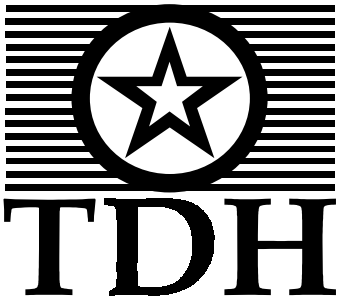

HEALTH FACILITY LICENSING AND COMPLIANCE DIVISION

TITLE 25 TEXAS ADMINISTRATIVE CODE

Chapter 139 Abortion Facility Reporting And Licensing Rules

EFFECTIVE FEBRUARY 5, 2004

Table of Contents
25 Texas Administrative Code
Chapter 139. Abortion Facility Reporting and Licensing Rules

Subchapter A. General Provisions.

§139.1. Purpose and Scope.

(a) Purpose. The purpose of this chapter is to implement the Texas Abortion Facility Reporting and Licensing Act, Health and Safety Code (HSC), Chapter 245, which provides the Texas Board of Health with the authority to establish rules governing the licensing and regulation of abortion facilities and to establish annual reporting requirements for each abortion performed.

(b) Scope and applicability.

(1) Licensing requirements.

(A) A person may not establish or operate an abortion facility in Texas without a license issued under this chapter unless the person is exempt from licensing requirements.

(B) The following need not be licensed under this chapter:

(i) a hospital licensed under HSC, Chapter 241;

(ii) an ambulatory surgical center licensed under HSC, Chapter 243; or

(iii) the office of a physician licensed under Subtitle B, Title 3, Occupations Code, unless the office is used for the purpose of performing more than 50 abortions in any 12 month period.

(2) Reporting requirements. All licensed abortion facilities and facilities and persons exempt from licensing must comply with §139.4 of this title (relating to Annual Reporting Requirements for All Abortions Performed).

§139.2. Definitions.

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

(1) Abortion--Any act or procedure performed after pregnancy has been medically verified with the intent to cause the termination of a pregnancy other than for the purpose of either the birth of a live fetus or removing a dead fetus. This term does not include birth control devices or oral contraceptives.

(2) Abortion facility--A place where abortions are performed.

(3) Act--Texas Abortion Facility Reporting and Licensing Act, Health and Safety Code, Chapter 245.

(4) Administrator--A person who:

(A) is delegated the responsibility for the implementation and proper application of policies, programs, and services established for the licensed abortion facility; and

(B) meets the qualifications established in §139.46(2) of this title (relating to Licensed Abortion Facility Staffing Requirements and Qualifications).

(5) Affidavit - A written statement, sworn to or affirmed, and witnessed by a witness whose signature and printed name appears on the affidavit. "Notarized affidavit" in these rules means an affidavit in which the statement is witnessed by a notary acting pursuant to Government Code, Chapter 406.

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

(A) a corporation--includes each officer, consultant, 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, consultant, 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, consultant, or the equivalent under the specific business arrangement and each parent company.

(7) Ambulatory surgical center --An ambulatory surgical center licensed under Health and Safety Code, Chapter 243.

(8) Anniversary Date -- The same month and day of each year as the expiration date of the license.

(9) Applicant--The owner of an abortion facility which is applying for a license under the Act. For the purpose of this chapter, the word "owner" includes non-profit organization.

(10) Board--The Texas Board of Health.

(11) Certified nurse-midwife (CNM)--A person who is:

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

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

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

(12) Certified registered nurse anesthetist (CRNA)--A person who is currently licensed under the Nursing Practice Act, Texas Occupations Code, Chapters 301 and 304, as a registered nurse, has current certification from the Council of Certification-Recertification of the American Association of Nurse Anesthetists, and is currently authorized by the Board of Nurse Examiners as a certified registered nurse anesthetist.

(13) Change of ownership--A sole proprietor who transfers all or part of the facility's ownership to another person or persons; the removal, addition, or substitution of a person or persons as a partner in a facility owned by a partnership; or a corporate sale, transfer, reorganization, or merger of the corporation which owns the facility if sale, transfer, reorganization, or merger causes a change in the facility's ownership to another person or persons.

(14) Clinical nurse specialist--A person who is currently licensed under the Nursing Practice Act, Texas Occupations Code, Chapters 301 and 304, and recognized as a clinical nurse specialist by the Board of Nurse Examiners.

(15) Condition on discharge--A statement on the condition of the patient at the time of discharge.

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

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

(18) Department--The Texas Department of Health.

(19) Director--The director of the Health Facility Licensing and Compliance Division of the Texas Department of Health or his or her designee.

(20) 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 a person's 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 viruses and bacteria with a chemical germicide registered as a hospital disinfectant by the EPA.

(21) Education/information staff--A professional or nonprofessional person who is trained to provide information on abortion procedures, alternatives, informed consent, and family planning services.

(22) Facility-- A licensed abortion facility as defined in this section.

(23) Health care facility--Any type of facility or home and community support services agency licensed to provide health care in any state or is certified for Medicare (Title XVIII) or Medicaid (Title XIX) participation in any state.

(24) Health care worker--Any person who furnishes health care services in a direct patient care situation under a license, certificate, or registration issued by the State of Texas or a person providing direct patient care in the course of a training or educational program.

(25) 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.).

(26) Immediate jeopardy to health and safety--A situation in which there is a high probability that serious harm or injury to patients could occur at any time or already has occurred and may well occur again if patients are not protected effectively from the harm or if the threat is not removed.

(27) Inspection – An on-site inspection by the department in which a standard-by-standard evaluation is conducted.

(28) Licensed abortion facility – A place licensed by the department under Health and Safety Code, Chapter 245, where abortions are performed.

(29) Licensed mental health practitioner--A person licensed in the State of Texas to provide counseling or psychotherapeutic services.

(30) Licensed vocational nurse (LVN)--A person who is currently licensed under Texas Occupations Code, Chapter 302, as a licensed vocational nurse.

(31) Licensee--A person or entity who is currently licensed as an abortion facility.

(32) Medical consultant--A physician who is designated to supervise the medical services of the facility.

(33) Midlevel provider – A midlevel provider is:

(A) an advance practice nurse who is registered currently licensed under the Nurse Practice Act, Texas Occupations Code, Chapters 301 and 304, and is recognized as an advanced practice nurse by the Board of Nurse Examiners (BNE) for the State of Texas. Advanced practice nurses may include, but not be limited to, the following:

(i) certified registered nurse anesthetist;

(ii) certified nurse midwife;

(iii) nurse practitioner;

(iv) clinical nurse specialist; and

(v) other titles as approved by the BNE; or

(B) a physician assistant currently licensed under the Physician Assistant Licensing Act, Texas Occupations Code, Chapter 204.

(34) Nonprofessional personnel--Personnel of the facility who are not licensed or certified under the laws of this state to provide a service and must function under the delegated authority of a physician, registered nurse, or other licensed health professional who assumes responsibility for their performance in the licensed abortion facility.

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

(36) Notarized copy--A copy attached to a notarized affidavit which states that the attached copy(ies) are true and correct copies of the original documents.

(37) Nurse practitioner - A person who is currently licensed under the Nursing Practice Act, Texas Occupations Act, Chapters 301 and 304, and recognized as a nurse practitioner by the Board of Nurse Examiners.

(38) Patient--A pregnant female on whom an abortion is performed, but shall in no event be construed to include a fetus.

(39) Person--Any individual, firm, partnership, corporation, or association.

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

(41) 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 system(s) operation(s) of the facility as the system(s) operation(s) apply to the deficiency.

(42) Postprocedure infection--An infection acquired at or during an admission to a facility; there must be no evidence that the infection was present or incubating at the time of admission to the facility. Postprocedure infections and their complications that may occur after an abortion include, but are not limited to, endometritis and other infections of the female reproductive tract, laboratory-confirmed or clinical sepsis, septic pelvic thrombophlebitis, and disseminated intravascular coagulopathy.

(43) Pregnant unemancipated minor certification form -- The document prepared by the Texas Department of Health and used by physicians to certify the medical indications supporting the judgment for the immediate abortion of a pregnant minor.

(44) Pre-inspection conference--A conference held with department staff and the applicant or his or her representative to review licensure standards, inspection documents, and provide consultation prior to the on-site licensure inspection.

(45) Professional personnel--Patient care personnel of the facility currently licensed or certified under the laws of this state to use a title and provide the type of service for which they are licensed or certified.

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

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

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

(49) Sedation/analgesia levels -- Levels of sedation /analgesia include:

(A) minimal sedation (anxiolysis);

(B) moderate sedation/analgesia ("conscious sedation");

(C) deep sedation/analgesia; and

(D) general anesthesia.

(50) Semicritical items--Items that come in contact with nonintact skin or mucous membranes. Semicritical items may include respiratory therapy equipment, anesthesia equipment, bronchoscopes, and thermometers.

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

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

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

(54) Supervision--Authoritative procedural guidance by a qualified person for the

accomplishment of a function or activity that includes initial direction and periodic inspection of the actual act of accomplishing the function or activity.

(55) Third trimester certification form--The document prepared by the Texas Department of Health and used by physicians to certify the medical indications supporting the judgment for the abortion of a viable fetus during the third trimester of pregnancy.

(56) Third trimester--A gestational period of not less than 26 weeks (following last - menstrual period (LMP)).

(57) Unemancipated minor-- A minor who is unmarried and has not had the disabilities of minority removed under the Texas Family Code, Chapter 31.

§139.3. Unlicensed Facility.

(a) If the Texas Department of Health (department) has reason to believe that a person or facility may be providing abortion services without a license as required by the Act and this chapter, the department shall notify the person or facility in writing by certified mail, return receipt requested. The person or facility shall submit to the department the following information within 10 days of receipt of the notice:

(1) an application for a license and the license fee; or

(2) a notarized affidavit to support exemption under §245.004 of the Act, including any and all documentation. The notarized affidavit shall attest to the fact that the person or facility is exempt from licensing as specified in §139.1(b) of this title. The form of notarized affidavit to support exemption will be provided by the department.

(b) If the person or facility has submitted an application for a license, the application will be processed in accordance with §139.23 of this title (relating to Application Procedures and Issuance of Licenses).

(c) If the person or facility fails to respond to the notice, either by submitting an application for a license or a notarized affidavit of exemption, the department may seek injunctive relief as prescribed in Health and Safety Code, Chapter 245.

§139.4. Annual Reporting Requirements for All Abortions Performed.

(a) The purpose of this section is to implement the abortion reporting requirements of the Texas Abortion Facility Reporting and Licensing Act (Act), Health and Safety Code, §245.011, which mandates that each abortion facility must submit an annual report to the Texas Department of

Health on each abortion performed at the abortion facility. This section applies to any place where abortions are performed, and therefore applies to licensed, unlicensed, and exempt facilities (including physicians).

(b) Abortion facilities must submit an abortion report on each abortion that was performed at the facility on at least an annual basis. The facility may choose to submit the abortion reports on a monthly or quarterly basis for greater efficiency.

(c) The reporting period for each abortion facility is January 1-December 31 of each year. Each facility must submit the abortion report(s) to the department no later than January 31 of the subsequent year.

(d) The abortion reports must be submitted:

(1) on forms approved by the department, by certified mail marked as confidential, to the Texas Department of Health, Bureau of Vital Statistics, P.O. Box 4124, Austin, Texas 78765-4124;

(2) on a floppy disk in a format approved by the department, by certified mail marked as confidential, to the Texas Department of Health, Bureau of Vital Statistics, P.O. Box 4124, Austin, Texas 78765-4124; or

(3) via a modem in a format approved by the department.

(e) The first annual reporting period for a licensed abortion facility commences on the day the initial license is issued. The report(s) must contain data for the calendar year in which the initial license is issued. If the abortion facility's licensure status changes, the report(s) must contain data from the date the initial license was issued through the date the initial license expired, was revoked, was suspended, or was withdrawn.

(f) If a change of ownership has occurred, the previous owner shall submit the report(s) commencing from the date of the previous reporting period and ending on the date the change in ownership of the facility occurred; the report(s) is due 30 days after the date of acquisition. The annual reporting period for the newly acquired facility commences on the day the initial license is issued and shall contain data for the calendar year in which the initial license is issued. If the newly acquired facility's licensure status changes, the report(s) must contain data from the date the initial license was issued through the date the initial license expired, was revoked, was suspended, or was withdrawn.

§139.5 Additional Reporting Requirements for Physicians. In addition to the annual reporting required by §139.4 of this title (relating to Annual Reporting Requirements for All Abortions

Performed), physicians must comply with this section when performing third trimester abortions or when performing emergency abortions on certain minors.

