DEPARTMENT OF
STATE HEALTH SERVICES
REGULATORY LICENSING GROUP
FACILITY LICENSING GROUP

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CHAPTER 137
BIRTHING CENTER
LICENSING RULES

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BIRTHING CENTER LICENSING RULES
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Subchapter A. General Provisions.

§137.1. Purpose and Scope.

(a) The purpose of this chapter is to implement the Texas Birthing Center Licensing Act, Health and Safety Code, Chapter 244, which requires birthing centers (centers) to be licensed by the Department of State Health Services (department) and requires the department to adopt rules governing the licensing and regulation of centers.

(b) This chapter establishes general provisions, licensing procedures, enforcement, and operational and clinical standards for the provision and coordination of treatment and services.

(c) This chapter applies to all centers as defined in §137.2 of this title (relating to Definitions). Such centers must be licensed in accordance with the provisions of this chapter. A person may not engage in the business of providing center services, or represent to the public that the person is a provider of such services for pay or other consideration without a license.

§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) Admission--A client that is accepted by the center after a risk assessment is performed.

(5) 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.

(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.

(7) Birth attendant--A physician, certified nurse-midwife (CNM), or a licensed midwife.

(8) Center--A facility, place, or institution where a woman is scheduled to give birth. This term does not include a hospital, ambulatory surgical center, a nursing home, or the residence of the woman giving birth.

(9) 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, 303 and 304;

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

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

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

(11) Clinical care--Direct provision of care to center clients.

(12) 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 by performing the minimum duties set out in §137.48(d) of this title (relating to Labor and Birth Procedures).

(13) 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.

(14) Critical item--All surgical instruments and objects that are introduced directly into the bloodstream or into other normally sterile areas of the body.

(15) Decontamination--The physical and chemical process that renders an inanimate object safe for further handling.

(16) Department--The Department of State Health Services.

(17) 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.

(18) 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 certified for Medicare (Title XVIII) and Medicaid (Title XIX) participation in any state.

(19) 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) 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) 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) Licensed premises--The location stated or described in the application that is licensed by the department.

(24) Licensed vocational nurse (LVN)--A person who is currently licensed under the Nurse Practice Act, Texas Occupations Code, Chapters 301, 303, and 304, as a licensed vocational nurse.

(25) Low-risk pregnancy--A pregnancy that is determined by history, application of a risk assessment, and prenatal care that broadly predicts an outcome of a normal, uncomplicated pregnancy.

(26) Manager--The manager of the Facility Licensing Group of the Department of State Health Services or his or her designee.

(27) Midwife--A certified nurse-midwife (CNM) or a licensed midwife.

(28) Noncritical items--Items that come in contact with intact skin.

(29) Notarized copy--A sworn affidavit stating that attached copies are true and correct copies of the original documents.

(30) Person--An individual, firm, partnership, corporation, or association.

(31) Physician--A person who is currently licensed under the Medical Practice Act, Texas Occupations Code, Chapters 151-165, to practice medicine.

(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.

(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.

(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.

(35) Policy--A written document which describes all procedures to be followed at the facility including medical and personnel issues which is to be maintained at the licensed premises for a minimum of five years.

(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.

(37) Quality assurance--An ongoing, objective, and systematic process of monitoring, evaluating, and improving the quality, appropriateness, and effectiveness of care.

(38) Quality improvement--An organized, structured process that selectively identifies improvement projects to achieve improvements in products or services.

(39) Referral hospital--A hospital that a center has identified as capable of providing care and services to mothers or infants who require the services of a physician.

(40) Registered nurse (RN)--A person who is currently licensed under the Nurse Practice Act, Texas Occupations Code, Chapters 301, 303, and 304 as a registered nurse.

(41) Risk-assessment--A process by which application of historical, physical, and laboratory data is used for the prediction of pregnancy outcome.

(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.

(43) Standards--Minimum requirements under the Act and this chapter.

(44) Sterile field--The operative area of the body and anything that directly contacts this area.

(45) Sterilization--The use of a physical or chemical procedure to destroy all microbial life, including bacterial endospores.

(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.

§137.3. Licensing Fees.

(a) The schedule of fees for a license is as follows:

(1) initial license fee is $2,000;

(2) renewal license fee is $2,000; and

(3) change of ownership license fee is $2,000.

(b) The department will not consider an application as officially submitted until the applicant pays the licensing fee. The fee must accompany the application form.

(c) A license fee paid to the department is not refundable.

(d) Any remittance submitted to the department in payment of a required license fee must be in the form of a personal check, certified check, or money order made payable to the Department of State Health Services.

(e) For all renewal licenses, the department is authorized to collect subscription and convenience fees, in amounts determined by the TexasOnline Authority, to recover costs associated with renewal processing through TexasOnline, in accordance with Texas Government Code, §2054.111.

(f) The department may make periodic reviews of its license fee schedule to ensure that the fees imposed are in amounts reasonable and necessary to defray the cost to the department of administering the Act.

§137.4. General Provisions for Licensure.

(a) All first-time applications for a license are applications for an initial license.

(b) The applicant must be at least 18 years of age.

(c) A separate license is required for each place of business.

