25 Texas Administrative Code
Chapter 137 Birthing Center Licensing Rules

§137.2. Definitions. The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise.

(1) Act--Texas Birthing Center Licensing Act, Health and Safety Code, Chapter 244, relating to the licensure and regulation of centers.

(2) Acute postpartum period--A minimum of two hours following the delivery of the placenta and until the client is clinically stable.

(3) Administrator--A person who is delegated the responsibility for the implementation and proper application of policies, programs, and services established for the center.

(4) Affiliate--With respect to an applicant or owner which is:

(A) a corporation--includes each officer, director, stockholder with a direct ownership of at least 5.0%, subsidiary, and parent company;

(B) a limited liability company--includes each officer, member, and parent company;

(C) an individual--includes:

(i) the individual's spouse;

(ii) each partnership and each partner thereof of which the individual or any affiliate of the individual is a partner; and

(iii) each corporation in which the individual is an officer, director, or stockholder with a direct ownership of at least 5.0%;

(D) a partnership--includes each partner and any parent company; and

(E) a group of co-owners under any other business arrangement--includes each officer, director, or the equivalent under the specific business arrangement and each parent company.

~~(5) Annual license--A license that is issued annually to a center, other than an initial license.~~

(5) ~~(6)~~ Applicant--The owner of a center which is applying for a license under the Act. This is the person in whose name the license will be issued.

(6) ~~(7)~~ Birth attendant--A physician, certified nurse-midwife (CNM), or a Licensed Midwife ~~documented midwife~~.

~~(8) Board of Health--The Texas Board of Health.~~

(7) ~~(9)~~ Center--A facility, place, or institution where a woman is scheduled to give birth following a normal, uncomplicated ~~(low-risk)~~ pregnancy. This term does not include a hospital, ambulatory surgical center, a nursing home, or the residence of the woman giving birth.

(8) ~~(10)~~ Certified nurse-midwife (CNM)--A person who is:

(A) a registered nurse who is currently licensed under the Nursing Practice Act, Texas Occupations Code, Chapters 301 and 304;

(B) recognized as an advanced practice nurse by the Board of Nurse Examiners for the State of Texas; and

(C) certified by the American College of Nurse-Midwives (ACNM) or ACNM Accreditation Council.

(9) ~~(11)~~ Client--A woman who is scheduled to give birth at a center and the newborn ~~infant~~ of that birth.

(10) ~~(12)~~ Clinical Care--Direct provision of care to center clients.

(11) ~~(13)~~ Clinical care provider--A registered nurse (RN), licensed vocational nurse (LVN), physician assistant (PA), or adult unlicensed staff person who is capable of recognizing complications and who can care for the mother and newborn ~~infant~~ by performing the minimum duties set out in §137.48(d) of this title (relating to Labor and Birth Procedures).
(12) ~~(14)~~ Clinical director--A person who is responsible for advising and consulting with the staff of a center on all matters relating to the clinical management of all clients.
(13) ~~(15)~~ Critical item--All surgical instruments and objects that are introduced directly into the bloodstream or into other normally sterile areas of the body.
(14) ~~(16)~~ Decontamination--The physical and chemical process that renders an inanimate object safe for further handling.
(15) ~~(17)~~ Department--The Department of State Health Services ~~Texas Department of Health~~.
(16) ~~(18)~~ Manager ~~Director~~--The manager ~~director~~ of the Facility Licensing Group ~~Health Facility Licensing and Compliance Division~~ of the Department of State Health Services ~~Texas Department of Health~~ or his or her designee.
(17) ~~(19)~~ Disinfection--The destruction or removal of vegetative bacteria, fungi, and most viruses but not necessarily spores; the process does not remove all organisms but reduces them to a level that is not harmful to health. There are three levels of disinfection:
(A) high level disinfection--kills all organisms, except high levels of bacterial spores, and is effected with a chemical germicide cleared for marketing as a sterilant by the Food and Drug Administration;
(B) intermediate-level disinfection--kills mycobacteria, most viruses, and bacteria with a chemical germicide registered as a "tuberculocide" by the Environmental Protection Agency (EPA); and
(C) low-level disinfection--kills some virus and bacteria with a chemical germicide registered as a hospital disinfectant by the EPA.
~~(20) Documented midwife--A person who practices midwifery and is documented under the Texas Midwifery Act, Texas Occupations Code, Chapter 203.~~
(18) ~~(21)~~ Health care facility--Any type of facility or home and community support services agency licensed (or equivalent) to provide health care in any state or ~~is~~ certified for Medicare (Title XVIII) and Medicaid (Title XIX) participation in any state.
(19) ~~(22)~~ Hospital--A facility that is licensed under the Texas Hospital Licensing Law, Health and Safety Code, Chapter 241 or, if exempt from licensure, certified by the United States Department of Health and Human Services as in compliance with conditions of participation for hospitals in Title XVIII, Social Security Act (42 United States Code, §1395 et seq.).
(20) ~~(23)~~ Initial license--The first license that is issued to an applicant indicating that the center meets all requirements of this chapter for a license.
(21) ~~(24)~~ Licensed health care professional--An individual licensed in the state of Texas to provide specific health care services within a defined scope of practice by their licensing rules~~,~~ or Act.
(22) Licensed Midwife - A person who practices midwifery and is licensed under the Texas Midwifery Act, Texas Occupations Code, Chapter 203.