(1) Reporting requirements for third trimester abortions.

(A) The purpose of this paragraph is to establish procedures for reporting third trimester abortions as required by the Texas Medical Practice Act, Texas Occupations Code, Chapters 151-165.

(B) A physician who performs a third trimester abortion of a viable fetus with a biparietal diameter of 60 millimeters or greater shall certify in writing to the Texas Department of Health the medical indications supporting the physician's judgment that the abortion is either necessary to prevent the death or a substantial risk of serious impairment to the physical or mental health of the woman or the fetus has a severe and irreversible abnormality, as identified through reliable diagnostic procedures.

(C) The certification shall be made on a form approved by the board.

(D) The physician shall return by certified mail, marked as confidential, the certification form and may submit any supporting documents to the Texas Department of Health, Bureau of Vital Statistics, P.O. Box 4124, Austin, Texas 78765-4124, not later than the 30th day after the date the abortion was performed.

(E) The department will retain the certification form and supporting documents as a cross-reference to the annual reporting requirements of the Act and this section. The certification form and supporting documents retained by the department are confidential. Any release of the documents will be in accordance with the provisions of the Texas Medical Practice Act, Texas Occupations Code, Chapters 151-165.

(F) A physician performing abortions at a licensed abortion facility who fails to submit the certification form required under this paragraph may subject the licensed facility to denial, suspension, probation, or revocation of the license in accordance with §139.32 of this title (relating to License Denial, Suspension, Probation, or Revocation).

(2) Reporting requirements for emergency abortions performed on unemancipated minors.

(A) The purpose of this paragraph is to establish procedures for reporting emergency abortions performed on unemancipated minors, as authorized by Family Code, §33.002(a)(4)(B).

(B) A physician who performs an emergency abortion on an unemancipated

minor shall certify in writing to the Texas Department of Health the medical indications supporting the physician's judgment that the abortion is necessary either to avert her death or to avoid a serious risk of substantial and irreversible impairment of a major bodily function, as identified through reliable diagnostic procedures.

(C) The certification shall be made on a form approved by the board.

(D) The physician shall return by certified mail, marked as confidential, the certification form to the Texas Department of Health, Bureau of Vital Statistics, P.O. Box 4124, Austin, Texas 78765-4124 not later than 30 days after the date the abortion was performed.

(E) A physician performing abortions at a licensed abortion facility who fails to submit the certification form required by this paragraph may subject the licensed facility to denial, suspension, probation, or revocation of the license in accordance with §139.32 of this title (relating to License Denial, Suspension, Probation, and Revocation).

(F) If the physician provides parental notice as prescribed by Family Code, §33.002(a)(1), or if the minor has obtained judicial approval as authorized by Family Code, §33.002(a)(2) or §33.002(a)(3), the emergency certification form is not required.

§139.6. Public Information; Toll-Free Telephone Number.

(a) An abortion facility shall provide to a woman, at the time the woman initially consults the facility, a written statement indicating the number of the toll-free telephone number maintained under subsection (d) of this section. The written statement must be available in English and Spanish.

(1) The following form is an example of the statement in English.

Figure: 25 TAC §139.6(a)(1).

(2) The following form is an example of the statement in Spanish.

Figure: 25 TAC §139.6(a)(2).

(b) The department on request shall make the following information available to the public:

(1) the status of the license of any abortion facility;

(2) the date of the last inspection of the facility, any violation discovered during that inspection that would pose a health risk to a patient at the facility, any challenge raised by the facility to the allegation that there was a violation, and any corrective action that is acceptable to the

department and that is being undertaken by the facility with respect to the violation; and

(3) an administrative or civil penalty imposed against the facility or a physician who provides services at the facility, professional discipline imposed against a physician who provides services at the facility, and any criminal conviction of the facility or a physician who provides services at the facility that is relevant to services provided at the facility.

(c) Subsection (b) of this section does not require the department to provide information that is not in the possession of the department. In accordance with §245.023(b) of the Act, the Texas State Board of Medical Examiners (board) is required to provide to the department information in the possession of the board that the department is required to provide under subsection (b) of this section.

(d) In accordance with Health and Safety Code, §245.023(c), the department shall maintain a toll-free telephone number that a person may call to obtain the information described by subsection (b) of this section.

(e) This section does not authorize the department to the release of the name, address, or phone number of any employee or patient of an abortion facility or of a physician who provides services at an abortion facility.

§139.7. Unique Identifying Number; Disclosure in Advertisement.

(a) The department shall assign to each licensed abortion facility a unique license number that may not change during the period the facility is operating in this state.

(b) A licensed abortion facility shall include the unique license number assigned to the facility by the department in any abortion advertisement directly relating to the provision of abortion services at the facility. If more than one location is advertised in a single advertisement, the license number(s) for each location shall be included in the advertisement. The facility shall document efforts to place the unique license number in advertisements within each specific deadline for each advertisement.

(c) In this section, "abortion advertisement" means:

(1) any communication that advertises the availability of abortion services at a licensed abortion facility and that is disseminated through a public medium, including an advertisement in a newspaper or other publication or an advertisement on television, radio, or any other electronic medium; or

(2) any commercial use of the name of the licensed facility as a provider of abortion

services, including the use of the name in a directory, listing, or pamphlet.

§139.8. Quality Assurance.

(a) Quality Assurance (QA) Program. A licensed abortion facility must maintain a QA program in the facility which shall be implemented by a QA committee. The QA program shall be ongoing and have a written plan of implementation. This plan must be reviewed and updated or revised at least annually by the QA Committee. The QA program shall include measures for quality improvement in the measurement of the facility's delivery of service. Quality assurance documents pertinent to the facility shall be kept within the facility.

(b) QA committee membership. At a minimum, the QA committee must consist of at least:

(1) the medical consultant designated by the facility;

(2) a midlevel provider, a registered nurse, or a licensed vocational nurse; and

(3) at least two other members of the facility's staff.

(c) Frequency of QA committee meetings. The QA committee, by consensus, shall meet at least quarterly to identify issues with respect to which quality assurance activities are necessary.

(d) Minimum responsibilities. The QA committee shall:

(1) evaluate all organized services related to patient care, including services furnished by contract;

(2) ensure that there is a review of any abortion procedure complication(s) and shall make use of the findings in the development and revision of facility policies;

(3) address issues of unprofessional conduct by any member of the facility's staff (including contract staff);

(4) monitor infection control as outlined in §139.49 of this title (relating to Infection Control Standards) and postprocedure infections as outlined in §139.41 of this title (relating to Policy Development and Review);

(5) address medication therapy practices;

(6) address the integrity of surgical instruments, medical equipment, and patient supplies; and

(7) address services performed in the facility as they relate to appropriateness of diagnosis and treatment.

(e) Patient care and service issues. The QA committee shall identify and address patient care services and information issues and implement corrective action plans as necessary.

(1) Identifying issues that necessitate corrective action. The QA committee shall be responsible for identifying issues that necessitate corrective action by the committee, such as issues which negatively affect care or services provided to patients.

(2) Plan of corrective action. The QA committee shall develop and implement plans of action to correct identified deficiencies.

(3) Remedial action. The QA committee shall take and document remedial action to address deficiencies found through the QA program. The facility shall document the outcome of the remedial action.

(f) Departmental review.

(1) The department will not use good faith efforts by the QA committee to identify and correct deficiencies as a basis for deficiency(ies), citation(s), or sanction(s).

(2) Department surveyors shall verify that:

(A) the facility has a QA committee which addresses concerns; and

(B) the facility staff know how to access that process.

Subchapter B. Licensing Procedures.

§139.21. General Requirements for Licensure.

An applicant for an abortion facility license must meet the following requirements.

(1) If the applicant for a license is an individual, the applicant must be at least 18 years of age.

(2) An abortion facility is required to apply for a separate license for each place of business.

(3) An abortion facility may not admit a patient for an abortion procedure until it has received an initial license.

(4) The licensed location must be in Texas.

(5) The licensee of the abortion facility is responsible for ensuring the facility's compliance with the Act and this chapter.

(6) An abortion facility license must be renewed annually until January 1, 2005. Renewal licenses issued January 1, 2005, through December 31, 2005, will expire in either one or two years, to be determined by the department prior to the time of license renewal. Renewal licenses issued January 1, 2006, or after, will expire in two years.

(7) An abortion facility shall prominently and conspicuously post the license issued under the Act for display in a public area of the facility that is readily accessible to patients, employees, and visitors.

(8) An abortion facility license may not be transferred or assigned from one person to another person.

(9) A licensed abortion facility shall have the financial ability to carry out its functions under the Act and this chapter.

§139.22. Fees.

(a) The schedule of fees for an abortion facility license for all new, change of ownership, and renewal applications received prior to January 1, 2005, is as follows:

(1) initial license fee--$2,500;

(2) renewal license fee--$2,500; and

(3) change of ownership license fee--$2,500.

(b) Fees for renewal licenses issued January 1, 2005, through December 31, 2005, will be either $2,500 for one year or $5,000 for two years. The licensure period will be determined by the department prior to the licensure renewal date.

(c) Fees for two-year renewals for an abortion facility license for all initial, change of ownership, and renewal applications received on or after January 1, 2006, are as follows:

(1) initial license fee--$5000;

(2) renewal license fee--$5000; and

(3) change of ownership license fee--$5000.

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

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

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

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

(h) 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.

(i) The department will assess an annual assessment fee as follows.

(1) In addition to application fees for initial, renewal, and change of ownership license fees, an annual assessment fee per year will be imposed by the department in amounts reasonable and necessary to defray costs.

(2) The amount of the one time per year annual assessment fee will be determined by the department on an annual basis.

(3) Fees will be divided into three categories based on a three year history:

(A) the average per year of the previous three years reported abortions equals less than 1000;

(B) the average per year of the previous three years reported abortions equals 1000 - 2999;

(C) the average per year of the previous three years reported abortions equals

3000 or more.

(4) Facilities identified in each category will be assessed a proportionate share of the costs.

(5) Licensees receiving an initial license will be assessed the least of the three fees in effect at the time of application for an initial or change of ownership license. The additional annual assessment fee is due at the same time as the application fee.

(6) The department shall notify each licensee of the amount assessed for the annual assessment fee by April 1, 2004, and by the first day of April for each subsequent year.

(7) The annual assessment fee must be received by the department no later than June 1, 2004, and the first day of June for each subsequent year.

(8) A licensee who fails to pay the assessed annual assessment fee will be subject to denial, revocation, probation, or suspension of a license as prescribed in §139.32 of this title (relating to License Denial, Suspension, Probation or Revocation).

§139.23. Application Procedures and Issuance of Licenses.

(a) Purpose. This section establishes the application procedures that an abortion facility must follow to obtain a license to operate as a licensed abortion facility in Texas.

(b) Definitions. The following terms when used in this section shall have the following meaning.

(1) Initial license--A license which is issued by the department to all first-time applicants for an abortion facility license (including those from unlicensed operating facilities and licensed facilities for which a change of ownership is anticipated, that meet the requirements of the Act and this chapter and have successfully completed the application procedures for an initial license as set out in subsection (c) of this section. This license expires 12 months after issuance up to January 1, 2005, and 24 months after January 1, 2005.

(2) Renewal license--A license issued by the department to a licensed abortion facility that meets all requirements of the Act and this chapter and has completed the application procedures for obtaining a renewal license as set out in subsection (d) of this section. Renewal licenses issued January 1, 2005, through December 31, 2005, will expire in either one or two years, to be determined by the department prior to the time of license renewal. Renewal licenses issued January 1, 2006, or after, will expire in two years.

(c) Application procedures for an initial license. This subsection establishes the application procedures for obtaining an initial license.

(1) Request for an application. Upon request for an abortion facility license, the Texas Department of Health (department) will furnish a person with an application packet. Applications may also be obtained and submitted through the department's web site.

(2) Application requirements. The applicant shall submit the information listed in subparagraph (C) of this paragraph to the department.

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

(B) The application form must be accurate and complete and must contain original signatures. The initial license fee must accompany the application.