(d) A center may not admit a client in labor until it has received an initial license.

(e) The licensed location must be in Texas.

(f) The owner of the center is responsible for ensuring the center's compliance with the Act and this chapter.

(g) A license must be renewed biannually.

(h) The license shall be displayed in a public area of the center that is readily accessible to patients, employees and visitors.

(i) The license may not be transferred or assigned from one person to another person.

(j) A center shall have the financial ability to carry out its functions under the Act and this chapter.

Subchapter B. Licensing Procedures.

§137.11. Application Procedures and Issuance of Licenses.

(a) The application.

(1) An applicant shall not misstate a material fact on any documents required to be submitted under this subsection.

(2) The application form must be accurate and complete and must contain original signatures. The nonrefundable license fee must be submitted with the application.

(3) The following information must be submitted on the original application form and the application shall be notarized:

(A) information on the applicant including name, street address, mailing address, social security number or federal tax identification number, and if applicable, date of birth and driver's license number;

(B) the name, mailing address, and street address of the center. The street address provided on the application must be the address from which the center will be operating and providing services;

(C) a list of names and business addresses of all persons who own any percentage interest in the applicant including:

(i) each limited partner and general partner if the applicant is a partnership; and

(ii) each shareholder, member, director, and officer if the applicant is a corporation, limited liability company or other business entity;

(D) a list of any businesses with which the applicant subcontracts and in which the persons listed under subparagraph (C) of this paragraph hold any percentage of the ownership;

(E) if the applicant has held or holds a center license or has been or is an affiliate of another licensed center, the relationship, including the name and current or last address of the other center and the date such relationship commenced and, if applicable, the date it was terminated;

(F) if the center is operated by or proposed to be operated under a management contract, the names and addresses of any person and organization having an ownership interest of any percentage in the management company;

(G) a written plan for the orderly transfer of care of the applicant's clients and clinical records if the applicant is unable to maintain services under the license;

(H) the organizational structure of the staffing for the center;

(I) the names and addresses of the physicians, certified nurse-midwives, licensed midwives and other clinical care providers who will provide services at the center;

(J) the following data concerning the applicant, the applicant's affiliates, and the managers of the applicant:

(i) any orders of denial, suspension, or revocation of a center license, a license for any health care facility in any state, or documentation as a midwife; or any other enforcement action, such as (but not limited to) court civil or criminal action;

(ii) any orders of denial, suspension, or revocation of or other

enforcement action against a center license, a license for any health care facility in any state, or documentation as a midwife which is or was proposed by the licensing agency and the status of the proposal;

(iii) surrendering a license before expiration of the license or allowing a license to expire in lieu of the department proceeding with enforcement action;

(iv) federal or state (any state) criminal felony arrests or convictions;

(v) federal or state Medicaid or Medicare sanctions or penalties relating to the operation of a health care facility;

(vi) operation of a health care facility that has been decertified in any state under Medicare or Medicaid; or

(vii) debarment, exclusion, or contract cancellation in any state from Medicare or Medicaid;

(K) for the two-year period preceding the application date, the following data concerning the applicant, the applicant's affiliates, and the managers of the applicant:

(i) federal or state (any state) criminal misdemeanor arrests or convictions;

(ii) federal or state (any state) tax liens;

(iii) unsatisfied final judgement(s);

(iv) eviction involving any property or space used as a center or health care facility in any state;

(v) injunctive orders from any court; or

(vi) unresolved final state or federal Medicare or Medicaid audit exceptions; and

(L) the telephone number, and fax number (if available) of the center and the telephone number where the administrator can usually be reached when the center is closed.

(b) Applicant copy. The applicant shall retain a copy of all documentation that is submitted to the department.

(c) Application processing. Upon the department's receipt of the application form, the required information described in subsection (a)(3) of this section, and the initial license fee from

an applicant, the department shall review the material to determine whether it is complete and correct.

(1) The time periods for reviewing the material shall be in accordance with §137.13 of this title (relating to Time Periods for Processing and Issuing a License).

(2) If a center receives a notice from the department that some or all of the information required under subsection (a)(3) of this section is deficient, the center shall submit the required information no later than 60 calendar days from the date of the notice.

(A) A center which fails to submit the required information within 60 calendar days from the notice date is considered to have withdrawn its application for an initial license. The license fee will not be refunded.

(B) A center which has withdrawn its application must reapply for a license in accordance with this section, if it wishes to continue the application process. A new license fee is required.

(d) Withdrawal of application process. If an applicant decides at any time not to continue the application process for an initial license, the application will be withdrawn upon written request from the applicant. The license fee will not be refunded.

(e) Issuance of an initial license and renewal procedures.

(1) Presurvey conference. Once the department has determined that the application form, the information required to accompany the application form, and the license fee are complete and correct, a representative from the department shall schedule a presurvey conference with the applicant in order to inform the applicant of the standards for the operation of the center. The presurvey conference may be waived by the department.

(2) Survey recommendation.

(A) The survey office shall verify compliance with the applicable provisions of the Act and this chapter and recommend that the center be issued an initial license or that the application be denied pursuant to §137.22 of this title (relating to License Denial, Suspension, Probation, or Revocation).