(23) ~~(25)~~ Licensed vocational nurse (LVN)--A person who is currently licensed under Texas Occupations Code, Chapters 301, 303, and 304 ~~Chapter 302~~ , as a licensed vocational nurse.
(24) ~~(26)~~ Low-risk pregnancy--A pregnancy that is determined by history, application of a risk assessment ~~criteria~~, and prenatal care that broadly predicts an outcome of a normal, uncomplicated pregnancy.
(25) ~~(27)~~ Midwife--A certified nurse midwife (CNM) or a Licensed Midwife ~~documented midwife~~.
(26) ~~(28)~~ Non-critical items--Items that come in contact with intact skin.
(27) ~~(29)~~ Notarized copy--A sworn affidavit stating that attached copies are true and correct copies of the original documents.
(28) ~~(30)~~ Person--An individual, firm, partnership, corporation, or association.
(29) ~~(31)~~ Physician--A person who is currently licensed under the Medical Practice Act, Texas Occupations Code, Chapters 151-165, to practice medicine.
(30) ~~(32)~~ Physician assistant (PA)--A person who is currently licensed under the Physician Assistant Licensing Act, Texas Occupations Code, Chapter 204, as a physician assistant.
(31) ~~(33)~~ Physician consultant--A physician who is currently licensed under the Medical Practice Act, Texas Occupations Code, Chapters 151-165, to practice medicine and who consults with a center.
(32) ~~(34)~~ Plan of correction--A written strategy for correcting a licensing violation. The plan of correction shall be developed by the facility and shall address the systems operations of the facility as the systems operations apply to the deficiency.
(33) ~~(35)~~ Policy--All center policies shall be in writing, dated and kept by the center for a minimum of five years. *(Marc please provide a definition for the word "policy".)*
(34) ~~(36)~~ Presurvey conference--A conference held with department staff and the applicant or his or her representatives to review licensure standards, survey documents, and provide consultation prior to the on-site licensure survey.
(35) ~~(37)~~ Quality assurance--An ongoing, objective, and systematic process of monitoring, evaluating, and improving the quality, appropriateness, and effectiveness of care.
(36) ~~(38)~~ Quality improvement--An organized, structured process that selectively identifies improvement projects to achieve improvements in products or services.
(37) ~~(39)~~ Referral hospital--A hospital that a center has identified as capable of providing care and services to ~~high-risk~~ mothers or infants who require the services of a physician.
(38) ~~(40)~~ Registered nurse (RN)--A person who is currently licensed under the Nurse Practice Act, Texas Occupations Code, Chapters 301 and 304 as a registered nurse.
(39) ~~(41)~~ Risk-assessment--A process by which application of historical, physical, and laboratory data is used for the prediction of pregnancy outcome.
(40) ~~(42)~~ Semi-critical items--Items that come in contact with nonintact skin or mucous membranes. Semi-critical items may include respiratory therapy equipment and thermometers.
(41) ~~(43)~~ Standards--Minimum requirements under the Act and this chapter.
(42) ~~(44)~~ Sterile field--The operative area of the body and anything that directly contacts this area.

(43) ~~(45)~~ Sterilization--The use of a physical or chemical procedure to destroy all microbial life, including bacterial endospores.
(44) ~~(46)~~ Survey--A survey or investigation conducted by a representative of the department to determine if a licensee is in compliance with the statute and this chapter. A survey may be conducted onsite, by mail, by telephone, or by electronic communication methods.
~~(47) Uncomplicated vaginal delivery - Spontaneous labor and delivery.~~

Subchapter D. Operational and Clinical Standards for the Provision and Coordination of Treatment and Services.

§137.31. Operational and Clinical Policies. A center shall develop, implement, and enforce written policies governing the center's total operation and ensure that these policies are administered so as to provide quality health services in a safe environment.

§137.32. Organizational Structure and Delegation of Authority.
(a) A center shall establish a written organizational structure which shall clearly define the lines of authority and the delegation of responsibility for professional and non-professional staff.
(b) The center shall appoint an administrator and a clinical director. The administrator and clinical director may be the same person and may be the owner.
(1) The administrator shall be responsible for implementing and supervising the operational policies of the center.
(2) The clinical director shall be responsible for implementing the clinical policies of the center.
(c) The owner of a center is responsible for ensuring total compliance with the Act and the provisions of this chapter.

§137.33. Personnel Policies. The center shall develop, implement, and enforce written policies governing all personnel staffed by the center. The personnel policies shall cover the following requirements:
(1) job descriptions for all personnel providing client care;
(2) orientation and training of all employees, volunteers, students and contractors;
(3) an annual written evaluation of employee performance;
(4) in-service ~~in service~~ and continuing education; and
(5) certification of all birth attendants by the American Heart Association or the American Red Cross in basic life support and the American Academy of Pediatrics or the American Heart Association in neonatal resuscitation.

§137.34. Qualifications and Duties of Staff.
(a) One person may act in the capacity of the administrator, the clinical director, and the birth attendant provided that person meets all the minimum qualifications set out in paragraphs (2)(A) and (3)(A) of this subsection and is capable of performing all of the duties specifically stated in paragraphs (1)(B), (2)(B), and (3)(B) of this subsection. The minimum qualifications and duties for the administrator, the clinical director, the birth