(C) The following documents must be submitted with the original application form prescribed by the department and shall be originals or notarized copies:

(i) information on the applicant including name, street address, mailing address, social security number or Franchise Tax ID number, date of birth, and driver's license number;

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

(iii) the telephone number of the facility, the telephone number where the administrator can usually be reached when the facility is closed, and if the facility has a fax machine, the fax number;

(iv) 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;

(v) a list of any businesses with which the applicant subcontracts and

in which the persons listed under clause (iv) of this subparagraph hold any percentage of the ownership;

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

(vii) if the facility 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;

(viii) a notarized affidavit attesting that the applicant is capable of meeting the requirements of this chapter;

(ix) an organizational structure of the staffing for the abortion facility. The organizational structure shall include full disclosure in writing of the names and addresses of all owners and persons controlling any ownership interest in the abortion facility. In the case of corporations, holding companies, partnerships, and similar organizations, the names and addresses of officers, directors, and stockholders, both beneficial and of record, when holding any percent, shall be disclosed. In the case of a non-profit corporation, the names and addresses of the officers and directors shall be disclosed;

(x) the name(s), address(es), and Texas physician license number(s) of the physician(s) (including the facility's designated medical consultant), and all midlevel providers who will provide services at the abortion facility;

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

(I) denial, suspension, probation, or revocation of an abortion facility license in any state, a license for any health care facility or a license for a home and community support services agency (agency) in any state; or any other enforcement action, such as (but not limited to) court civil or criminal action in any state;

(II) denial, suspension, probation, or revocation of or other enforcement action against an abortion facility license in any state, a license for any health care facility in any state, or a license for an agency in state 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 or agency;

(VI) operation of a health care facility or agency that has been decertified or terminated from participation in any state under Medicare or Medicaid; or

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

(xii) 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 judgments;

(IV) eviction involving any property or space used as an abortion facility or health care facility in any state;

(V) injunctive orders from any court; or

(VI) unresolved final federal or state (any state) Medicare or Medicaid audit exceptions.

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

(4) Application processing. Upon the department's receipt of the application form, the required information described in paragraph (2)(C) of this subsection, and the initial license fee from an applicant, the department shall review the material to determine whether it is complete and correct.

(A) The time periods for reviewing the material shall be in accordance with

§139.25 of this title (relating to Time Periods for Processing and Issuing a License).

(B) If an abortion facility receives a notice from the department that some or all of the information required under paragraph (2)(C) of this subsection is deficient, the facility shall submit the required information no later than six months from the date of the notice.

(i) A facility which fails to submit the required information within six months from the notice date is considered to have withdrawn its application for an initial license. The license fee will not be refunded.

(ii) A facility 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.

(5) Withdrawal from the 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.

(6) Issuance of an initial license.

(A) The time periods for processing an initial application shall be in accordance with §139.25 of this title.

(B) Effective period of an initial license. The initial license is valid for 12 months up to January 1, 2005, and 24 months after January 1, 2005. The initial license expires on the last day of the month ending the licensure period.

(C) Pre-inspection. Once the department has determined that the application form, the information required to accompany the application form, and the initial license fee are complete and correct, the department shall schedule a pre-inspection conference with the applicant in order to inform the applicant or his or her designee of the standards for the operation of the abortion facility. The department, at its discretion, may waive the pre-inspection conference. Upon recommendation by the pre-inspection conference, the department will issue an initial license to the facility.

(D) Pre-inspection recommendation. After the pre-inspection conference has been held, the department will:

(i) issue an initial license to the owner of a facility, if the facility is found to be in compliance with the department's requirements for initial licensure; or

(ii) deny the application if the facility has not complied with the department's requirements for issuing an initial license. The procedure for denial of a license shall be in accordance with §139.32 of this title (relating to License Denial, Suspension, Probation, or Revocation).

(7) A department representative shall inspect the abortion facility in accordance with §139.31 of this title (relating to On-Site Inspections and Complaint Investigations of a Licensed Abortion Facility) within 60 days after the issuance of an initial license. If the department determines that a facility is not in compliance with the provisions of the Act or this chapter after the initial onsite inspection, the department shall notify the facility. Notification shall be in accordance with §139.32 of this title.

(8) If for any reason, an applicant decides not to continue the application process, the applicant must submit to the department a written request to withdraw its application. If an initial license has been issued, the applicant shall cease providing abortion services and return the initial license 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.

(9) Continuing compliance by the abortion facility with the provisions of the Act and this chapter is required during the initial license period.

(d) Application procedures for renewal of a license.

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

(2) The licensee shall submit the following items to the department by certified mail, marked confidential, and postmarked no later than 30 days prior to the expiration date of the license:

(A) a complete and accurate renewal application form;

(B) current updated documents containing all the information required in subsection (c)(2)(C) of this section; and

(C) the renewal license fee.

(3) A facility shall not misstate a material fact on any documents required to be submitted to the department or required to be maintained by the facility in accordance with the provisions of the Act and this chapter.

(4) A department surveyor shall inspect a licensed abortion facility in accordance with §139.31(b) of this title.

(5) If a licensee makes timely and sufficient application for renewal, the license will not expire until the department issues the renewal license or until the department denies renewal of the license.

(A) 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.

(B) The department may propose to deny the issuance of a renewal license if:

(i) based on the inspection report, the department determines that the abortion facility does not meet or is in violation of any of the provisions of the Act or this chapter;

(ii) renewal is prohibited by the Texas Education Code, §57.491, relating to defaults on guaranteed student loans;

(iii) a facility discloses any of the actions or offenses listed in subsection (c)(2)(C)(xi) and (xii) of this section; and

(iv) a facility fails to file abortion reports in accordance with §139.4 of this title (relating to Annual Reporting Requirements for All Abortions Performed) or fails to ensure that the physicians report in accordance with §139.5 of this title (relating to Additional Reporting Requirements for Physicians).

(6) If a licensee makes a timely application for renewal of a license, and action to revoke, suspend, place on probation, 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.

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

(8) If the department revokes or does not renew a license, a person may apply for an initial license by complying with the requirements of the Act and this chapter at the time of reapplication. The department may refuse to issue a license if the reason for revocation or nonrenewal continues to exist.

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

(10) The procedures for revocation, suspension, probation, or denial of a license shall be in accordance with §139.32 of this title.

(e) Failure to timely renew a license.

(1) If a licensee fails to timely renew a license in accordance with subsection (d) of this section, the department shall notify the licensee that the facility must cease operation on the expiration date of the license.

(2) To continue providing services at the abortion facility after the expiration of the license, the owner must apply for an initial license in accordance with subsection (c) of this section.

(f) Frequency of inspections. Inspections of the abortion facility shall be performed at a frequency prescribed by and in accordance with §139.31 of this title (relating to On-Site Inspections and Complaint Investigations of a Licensed Abortion Facility).

§139.24. Change of Ownership or Services, and Closure of a Licensed Abortion Facility.

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

(1) A licensee shall not transfer or assign its license from one person to another person.

(2) The licensed abortion facility shall not materially alter any license issued by the department.

(3) A person who desires to receive a license in its name for a facility licensed under the name of another person or to change the ownership of any facility shall submit a 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 §139.23(c) of this title (relating to Application Procedures and Issuance of Licenses).

(4) 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.

(5) The pre-inspection conference may, at the department's discretion, be waived for an applicant of a licensed abortion facility for a change in control of ownership. If the pre-inspection conference is waived, the department will issue an initial license to the new owner of the facility.

(6) When a change of ownership has occurred, the department shall perform an on-site inspection of the facility within 60 days from the effective date of the change of ownership.

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

(8) 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).

(9) 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 licensed abortion facility changes its business name, business address, telephone number of the facility, administrator's telephone number, or fax number (if available), the administrator must notify the department in writing within 15 calendar days after the effective date of the change.

(2) If a licensed abortion facility changes its administrator, the facility shall provide the name of the new administrator and effective date to the department in writing no later than 15 calendar days following such change.

(c) The licensee shall notify the department at least 30 days in advance of a relocation.

(d) The licensee shall notify the department in writing within 15 calendar days when a licensed abortion facility ceases operation. The licensee shall return the original license to the department.

(e) A licensed abortion facility shall have a written policy for the preservation and release of active and inactive medical records in the event the facility closes.

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

(a) General.

(1) The date a license application is received is the date the application reaches the Health Facility Licensing and Compliance Division of the Texas Department of Health (department).

(2) An application for an initial license is complete when the department has received, reviewed, and found acceptable the information described in §139.23(c)(2)(C) 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 §139.23(d)(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 §139.24 of this title (relating to Change of Ownership or Services and Closure of a Licensed Abortion Facility).

(b) Time periods. An application from an abortion facility 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 facility 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 days for initial, renewal, and change of ownership applications.

(2) The second time period begins on the date the last item necessary to complete the application is received and ends on the date the license is issued. The second time period is 45 days for initial, renewal and change of ownership applications.

(c) Reimbursement of fees.

(1) In the event the application is not processed in the time periods stated in subsection (b) of this section, the applicant has the right to request that the department reimburse in full the fee paid in that particular application process. If the department does not agree that the established periods have been violated or finds that good cause existed for exceeding the established periods, the request will be denied.

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

(A) 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;

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

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

(d) Appeal. If the request for reimbursement as authorized by subsection (c) of this section is denied, the applicant may then appeal to the commissioner of health for a resolution of the dispute. The applicant shall give written notice to the commissioner requesting reimbursement of the fee paid because the application was not processed within the established time period. The department shall submit a written report of the facts related to the processing of the application and good cause for exceeding the established time periods. The commissioner will make the final decision and provide written notification of the decision to the applicant and the director.

(e) Hearings. If a hearing is proposed during the processing of the application, the time periods in §1.34 of this title (relating to Time Periods for Conducting Contested Case Hearings) are applicable.

Subchapter C. Enforcement.

§139.31. On-site Inspections and Complaint Investigations of a Licensed Abortion Facility.

(a) General. An on-site inspection shall determine if the requirements of the Act and this chapter are being met.

(1) An authorized representative of the department (surveyor) may enter the premises of a licensed abortion facility at reasonable times during business hours and at other times as it considers necessary to ensure compliance with:

(A) the Act and this chapter;

(B) an order of the commissioner of health (commissioner);

(C) a court order granting injunctive relief; or

(D) other enforcement actions.

(2) The surveyor is entitled to access all books, records, or other documents maintained by or on behalf of the facility to the extent necessary to ensure compliance with the Act, this chapter, an order of the commissioner, a court order granting injunctive relief, or other enforcement action. The department shall maintain the confidentiality of facility records as

applicable under federal or state law. Ensuring compliance includes permitting photocopying by a department surveyor or providing photocopies to a department surveyor of any records or other information by or on behalf of the department as necessary to determine or verify compliance with the Act or this chapter.

(3) By applying for or holding a license, the facility consents to entry and inspection of the facility by the department or representative of the department in accordance with the Act and this chapter.

(b) Inspection procedures.

(1) All onsite inspections will be unannounced and conducted, at least, annually.

(2) The department's surveyor shall hold a conference with the person who is in charge of a licensed abortion facility prior to commencing the inspection for the purpose of explaining the nature and scope of the inspection. The surveyor shall hold an exit conference with the person who is in charge of the facility when the inspection is completed, and the surveyor shall identify any records that were duplicated. Any original facility records that are removed from a facility shall be removed only with the consent of the facility.

(3) The department's authorized representative shall hold an exit conference and fully inform the person who is in charge of the facility of the preliminary finding(s) of the inspection and shall give the person a reasonable opportunity to submit additional facts or other information to the surveyor in response to those findings. The response shall be made a part of the inspection for all purposes and must be received by the department within 14 calendar days of receipt of the preliminary findings of the inspection by the facility.

(4) After the inspection is completed, the department shall provide the administrator of the facility specific and timely written notice of the findings of the inspection in accordance with paragraph (7) of this subsection.

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

(6) If the surveyor finds there are deficiencies, the department shall provide the facility with a statement of the deficiencies; the surveyor's recommendation for further action; or if there are no deficiencies found, a statement indicating this fact.

(7) If the department representative finds there are deficiencies, the facility and the department shall comply with the following procedure.

(A) The department shall provide the facility with a statement of deficiencies onsite at the time of the exit conference or within 14 calendar days of the exit conference.

(B) The facility administrator or person in charge 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 facility shall have the option to challenge any deficiency cited after receipt of the statement of deficiencies. A challenge to a deficiency(ies) shall be in accordance with this subparagraph.

(i) An initial challenge to a deficiency(ies) shall be submitted in writing no later than 14 calendar days from the facility's receipt of the statement of deficiencies to the program director for abortion facility licensing, Health Facility Licensing and Compliance Division, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756-3199. The initial written challenge shall include any and all documents supporting the facility's position.