(B) Upon recommendation by the survey office:

(i) the department shall issue an initial license to an applicant that has been found to be in compliance with the provisions of the Act and this chapter; or

(ii) the department shall deny the application if the center has been found to be out of compliance with the provisions of the Act and this chapter. The procedure for denial of a license shall be in accordance with §137.22 of this title.

(3) Effective period of initial license. The initial license is valid for 24 months. The initial license expires on the last day of the month ending the licensure period.

(4) General requirements during the initial license period.

(A) A center shall comply with the provisions of the Act and this chapter during the initial license period.

(B) If an applicant decides not to continue the application process, the application will be withdrawn upon written request. If an initial license has been issued, the applicant shall cease providing services and return the original license certificate to the department with its written request to withdraw. The department shall acknowledge receipt of the request to withdraw. The license fee will not be refunded.

(f) Procedures for renewing a license.

(1) The department will send notice of expiration to a licensee at least 60 calendar days before the expiration date of a license. If the licensee has not received notice of expiration from the department 45 calendar days prior to the expiration date, it is the duty of the licensee to notify the department and request a renewal form.

(2) The licensee shall submit the renewal form to the department postmarked no later than 30 calendar days prior to the expiration date of the license:

(A) a complete and correct renewal form which includes updated disclosure information and ownership and management information as required by subsection (a)(3) of this section; and

(B) the renewal license fee.

(3) The time periods for processing an application shall be in accordance with §137.13 of this title.

(4) If timely and sufficient application is made for renewal, the license will not expire until the department issues the license or until the department denies renewal of the license.

(5) The department shall issue a renewal license to a licensee who meets the minimum standards for a license in accordance with the provisions of the Act and this chapter.

(6) Renewal licenses will be valid for 24 months.

(g) Failure to timely renew.

(1) General.

(A) If a licensee fails to submit a timely and sufficient renewal form and fee in accordance with subsection (f) of this section, the department shall notify the licensee that the center must cease operation on the expiration date of the license.

(B) No services shall be provided at the center after the expiration of the license.

(2) Active military duty exception. If a licensee fails to timely renew his or her license because the licensee is or was on active duty with the armed forces of the United States of America serving outside the State of Texas, the licensee may renew the license pursuant to this paragraph.

(A) Renewal of the license may be requested by the licensee, the licensee's spouse, or an individual having power of attorney from the licensee. The renewal form shall include a current address and telephone number for the individual requesting the renewal.

(B) Renewal may be requested before or after the expiration of the license.

(C) A copy of the official orders or other official military documentation showing that the licensee is or was on active military duty serving outside the State of Texas shall be filed with the department along with the renewal form.

(D) A copy of the power of attorney from the licensee shall be filed with the department along with the renewal form if the individual having the power of attorney executes any of the documents required in this section.

(E) A licensee renewing under this paragraph shall pay the applicable renewal fee.

(F) A licensee is not authorized to operate the center for which the license was obtained after the expiration of the license unless and until the licensee actually renews the license.

(G) This paragraph applies to a licensee who is a sole practitioner or a partnership with only individuals as partners where all of the partners were on active duty with the armed forces of the United States serving outside the State of Texas.

(h) General requirements for renewal of license.

(1) After the issuance of the initial license, a licensee is eligible for subsequent renewal of the license biannually if the licensee continues to comply with the provisions of the Act and this chapter and has applied for renewal of the license in accordance with subsection (f) of this section.

(2) If a licensee makes a timely and sufficient application for renewal of a license, and an action to revoke, suspend, or deny renewal of the license is pending, the license does not

expire but does extend until the application for renewal is granted or denied after the opportunity for a formal hearing. A renewal license will not be issued unless the department has determined the reason for the proposed action no longer exists.

(3) Continuing compliance by the center with the provisions of the Act and this chapter is required during the previous 24-month license period in order for the license to be renewed.

(4) The licensee shall not misstate or omit a material fact on any documents required to be submitted to the department or required to be maintained by the center in accordance with the provisions of the Act and this chapter.

(5) During the license period, the center shall provide services to one or more clients and document the provision of services. The center must show proof that services have been provided under the license within the previous 24 months. Such documentation shall be available for review by a department surveyor.

(6) If a licensee decides not to continue the application process for the renewal of a license, the application may be withdrawn upon written request. The applicant shall cease providing services and return the original license certificate to the department with its written request to withdraw. The department shall acknowledge receipt of the request to withdraw. The license fee will not be refunded.

(i) On-site surveys. On-site surveys of the center shall be performed at a frequency prescribed by and in accordance with §137.21 of this title (relating to On-Site Surveys).

§137.12. Change of Ownership or Services and Closure.

(a) The following provisions apply to a change of ownership of a center and affect the condition of a license.

(1) A license is not transferable or assignable from one person to another person.

(2) A license issued by the department may not be materially altered in any way.

(3) A change of ownership of a center is effective when the name of the licensed person reflected on the license certificate and original application is changed by the department to reflect the name of the person applying for the change of ownership.