attendant, other clinical care providers and non-professional personnel of a center are as follows.
(1) Administrator.
(A) Qualifications.
(i) Shall not have been employed in the last year as an administrator with another center or health care facility at the time the center or facility was cited for violations of a licensing law or rule which resulted in enforcement action taken against the center or health related facility. For purposes of this clause only, the term "enforcement action" means license revocation, suspension, emergency suspension, or denial of a license or injunction action but does not include administrative or civil penalties.
(ii) Shall not have been convicted of a felony or misdemeanor listed in §137.22 of this title (relating to License Denial, Suspension, or Revocation).
(B) Duties.
(i) Administratively supervise the provision of services at the center.
(ii) Organize and direct the center's ongoing functions.
(iii) Employ qualified staff.
(iv) Ensure adequate education and evaluations of staff.
(v) Supervise non-professional staff.
(vi) Implement an effective budgeting and accounting system which must include an auditing system for monitoring state or federal funds. The administrator shall ensure all billings or insurance claims (e.g. Medicaid) submitted are accurate.
(vii) Ensure that issues and complaints relating to the conduct or actions by licensed health care professional(s) ~~and documented midwives~~ are addressed and if warranted, referred and reported to the appropriate board, and that such review and action taken is documented.
(viii) Administratively conduct or supervise the resolution(s) of complaint(s) received from clients in the delivery of their care or services received at the center.
(2) Clinical director.
(A) Qualifications. A licensed physician, a certified nurse-midwife (CNM), or a Licensed Midwife ~~documented midwife~~.
(B) Duties.
(i) Develop, implement, and monitor the clinical policies of a birthing center and ensure the adherence to these policies.
(ii) Advise and consult with the staff of the center on all matters relating to the clinical management of all clients.
(iii) Supervise all birth attendants and all other persons who provide direct client care.
(iv) Ensure the accuracy of public education information materials and activities in relation to pregnancy and birth, mother and newborn ~~infant~~ care, and the center.
(3) Birth attendant.
(A) Qualifications. A physician, certified nurse-midwife (CNM), or a Licensed Midwife ~~documented midwife~~.
(B) Duties. Responsible for the clinical care provided to clients of the center.
(4) Other Clinical Care Providers.
(A) Qualifications. Licensed, certified or trained appropriately for the care to be provided. Prior to providing direct client care the clinical director shall verify licensure, certification or competence. Shall be certified in CPR for health care providers.

(B) Duties. Provides care only under the supervision of a birth attendant in accordance with all laws, rules and policies appropriate to his or her professional scope of practice.
(5) Non-professional staff.
(A) Qualifications. Non-professional staff must be able to demonstrate the knowledge, skills, and abilities of their specified job duty within the center. This staff must be at least 16 years old.
(B) Duties. Responsible for the provision of non-clinical services such as housekeeping, laundry, and sanitation in the operation of the center.
(b) A center shall ensure that its birth attendants meet the following requirements.
(1) Licensed Midwives ~~Documented midwives~~ must be licensed ~~documented annually~~ in accordance with Texas Midwifery Act, Occupations Code, Chapter 203.
(2) Certified nurse midwives (CNM) must maintain certification as a CNM as defined in §137.2 of this title (relating to Definitions).
(3) Physicians must maintain current licensure as a physician as defined in §137.2 of this title (relating to Definitions).
(c) A center shall ensure that the personnel record for each employee includes
(1) job descriptions for all personnel providing client care;
(2) orientation and training of all employees, volunteers, students and contractors;
(3) an annual written evaluation of employee performance;
(4) in-service and continuing education;
(5) certification of all birth attendants by the American Heart Association or the American Red Cross in basic life support and the American Academy of Pediatrics or the American Heart Association in neonatal resuscitation; and
(6) verification of current licensure or a current copy of the license for licensed personnel.
~~:~~
~~(1) for licensed personnel, verification of current licensure or a current copy of the license; or~~
~~(2) a copy of required documentation which is issued by the department for documented midwives.~~

§137.36. Physical and Environmental Requirements for Centers. The physical and environmental requirements for a center are as follows.
(1) The center shall be located within a recommended 20 minutes but with a required maximum of 30 minutes normal driving time of a referral hospital. The department may approve the location of a center that is located a further distance away if the department finds that the health and safety of the clients of the center will not be adversely affected.
(2) The center must have the capacity to provide clients with liquid nourishment. The center may provide commercially packaged food to clients in individual servings. If other food is provided by the center, it will be subject to the requirements of §§229.161-229.173 of this title (relating to Food Service Sanitation).
(3) The center must have a safe and sanitary environment equipped and maintained to protect the health and safety of clients and staff.
(4) The center shall provide clean hand washing facilities for clients and staff including running water and soap.
(5) The center must have two functioning sinks and one toilet.

(6) The center must be equipped with emergency lighting and have a written fire and disaster plan.
(7) The center must have equipment available to sterilize instruments, equipment, and supplies before reuse in the center in accordance with §137.37 of this title (relating to Infection Control Standards).

§137.37. Infection Control Standards.
(a) A center shall develop, implement, and enforce written infection control policies and procedures to minimize the transmission of infection. Policies shall include educational course requirements; cleaning and laundry requirements; and decontamination, disinfection, sterilization, and storage of sterile supplies.
(b) Universal/standard precautions.
(1) Ensure that all staff comply with universal/standard precautions.
(2) Establish procedures for monitoring compliance with universal/standard precautions.
(3) Enforce a policy to ensure compliance of the center and all of the health care workers within the center with the Health and Safety Code, Chapter 85, Subchapter I, concerning the prevention of the transmission of HIV and HBV by infected health care workers.
(4) Require its health care workers to complete educational course work or training in infection control and barrier precautions, including basic concepts of disease transmission, scientifically accepted principles and practices for infection control and engineering and work practice controls.
(c) Cleaning and laundry.
(1) Adopt policies and procedures on cleaning the center.
(2) Adopt policies and procedures for the handling, processing, storing, and transporting of clean and dirty laundry.
(3) A center may provide cleaning and laundry services directly or by contract in accordance with Occupational Safety and Health Association standards.
(d) Policies shall include receiving, cleaning, decontaminating, disinfecting, preparing and sterilization of critical items (reusable items), as well as those for the assembly, wrapping, storage, distribution, and quality control of sterile items and equipment.
(1) Supervision. Shall be under the supervision of the clinical director.
(2) Quantity of sterile surgical instruments. Ensure that surgical instruments are sufficient in number to meet the needs of the center.
(3) Inspection of surgical instruments.
(A) All instruments shall undergo inspection before being packaged for reuse or storage. Routine inspection of instruments shall be made to assure clean locks, crevices, and serrations.
(B) Inspection procedures shall be thorough and include visual and manual inspection for condition and function.
(i) Cutting edges shall be checked for sharpness; tips shall be properly aligned, and instruments shall be clean and free from buildup of soap, detergent, dried blood, or tissue.
(ii) There shall be no evident cracks or fissures, and the hinges shall work freely.
(iii) There shall be no corrosion or pitting of the finish.
(iv) Rachets shall hold and be routinely tested.
(C) Instruments needing maintenance shall be taken out of service and repaired by a qualified surgical instruments repair person.