(ii) If the initial challenge is favorable to the department, the facility may request a review of the initial challenge by submitting a written request to the Director, Health Facility Licensing and Compliance Division, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756-3199. The facility shall submit its written request for review of the initial challenge no later than 14 calendar days of its receipt of the department's response to the initial challenge. The department will not accept or review any documents that were not submitted with the initial challenge. A determination by the Director, Health Facility Licensing and Compliance Division, relating to a challenge to a deficiency(ies) will be considered the final determination by the department.

(iii) The department shall respond to any written challenge submitted under clauses (i) or (ii) of this subparagraph no later than 14 calendar days from its receipt.

(D) 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 facility and request that the plan of correction be modified by telephone or resubmitted no later than 14 calendar days from receipt of such request by the facility.

(E) If the facility does not come into compliance by the required date of correction, the department may propose to deny, suspend, place on probation, or revoke the license in accordance with §139.32 of this title (relating to License Denial, Suspension, Probation, or Revocation).

(F) Acceptance of a plan of correction by the department does not preclude the department from taking enforcement action as appropriate under §139.32 of this title.

(8) The department shall refer issues and complaints relating to the conduct or action(s) by licensed health care professionals to their appropriate licensing boards.

(c) Complaints.

(1) In accordance with §139.50 of this title (relating to Disclosure Requirements), all licensed abortion facilities are required to provide the patient and her guardian, if present, if the patient is a minor at time of the initial visit or if guardianship is required, with a written statement that complaints relating to the abortion facility may be registered with the Director, Health Facility Licensing and Compliance Division, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756-3199.

(2) The department will evaluate all complaints against licensed abortion facilities. All complaints submitted to the department must be in writing and signed by the complainant. Only those allegations determined to be relevant to the Act or this chapter will be authorized for investigation. All information pertaining to a complaint is strictly confidential.

(3) The department or its authorized representative may enter the premises of an abortion facility during normal business hours as necessary to assure compliance with the Act and this chapter. The investigation may be conducted on-site, by phone or by mail.

(4) Conduct of the on-site investigation of a licensed abortion facility will include, but not be limited to:

(A) a conference prior to commencing the on-site investigation for the purpose of explaining the nature and scope of the investigation between the department's authorized representative and the administrator of the abortion facility, or his or her designee;

(B) an inspection of the facility;

(C) an inspection of medical records, personnel records, administrative files, reports, other records, and/or working papers;

(D) an interview with any physician or other health care practitioner, including abortion facility personnel who care for the recipient of abortion services;

(E) a conference at the conclusion of the inspection between the department's

representative and the administrator or his or her designee of the facility; and

(F) identification by the department's representative of any facility documents that have been reproduced.

(5) If the department finds that there are deficiencies following the on-site inspection, the provisions of subsection (b)(6) and (7) of this section will apply.

(6) The department will review the report of the investigation and determine the validity of the complaint.

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

(a) The department may refuse to issue or renew a license for a facility if the facility fails to comply with any provisions of the Act, or Health and Safety Code, Chapters 245 and 171.

(b) The department may suspend, place on probation, or revoke the license of a facility for one or more of the following reasons:

(1) the facility commits 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 Act;

(2) the facility or any of its employees materially alters any license issued by the department;

(3) the facility or its employees commits an act which causes immediate jeopardy to the health and safety of a patient;

(4) the facility is cited for deficiencies and fails to submit an acceptable plan of correction in accordance with this chapter;

(5) the facility has been cited for deficiencies and fails to timely comply with minimum standards for licensure within the dates designated in the plan of correction;

(6) the facility or any of its employees has aided, abetted, or permitted the commission of an illegal act;

(7) the facility or any of its employees fails to comply with any provisions of the Act or this chapter;

(8) the facility is not in compliance with minimum standards for licensure;

(9) the facility fails to provide the required application or renewal information;

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

(11) the facility discloses an action described in §139.23(c)(2)(C)(xii) and (xiii) of this title (relating to Application Procedures and Issuance of Licenses);

(12) the facility knowingly employs as the facility administrator or chief financial officer an individual who was convicted of a felony or misdemeanor listed in subsection (c) of this subsection;

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

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

(c) 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.

(1) In determining whether a criminal conviction directly relates to the duties and responsibilities of the ownership or operation of a licensed abortion facility, and in determining the fitness of a person who has been convicted of a crime to perform such duties and responsibilities, the department shall consider the provisions of Texas Occupations Code, Chapter 53.

(2) 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.

(3) The following felonies and misdemeanors directly relate to the duties and responsibilities of the ownership or operation of a licensed abortion facility because these criminal offenses demonstrate impaired ability to own or operate a facility:

(A) a misdemeanor violation of Health and Safety Code (HSC), Chapter 244;

(B) a misdemeanor or felony involving moral turpitude;

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

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

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

(F) a misdemeanor or felony under the Texas Penal Code (TPC), Title 5, involving a patient or client of any health care facility, a home and community support services agency or a health care professional;

(G) a misdemeanor or felony under the TPC:

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

(ii) Title 5 - offenses against the person;

(iii) Title 7 - offenses against property;

(iv) Title 8 - offenses against public administration;

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

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

(vii) Title 11 - offenses involving organized crime.

(4) Offenses listed in paragraph (3) of this subsection are not exclusive in that the department may consider similar criminal convictions from other state, federal, foreign or military jurisdictions which indicate an impaired ability or tendency for the person to be unable to own or operate a facility.

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

(d) All proceedings for the denial, suspension, probation, or revocation of a license under this section will be conducted at the State Office of Administrative Hearings, and in accordance with Chapter 245 of the Texas Health and Safety Code, Chapter 2001 of the Texas Government Code,

and the Formal Hearing Procedures of the Texas Department of Health (Texas Administrative Code, Title 25, Part 1).

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

(f) After an inspection in which deficiencies were cited by the surveyor, a facility 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 facility, 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 an inspection of the facility 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 revokes or does not renew a license, a person may reapply for a license (subject to subsection (d) 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 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 non-renewal, a license holder shall return the original license certificate to the department.

(j) Upon a licensee's felony conviction, felony probation revocation, revocation of parole, or revocation of mandatory supervision, the license shall be revoked.

(k) If the department finds that a licensed abortion facility is in repeated noncompliance with Health and Safety, Chapter 245, or rules adopted under this chapter, but the noncompliance does not

in any way involve the health and safety of the public or an individual, the department may schedule the facility for probation rather than suspending or revoking the facility's license.

(l) The department may suspend or revoke the license of a licensed abortion facility that does not correct items that were in noncompliance or that does not comply with Health and Safety Code, Chapter 245, or rules adopted under this chapter within the applicable probation period.

(m) The department may suspend or revoke a license to be effective immediately when a situation(s) is identified that poses immediate jeopardy to the health and safety of person(s) at the facility.

(1) The department shall immediately give the licensee adequate notice of the action taken, the legal grounds for the action, and the procedure governing appeal of the action.

(2) The department shall set a hearing date not later than the 14th day after the effective date of the suspension or revocation.

(3) The department shall also notify the facility in writing of the emergency action, the legal grounds for the action, the effective date of the emergency action, the procedure governing appeal of the action, and the date set for the hearing. This notice shall be sent by certified mail, return receipt requested, or by personal delivery. The hearing shall be conducted at the State Office of Administrative Hearings, and pursuant to the Texas Health and Safety Code, Chapter 245, Texas Government Code, Chapter 2001 and the department's formal hearing procedures set out in Chapter 1 of this title.

(n) If a person violates the licensing requirements of the Act or rules adopted under the Act, the department may petition the district court for a temporary restraining order to restrain the person from continuing the violation or operating without a license.

(o) If a person operates a facility without a license as required by this chapter and the Act, the person is liable for a civil penalty of not less than $1,000 nor more than $2,500 for each day of violation.

(p) If a facility has had enforcement action taken by the department against it, the facility, its owner(s), or its affiliate(s) may not apply for a facility license for one year following the effective date of the enforcement action. For purposes of this subsection only, the term "enforcement action" means license revocation, suspension, emergency suspension, or denial or injunctive action but does not include administrative penalties or civil penalties. If the department prevails in one enforcement action (e.g., injunctive action) against the facility but also proceeds with another enforcement action (e.g., revocation) based on some or all of the same violations, but the department does not prevail in the second enforcement action (e.g., the facility prevails), the prohibition in this paragraph does not

apply.

(q) If the department suspends a license, the suspension shall remain in effect until the department determines that the reason for suspension no longer exists. An authorized representative of the department shall conduct an on-site inspection of the facility prior to making a determination.

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

(r) If the department revokes or does not renew a license and the one-year period described in subsection (p) of this section has passed, a person may reapply for a license 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 revocation or nonrenewal continues to exist.

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

(t) After an on-site inspection in which deficiencies were cited by the surveyor, a facility may surrender its license before expiration or allow its license to expire in lieu of the department proceeding with enforcement action. A facility may surrender before the expiration date by returning its original license to the department. If a facility surrenders or allows expiration of the license, the facility, its owner(s), and its affiliates may not reapply for a license for six months from the date of the surrender or expiration.

§139.33. Administrative Penalties, Injunction, Criminal Penalties, and Civil Penalties.

(a) Administrative penalties.

(1) The department may assess an administrative penalty against a person who violates the Act or this chapter.

(2) The penalty may not exceed $1,000 for each violation. Each day of a continuing violation constitutes a separate violation.

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

(A) the seriousness of the violation;

(B) the history of previous violations;

(C) the amount necessary to deter future violations;

(D) efforts made to correct the violation; and

(E) any other matters that justice may require.

(4) All proceedings for the assessment of an administrative penalty under this section will be conducted at the State Office of Administrative Hearings, and pursuant to the Texas Health and Safety Code (HSC), Chapter 245, the Texas Government Code, Chapter 2001, and the department's formal hearing procedures set out in Chapter 1 of this title.

(5) The department may assess costs against facilities in administrative proceedings in accordance with HSC, Chapter 245.

(b) Injunction, criminal penalties, and civil penalties. In addition to administrative penalties, the Texas Health and Safety Code, Chapter 245, provides for injunctive relief and civil penalties for violations of that chapter and violations of these rules. Chapter 245 also provides for criminal penalties for certain violations described therein.

Subchapter D. Minimum Standards for Licensed Abortion Facilities.

§139.41. Policy Development and Review.

(a) The licensee shall be responsible for the conduct of the licensed abortion facility and shall assume full legal responsibility for developing, implementing, enforcing, and monitoring written policies governing the facility's total operation and for ensuring that these policies comply with the Act and the applicable provisions of this chapter and are administered so as to provide health care in a safe and professionally acceptable environment. These written polices shall include at a minimum the following:

(1) administrative policies governing the administration of the facility, covering at a minimum:

(A) personnel;

(B) employee orientation, training, and evaluation;

(C) employee and patient record system;

(D) auditing system for monitoring state or federal funds;

(E) advertisements for the facility;

(F) accuracy of public education information materials and activities in relation to abortion, birth control, and sexually-transmitted diseases;

(G) patient education/information services and referral services;

(H) reporting requirements; and

(I) procedures for the resolution of complaints regarding care or services rendered by licensed health professionals and other members of the facility staff, including contract services or staff. The facility shall document the receipt and the disposition of the complaint. The investigation and documentation must be completed within 30 calendar days after the facility receives the complaint, unless the facility has and documents reasonable cause for a delay.

(2) clinical policies governing medical and clinical practices and procedures of the facility, covering at a minimum:

(A) the provision of medical and clinical services;

(B) the provision of laboratory services;

(C) examination of fetal tissue;

(D) disposition of medical waste;

(E) emergency services;

(F) condition on discharge procedures;

(G) clinical records;

(H) reporting and filing requirements; and

(I) monitoring postprocedure infection(s).

(3) a policy to ensure that the facility is in compliance with fire safety provisions as required by the local codes;

(4) policies on decontamination, disinfection, and sterilization, and storage of sterile supplies;

(5) policies for parental notice for unemancipated pregnant minors as stipulated in Family Code, Chapter 33;

(6) policies for informed consent as stipulated in Health and Safety Code, Chapter 171, the Woman's Right to Know Act;

(7) policies for reporting suspected abuse or neglect as stipulated in Family Code, Chapter 261; and

(8) policies to ensure all women who present to obtain an abortion provide identification that includes the woman's date of birth.

(A) If the woman does not have identification stating her date of birth, she will be required to execute an affidavit on a form published by the department indicating that she does not have appropriate identification and indicating her date of birth on the affidavit.

Figure: 25 TAC §139.41(a)(8)(A)

(B) The facility will keep a copy of the identification presented or the affidavit in its files.