(4) A person who desires to receive a license in its name for a center licensed under the name of another person or to change the ownership of any center shall submit a new license application and the initial license fee at least 60 calendar days prior to the desired date of the change of ownership. The application shall be in accordance with §137.11(a) of this title (relating to Application Procedures and Issuance of Licenses).

(5) An application for a change of ownership shall include a notarized affidavit signed by the previous owner acknowledging agreement with the change of ownership. If the applicant is a corporation, the application shall include a copy of the applicant's articles of incorporation. If the applicant is a business entity other than a corporation, the applicant shall include a copy of the sales agreement.

(6) The previous owner's license shall be void on the effective date of the change of ownership.

(7) This subsection does not apply if a licensee is simply revising its name as allowed by law (i.e., a corporation is amending the articles of incorporation to revise its name).

(8) The sale of stock of a corporate licensee does not cause this subsection to apply.

(b) The following business changes affect the condition of a license and shall be reported to the department.

(1) If a center changes its business name, business address, telephone number of the center, administrator's telephone number, or fax number, the administrator must notify the department in writing within 15 calendar days after the effective date of the change.

(2) If a center changes its administrator, the center shall provide the name of the new administrator and effective date to the department in writing no later than 30 calendar days following such change.

(c) The licensee shall notify the department in writing within 15 calendar days when a center ceases operation. The licensee shall return the original license certificate to the department with the written notification.

§137.13. Time Periods for Processing and Issuing a License.

(a) Definition. For purposes of this section, license means a license, permit, registration, or certificate issued by the Department of State Health Services (department) for a birthing center.

(b) General. Time periods for processing and issuing a license.

(1) The date a license application is received is the date the application reaches the Facility Licensing Group of the Department of State Health Services (department).

(2) An application for an initial license is complete when the department has received, reviewed, and found acceptable the information described in §137.11(a)(3) of this title (relating to Application Procedures and Issuance of Licenses).

(3) An application for a renewal license is complete when the department has received, reviewed, and found acceptable the information described in §137.11(f)(2) of this title.

(4) An application for a change of ownership license is complete when the department has received, reviewed, and found acceptable the information described in §137.12 of this title (relating to Change of Ownership or Services and Closure).

(c) Time periods. An application from a center for an initial license, renewal license, or change of ownership license shall be processed in accordance with the following time periods.

(1) The first time period begins on the date the department receives the application and ends on the date the license is issued, or if the application is received incomplete, the period ends on the date the center is issued a written notice that the application is incomplete. The written notice shall describe the specific information that is required before the application is considered complete. The first time period is 45 calendar days.

(2) The second time period is 45 calendar days, which begins on the date the last item (information or fee) necessary to complete the application is received by the department and ends on the date the license is issued, or the facility is issued a written notice that the application is being proposed for denial.

(3) If the applicant fails to submit the requested information and/or fee within 135 days of the date the department issued the written notice to the applicant as described in paragraph (1) of this subsection, that the application is incomplete and/or additional fees are owed, the application is considered withdrawn. Fees paid are not refundable. There will be no refund of the fee except as provided by subsections (d) and (f) of this section. A new application and fee must be submitted to the department.

(d) Reimbursement of fees.

(1) In the event the application is not processed in the time periods stated in subsection (c) of this section, the applicant has the right to make a written request within 30 days of the end of the second period that the department reimburse in full the fee paid in that particular application process.

(2) If the department finds that good cause existed for exceeding the established periods, the request will be denied. The department will notify the applicant in writing of the denial of the reimbursement within 30 days of the department's receipt of the request for reimbursement.

(e) Good cause for exceeding the period established is considered to exist if:

(1) the number of applications for licenses to be processed exceeds by 15% or more the number processed in the same calendar quarter the preceding year;

(2) another public or private entity utilized in the application process caused the delay;

(3) conditions in violation of the rules exist which are noted in recent investigations or inspections;

(4) the application is being held pending completion of an investigation, inspection, or enforcement action;

(5) the application is incomplete in information, signature, and/or fee amount submitted; or

(6) other conditions existed giving good cause for exceeding the established periods.

(f) Appeal. If the request for reimbursement as authorized by subsection (d)(1) of this section is denied, the applicant may, within 30 days of being notified of the denial, appeal to the department for a resolution of the dispute. The applicant shall give written notice to the department requesting reimbursement of the fee paid because the application was not processed within the established time period. Within 30 days of receiving the appeal, the department shall submit a written report to the commissioner of the facts related to the processing of the application and describing the good cause for exceeding the established time periods. The commissioner then has 30 days to make the final decision and provide written notification of the decision to the applicant and the manager.

(g) Hearings shall be conducted under the provision of contested case hearings pursuant to the Fair Hearing Procedures found in §§1.51-1.55 of this title.

Subchapter C. Survey Procedures and Enforcement.

§137.21. On-Site Surveys.

(a) Requirement for on-site surveys. A representative of the department may enter the premises of a license applicant or license holder at reasonable times to conduct a survey incidental to the issuance of a license, and at other times as it considers necessary to ensure compliance with the Act and the rules adopted under the Act.

(b) Initial on-site survey.

(1) The department shall conduct the on-site survey within 90 calendar days of the date of issuance of the initial license to determine if the center meets the requirements of the Act and this chapter.