(D) Instrument identification shall not damage the instrument or its protective finish or compromise the sterilization process.
(4) Items to be disinfected and sterilized.
(A) Critical items.
(i) Must be sterilized in accordance with this subsection.
(ii) All items that come in contact with a ~~the~~ sterile field during an ~~the~~ operative procedure must be sterile.
(B) Semi-critical items. High-level disinfection shall be used for semi-critical items.
(C) Non-critical items. Intermediate-level or low-level disinfection shall be used for non-critical items.
(5) Equipment and sterilization procedures. Effective sterilization of instruments depends on performing correct methods of cleaning, packaging, arrangement of items in the sterilizer, and storage. The following procedures shall be included in the written policies as required in this paragraph to provide effective sterilization measures.
(A) Equipment. A center shall provide sterilization equipment adequate to meet the requirements for sterilization of critical items. Equipment shall be maintained and operated to perform, with accuracy, the sterilization of critical items.
(B) Environmental requirements. Where cleaning, preparation, and sterilization functions are performed in the same room or unit, soiled or contaminated supplies and equipment shall be physically separated from the clean or sterilized supplies and equipment.
(i) A center shall have a sink for hand washing. This sink shall not be used for cleaning instruments or disposal of liquid waste.
(ii) A center shall have a separate sink for cleaning instruments and disposal of liquid waste. Hand washing may only be performed at this sink after it has been disinfected.
(C) Preparation for sterilization.
(i) All items to be sterilized shall be prepared to reduce the bioburden. All items shall be thoroughly cleaned, decontaminated, and prepared in a clean, controlled environment.
(ii) One of the following methods of cleaning and decontamination shall be used as appropriate.
(I) Manual cleaning. Manual cleaning of instruments at the sink is permitted.
(II) Ultrasonic cleaning. The water must be changed more than once a shift. The chambers shall be covered to prevent potential hazards to personnel from aerosolization of the contents.
(III) Washer-sterilizers. These machines must reach a temperature of 140 degrees Celsius (285 degrees Fahrenheit).
(IV) Washer-decontaminator machines.
(iii) All articles to be sterilized shall be arranged so all surfaces will be directly exposed to the sterilizing agent for the prescribed time and temperature.
(D) Packaging.
(i) All wrapped articles to be sterilized shall be packaged in materials recommended for the specific type of sterilizer and material to be sterilized, and to provide an effective barrier to microorganisms. Acceptable packaging includes peel pouches, perforated metal trays, or rigid trays. Muslin packs must be limited in size to 12 inches by 12 inches by 20 inches with a maximum weight of 12 pounds. Wrapped instrument trays must not exceed 17 pounds.

(ii) All items shall be labeled for each sterilizer load as to the date and time of sterilization, the sterilizing load number, and the equipment ~~autoclave~~.
(E) External chemical indicators.
(i) External chemical indicators, also known as sterilization process indicators, shall be used on each package to be sterilized, including items being flash sterilized to indicate that items have been exposed to the sterilization process.
(ii) The indicator results shall be interpreted according to the manufacturer's written instructions and indicator reaction specifications.
(F) Biological indicators.
(i) The efficacy of the sterilizing process shall be monitored with reliable biological indicators appropriate for the type of sterilizer used.
(ii) Biological indicators shall be included in at least one run a month.
(iii) If a test is positive, the sterilizer shall immediately be taken out of service. A malfunctioning sterilizer shall not be put back into use until it has been serviced and successfully tested according to the manufacturer's recommendations.
(iv) All available items shall be recalled and reprocessed if a sterilizer malfunction is found; and a list of all items which were used after the last negative biological indicator test shall be submitted to the administrator.
(G) Sterilizers. Sterilizers shall be used according to manufacturer's written instructions.
(H) Maintenance of sterility.
(i) Items that are properly packaged and sterilized will remain sterile indefinitely unless the package becomes wet or torn, has a broken seal, is damaged in some way, or is suspected of being compromised.
(ii) All packages must be inspected before use. If a package is torn, wet, discolored, has a broken seal, or is damaged, the item may not be used. The item must be returned to sterile processing for reprocessing.
(I) Commercially packaged items are considered sterile according to the manufacturer's instructions.
(J) Storage of sterilized items. The loss of sterility is event-related, not time related. The center shall ensure proper storage and handling of items in a manner that does not aid the compromise of the packaging of the product.
(i) Sterilized items shall be transported so as to maintain cleanliness, sterility, and to prevent physical damage.
(ii) Sterilized items shall be stored in well-ventilated, limited access areas with controlled temperature and humidity.
(iii) Sterilized items shall be positioned so that the packaging is not crushed, bent, compressed, or punctured.
(iv) Storage of supplies shall be in areas that are designated for storage.
(K) Disinfection.
(i) The manufacturer's written instructions for the use of disinfectants shall be followed.
(ii) An expiration date, determined according to manufacturer's written recommendations, shall be marked on the container of disinfection solution currently in use.
(iii) Disinfectant solutions shall be kept covered and used in well ventilated areas.
(L) Performance records.
(i) Performance records for all sterilizers shall be maintained for each cycle. These records shall be retained and available for review for a minimum of two years.