(b) The licensee, in fulfilling its responsibility under subsection (a) of this section, shall review the facility's written policies and procedures periodically, but no less than once every two years; date to indicate time of last review; revise as necessary; and enforce.

§139.42. Delegation of Authority and Organizational Structure.

(a) Delegation of authority.

(1) The licensee shall appoint a medical consultant who shall be responsible for:

(A) implementing and enforcing the clinical policies of the facility; and

(B) supervising all medical services provided at the facility, such as medical, nursing, clinical, laboratory, and information/education services.

(2) The licensee shall appoint an administrator who shall be responsible for implementing and supervising the administrative policies of the facility.

(3) The licensee shall designate in writing a person who meets the qualifications of an administrator to act in the absence of the administrator.

(b) Organizational structure. The licensee shall develop a written organization structure which shall be in a chart format or a narrative explanation that provides a description of the structure of the licensed abortion facility and defines the lines of authority.

(1) The written organizational structure shall include, at a minimum, the identification of the licensee, medical consultant, administrator, and clinical staff.

(2) The written organizational structure shall clearly define the lines of authority and the delegation of responsibility for professional and non-professional staff (including the medical consultant, the administrator, the medical and clinical staff, and ancillary staff).

§139.43. Personnel Policies.

The licensee shall develop, implement and enforce policies which shall govern all personnel staffed by the facility using the following minimum criteria:

(1) job descriptions, including qualifications for all personnel providing direct or indirect patient care;

(2) a requirement for orientation of all employees, volunteers, students and contractors to the policies and objectives of the facility and participation by all personnel in employee training specific to their job;

(3) job-related training for each position;

(4) a requirement for an annual evaluation of employee performance;

(5) in service and continuing education requirements;

(6) a requirement that all personnel providing direct patient care be currently certified in basic life support by the American Heart Association, the American Red Cross, or the American

Safety and Health Institute, or in accordance with their individual professional licensure requirements, and if required in their job description or job responsibilities;

(7) a requirement that all personnel having direct contact with patients (employed or contracting with the facility) sign a statement that they have read, understand, and will respect the rights of all patients as established in §139.51 of this title (relating to Patient Rights at the Facility); and

(8) a requirement that all personnel complete a training program developed jointly by the department and the Department of Protective and Regulatory Services (DPRS) concerning their individual duties to report child abuse, how to identify and recognize abuse, and the jurisdiction of DPRS and local law enforcement over child abuse.

§139.44. Orientation, Training, and Demonstrated Competency.

(a) A licensed abortion facility shall develop and implement a written orientation and training program to familiarize all employees (including office staff) with the facility's policies, philosophy, job responsibilities of all staff, and emergency procedures.

(b) In implementing the orientation and training program, a licensed abortion facility shall orient and train each employee to ensure, through demonstrated competency, that:

(1) the employee understands his or her specific job description;

(2) the employee understands the facility's policy and procedure manual, including protocols and description of the roles and responsibilities of all personnel;

(3) the employee understands, at a minimum but not limited to, the following:

(A) coordination and treatment of patient care;

(B) sterilization and infection control policies;

(C) patient education/information;

(D) informed consent policies;

(E) abortion techniques provided at that facility;

(F) care of the patient before, during, and after an abortion procedure;

(G) patient rights;

(H) possible complications of the abortion procedure; and

(I) prevention of infectious diseases.

(c) The facility shall ensure that staff responsible for sterilization of critical surgical instruments are trained by the facility to meet the requirements of §139.49(d) of this title (relating to Infection Control Standards) and demonstrate competency in performing the sterilization procedures at the facility.

(d) The facility shall ensure that all staff are aware of the reporting requirements for child abuse or neglect under Family Code, §261.101; and reporting requirements for family violence under Family Code, §73.02 and §73.03.

(e) The facility shall document in each employee's personnel record evidence of all training and orientation received.

§139.45. Personnel Records.

An individual personnel record shall be maintained on each person employed by the licensed abortion facility which shall include, but not be limited to, the following:

(1) current job description for the employee, which is reviewed and revised as needed;

(2) verification of current license and certification of personnel required to have a license and or certification;

(3) clinical laboratory tests results and vaccinations if required by law (e.g., Mycobacterium tuberculosis, hepatitis B virus);

(4) documentation of the education, training, and experience of the employee, in addition to a copy or verification of the employee's current license or certification credentials, or both; and

(5) documentation of the employee's orientation, in-service and other educational programs provided by the licensed abortion facility (training), and employee evaluation.

§139.46. Licensed Abortion Facility Staffing Requirements and Qualifications.

A licensed abortion facility shall have an adequate number of personnel qualified under this section available to provide direct patient care as needed by all patients; and administrative and non-clinical services needed to maintain the operation of the facility in accordance with the provisions of the Act and this chapter.

(1) Medical consultant. The medical consultant shall be a physician.

(2) Administrator.

(A) The administrator shall be at least 18 years of age and shall meet at least one of the following qualifications:

(i) be a licensed health care professional;

(ii) have a baccalaureate degree, a post graduate degree, or a professional degree and one year administrative experience in a health care or health-related field; or

(iii) have a minimum of two years of administrative experience in a health care or health-related facility.

(B) The administrator shall not have been employed in the last year as an administrator with another abortion facility or health-related facility at the time the facility was cited for violations of a licensing law or rule which resulted in enforcement action taken against the abortion facility or health-related facility. For purposes of this subparagraph only, the term "enforcement action" means license revocation, suspension, emergency suspension, probation, denial or injunctive action but does not include administrative penalties or civil penalties. If the department prevails in one enforcement action (e.g., injunctive action) against the facility but also proceeds with another enforcement action (e.g., revocation) based on some or all of the same violations, but the department does not prevail in the second enforcement action (e.g., the facility prevails), the prohibition in this paragraph does not apply.

(C) The administrator shall not have been convicted of a felony or misdemeanor listed in §139.32 of this title (relating to License Denial, Suspension, Probation, or Revocation).

(3) Direct patient care staff.

(A) Medical staff. The medical staff shall include a physician and may include midlevel providers.

(B) Nursing staff. The nursing staff shall include a registered nurse(s) or a

licensed vocational nurse(s).

(C) Education and information staff. Staff providing education and information services at the facility shall be a person(s) who is trained to provide information on surgical abortion procedures, medical abortions, alternatives to abortion, consent form, and family planning services, and meets at least one of the following additional qualifications:

(i) has one year experience in a health care facility;

(ii) has a baccalaureate degree; or

(iii) is a licensed professional mental health practitioner who provides therapeutic intervention.

(D) Laboratory staff. The laboratory staff shall include a person(s) who is trained to provide the laboratory services for the facility as determined by the medical consultant.

(4) Ancillary staff. Ancillary staff may include professional or nonprofessional staff who shall have training and experience to perform duties as prescribed by the administrator and the medical consultant as needed.

(5) Anesthesia staff. Minimum staffing is required for each level of sedation/analgesia and for general anesthesia if offered by the facility and as established in §139.59 of this title (relating to Anesthesia Services).

§139.47. Licensed Abortion Facility Administration.

(a) The administrator shall be responsible for implementing and supervising the administrative policies of the facility.

(b) The administrator shall:

(1) employ a qualified staff adequate in number to:

(A) provide the medical and clinical services;

(B) provide the non-clinical services; and

(C) maintain the abortion facility;

(2) ensure that employment of personnel is without regard to age, race, religion, or

national origin;

(3) ensure that all medical and clinical personnel hold current Texas licenses to practice their respective disciplines/professions, if applicable;

(4) develop and make available to all staff and the department, a policy and procedure manual including protocols and description of the roles and responsibilities of all personnel;

(5) ensure that assignment of duties and functions to each employee are commensurate with his/her licensure, certification, and experience and competence;

(6) ensure that staff receive training, education, and orientation to their specific job description, facility personnel policies, philosophy, and emergency procedures in accordance with this section;

(7) schedule employee evaluations;

(8) maintain employee and patient records;

(9) ensure the accuracy of public education information materials and activities in relation to abortion, birth control, and sexually-transmitted diseases. The department shall be the primary resource for human immunodeficiency virus (HIV) education, prevention, risk reduction materials, policies, and information. Educational materials may be obtained by writing or calling the Texas Department of Health Warehouse, Literature and Forms, 1100 West 49th Street, Austin, Texas 78756, (512) 458-7761;

(10) implement an effective budgeting, accounting, and auditing system for receipt of state or federal funds;

(11) ensure that all advertisements for the facility include the unique identifying license number assigned by the department in accordance with §139.7 of this title (relating to Unique Identifying Number; Disclosure in Advertisement);

(12) ensure that a woman, at the time of initial on-site consultation, receives the information required to be disclosed under §139.50 of this title (relating to Disclosure Requirements); and

(13) ensure that the reporting requirements of §139.4 of this title (relating to Annual Reporting Requirements For All Abortions Performed) are performed.

(c) A licensed abortion facility shall report violations of practice acts and conditions of

license for its licensed health care professional(s) to the appropriate licensing board. If the patient is unsatisfied with the facility's findings, the facility shall provide the complainant with the name, address, and telephone number of the appropriate licensing board. The facility shall document the review and action taken by the facility.

§139.48. Physical and Environmental Requirements.

The physical and environmental requirements for a licensed abortion facility are as follows.

(1) A facility must:

(A) have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients and staff at all times;

(B) equip each procedure room so that procedures can be performed in a manner that assures the physical safety of all individuals in the area;

(C) have a separate recovery room;

(D) have a written protocol for emergency evacuation for fire and other disasters tailored to the facility's geographic location. Each staff member employed by or under contract with the facility shall be able to demonstrate their role or responsibility to implement the facility's emergency evacuation protocol required by this subparagraph;

(E) store hazardous cleaning solutions and compounds in a secure manner and label substances;

(F) have the capacity to provide patients with liquids. The facility may provide commercially packaged food to patients in individual servings. If other food is provided by the facility, it will be subject to the requirements of §§229.161-229.171 of this title (relating to Food Service Sanitation);

(G) provide clean hand washing facilities for patients and staff including running water, and soap;

(H) have two functioning sinks and a functioning toilet; and

(I) have equipment available to sterilize instruments, equipment, and supplies in accordance with §139.49(d) of this title (relating to Infection Control Standards) before use in the facility.

(2) The equipment for vacuum aspiration shall be electrically safe and designed to prevent reverse pump action.

(3) Projects involving alterations of and additions to existing buildings shall be programmed and phased so that on-site construction will minimize disruptions of existing functions. Access, exitways, and fire protection shall be maintained so that the safety of the occupants will not be jeopardized during construction.

§139.49. Infection Control Standards.

(a) Written policies. A licensed abortion facility shall develop, implement, and enforce infection control policies and procedures to minimize the transmission of postprocedure infections. These policies shall include, but not be limited to, the prevention of the transmission of human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), Mycobacterium tuberculosis (TB), and Streptococcus species (SP); educational course requirements; cleaning and laundry requirements; and decontamination, disinfection, sterilization, and storage of sterile supplies.

(b) Prevention and control of the transmission of HIV, HBV, HCV, TB, and SP.

(1) Universal/standard precautions.

(A) An abortion facility shall ensure that all staff comply with universal/standard precautions as defined in this paragraph.

(i) Universal/standard precautions includes procedures for disinfection and sterilization of reusable medical devices and the appropriate use of infection control, including hand washing, the use of protective barriers, and the use and disposal of needles and other sharp instruments.

(ii) Universal/standard precautions synthesize the major points of universal precautions with the points of body substance precautions and applies them to all patients receiving care in facilities, regardless of their diagnosis or presumed infection status.

(I) Universal/standard precautions apply to:

(-a-) blood;

(-b-) body fluids, secretions, and excretions except sweat, regardless of whether or not they contain visible blood;

(-c-) nonintact skin; and

(-d-) mucous membranes.

(II) Universal/standard precautions are designed to reduce the risk of transmission of microorganisms from both recognized and unrecognized sources of infection in facilities.

(B) A licensed abortion facility shall establish procedures for monitoring compliance with universal/standard precautions described in subparagraph (A) of this paragraph.

(2) Health care workers infected with the HIV or HBV. A licensed abortion facility shall adopt, implement, and enforce a written policy to ensure compliance of the facility and all of the health care workers within the facility with the Health and Safety Code, Chapter 85, Subchapter I, concerning the prevention of the transmission of HIV and HBV by infected health care workers.