(2) The on-site survey shall include a standard-by-standard evaluation.

(3) At the time of the initial on-site survey, the center shall assure that the administrator or his or her designee(s) is present during the survey.

(4) If at the time of the initial on-site survey, the center has not admitted its first client for antepartum, intrapartum, or postpartum care, the center must notify the Manager, Health Facility Compliance Group, Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756, when the first such admission and care delivery does occur.

(A) Within seven calendar days of the first client admission, the center shall submit a copy of the clinical record to the department for review.

(B) The department shall review the clinical record(s) to evaluate the center's compliance with the care delivery standards of this chapter.

(5) Upon completion of the on-site survey, a department surveyor shall verify a center's compliance with the provisions of the Act and this chapter and recommend to the department:

(A) that the center's initial license be continued for the duration of the initial license period; or

(B) that the department propose an enforcement action.

(c) Subsequent on-site surveys. After the initial on-site survey that is required for an initial license under subsection (b) of this section, an on-site survey shall be performed at least every three years with the following exceptions.

(1) If the department has written deficiencies for the center under the following provisions of this chapter, that may pose a threat to the health and safety of the center's clients and/or staff, the department shall conduct another on-site survey no later than one year after issuance of the initial or renewal license:

(A) §137.31 of this title (relating to Operational and Clinical Policies);

(B) §137.32 of this title (relating to Organizational Structure and Delegation of Authority);

(C) §137.33(4) and (5) of this title (relating to Personnel Policies);

(D) §137.34 of this title (relating to Qualifications and Duties of Staff);

(E) §137.36 of this title (relating to Physical and Environmental Requirements for Centers);

(F) §137.37 of this title (relating to Infection Control Standards);

(G) §137.38 of this title (relating to Disposition of Medical Waste);

(H) §137.39 of this title (relating to General Requirements for the Provision and Coordination of Treatment and Services);

(I) §137.40 of this title (relating to Risk Assessments);

(J) §137.41 of this title (relating to Emergency Services);

(K) §137.48 of this title (relating to Labor and Birth Procedures);

(L) §137.49 of this title (relating to Care of the Newborn);

(M) §137.50 of this title (relating to Discharge Procedures); and

(N) §137.55 of this title (relating to Other State and Federal Compliance Requirements).

(2) If the department has taken enforcement action against a center and the action allowed the center to remain licensed, the department shall conduct another on-site survey.

(3) This subsection does not limit complaint surveys by the department.

(d) Survey procedures.

(1) Prior to the survey, the department may notify the applicant or licensee, in writing by fax or mail to the mailing address of the center, of the date and time of the survey. The department is not required to notify the applicant or licensee prior to a complaint investigation.

(2) At the start of the survey, the department's surveyor shall notify the person who is in charge of a center of the nature and scope of the survey.

(3) Except for a complaint investigation or a follow-up visit, a survey will include a standard-by-standard evaluation.

(4) When the survey is completed, the surveyor shall hold an exit conference and fully inform the person who is in charge of the center of the preliminary findings of the survey and shall give the person a reasonable opportunity to submit additional facts or other information to the surveyor in response to those findings. A written response may be filed and must be received by the department within 14 calendar days of receipt of the preliminary findings of the survey by the center. The surveyor shall identify any records that were duplicated. Any original center records that are removed from a center shall be removed only with the consent of the center.

(5) After the survey is completed, the department shall provide the administrator of the center specific and timely written notice of the findings of the survey within 14 calendar days of the exit conference.

(6) If the department determines that the center is in compliance with minimum standards at the time of the on-site inspection, the department will send a license to the center, if applicable.

(7) If the surveyor determines there are no deficiencies found, a statement shall be provided to the center indicating this fact.

(8) If the surveyor finds there are deficiencies, the center and the department shall comply with the following procedure.

(A) The department shall provide the center with a statement of deficiencies within 14 calendar days of the exit conference.

(B) The center administrator shall sign the written statement of deficiencies and return it to the department with its plan of correction(s) for each deficiency within 14 calendar days of its receipt of the statement of deficiencies. The signature does not indicate the person's agreement with deficiencies stated on the form.

(C) The department shall determine if the written plan of correction is acceptable. If the plan of correction(s) is not acceptable to the department, the department shall notify the center and request that the plan of correction be modified and resubmitted no later than 14 calendar days from the date notified.

(D) The center shall come into compliance in accordance with the plan of correction or no later than 60 calendar days prior to the expiration of the license, whichever is sooner.

(E) Acceptance of a plan of correction by the department does not preclude the department from taking enforcement action as appropriate under §137.22 of this title (relating to License Denial, Suspension, Probation, or Revocation).

(9) The department may refer issues and complaints relating to the conduct or actions by licensed health care professionals to their appropriate boards.

§137.22. License Denial, Suspension, Probation, or Revocation.

(a) The department may deny, suspend, or revoke a license if the licensee or the center:

(1) violates a provision of Texas Birthing Center Licensing Act, Health and Safety Code, Chapter 244;

(2) fails to meet a requirement of this chapter;

(3) fails to comply with an order of the commissioner of health or another enforcement procedure under the Act;

(4) is involved in any action as described in §137.11(a)(3)(J)-(K) of this title (relating to Application Procedures and Issuance of Licenses); or

(5) has been convicted of a felony or misdemeanor if the crime directly relates to the duties and responsibilities of a center.

