesia Services.**

(1) The birthing center shall provide facilities and equipment for the provision of anesthesia services commensurate with the obstetric procedures planned for the facility.

(2) The clinical director shall ensure the safety of anesthesia services administered to patients by clinical staff through written policies and protocols approved by the clinical staff for anesthetic agents, delivery of anesthesia and potential hazards of anesthesia.

(3) A clinical staff member shall monitor patients who receive anesthesia or analgesics.

**R432-550-19. Laboratory Services.**

(1) The birthing center shall provide direct or contract laboratory and associated services according to facility policy and to meet the needs of patients.

(2) Laboratory reports or results shall be reported promptly to the attending clinical staff member and documented in the patient's medical record.

(3) Laboratory services shall be provided according to CLIA requirements.

**R432-550-20. Medical Records.**

- (1) Medical records shall be complete, accurately documented and systematically organized to facilitate retrieval and compilation of information.
- (2) An employee designated by the administrator shall be responsible and accountable for the processing of medical records.
- (3) The medical record and its contents shall be safeguarded from loss, defacement, tampering, fires and floods.
- (4) Medical records shall be protected against access by unauthorized individuals. Birthing centers shall:
  - (a) keep medical record information confidential; and
  - (b) obtain consent from the patient before releasing client information identifying the client, including photographs, unless release is otherwise allowed or required by law.
- (5) Medical records shall be retained for at least five years after the last date of patient care. Records of minors, including records of newborn infants, shall be retained for three years after the minor reaches legal age under Utah law, but in no case less than five years.
- (6) The birthing center shall maintain an individual medical record for each patient which shall include but is not limited to written documentation of the following:
  - (a) admission record with demographic information and patient identification data;
  - (b) history and physical examination which shall be up-to-date upon the patient's admission;
  - (c) written and signed informed consent;
  - (d) orders by a clinical staff member;
  - (e) record of assessments, plan of care and services provided;
  - (f) record of medications and treatments administered;
  - (g) laboratory and radiology reports;
  - (h) discharge summary for mother and newborn to include a note of condition, instructions given and referral as appropriate;
  - (i) prenatal care record containing at least prenatal blood serology, Rh factor determination, past obstetrical history and physical examination and documentation of fetal status;
  - (j) monitoring of progress in labor with assessment of maternal and newborn reaction to the process of labor;
  - (k) fetal monitoring record;
  - (l) labor and delivery record, including type of delivery, record of anesthesia and operative procedures if any; and
  - (m) documentation that the patient is informed of the statement of patient rights.
- (7) The records of newborn infants shall include the following:
  - (a) date and hour of birth, birth weight and length, period of gestation, gender and condition of infant on delivery including Apgar scores and resuscitative measures;
  - (b) mother's name or unique identification;
  - (c) record of ophthalmic prophylaxis; and
  - (d) the identification number of the screening kit used to screen for metabolic diseases, documentation that metabolic screening, genetic screening, PKU or other metabolic disorders reports were completed or refused by the client.
- (8) An alongside midwifery unit may integrate medical records with the medical record system of the adjoining hospital.

**R432-550-21. Housekeeping Services.**

- (1) The facility shall provide adequate housekeeping services to maintain a clean and sanitary environment.
- (2) The facility shall develop and implement written housekeeping policies and procedures.

**R432-550-22. Laundry Services.**

- (1) The facility shall develop and implement written policies and procedures for storage and processing of clean and soiled linen.
- (2) Clean linen shall be stored, handled and transported to prevent contamination. Linens shall be maintained in good repair.
- (3) Soiled linen shall be handled, transported, stored and processed in a manner to prevent both leakage and the spread of infection.

**R432-550-23. Maintenance, Physical Environment, and Safety.**

- (1) The facility shall provide adequate maintenance service to ensure that facility equipment and grounds are maintained in a clean and sanitary condition and in good repair.
- (2) The facility shall develop and implement a written maintenance program which shall include a preventive maintenance schedule for major equipment and physical plant systems.

**R432-550-24. General Maintenance.**

- (1) The facility shall maintain facility buildings, fixtures, equipment and spaces in operable condition.
- (2) The facility shall provide a safe, clean and sanitary environment.
- (3) The facility shall conduct a pest-control program that ensures the facility is free from vermin.
- (4) Direct or contract pest-control programs shall comply with Title 4, Chapter 14.
- (5) Documentation shall be maintained for Department review.

**R432-550-25. Waste Processing Service.**

Facilities and equipment shall be provided for the sanitary storage and treatment or disposal of all categories of waste, including hazardous and infectious wastes if applicable, using techniques acceptable to the Department of Environmental Quality, and the local health department having jurisdiction.

**R432-550-26. Lighting.**

The facility shall provide adequate and comfortable lighting to meet the needs of patients and personnel.

**R432-550-27. Limitations of Services.**

(1) Birthing center policy shall establish a written risk assessment system to assess the individual risk for each maternal patient.

(2) A clinical staff member shall perform and document a risk assessment for each maternal patient to ensure the patient needs:

(a) fall within the scope of practice and standards of care included in the clinical staff member's professional practice act and within facility policy; and

(b) meet the eligibility requirements for a low risk maternal patient.

(3) Clients shall become ineligible for birthing center care upon development of:

(a) a clinical need for anesthesia or analgesia other than those used in a setting where anesthesia and analgesia are limited in accordance with the facility's written protocols; or

(b) any condition identified intrapartum or postpartum which will be likely to adversely affect the health of the maternal patient or infant and will require management in a general hospital.

**R432-550-28. Penalties.**

Any person who violates any provision of this rule may be subject to the penalties enumerated in Title 26, Chapter 21, Section 11 and R432-3-7 and be punished for violation of a class A misdemeanor as provided in Title 26, Chapter 21, Section 16.

**KEY: health care facilities**

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