(3) Educational course work and training. A licensed abortion facility shall 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. To fulfill the requirements of this paragraph, course work and training may include formal education courses or in-house training or workshops provided by the facility. The course work and training shall include, but not be limited to:

(A) HIV infection prevention; and

(B) HBV, HCV, TB, and SP infection prevention based on universal/standard precautions as defined in paragraph (1) of this subsection;

(C) bidirectional aspect of disease transmission; and

(D) epidemic control.

(c) Cleaning and laundry policies and procedures.

(1) A licensed abortion facility shall develop, implement, and enforce written policies and procedures on cleaning the procedure room(s).

(2) A licensed abortion facility shall develop, implement, and enforce written policies and procedures for the handling, processing, storing, and transporting of clean and dirty laundry.

(3) A licensed abortion facility may provide cleaning and laundry services directly or by contract in accordance with Occupational Safety and Health Association's standards 29 Code of Federal Regulations, Subpart Z. Bloodborne Pathogens.

(d) Policies and procedures for decontamination, disinfection, sterilization, and storage of sterile supplies. A licensed abortion facility shall have written policies covering its procedures for the decontamination and sterilization activities performed. Policies shall include, but not be limited to, the receiving, cleaning, decontaminating, disinfecting, preparing and sterilization of critical items (reusable items), as well as those for the assembly, wrapping, storage, distribution, and the monitoring and control of sterile items and equipment.

(1) Supervision. The decontamination, disinfection, and sterilization of all supplies and equipment shall be under the supervision of a person qualified by education, training, or experience.

(2) Quantity of sterile surgical instruments. The facility shall ensure that surgical instruments are sufficient in number to permit sterilization of the instrument(s) used for each procedure and adequate to perform conventional cervical dilatation and curettage.

(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 box locks shall be clean and free from buildup of soap, detergent, dried blood, or tissue.

(ii) There shall be no evident cracks or fissures in the box locks, and the hinges shall work freely.

(iii) Ratchets shall hold and be routinely tested.

(iv) There shall be no corrosion or pitting of the finish.

(C) Instruments needing maintenance shall be taken out of service and repaired by someone qualified to repair surgical instruments.

(D) To protect the instrument and its protective finish, impact markers or electric engravers shall not be used for instrument identification. Instrument identification shall be accomplished by the instrument manufacturer, employing methods which will not damage the instrument or its protective finish.

(4) Items to be disinfected and sterilized.

(A) Critical items.

(i) Critical items include all surgical instruments and objects that are introduced directly into the bloodstream or into other normally sterile areas of the body and must be sterilized in accordance with this subsection.

(ii) All items that come in contact with the sterile field during the operative procedure must be sterile.

(B) Semicritical items.

(i) Semicritical items include items that come in contact with nonintact skin or mucous membranes. Semicritical items shall be free of microorganisms, except bacterial spores. Semicritical items may include respiratory therapy equipment, anesthesia equipment, bronchoscopes, and thermometers.

(ii) High-level disinfection shall be used for semicritical items.

(C) Noncritical items.

(i) Noncritical items include items that come in contact with intact skin.

(ii) 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 licensed abortion facility shall provide sterilization equipment adequate to meet the requirements of this paragraph for sterilization of critical items. Equipment shall be maintained and operated to perform, with accuracy, the sterilization of critical

items.

(B) Environmental requirements. Where cleaning, preparation, and sterilization functions are performed in the same room or unit, the physical facilities, equipment, and the written policies and procedures for their use shall be such as to effectively separate soiled or contaminated supplies and equipment from the clean or sterilized supplies and equipment.

(i) A facility shall have a sink for hand washing. This sink shall not be used for cleaning instruments or disposal of liquid waste.

(ii) A facility shall have a separate sink for cleaning instruments and disposal of liquid waste. Hand washing shall only be performed at this sink after it has been disinfected.

(C) Preparation for sterilization.

(i) All items to be sterilized shall be prepared to reduce the bioburden. All items shall be thoroughly cleaned, decontaminated and prepared in a clean, controlled environment. Cleaning is the removal of all adherent visible soil from the surfaces, crevices, joints, and lumens of instruments. Decontamination is the physical/chemical process that renders an inanimate object safe for further handling.

(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. Ultrasonic cleaning of instruments cleans by cavitation and reduces the need for hand scrubbing. When grossly soiled items are placed in the ultrasonic cleaner the water must be changed more than once a shift. If using this method for cleaning, chambers shall be covered to prevent potential hazards to personnel from aerosolization of the contents.

(III) Washer-sterilizers. Washer-sterilizers clean by using rotating spray arms to create water jets that clean by impingement and appropriate soap and disinfectant. These machines must reach a temperature of 140 degrees Celsius (285 degrees Fahrenheit).

(IV) Washer-decontaminator machines. Washer-decontaminator machines clean by numerous water jets and a high-pH of detergent even if

instruments are grossly soiled. The thorough cleaning is followed by a neutralizing rinse to quickly restore the pH to neutral.

(iii) All articles to be sterilized shall be arranged so all surfaces will be directly exposed to the sterilizing agent for the prescribed time and temperature.

(D) Packaging.

(i) All wrapped articles to be sterilized shall be packaged in materials recommended for the specific type of sterilizer and material to be sterilized, and to provide an effective barrier to microorganisms. Acceptable packaging includes peel pouches, perforated metal trays, or rigid trays. Muslin packs must be limited in size to 12 inches by 12 inches by 20 inches with a maximum weight of 12 pounds. Wrapped instrument trays must not exceed 17 pounds.

(ii) All items shall be labeled for each sterilizer load as to the date and time of sterilization, the sterilizing load number, and the autoclave.

(E) External chemical indicators.

(i) External chemical indicators, also known as sterilization process indicators, shall be used on each package to be sterilized, including items being flash sterilized to indicate that items have been exposed to the sterilization process.

(ii) The indicator results shall be interpreted according to the manufacturers' written instructions and indicator reaction specifications.

(F) Biological indicators.

(i) The efficacy of the sterilizing process shall be monitored with reliable biological indicators appropriate for the type of sterilizer used (e.g., Bacillus stearothermophilus for steam sterilizers).

(ii) Biological indicators shall be included in at least one run each day of use for steam sterilizers.

(iii) A log shall be maintained with the load identification, biological indicator results, and identification of the contents of the load.

(iv) 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.

(v) All available items shall be recalled and reprocessed if a sterilizer malfunction is found. A list of all items which were used after the last negative biological indicator test shall be submitted to the administrator.

(G) Sterilizers.

(i) 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.

(ii) Other sterilizers shall be used in accordance with the manufacturer's instructions.

(H) Maintenance of sterility.

(i) Items that are properly packaged and sterilized will remain sterile indefinitely unless the package becomes wet or torn, has a broken seal, is damaged in some way, or is suspected of being compromised.

(ii) Medication or materials within a package that deteriorate with the passage of time, shall be dated according to the manufacturer's recommendations.

(iii) All packages must be inspected before use. If a package is torn, wet, discolored, has a broken seal, or is damaged, the item may not be used. The item must be returned to sterile processing for reprocessing.

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

(J) Storage of sterilized items. The loss of sterility is event-related, not time related. The facility shall ensure proper storage and handling of items in a manner that does not compromise the packaging of the product.

(i) Sterilized items shall be transported so as to maintain cleanliness and 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 so that their sterility is not compromised.

(iv) Storage of supplies shall be in areas that are designated for storage.

(K) Disinfection.

(i) The manufacturer's written instructions for the use of disinfectants shall be followed.

(ii) An expiration date, determined according to manufacturer's written recommendations, shall be marked on the container of disinfection solution currently in use.

(iii) Disinfectant solutions shall be kept covered and used in well ventilated areas.

(L) Performance records.

(i) Performance records for all sterilizers shall be maintained for each cycle. These records shall be retained and available for review for a minimum of two years.

(ii) Each sterilizer shall be monitored during operation for pressure, temperature, and time at desired temperature and pressure. A record shall be maintained either manually or machine generated and shall include:

(I) the sterilizer identification;

(II) sterilization date and time;

(III) load number;

(IV) duration and temperature of exposure phase (if not provided on sterilizer recording charts);

(V) identification of operator(s);

(VI) results of biological tests and dates performed; and

(VII) time-temperature recording charts from each sterilizer (if not provided on sterilizer recording charts).

(M) Preventive maintenance. Preventive maintenance of all sterilizers shall be performed according to individual policy on a scheduled basis by qualified personnel, using the sterilizer manufacturer's service manual as a reference. A preventive maintenance record shall be maintained for each sterilizer. These records shall be retained at least two years and shall be available for review to the facility within two hours of request by the department.

§139.50. Disclosure Requirements.

(a) At the time of a woman's initial consultation with a licensed abortion facility, the facility shall comply with the following.

(1) Provide the woman with a written statement indicating the number of the toll-free telephone line which is maintained by the department to provide specific information relating to licensed abortion facilities in Texas. The statement shall be in accordance with §139.6 of this title (relating to Public Information; Toll-free Telephone Number).

(2) Provide the woman with a written statement identifying the department as the responsible agency for facility complaint investigations. The statement shall inform persons to register complaints with the Director, Health Facility Licensing and Compliance Division, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756. Complaints must be registered with the department in writing. A complainant must provide his/her name. All complaints shall be confidential.

(3) Provide the woman with a copy of the department's "A Woman's Right to Know" booklet created for women seeking an abortion, if the woman chooses to view it.

(4) Provide the woman with a copy of the department's "A Woman's Right to Know" resource directory (required by Health and Safety Code, §171.015), if the woman chooses to view it.

(5) Inform the woman of her option to view the department's "A Woman's Right to Know" booklet and resource directory on the world wide web and provide her with the internet address for obtaining the information.

(6) Provide the woman with a written statement that she may call the department at (888) 973-0022 if the facility does not provide her with the information required in paragraphs (3) and (4) of this subsection.

(b) The facility shall ensure that the woman has been provided with all information required for voluntary and informed consent, as mandated by HSC, §171.012(a)(1)-(2) at least 24 hours prior to the abortion procedure.

(c) The facility shall initiate a clinical record for the woman at the time of the initial consultation. The following information pertaining to disclosure, as described in this section, must be documented in the clinical record:

(1) the date and time of the initial consultation;

(2) the method by the which the information required under subsections (a) and (b) of this section was provided; and

(3) the name and title of individual(s) who provided or verified the information required under subsections (a) and (b) of this section.

§139.51. Patient Rights at the Facility.

A licensed abortion facility shall ensure that all patients:

(1) be allowed to make her own choice and self-determination;

(2) are ensured the right to personal privacy and confidentiality of her choices and decisions;

(3) are ensured the right to voluntary and informed consent as defined in Health and Safety Code (HSC), §171.012, without paying a fee for the informational materials;

(4) are ensured individual counseling concerning private medical information and to be given a private opportunity to ask questions;

(5) be allowed to view their medical record, including the sonogram, if one has been performed, at any time as provided by law;

(6) have access to care and treatment consistent with available resources and generally accepted standards regardless of race, creed, and national origin;

(7) are allowed to ask additional questions after giving consent and to withdraw consent while still medically safe to do so;

(8) are provided freedom from abuse, neglect, or exploitation as those terms are defined in §1.204 of this title (relating to Abuse, Neglect, or Exploitation Defined); and

(9) be allowed to review the department's informational materials as described in HSC, §§171.014 and 171.015.

§139.52. Patient Education/Information Services.

(a) A licensed abortion facility shall ensure patient education/information services are provided to each patient to:

(1) ensure compliance with Health and Safety Code, §§171.011 and 171.012, concerning informed consent by utilizing the department's certification form, signed by the woman prior to an abortion procedure, and maintained in the patient's clinical record;
Figure: 25 TAC §139.52(a)(1)

(2) prepare the patient for surgery in a manner that facilitates her safety and comfort;

(3) assist the patient in reaching a decision about the method of post-procedure birth control she will use, if any, and respect her choices; and

(4) ensure, when medically appropriate, the patient is advised of the physician's obligation to take all reasonable steps to maintain the life and health of a child who is born alive.

(b) A licensed abortion facility shall, if needed, refer a patient to a licensed mental health practitioner who provides therapeutic intervention.

§139.53. Medical and Clinical Services.

(a) Surgical abortion.

(1) The medical consultant shall be responsible for implementing and supervising the medical and clinical policies of the facility.

(2) All medical and clinical services of the facility, with the exception of the abortion procedure, must be provided under the direction of a physician or registered nurse who assumes responsibility for the clinical employees' performance in the facility.