(A) In determining whether a criminal conviction directly relates, the department shall consider the provisions of Texas Occupations Code, Chapter 53.

(B) The department may deny a person a license or suspend or revoke an existing license on the grounds that the person has been convicted of a felony or misdemeanor that directly relates to the duties and responsibilities of the ownership or operation of a facility. The department shall apply the requirements of the Texas Occupations Code, Chapter 53.

(i) The department is entitled to obtain criminal history information maintained by the Texas Department of Public Safety (Government Code, §411.122), the Federal Bureau of Investigation Identification Division (Government Code, §411.087) or any other law enforcement agency to investigate the eligibility of an applicant for an initial or renewal license and to investigate the continued eligibility of a licensee.

(ii) In determining whether a criminal conviction directly relates, the department shall consider the provisions of the Texas Occupations Code, §53.022 and §53.023.

(iii) The following felonies and misdemeanors directly relate because these criminal offenses adversely affect a person's ability to own or operate a facility:

(I) a misdemeanor or felony involving moral turpitude;

(II) a misdemeanor or felony relating to deceptive business practices;

(III) a misdemeanor or felony of practicing any health-related profession without a required license;

(IV) a misdemeanor or felony under any federal or state law relating to drugs, dangerous drugs, or controlled substances;

(V) a misdemeanor or felony under the Texas Penal Code (TPC):

(-a-) Title 4 - offenses of attempting or conspiring to commit any of the offenses in this clause;

(-b-) Title 5 - offenses against the person;

(-c-) Title 7 - offenses against property;

(-d-) Title 8 - offenses against public administration;

(-e-) Title 9 - offenses against public order and decency;

(-f-) Title 10 - offenses against public health, safety or morals; or

(-g-) Title 11 - offenses involving organized crime.

(VI) offenses listed in clause (iii) of this subparagraph are not exclusive in that the department may consider similar criminal convictions from other state, federal, foreign or military jurisdictions which indicate an inability or tendency for the person to be unable to own or operate a facility.

(VII) a license holder's license shall be revoked on the license holder's imprisonment following a felony conviction, felony community supervision revocation, revocation of parole, or revocation of mandatory supervision.

(6) fails to comply with applicable requirements within a designated probation period;

(7) has a history of failure to comply with the rules adopted under this chapter;

(8) has aided, abetted or permitted the commission of an illegal act;

(9) has committed fraud, misrepresentation, or concealment of a material fact on any documents required to be submitted to the department or required to be maintained by the facility pursuant to the provisions of this chapter;

(10) fails to pay administrative penalties; or

(11) fails to implement plans of corrections to deficiencies cited by the department.

(b) Notice. If the department proposes to deny, suspend or revoke a license, the department shall send a notice of the proposed action by certified mail, return receipt requested, at the address shown in the current records of the department or the department may personally

deliver the notice. The notice to deny, suspend, or revoke a license shall state the alleged facts or conduct to warrant the proposed action, provide an opportunity to demonstrate or achieve compliance, and shall state that the applicant or license holder has an opportunity for a hearing before the action taken is final.

(c) Within 25 days after the date of the notice, the applicant or license holder may notify the department, in writing, of acceptance of the department's determination. If the applicant or license holder does not accept the proposed action, a hearing may be requested. The request for a hearing must be submitted in writing to the Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756.

(1) A hearing shall be conducted pursuant to the Administrative Procedure Act, Texas Government Code, Chapter 2001 and the department's formal hearing procedures in §§1.21, 1.23, 1.25, and 1.27 of this title (relating to Formal Hearing Procedures).

(2) If the applicant or licensee does not request a hearing in writing within 25 days after the date of the notice, the licensee is deemed to have waived the opportunity for a hearing and the proposed action shall be taken.

(3) If the applicant or licensee fails to appear or be represented at the scheduled hearing, the applicant or licensee is deemed to have waived the right to a hearing and the proposed action shall be taken.

(d) A person who has had a center license revoked under this section may not apply for a license under this chapter for one year following the date of revocation.

(e) Probation. In lieu of suspending or revoking the license, the department may schedule the facility for a probation period of not less than 30 days if the facility is found in repeated noncompliance and the facility's noncompliance does not endanger the health and safety of the public.

(f) After a survey in which deficiencies were cited by the surveyor, a center may submit its license for voluntary cancellation in lieu of the department proceeding with enforcement action. The department may accept such submission or reject it and proceed with an enforcement action. The center, its owner(s), and its affiliates may not reapply for a license for six months from the date of the surrender or expiration.

(g) If the department suspends a license, the suspension shall remain in effect until the department determines that the reason for suspension no longer exists. A department surveyor shall conduct a survey of the center prior to making a determination.

(1) During the time of suspension, the suspended license holder shall return the original license certificate to the department.

(2) If a suspension overlaps a renewal date, the suspended license holder shall comply with the renewal procedures in this chapter; however, the department may not renew the license until the department determines that the reason for suspension no longer exists.