(ii) Each sterilizer shall be monitored during operation for pressure, temperature, and time at desired temperature and pressure. A record shall be maintained either manually or machine generated and shall include:
(I) the sterilizer identification;
(II) sterilization date and time;
(III) load number;
(IV) duration and temperature of exposure phase;
(V) identification of operator(s);
(VI) results of biological tests and dates performed; and
(VII) time-temperature recording charts from each sterilizer.
(M) Preventive maintenance of all sterilizers shall be performed according to policy on a scheduled basis by qualified personnel, using the sterilizer manufacturer's service manual as a reference. A record shall be maintained for each sterilizer, retained at least two years, and shall be available for review.

§137.38. Disposition of Medical Waste. A center shall meet requirements set forth by the department in §§1.131-1.137 of this title (relating to Definition, Treatment, and Disposition of Special Waste from Health Care Related Facilities).
(1) All special waste including blood, body fluids, placentas, sharps and biological indicators, shall be disposed of in accordance with §§1.131 - 1.137 of this title.
(2) Placentas shall not be placed in the trash or dumpster for disposal.
(3) A center may give the placenta to the client at the time of discharge upon request by the client.

§137.39. General Requirements for the Provision and Coordination of Treatment and Services.
(a) A center shall develop, implement, and enforce policies for the provision and coordination of treatment and services.
(b) The center is responsible for all care provided to center clients on its licensed premise.
(c) ~~(b)~~ A center and the client shall have a written agreement for services. The center shall obtain an acknowledgment of receipt of the agreement. The center shall comply with the terms of the agreement. The written agreement shall include, the following:
(1) services to be provided;
(2) who will provide the services ~~supervision by the center of services provided~~; and
(3) charges for services rendered ~~if the charges will be paid in full or in part by the client or the client's family, or on request~~.
(d) ~~(c)~~ When services are provided through a contract, a center must assure that these services are also provided in a safe and effective manner. If a center utilizes independent contractors, there shall be a written agreement between such independent contractors (i.e., per hour, per visit) and the center. The agreement shall be enforced by the center and clearly designate:
(1) that clients are accepted for care only by the center;
(2) the services to be provided by both parties;
(3) the necessity to conform to the Act, this chapter, and all applicable center policies, including personnel qualifications; and
(4) the manner in which services will be coordinated and evaluated by the center.

(e) ~~(d)~~ A center shall not commit an intentional or negligent act that adversely affects the health or safety of a client.
(f) ~~(e)~~ A center must ensure that its licensed health care professionals ~~and documented midwives~~ practice within the scope of their practice and within the constraints of applicable state laws and regulations governing their practice and must follow the facility's written policies and procedures.
~~(f) A center that provides care or services to a client based upon laboratory, radiological, or ultrasonography reports or medical records from another state or country, shall have these reports and records reviewed by a licensed health care professional within his or her scope of practice. The clinical record shall contain evidence of the licensed health care professional's review of these reports and records and of any recommendations.~~
(g) A center may accept student midwives to provide them with ~~their~~ clinical experience ~~in accordance with the educational requirements as specified in Title 22 Texas Administrative Code, Chapter 831, Subchapter C (relating to Education)~~.
(h) If a center has a contract or agreement with an accredited school of health care to use their center for a portion of a students' clinical experience, those students may provide care under the following conditions.
(1) Students may be used in centers, provided the instructor gives classroom supervision and assumes responsibility for all student activities occurring within the center.
(2) A student may administer medications only if:
(A) on assignment as a student of their school of health care; and
(B) the birth attendant within their licensed scope of practice is on the premises and directly supervises the administration of medication by the student.
(3) Students shall not be considered when determining staffing needs required by the center.

§137.40. Risk Assessments.
(a) Risk assessment system. A center shall adopt, implement, and enforce a written risk assessment system that complies with this section, conforms to accepted standards of practice, and has been approved by the center's clinical director. The center shall apply the risk assessment system to clients prior to acceptance as a center client ~~admission~~ and throughout the pregnancy for continuation of services and during the postpartum period.
(b) Admission. A birth attendant shall perform the risk assessment of a potential client prior to accepting the client for admission and shall only admit a client that has been assessed to have a low-risk pregnancy.
(c) Change in risk status, transfer, and referral. Criteria for the assessment of a client who develops complications during pregnancy that would require the transfer or referral of the client or newborn ~~infant~~ from the center shall be reviewed and updated annually by the clinical director.
(1) The center shall recognize and document in the client's clinical record when the client's condition deviates from a low-risk pregnancy at any time during the antepartum, intrapartum, or postpartum period. The center shall refer or transfer the client to a hospital or physician consultant in accordance with the written policies described in paragraph (2) of this subsection.

(2) The center shall enforce policies for the transfer or referral of a client or newborn ~~infant~~ to a physician consultant or a referral hospital. The written policies shall include provisions:
(A) for transfer ~~or referral~~ to a hospital if emergency care is required;
(B) for notifying the receiving physician prior to the transfer;
(C) for notifying the receiving hospital prior to the transfer;
(D) for sending a copy of the clinical record to the hospital or physician consultant at the time of transfer; and
(E) describing the duties and responsibilities of staff during the transfer procedure.
(3) The center shall document the transfer or referral in the client's clinical record in accordance with §137.53(9)(Q) of this title (relating to Clinical Records).

§137.41. Emergency Services. The center shall provide emergency services to clients when a critical situation ~~period~~ develops at the center ~~during delivery~~.
(1) A center shall have an emergency call system for use when there is a critical situation ~~period~~. The center shall have available in the center personnel trained in cardiopulmonary resuscitation (CPR) to be available whenever there is a client in labor or during acute ~~immediately~~ postpartum period.
(2) A center shall provide emergency equipment and emergency medications as follows:
(A) oxygen;
(B) newborn ~~airways and~~ manual ~~infant~~ breathing bags;
(C) suction equipment for newborns;
(D) a neutral thermal environment for resuscitation; and
(E) other medications and equipment as approved by the clinical director.