(3) A licensed abortion facility must ensure that a surgical consent form is signed by the patient prior to the procedure being started, that the patient is informed of the risks and the benefits of the procedure, and that the patient recognizes the alternatives to abortion. Informed consent shall be in accordance with rules adopted by the Texas Medical Disclosure Panel under §601.2 of this title (relating to Procedures Requiring Full Disclosure--List A), §601.4 of this title (relating to Disclosure and Consent Form), and Health and Safety Code (HSC), §171.011 (relating to Informed Consent Required), and §171.012 (relating to Voluntary Informed Consent).

(4) A licensed abortion facility shall ensure that the attending physician has obtained and documented a preoperative history, physical exam, and laboratory studies, including verification of pregnancy.

(5) A licensed abortion facility shall ensure that:

(A) the attending physician examines each patient immediately prior to surgery to evaluate the risk to the procedure; and

(B) the person administering the anesthetic agent(s) examines the patient immediately prior to surgery to evaluate the risk of anesthesia.

(6) The administration of anesthesia must be in accordance with §139.59 of this title (relating to Anesthesia Services).

(7) An abortion shall be performed only by a physician.

(8) A physician, midlevel provider, registered nurse, or licensed vocational nurse must be in the facility whenever there is a patient in the procedure room or recovery room. While a patient is in the procedure room or recovery room she shall not be left unattended.

(9) The recovery room(s) at the facility must be supervised by a physician, midlevel provider, or registered nurse. This supervisor must be available for recovery room staff within a recommended 10 minutes with a maximum required 15 minutes while any patient is in the recovery room.

(10) A physician shall be available for the facility while any patient is in the recovery room within a recommended 10 minutes and a maximum required 15 minutes.

(11) The facility must ensure that a patient is fully reactive and her vital signs are stable before discharging the patient from the facility upon written order by the attending physician.

(12) All fetal tissue must be examined grossly at the time of the procedure. In the absence of visible fetal parts or placenta, the tissue may be examined by magnification for the detection of villi. If this examination is inconclusive, the tissue shall be sent to a pathology lab. The results of the tissue examination shall be recorded in the patient's clinical record.

(13) A facility shall meet the 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).

(b) Medical abortion.

(1) The medical consultant shall be responsible for implementing and supervising the medical and clinical policies of the facility.

(2) All medical and clinical services of the facility, with the exception of the abortion procedure, must be provided under the direction of a physician or registered nurse who assumes responsibility for the clinical employees' performance in the facility.

(3) A licensed abortion facility shall ensure:

(A) the physician(s) providing medical abortion is able to accurately date a pregnancy;

(B) the physician(s) is able to determine that the pregnancy is not an ectopic gestation;

(C) the physician(s) is able to provide surgical intervention or provide for the patient to receive a surgical abortion if necessary; and

(D) patients have access to medical facilities equipped to provide blood transfusion and patient resuscitation, if necessary.

(4) A licensed abortion facility shall ensure follow-up examination and services are provided to patients requesting medical abortion.

(5) A licensed abortion facility shall ensure that the attending physician has obtained and documented a pre-procedure history, physical exam, and laboratory studies, including verification of pregnancy.

(6) A licensed abortion facility shall ensure:

(A) written consent is obtained from the patient prior to the commencement of the abortion procedure;

(B) the patient is informed of the risks and benefits of the procedure;

(C) the patient is informed of the possibility that a surgical abortion may be required;

(D) the patient is informed of the alternatives to abortion; and

(E) informed consent is in accordance with rules adopted by the Texas Medical Disclosure Panel under §601.2 of this title (relating to Procedures Requiring Full Disclosure--List A), §601.4 of this title (relating to Disclosure and Consent Form), and HSC, §§171.011 (relating to Informed Consent Required), and 171.012 (relating to Voluntary Informed Consent).

(7) A licensed abortion facility shall provide the patient with written discharge instructions including a direct referral to a physician who will accept the patient for surgical abortion.

§139.54. Health Care Services.

(a) Definition. For the purposes of this section, the term "health care professional" includes:

(1) a physician;

(2) midlevel providers;

(3) a registered nurse;

(4) a licensed vocational nurse; or

(5) licensed mental health practitioner.

(b) Nursing services.

(1) A licensed abortion facility 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.

(2) A licensed abortion facility must ensure that licensed vocational nurses (LVNs) have been instructed and have demonstrated competence in the technique for administering intravenous fluids or medications and extracting blood for laboratory tests if allowing LVNs to perform such tasks.

(3) A licensed abortion facility may allow an LVN, whose formal training does not include venipuncture procedures, to perform such procedure if a physician, midlevel provider, or registered nurse (RN) documents that the LVN (by name) has received instruction in the performance of venipuncture and is qualified to perform such procedure.

(4) A licensed abortion facility may allow physicians to train non-licensed personnel, age 18 years or above, to extract blood for laboratory testing and to administer intravenous fluids.

(c) Student health care professionals. If the facility has a contract or agreement with an accredited school of health care to use their facility for a portion of the students' clinical experience, those students may provide care under the following conditions.

(1) Students may be used in facilities, provided the instructor gives class supervision and assumes responsibility for all student activities occurring within the facility. If the student is licensed, such as a licensed vocational nurse attending a registered nurse program for licensure as a registered nurse, the facility shall ensure that the administration of any medication(s) is within the student's licensed scope of practice.

(2) All instruction must be provided by the school's instructor or his or her designee.

(3) A student may administer medications only if:

(A) on assignment as a student of their school of health care; and

(B) the instructor is on the premises and directly supervises the administration of medication by an unlicensed student and the administration of such medication is within the instructor's licensed scope of practice.

(4) Students shall not be used to fulfill the requirement for administration of medications by licensed personnel.

(5) Students shall not be considered when determining staffing needs required by the facility

§139.55. Clinical Records.

(a) A licensed abortion facility shall maintain a daily patient roster of all patients receiving abortion services. This daily patient roster shall be retained for a period of five years.

(b) A licensed abortion facility shall establish and maintain a clinical record for each patient. A licensed abortion facility shall maintain the record to assure that the care and services provided to each patient is completely and accurately documented, readily, and systematically organized to facilitate the compilation and retrieval of information. Information required for the annual abortion report shall be readily retrievable from the clinical record.

(1) The facility shall have written procedures which are adopted, implemented, and

enforced regarding the removal of records and the release of information. A facility shall not release any portion of a patient record to anyone other than the patient except as allowed by law.

(2) All information regarding the care and services shall be centralized in the record and be protected against loss or damage and unofficial use.

(3) The facility shall establish an area for patient record storage. The patient records must be retrievable within two hours by the facility for patients whose date of the last visit is less than twelve months. For patients whose date of the last visit is greater than twelve months, records must be retrievable within ten days.

(4) The facility shall ensure that each record is treated with confidentiality.

(5) 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 subsection (d) of this section. Systems shall assure that entries regarding the delivery of care or services are not altered without evidence and explanation of such alteration.

(6) A facility shall maintain clinical records in their original state. Each entry shall be accurate, dated with the date of entry, and signed 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.

(7) Inactive patient records may be preserved and stored on microfilm, optical disc or other electronic means. Security shall be maintained and the record must be retrievable within ten days by the facility.

(c) The clinical record shall contain:

(1) patient identifying information;

(2) name of physician;

(3) diagnosis;

(4) history and physical;

(5) laboratory reports;

(6) report of gross and/or microscopic examination of tissue obtained during a surgical abortion;

(7) allergies/drug reactions;

(8) physician's orders;

(9) progress notes to include at a minimum, notations of vital signs; signs and symptoms; response to medication(s) and treatment(s); and any changes in physical or emotional condition(s). These notations shall be written, dated, and signed by the individual(s) delivering patient care no later than 10 days from the day the patient is discharged from the facility;

(10) education/information and referral notes;

(11) signed patient consent form;

(12) medication administration records. Notations of all pharmaceutical agents shall include the time and date administered, the name of the individual administering the agent, and the signature of the person making the notation if different than the individual administering the agent;

(13) condition on discharge;

(14) the medical examination or written referral, if obtained;

(15) physician documentation of viability or nonviability of fetus(es) at a gestational age greater than 26 weeks; and

(16) for patients receiving moderate sedation/analgesia or deep sedation/analgesia:

(A) a minimum of blood pressure, pulse, and respirations shall be obtained and recorded before sedation, during sedation, during the procedure, during the initial recovery period, and before discharge from the facility; and

(B) the patient's blood oxygenation shall be assessed and recorded, a minimum of at the time of sedation, during the procedure, and after the procedure.

(d) A licensed abortion facility shall retain clinical records for adults for seven years from the time of discharge and clinical records for minors for five years past the age the patient reaches majority.

(e) A licensed abortion facility may not destroy patient records that relate to any matter that is involved in litigation if the facility knows the litigation has not been finally resolved.

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

§139.56. Emergency Services.

(a) A licensed abortion facility must have a readily accessible written protocol for managing medical emergencies and the transfer of patients requiring further emergency care to a hospital. The facility shall ensure that the physicians who practice at the facility have admitting privileges or have a working arrangement with a physician(s) who has admitting privileges at a local hospital in order to ensure the necessary back-up for medical complications.

(b) The facility must have the necessary equipment and personnel for cardiopulmonary resuscitation as described in §139.59 of this title (relating to Anesthesia Services).

(c) Personnel providing direct patient care shall be currently certified in basic life support by the American Heart Association or the American Red Cross, or in accordance with their individual professional licensure requirements, and if required in their job description or job responsibilities.

§139.57. Discharge and Follow-up Referrals.

(a) A licensed abortion facility shall develop and implement written discharge instructions which shall include:

(1) a list of complications (developed by the facility in conjunction with a physician who practices in the facility) that warrant the patient contacting the facility, which shall include, but not be limited to:

(A) pain;

(B) fever; and

(C) bleeding;

(2) a statement of the facility's plan to respond to the patient in the event the patient

experiences any of the complications listed in the discharge instructions to include:

(A) the mechanism by which the patient may contact the facility on a 24 hour basis by telephone answering machine or service or by direct contact with an individual;

(B) the facility's requirement that every reasonable effort be made and documented to respond to the patient within 30 minutes of the patient's call;

(C) assurance that the responding individual shall be a physician, physician extender, registered nurse, or licensed vocational nurse; and

(D) information that the patient may also contact the emergency medical service or present for care at the emergency room of a hospital in addition to contacting the facility; and

(3) information concerning the need for a post-abortion examination.

(b) A facility shall provide a patient with a copy of the written discharge instructions described in subsection (a) of this section.

(c) The facility shall develop and implement written policies and procedures for:

(1) examination or referral of all patients who report complications, as identified in the list required by subsection (a)(1) of this section, to the facility after an abortion procedure. The written policy and procedure shall require:

(A) the facility to maintain a written system of documentation of patients who report post-abortion complications within 14 days of the procedure date;

(B) documentation of the facility's action following a patient's reporting of post-abortion complications to be placed in the patient's record; and

(C) the patients' records to be maintained for adults for seven years and for minors five years past the age the patient reaches majority; and

(2) periodic review of the record keeping system for post-abortion complications to identify problems and potential problems and to make changes in order to resolve the problems.

§139.58. Reporting Requirements.

A licensed abortion facility shall report a woman's death if it results from a complication(s) of an

abortion. The report shall be made by phone or fax within one business day after the facility is notified of the death to the director of Health Facility Licensing and Compliance Division, Texas Department of Health, 1100 West 49th Street, Austin, Texas 78756, Telephone (512) 834-6646, or Fax (512) 834-4514 or (512) 834-6709.

§139.59. Anesthesia Services.

(a) Organization of anesthesia services. The organization of anesthesia services shall be appropriate to the scope of the services offered.

(b) General. A licensed abortion facility may provide various levels of sedation/analgesia and/or general anesthesia as defined in subsection (c) of this section. The patient may progress spontaneously from one level to another. The determination of patient monitoring and staffing requirements shall be based on the provisions set out in this section and the patient's acuity and the potential response of the patient to the procedure.

(c) Definitions.

(1) Minimal sedation (anxiolysis) - A drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilatory and cardiovascular functions are unaffected.

(2) Moderate sedation/analgesia ("conscious sedation") - A drug-induced depression of consciousness during which patients respond purposefully (reflex withdrawal from a painful stimulus is NOT considered a purposeful response) to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained.

(3) Deep sedation/analgesia - A drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained.

(4) General anesthesia - A drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory function is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired.

(d) Minimum staffing for the management of the various levels of sedation/analgesia.