(3) If suspension is for more than one year, the suspended license holder may apply to the department for cancellation of the suspension only after one year following the initial date of the suspension.

(h) If the department denies, revokes, or does not renew a license, a person may reapply for a license (subject to subsection (b) of this section), by complying with the requirements and procedures in this chapter at the time of reapplication. The department may refuse to issue a license if the reason for denial, revocation, or non-renewal continues to exist and may consider the enforcement history of the applicant, administrator or clinical director in making such a determination.

(i) Upon revocation or nonrenewal, a license holder shall return the original license certificate to the department.

§137.23. Emergency Suspension.

(a) The department may issue an emergency order to suspend a license issued under this chapter if the department has reasonable cause to believe that the conduct of a license holder creates an immediate danger to the public health and safety.

(b) On written request of the license holder, the department shall conduct a hearing to determine if the emergency suspension is to continue, to be modified or to be rescinded. The hearing shall not be conducted earlier than the seventh day or later than the 10th day after the date the notice of the emergency suspension is sent to the license holder.

(c) The hearing and any appeal are governed by the department's rules for a contested case hearing and Government Code, Chapter 2001.

§137.24. Administrative Penalties.

(a) Imposition of penalty.

(1) The department may impose an administrative penalty on a person licensed under this chapter who violates the Act, this chapter, or an order adopted under this chapter.

(2) A penalty collected under this section shall be deposited in the state treasury in the general revenue fund.

(3) A proceeding to impose the penalty is considered to be a contested case under Government Code, Chapter 2001.

(b) Amount of penalty.

(1) The amount of the penalty may not exceed $1,000 for each violation. Each day a violation continues or occurs is a separate violation for purposes of imposing a penalty. The total amount of the penalty assessed for a violation continuing or occurring on separate days under this paragraph may not exceed $5,000.

(2) In determining the amount of an administrative penalty assessed under this section, the department shall consider:

(A) the seriousness of the violation, including the nature, circumstances, extent, and gravity of the violation;

(B) the threat to health or safety caused by the violation;

(C) the history of previous violations;

(D) the amount necessary to deter a future violation;

(E) whether the violator demonstrated good faith, including whether the violator made good faith efforts to correct the violation; and

(F) any other matter that justice may require.

(c) Report and notice of violation and penalty.

(1) If the department initially determines that a violation occurred, the department shall give written notice of the report by certified mail to the person alleged to have committed the violation following the survey exit date.

(2) The notice must include:

(A) a brief summary of the alleged violation;

(B) a statement of the amount of the recommended penalty based on the factors listed in subsection (b)(2) of this section; and

(C) a statement of the person's right to a hearing on the occurrence of the violation, the amount of the penalty, or both.

(d) Penalty to be paid or hearing requested.

(1) Within 20 calendar days after the date the notice under subsection (c) of this section, is mailed, the person in writing may:

(A) accept the determination and recommended penalty of the department; or

(B) make a request for a hearing on the occurrence of the violation, the amount of the penalty, or both; and

(C) request a pre-hearing conference to discuss the violation.

(2) If the person accepts the determination and recommended penalty or if the person fails to respond to the notice, the commissioner of health (commissioner) or the commissioner's designee by order shall approve the determination and impose the recommended penalty.

(e) Hearing.

(1) If the person requests a hearing, it shall be conducted pursuant to the Administrative Procedure Act, Texas Government Code, Chapter 2001 and the department's formal hearing procedures.

(2) All hearings shall be held in accordance with the requirements of the Health and Safety Code, Chapter 244.

(f) Options following decision: pay or appeal. Within 30 calendar days after the date the order of the commissioner or commissioner's designee that imposes an administrative penalty becomes final, the person shall:

(1) pay the penalty; or

(2) appeal the penalty by filing a petition for judicial review of the commissioner's order contesting the occurrence of the violation, the amount of the penalty, or both; and

(3) all appeals shall be under the substantial evidence rule.

(g) Stay of enforcement of penalty. Stay of enforcement of penalty shall follow the procedures listed in Health and Safety Code, §244.016.

(h) Collection of penalty. Collection of penalty shall follow the procedure listed in Health and Safety Code, §244.016.

(i) Remittance of penalty and interest. The remittance of penalty and interest is governed by Health and Safety Code, §244.016(g).

§137.25. Complaints.

(a) In accordance with §137.42 of this title (relating to Disclosure Requirements), all licensed centers are required to provide a client, and her guardian if the client is a minor or if guardianship is required, at the time of the initial visit, with a written statement that complaints relating to the center may be registered with the Manager, Health Facility Compliance Group,

Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756; Telephone (888) 973-0022; (512) 834-6650; and Fax (512) 834-6653.

(b) Complaints may be registered with the department by telephone, fax or in writing at the address listed in subsection (a) of this section. A complainant may provide his or her name, address, and phone number to the department. Anonymous complaints may be registered if the complainant provides sufficient information.

(c) The department will evaluate all complaints received.

(d) A complaint containing allegations that are a violation of the Act or this chapter will be investigated by the department.