§137.42. Disclosure Requirements.
(a) At the time of initial visit a center must provide the client, and if the client is a minor, his or her guardian:
(1) a written statement that complaints may be registered with the Manager ~~Director~~, Health Facility Compliance Group ~~Licensing and Compliance Division~~, Department of State Health Services ~~Texas Department of Health~~, 1100 West 49th Street, Austin, Texas 78756; telephone (888) 973-0022; (512) 834-6650; Fax (512) 834-6653; and
(2) a disclosure statement and informed consent that explains the benefits, limitations, and risks of the services available to the client, and that describes the collaborative arrangements that the center has with physicians and referral hospitals.
(b) A center shall ensure that its Licensed Midwives ~~documented midwives~~ meet the disclosure requirements in the Texas Midwifery Act, Texas Occupations Code, Chapter 203.

§137.43. Prenatal Care. When prenatal care is provided, the center shall comply with accepted standards of practice.

§137.44. Parenting and Postpartum Counseling.
(a) A birthing center that provides prenatal care to a pregnant woman during gestation or at delivery of an infant shall:

(1) provide the woman with a resource list of the names, addresses, and telephone numbers of professional organizations that provide postpartum counseling and assistance to parents;
(2) document in the patient's record that the patient received the information described in paragraph (1) of this subsection; and
(3) retain the documentation for at least three years in the birthing center records.
(b) The list must include resources a parent may contact to receive counseling and assistance for postpartum depression and other emotional traumas associated with pregnancy and parenting.
(c) A birthing center that provides prenatal care to a woman during gestation or at delivery is presumed to have complied with this section, if the woman received prior prenatal care from another birthing center, physician, or midwife in this state during the same pregnancy.

§137.46. Physician Consultant Procedures.
(a) A center shall adopt, implement, and enforce written procedures for consultation with physicians for clients who develop medical complications.
(b) A physician consultant shall be a Texas licensed physician, preferably who practices obstetrics and/or pediatrics, and who is readily available by telephone or who is able to be present in the center or hospital to deliver emergency care.

§137.47. Procedures for Drugs and Biologicals.
(a) Drugs and biologicals must be handled and stored in a safe and effective manner in accordance with written policies and procedures established by the center and state and federal laws.
(b) Drugs must be administered according to established written policies and procedures and accepted standards of practice, in accordance with state and federal laws.

§137.48. Labor and Birth Procedures.
(a) Labor and birth shall be managed and attended by a birth attendant.
(b) The birth attendant shall be trained in the use of emergency equipment.
(c) A center shall ensure that its birth attendants encourage a client to seek medical care if the birth attendant recognizes a sign or symptom of a complication to the client's childbirth.
(d) Other clinical care provider(s) and/or a birth attendant, shall be physically present in the center whenever a client is in the center until the client is discharged. The clinical care provider shall be capable of performing the following minimum duties:
(1) monitoring the fetal heartbeat;
(2) monitoring the mother's blood pressure, pulse, and temperature;
(3) performing adult and infant cardiopulmonary resuscitation, if needed;
(4) monitoring the newborn’s ~~infant's~~ heart rate, respiratory rate and body temperature; and
(5) assessing the client's fundus and blood loss.
(e) A birth attendant shall be physically present to conduct the delivery and be available during the acute postpartum period.
(f) Interventions shall be limited to those required to accomplish a vaginal delivery.

(g) No general, epidural, or subdural anesthetic agent shall be administered in a center.
~~(h) A center shall ensure that its documented midwives do not violate the labor and delivery provisions of the Texas Midwifery Act, Texas Occupations Code, Chapter 203, concerning prohibited acts and criminal penalties.~~

§137.49. Care of the Newborn ~~Infant~~. A center shall adopt, implement, and enforce written policies and procedures for the care of the newborn ~~infant~~. The clinical director shall review and revise the policies as necessary to reflect current practices. The policies shall include the following:
(1) resuscitation of the newborn;
(2) prophylactic treatment of the eyes;
(3) documentation of a physical examination of the newborn performed before discharge;
(4) referral for any abnormalities or problems;
(5) the collection of blood for newborn screening; and
(6) procedures for the detection of Rh and ABO isoimmunization.

§137.50. Discharge Procedures.
(a) The mother and newborn ~~infant~~ shall be discharged from the center when both are clinically stable and have met discharge criteria established by the center.
(b) The mother and newborn ~~infant~~ shall not be discharged prior to two hours from the time of placenta ~~birth~~.
(c) If the mother or newborn ~~infant~~ remain at the center for medical reasons for more than 24 hours after birth, a report shall be filed with the Manager, Department of State Health Services ~~Texas Department of Health~~, Health Facility Compliance Group ~~Licensing and Compliance Division~~, 1100 West 49th Street, Austin, Texas 78756. The report shall be filed within 48 hours after the birth describing the circumstances and reasons for the extended stay.
(d) A center must provide the mother with written discharge instructions. The discharge instructions must include written guidelines detailing how the mother may obtain emergency assistance for herself and newborn ~~infant~~.

§137.51. Postpartum and Postnatal Care of the Mother and Newborn ~~Infant~~. The center shall develop, implement, and enforce written policies to provide follow-up postnatal and postpartum care to the newborn ~~infant~~ and the mother either directly or by referral. Follow-up care may be provided in the center, at the mother's residence, by telephone, or by a combination of these methods in accordance with accepted standards of practice.