(1) Minimal sedation (anxiolysis). The minimum staffing required for administering minimal sedation (anxiolysis) and local anesthetic shall include the physician and sufficient support staff to perform the procedure.

(2) Moderate sedation/analgesia ("conscious sedation").

(A) The minimum staffing required for administering moderate sedation/analgesia ("conscious sedation") shall always include a minimum of:

(i) a physician, trained and experienced in the use of moderate sedation/analgesia ("conscious sedation"), airway management and resuscitation to manage the care of the patient; and

(ii) one trained, competent clinic staff person to monitor the patient at all times in the procedure and recovery room.

(B) The medical or nursing staff managing the anesthesia care of the patient under moderate sedation/analgesia ("conscious sedation") shall have no other responsibilities that would leave the patient unattended or compromise continuous monitoring.

(3) Deep sedation/analgesia.

(A) The minimum staffing during deep sedation/analgesia shall be in accordance with subsection (h) of this section.

(B) The person qualified and performing the administration of deep sedation/analgesia may not be the physician performing the procedure.

(4) General anesthesia.

(A) The minimum staffing during general anesthesia shall be in accordance with subsection (i) of this section.

(B) The person qualified and performing the administration of general anesthesia may not be the physician performing the procedure.

(e) Minimum training and knowledge.

(1) Minimal sedation (anxiolysis). All staff members managing the care of a patient under minimal sedation (anxiolysis) shall be certified in basic life support (BLS) with bi-annual

recertification.

(2) Moderate sedation/analgesia ("conscious sedation").

(A) The medical or nursing staff managing the care of a patient receiving moderate sedation/analgesia ("conscious sedation") shall at a minimum have the following:

(i) training in BLS with bi-annual recertification;

(ii) annual training in the recognition of the cardiovascular and respiratory side effects of sedatives, as well as the variability of patient response; and

(iii) current knowledge of emergency supplies and equipment inventory and their use.

(B) The physician, physician extender, or nurse administering the medications shall know the pharmacology of the medications administered.

(3) Deep sedation/analgesia. The minimum training and knowledge required for providing deep sedation shall be in accordance with subsection (h) of this section.

(4) General anesthesia. The minimum training and knowledge required for providing general anesthesia shall be in accordance with subsection (i) of this section.

(f) Clinical and equipment standards for minimal sedation (anxiolysis) and local anesthetic. For licensed facilities administering minimal sedation (anxiolysis) or local anesthetic, the facility must have at a minimum, the following emergency equipment for local anesthetic and/or light sedation management:

(1) oxygen;

(2) mechanical ventilatory assistance equipment that includes airways and manual breathing bag;

(3) the ability to monitor blood pressure;

(4) emergency drugs as specified by the physician(s) on staff; and

(5) functioning oral suction machine apparatus.

(g) Procedure room requirements for moderate sedation/analgesia ("conscious sedation") and

deep sedation/analgesia.

(1) Moderate sedation/analgesia ("conscious sedation"). The minimum standards for the procedure room(s) where moderate sedation/analgesia ("conscious sedation") is administered are as follows.

(A) The facility shall have the capability of monitoring blood pressure and oxygen saturation as well as a functioning oral suction machine apparatus.

(B) All patients receiving moderate sedation/analgesia ("conscious sedation") shall have a functional intravenous access in place. A functional intravenous access shall be placed in a patient's vein prior to the procedure and maintained until the patient has recovered from the effects of sedation as determined by the person administering the sedation or the physician performing the procedure.

(C) Emergency supplies and equipment shall be readily accessible and shall include the necessary drugs and equipment to resuscitate a non-breathing and unconscious patient. There shall be documentation that all emergency equipment and drugs are checked and maintained on a scheduled basis.

(D) Pharmacological antagonist medications and staff trained to administer these medications shall be readily available.

(2) Deep sedation/analgesia. The minimum standards for the procedure room where deep sedation/analgesia is administered shall be in accordance with subsection (h) of this section.

(3) General anesthesia. The minimum standards for the procedure room where general anesthesia is administered shall be in accordance with subsection (i) of this section.

(h) Standards for administering deep sedation/analgesia.

(1) A licensed abortion facility which provides deep sedation/analgesia shall provide professional staff; equipment for the administration (of deep sedation/analgesia); a post anesthesia care area; monitoring equipment for procedure room and post anesthesia recovery area sufficient for the provision of deep sedation/analgesia in accordance with the following American Society for Anesthesiologists standards and guidelines:

(A) Practice Guidelines for Sedation and Analgesia by Non-Anesthesiologists, dated April 2002;

(B) Standards, Guidelines, and Statements, dated October 2002, specifically:

(i) Basic Anesthetic Monitoring, dated October 21, 1986, as amended October 21, 1998; and

(ii) Standards for Post-Anesthesia Care, dated October 12, 1988, as amended October 19, 1994.

(2) If the provisions contained in the guidelines listed in paragraph (1) of this subsection conflict with this section, the provisions of this section supersede.

(3) Copies of the standards and guidelines are available for review at the Texas Department of Health, Health Facility Licensing and Compliance Division, Exchange Building, 8407 Wall Street, Austin, Texas 78754. Copies may also be obtained by writing the American Society of the Anesthesiologists, 520 North West Highway, Park Ridge, Illinois 60068-2573; Internet www.ASAhq.org; or by telephone at (847) 825-5586.

(i) Standards for administering general anesthesia.

(1) A licensed abortion facility which provides general anesthesia shall provide professional staff; equipment for the administration of general anesthesia; a post anesthesia care area; and monitoring equipment for procedure room and post anesthesia recovery area sufficient for the provision of general anesthesia. General anesthesia shall be provided in accordance with the following American Society for Anesthesiologists standards and guidelines: American Society of Anesthesiologists Standards, Guidelines, and Statements, dated October 2002, specifically:

(A) Guidelines for Office-Based Anesthesia, dated October 13, 1999;

(B) Basic Standards for Pre-anesthesia Care, dated October 14, 1987;

(C) Basic Anesthetic Monitoring, dated October 21, 1986, as amended October 21, 1998;

(D) Standards for Post-Anesthesia Care, dated October 12, 1988, as amended October 19, 1994; and

(E) Guidelines for Ambulatory Anesthesia and Surgery, dated October 11, 1997, as amended October 21, 1998.

(2) If the provisions contained in the guidelines listed in paragraph (1) of this subsection conflict with this section, the provisions of this section supersede.

§139.60. Other State and Federal Compliance Requirements.

(a) A licensed abortion facility must be in compliance with all state and federal laws pertaining to handling of drugs.

(b) A licensed abortion facility that provides laboratory services shall meet the Clinical Laboratory Improvement Amendments of 1988, 42 United States Code, §263a, Certification of Laboratories (CLIA 1988). CLIA 1988 applies to all facilities 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.

(c) A licensed abortion facility shall ensure that its physicians comply with the Medical Practice Act, Texas Occupations Code, Chapters 151-165, while functioning in his or her capacity at or for the facility.

(d) A licensed abortion facility utilizing the services of a physician assistant(s) shall ensure that its physicians assistants comply with the Physician Assistant Licensing Act, Texas Occupations Code, Chapter 204, while functioning in his or her capacity at or for the facility.

(e) A licensed abortion facility utilizing the services of a registered nurse shall ensure that its registered nurses comply with the Nursing Practice Act, Texas Occupations Code, Chapters 301 and 304, while functioning in his or her capacity at or for the facility.

(f) A licensed abortion facility utilizing the services of a licensed vocational nurse(s) shall ensure that its vocational nurse(s) comply with the Board of Vocational Nurse Examiners rules Texas Occupations Code, Chapter 302, while functioning in his or her capacity at or for the facility.

(g) A licensed abortion facility that provides pharmacy services shall obtain a license as a pharmacy if required by the Texas Pharmacy Act, Texas Occupations Code, Chapters 551-569.

(h) A licensed abortion facility shall comply with the following federal Occupation Safety and Health Administration requirements:

(1) 29 Code of Federal Regulations, Subpart E, §1910.38, concerning employee emergency plans and fire prevention plans;

(2) 29 Code of Federal Regulations, Subpart I, §1910.132, concerning general requirements for personal protective equipment;

(3) 29 Code of Federal Regulations, Subpart I, §1910.133, concerning eye and face protection;

(4) 29 Code of Federal Regulations, Subpart I, §1910.138, concerning hand protection;

(5) 29 Code of Federal Regulations, Subpart L, §1910.157, concerning portable fire extinguishers;

(6) 29 Code of Federal Regulations, Subpart Z, §1910.1030, concerning blood borne pathogens;

(7) 29 Code of Federal Regulations, Subpart Z, §1910.1200, Appendices A-E, concerning hazard communication (hazardous use of chemicals); and

(8) 29 Code of Federal Regulations, Subpart K, §1910.151, concerning medical services and first aid.

(i) A licensed abortion facility 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 licensed abortion facility 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 licensed abortion facility shall comply with the requirements of the Family Code, §33.002 (relating to Parental Notice).

(l) A licensed abortion facility shall comply with the requirements of Health and Safety Code, Chapter 171, the Woman's Right to Know Act.

(m) A licensed abortion facility shall comply with the requirements of Occupations Code, Chapter 102, Solicitation of Patients.

Figure: 25 TAC, §139.6(a)(1)

TOLL-FREE TELEPHONE NUMBER

1-888-973-0022

You have the right to access certain information concerning this abortion facility by using the toll-free telephone number listed above. If you make a call to the number, your identity will remain anonymous.

The toll-free telephone line can provide you with the following information:

- whether this abortion facility is licensed by the Texas Department of Health;
- the date of the last inspection of this facility by the Texas Department of Health and any violations of law or rules discovered during that inspection that may pose a health risk to you;
- any relevant fine, penalty, or judgment rendered against this facility or a doctor who provides services at this facility.

Figure: 25 TAC, §139.6(a)(2)

Línea de información gratuita

1-888-973-0022

Usted tiene el derecho de obtener cierta información concerniente a este centro de aborto usando la línea de información gratuita que aparece arriba. Si usted llama a este número, su identidad permanecerá anónima.

La línea de información gratuita puede ofrecerle la siguiente información:

- Si este centro de aborto tiene licencia del Departamento de Salud de Texas.
- La fecha de la última inspección de este centro por el Departmento de Salud de Texas, y cualquier infracción de la ley o de las reglas descubierta durante esa inspección, que pudiera poner en peligro su salud.
- Cualquier multa, pena o sentencia impuesta en contra de este centro o de algún doctor que preste servicios en ese lugar."

Figure: 25 TAC §139.41(a)(8)(A)

Affidavit

I, _____, swear or affirm that my date of birth is _____,_____ , and that I do not have appropriate identification that states my date of birth.

Signature: _____

Printed name:_____

Witness:_____

Printed name of witness:_____

Figure: 25 TAC, §139.52(a)(1)

CERTIFICATION

Each item on this certification form must be reviewed. The woman should place her initials beside each statement and sign the bottom of the form.

I certify that the following information was presented to me, at least 24 hours prior to the abortion, by the physician who is to perform the abortion or by the referring physician:

_____ the name of the physician who will perform the abortion;

_____ the particular medical risks associated with the particular abortion procedure to be employed; including when medically accurate:

- _____ the risk of infection and hemorrhage;
- _____ the potential danger to subsequent pregnancy and of infertility; and
- _____ the possibility of increased risk of breast cancer following an induced abortion and the natural protective effect of a completed pregnancy in avoiding breast cancer.

_____ the probable gestational age of the unborn child at the time the abortion is to be performed; and

_____ the medical risks associated with carrying the child to term.

The physician who is to perform the abortion or the physician's agent has informed me that:

_____ medical assistance benefits may be available for prenatal care, childbirth, and neonatal care;

_____ the father is liable for assistance in the support of the child without regard to whether the father has offered to pay for the abortion;

_____ public and private agencies provide pregnancy prevention counseling and medical referrals for obtaining pregnancy prevention medications or devices; and

I have also been informed that:

____ I have the right to review the printed materials prepared by the Texas Department of Health entitled the "A Woman's Right to Know" booklet and the resource directory, which describe the unborn child and list agencies that offer alternatives to abortion, and that those materials must be given to me if I choose to view them;

_____ "A Woman's Right to Know" booklet and resource directory are also accessible on an Internet website sponsored by the department.

I made the following choice (choose one of the following):

_____ I requested and was provided a printed copy of "A Woman's Right to Know" booklet and the resource directory.

_____ I chose to review the "Woman's Right to Know" materials on this website.

_____ I declined the informational materials.

_____

Signature Date

_____

Printed Name