(e) A department representative (surveyor) may enter the premises of a center at reasonable times as necessary to assure compliance with the Act and this chapter. The department is not required to notify the applicant or licensee prior to a complaint investigation.

(f) If the department determines that the complaint does not come within the department's jurisdiction, the department shall advise the complainant and, if possible, refer the complainant to the appropriate governmental agency for handling such a complaint.

(g) The department shall inform in writing a complainant who identifies himself or herself by name and address of the final disposition of the complaint.

(h) A person may file a complaint with the department against a birthing center licensed under this chapter. A person who files a false complaint may be prosecuted under the Penal Code.

§137.26. Appointment and Qualifications of a Monitor.

(a) The department may appoint a monitor for a birthing center to ensure compliance with this chapter when the center's failure to comply with this chapter creates a serious threat to the health and safety of the public.

(b) The birthing center shall be liable for the cost of the monitor.

(c) The birthing center may propose up to three persons to act as a monitor. The department shall approve the monitor. The monitor shall be an individual or team of individuals, and must include a professional with birthing center experience. The monitor may not be or include individuals who are current or former employees of the birthing center or an affiliated facility. The purpose of the monitor is to observe, supervise, consult, and educate the birthing center employees, and report back to the department according to the terms of the agreed order.

(d) A professional with birthing center experience shall:

(1) have a minimum of three years clinical experience providing care to pregnant women and newborns;

(2) be a certified nurse-midwife, licensed midwife, or physician with obstetrical experience; and

(3) be currently licensed or certified in the State of Texas.

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 nonprofessional 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 and continuing education;

(5) certification of all birth attendants by the American Heart Association or the American Red Cross in basic life support for health care providers; and

(6) certification of all birth attendants by 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 nonprofessional 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, Probation, 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) 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.

(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 care, and the center.

(3) Birth attendant.

(A) Qualifications. A physician, certified nurse-midwife (CNM), or a licensed 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) Nonprofessional staff.

(A) Qualifications. Nonprofessional 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 nonclinical 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 must be licensed 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.

(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) evidence of current 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.

§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 Texas Food Establishments).

(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 complies 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 human immunodeficiency virus (HIV) and hepatitis B virus (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 sterile field during an operative procedure must be sterile.

(B) Semi-critical items. High-level disinfection shall be used for semi-critical items.

(C) Noncritical items. Intermediate-level or low-level disinfection shall be used for noncritical 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) Sterilizers. Steam sterilizers (saturated steam under pressure) shall be utilized for sterilization of heat and moisture stable items. Steam sterilizers shall be used according to manufacturer's written instructions.

(C) 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.

(D) 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.

(E) 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.

(F) 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.

(G) 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.

(H) Sterilizers. Sterilizers shall be used according to manufacturer's written instructions.

(I) 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.

(J) Commercially packaged items. Commercially packaged items are considered sterile according to the manufacturer's instructions.

(K) 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.

(L) 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.

(M) 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.

(N) 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 premises.

(c) 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; and

(3) charges for services rendered.

(d) 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) A center shall not commit an intentional or negligent act that adversely affects the health or safety of a client.

(f) A center must ensure that its licensed health care professionals 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.

(g) A center may accept student midwives to provide them with clinical experience.

(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 student’s 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 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 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 to a physician consultant or a referral hospital. The written policies shall include provisions:

(A) for transfer 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)(R) of this title (relating to Clinical Records).

§137.41. Emergency Services. The center shall provide emergency services to clients when a critical situation develops at the center.

(1) A center shall have an emergency call system for use when there is a critical situation. 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 postpartum period.

(2) A center shall provide emergency equipment and emergency medications as follows:

(A) oxygen;

(B) newborn manual 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, Health Facility Compliance Group, Department of State Health Services, 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 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 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.

§137.49. Care of the Newborn. A center shall adopt, implement, and enforce written policies and procedures for the care of the newborn. 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 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 shall not be discharged prior to two hours from the time of placenta.

(c) If the mother or newborn 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, Health Facility Compliance Group, 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.

§137.51. Postpartum and Postnatal Care of the Mother and Newborn. The center shall develop, implement, and enforce written policies to provide follow-up postnatal and postpartum care to the newborn 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.

(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;

(C) postpartum infections;

(D) all cases transferred to a hospital for delivery, care of newborn, 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 on-site 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 subsection. 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 required to be given a client by a licensed 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 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;

(R) documentation of client transfers or referrals, if applicable; and

(S) 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 of Health Facility Compliance Group, Department of State Health Services, 1100 West 49th Street, Austin, Texas 78756:

(A) a death of a client, newborn, or death of a fetus during the course of labor occurring in the center; and

(B) a death of a client or newborn 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 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 shall ensure that all licensed midwives utilized do 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 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 (CLIA 88), 42 Code of Federal Regulations, §§493.1-493.1780 (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, 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 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.

(j) 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.

(k) 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).

(l) A birthing center shall comply with Health and Safety Code, Chapter 47, relating to Hearing Loss in Newborns.

(m) 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.

(n) A center shall ensure that its birth attendants comply with the Health and Safety Code, §81.091, (relating to Ophthalmia Neonatorum Prevention; Criminal Penalty).

(o) 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).