§137.52. Quality Assurance.
(a) Quality assurance program. The center shall adopt, implement, and enforce a written quality assurance (QA) program that includes all health and safety aspects of client care for both mother and newborn ~~infant~~.
(1) The quality assurance program shall include, but not be limited to:
(A) a review of the clinical record(s);
(B) incidences of morbidity and mortality of mother and newborn ~~infant~~;
(C) postpartum infections;

(D) all cases transferred to a hospital for delivery, care of newborn ~~infant~~, or postpartum care of mother;
(E) incidents, problems and potential problems identified by staff of the center, including infection control;
(F) address issues of unprofessional conduct by any member of the center's staff (including contract staff);
(G) address the integrity of surgical instruments, medical equipment, and patient supplies;
(H) address client referrals and consultations;
(I) address medication therapy practices, if applicable; and
(J) problems with compliance with any federal and state laws and rules.
(2) This program must be reviewed and updated or revised at least annually.
(3) The results of the quality assurance program must be reviewed and documented at least quarterly.
(b) Quality assurance issues. The center shall identify and address quality assurance issues and implement corrective action plans as necessary. The outcome of any corrective action plans shall be documented. The outcome of the remedial action shall be documented.
(c) Departmental review.
(1) A representative(s) of the department shall verify that the center has a quality assurance program which addresses quality concerns and that center staff know how to access that process.
(2) Attempts by the center to identify and correct deficiencies will not be used by the department as a basis for adverse action against the center.

§137.53. Clinical Records. The center must adopt, implement, enforce and maintain a clinical record system to assure that the care and services provided to each client is completely and accurately documented, and systematically organized to facilitate the compilation and retrieval of information. At the time of an onsite survey, all clinical records shall be readily retrievable for review within two hours of the request.
(1) For each client, a center may keep a single file or separate files for each stage of service provided to the client.
(2) The center shall have written procedures which are adopted, implemented, and enforced regarding the removal of records and the release of information. A center shall not release any portion of a client record to anyone other than the client except as allowed by law.
(3) All information regarding the client's care and services shall be centralized in the client's record and be protected against loss or damage.
(4) The center shall establish an area for client record storage at the center's place of business. The client record shall be stored at the place of business from which services are actually provided.
(5) The center shall ensure that each client's record is treated with confidentiality, safeguarded against loss and unofficial use, and is maintained according to professional standards of practice.
(6) The clinical record shall be an original, a microfilmed copy, an optical disc imaging system, or a certified copy. An original record includes manually signed paper records or

electronically signed computer records. Computerized records shall meet all requirements of paper records including protection from unofficial use and retention for the period specified in paragraph (10) of this section. Systems shall assure that entries regarding the delivery of care or services may not be altered without evidence and explanation of such alteration.
(7) Each entry to the client record shall be accurate, signed, and dated with the date of entry by the individual making the entry. Correction fluid or tape shall not be used in the record. Corrections shall be made by striking through the error with a single line and shall include the date the correction was made and the initials of the person making the correction.
(8) Inactive client records may be preserved and stored on microfilm, optical disc or other electronic means. Security shall be maintained and records must be readily retrievable by the center within two hours of a request for a record(s) by the department.
(9) The clinical record must contain the following:
(A) client identifying information;
(B) name of the client's birth attendant(s) and the name of all other clinical care providers;
(C) initial risk assessment;
(D) a disclosure statement and informed consent that is signed by a client that explains the benefits, limitations, and risks of the services available to them at the center, and that describes the collaborative arrangements that the center has with physicians and with referral hospitals;
(E) the informed choice agreement ~~disclosure statement~~ required to be given a client by a Licensed Midwife ~~documented midwife~~, if applicable;
(F) record of antepartum (prenatal) care;
(G) history and physical examination of the clients;
(H) laboratory procedures;
(I) progress notes shall be written, signed and dated by the person rendering the service on the day service is rendered and incorporated into the client record on a timely basis;
(J) medication list and medication administration record, if applicable;
(K) intrapartum care;
(L) newborn ~~infant~~ care;
(M) postpartum care;
(N) allergies and medication reactions;
(O) documentation for consultation;
(P) refusal of the client to comply with advice or treatment;
(Q) discharge summary~~, including the reason for discharge or transfer and the center's documented notice to the client or the client's guardian and the client's physician~~; ~~and~~
(R) documentation of client transfers or referrals if applicable; and
(S) ~~(R)~~ documentation that:
(i) a birth certificate was filed; or
(ii) if applicable, a death certificate was filed.
(10) A center shall retain original client records for a minimum of five years after the discharge of the client. The center may not destroy client records that relate to any matter that is involved in litigation if the center knows the litigation has not been finally resolved.

(11) If a center closes, there shall be an arrangement for the preservation of inactive records to ensure compliance with this section. The center shall send the department written notification of the reason for closure, the location of the client records and the name and address of the client record custodian. If a center closes with an active client roster, a copy of the active client record shall be transferred with the client to the receiving center or other health care facility in order to assure continuity of care and services to the client.

§137.54. Reporting and Filing Requirements.
(a) Reportable conditions and incidents.
(1) A center shall report communicable diseases required to be reported under the Health and Safety Code, §81.042, and in accordance with the department's rules under §§97.2-97.5 of this title (relating to Control of Communicable Diseases).
(2) The following incidents shall be reported to the department in writing, by mail, or fax within five calendar days of the occurrence to the Manager ~~director~~ of Health Facility Compliance Group ~~Licensing and Compliance Division~~, Department of State Health Services ~~Texas Department of Health~~, 1100 West 49th Street, Austin, Texas 78756:
(A) a death of a client, newborn ~~infant~~, or death of a fetus during the course of labor occurring in the center; and
(B) a death of a client or newborn ~~infant~~ occurring within 24 hours of discharge from the center or transfer to another health care facility.
(b) Birth certificate filing requirements.
(1) A center administrator or his or her designee shall:
(A) file a birth certificate for each birth at the center; or
(B) ensure that its birth attendants file the birth certificate in accordance with the Health and Safety Code, §192.003.
(2) A center administrator, his or her designee, or any of its birth attendants shall comply with Health and Safety Code, §195.003 and §195.004.
(c) Death certificate filing requirements. A center administrator or birth attendant shall file a death certificate in accordance with subsection (a)(2) of this section.
(d) Data collection for birth defects. If the department ~~Board of Health (board)~~ requires data collection concerning birth defects under the Health and Safety Code, §87.022, the center or its birth attendants shall make available for review by the department or by an authorized agent clinical records or other information that are in the center's or birth attendant's custody or control and that relate to the occurrence of a birth defect specified by the board.

§137.55. Other State and Federal Compliance Requirements.
(a) A center utilizing the services of a Licensed Midwife ~~documented midwife~~ shall ensure that its Licensed Midwife(ives) ~~documented midwife(ives)~~ does not violate the Texas Midwifery Act, Texas Occupations Code, Chapter 203, concerning prohibited acts and criminal penalties, while functioning in his or her capacity at or for the center.
(b) A center shall ensure that its Licensed Midwives ~~documented midwives~~ comply with Title 22 Texas Administrative Code, Chapter 831 (relating to Midwifery), while functioning in his or her capacity at or for the center.

(c) A center that provides laboratory services shall meet the Clinical Laboratory Improvement Amendments of 1988, 42 United States Code, §263a, Certification of Laboratories (CLIA 1988). CLIA 1988 applies to all centers with laboratories that examine human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. If a center accepts laboratory test results from another state or foreign country, such as Mexico, the laboratory documents must be reviewed and approved by a licensed health professional within his or her scope of practice.
(d) A center utilizing the services of a registered nurse(s) shall ensure that its registered nurse(s) comply with the Nursing Practice Act, Texas Occupations Code, Chapters 301, 303, and 304, while functioning in his or her capacity at or for the center.
(e) A center utilizing the services of a licensed vocational nurse(s) shall ensure that its licensed vocational nurse(s) comply with Texas Occupations Code, Chapters 301 ~~302~~, 303, and 304, while functioning in his or her capacity at or for the center.
(f) A center utilizing the services of a physician(s) shall ensure that its physician(s) comply with the Medical Practice Act, Texas Occupations Code, Chapters 151-165, while functioning in his or her capacity at or for the center.
(g) A center utilizing the services of a physician assistant(s) shall ensure that its physician assistant(s) comply with the Physician Assistant Licensing Act, Texas Occupations Code, Chapter 204, while functioning in his or her capacity at or for the center.
(h) A center that provides pharmacy services shall obtain a license as a pharmacy if required by the Texas Pharmacy Act, Texas Occupations Code, Chapters 551-569.
~~(i) A center shall comply with the following federal Occupational Safety and Health Administration requirements:~~
~~(1) 29 Code of Federal Regulations, Subpart E, §1910.38, concerning employee emergency plans and fire prevention plans;~~
~~(2) 29 Code of Federal Regulations, Subpart I, §1910.132, concerning general requirements for personal protective equipment;~~
~~(3) 29 Code of Federal Regulations, Subpart I, §1910.133, concerning eye and face protection;~~
~~(4) 29 Code of Federal Regulations, Subpart I, §1910.138, concerning hand protection;~~
~~(5) 29 Code of Federal Regulations, Subpart L, §1910.157, concerning portable fire extinguishers;~~
~~(6) 29 Code of Federal Regulations, Subpart Z, §1910.1030, concerning blood borne pathogens; and~~
~~(7) 29 Code of Federal Regulations, Subpart Z, §1910.1200, Appendices A-E, concerning hazard communication (hazardous use of chemicals).~~
~~(8) 29 Code of Federal Regulations, Subpart K, §1910.151, concerning medical services and first aid.~~ *(Comment: These areas are addressed above under infection control universal/standard precautions. Other licensed facility types do no require compliance in this much detail.)*
(j) A center shall not use adulterated or misbranded drugs or devices in violation of the Health and Safety Code, §431.021. Adulterated drugs and devices are described in Health and Safety Code, §431.111. Misbranded drugs or devices are described in Health and Safety Code, §431.112.
(k) A center shall not commit a false, misleading, or deceptive act or practice as that term is defined in the Deceptive Trade Practices-Consumer Protection Act, Business and Commerce Code, §17.46.

(l) A birthing center must provide voluntary paternity establishment services in accordance with:
(1) the Health and Safety Code, §192.012, Record of Acknowledgment of Paternity; and
(2) the rules of the Office of the Attorney General found at 1 Texas Administrative Code, Chapter 55, Subchapter J (relating to Voluntary Paternity Acknowledgment Process).
(m) A birthing center shall comply with Health and Safety Code, Chapter 47, relating to Hearing Loss in Newborns.
(n) A center shall ensure that its birth attendants comply with Health and Safety Code, §81.090 (relating to serologic testing during pregnancy). The center shall ensure that the results of any HIV test are kept confidential pursuant to the Health and Safety Code, §81.103.
(o) A center shall ensure that its birth attendants comply with the Health and Safety Code, §81.091, (relating to ophthalmia neonatorum prevention).
(p) A center shall ensure that its birth attendants cause the newborn screening tests to be performed as required by:
(1) the Health and Safety Code, §33.011 (relating to Test Requirement); and
(2) Texas Occupations Code, §203.354 (relating to Newborn Screening).

(Items highlighted in yellow need to be checked for accuracy. Items ~~struck through~~ and new language in blue were recommendations made by stakeholders during the Birthing Center Rules Stakeholder Group Meeting 2 12 2007.)