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PRINTED: 11/12/2018
FORM APPROVED

Texas Health and Human Services Commission

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING: B. WING	(X3) DATE SURVEY COMPLETED
	007804		11/06/2018

NAME OF PROVIDER OR SUPPLIER: HILLTOP WOMENS REPRODUCTIVE CLINIC

STREET ADDRESS, CITY, STATE, ZIP CODE: 500 EAST SCHUSTER BUILDING B, EL PASO, TX 79902

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
S 000	TAC 139.1 Initial Comments Note: The State Form is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be referred to the Office of the Texas Attorney General (OAG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately. (a) Purpose. The purpose of this chapter is to implement the Texas Abortion Facility Reporting and Licensing Act, Health and Safety Code, Chapter 245, which provides the Health and Human Services Commission with the authority to establish rules governing the licensing and regulation of abortion facilities and to establish annual reporting requirements for each abortion performed. This chapter also implements the Woman's Right to Know Act, Health and Safety Code, Chapter 171. (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 Health and Safety Code, Chapter 241; (ii) an ambulatory surgical center licensed	S 000		

SOD - State Form
LABORATORY DIRECTOR [redacted] PROVIDER REPRESENTATIVE'S SIGNATURE [redacted] TITLE Nurse Administrator (X6) DATE ~~9-26-18~~ 11-26-18

STATE FORM [redacted] TXF811 If continuation sheet 1 of 2 [redacted]

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6 000	Continued From page 2 in part, "The following words and terms, when used in this chapter, shall have the following meanings, unless the context clearly indicates otherwise. ... (3) Act--Texas Abortion Facility Reporting and Licensing Act, Health and Safety Code, Chapter 245. ... (28) Licensee--A person or entity who is currently licensed as an abortion facility. Per Texas Health and Safety Code Chapter 245, Subtitle B: Sec. 245.002. DEFINITIONS. In this chapter: (1) "Abortion" means the act of using or prescribing an instrument, a drug, a medicine, or any other substance, device, or means with the intent to cause the death of an unborn child of a woman known to be pregnant. The term does not include birth control devices or oral contraceptives. An act is not an abortion if the act is done with the intent to: (A) save the life or preserve the health of an unborn child; (B) remove a dead, unborn child whose death was caused by spontaneous abortion; or (C) remove an ectopic pregnancy. (2) "Abortion facility" means a place where abortions are performed. (3) Repealed by Acts 2015, 84th Leg., R.S., Ch. 1, Sec. 3.1639(62), eff. April 2, 2015. (4) "Department" means the Department of State Health Services. (4-a) "Ectopic pregnancy" means the implantation of a fertilized egg or embryo outside	6 000		

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6 000	Continued From page 3 of the uterus. (4-b) "Executive commissioner" means the executive commissioner of the Health and Human Services Commission. (5) "Patient" means a female on whom an abortion is performed, but does not include a fetus. (6) "Person" means an individual, firm, partnership, corporation, or association. Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by: Acts 2015, 84th Leg., R.S., Ch. 1 (S.B. 219), Sec. 3.0685, eff. April 2, 2015. Acts 2015, 84th Leg., R.S., Ch. 1 (S.B. 219), Sec. 3.1639(62), eff. April 2, 2015. Acts 2017, 85th Leg., R.S., Ch. 441 (S.B. 8), Sec. 8, eff. September 1, 2017. Sec. 245.010. MINIMUM STANDARDS. (a) The rules must contain minimum standards to protect the health and safety of a patient of an abortion facility and must contain provisions requiring compliance with the requirements of Subchapter B, Chapter 171. On and after September 1, 2014, the minimum standards for an abortion facility must be equivalent to the minimum standards adopted under Section 243.010 for ambulatory surgical centers. (b) Only a physician as defined by Subtitle B, Title 3, Occupations Code, may perform an abortion. (c) Repealed by Acts 2013, 83rd Leg., 2nd C.S., Ch. 1, Sec. 8, eff. September 1, 2014. (d) This section does not authorize the executive commissioner to: (1) establish the qualifications of a licensed practitioner; or (2) permit a person to provide health care	6 000		

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6 000	Continued From page 4 services who is not authorized to provide those services under other laws of this state. Acts 1989, 71st Leg., ch. 678, Sec. 1, eff. Sept. 1, 1989. Amended by Acts 1997, 75th Leg., ch. 23, Sec. 1, eff. Sept. 1, 1997; Acts 2001, 77th Leg., ch. 1420, Sec. 14.789, eff. Sept. 1, 2001; Acts 2003, 78th Leg., ch. 999, Sec. 4, eff. Sept. 1, 2003. Amended by: Acts 2013, 83rd Leg., 2nd C.S., Ch. 1, Sec. 4, eff. October 29, 2013. Acts 2013, 83rd Leg., 2nd C.S., Ch. 1, Sec. 8, eff. September 1, 2014. Acts 2015, 84th Leg., R.S., Ch. 1 (S.B. 219), Sec. 3.0689, eff. April 2, 2015. Per Subtitle B, Title 3, Occupations Code: Sec. 162.151. DEFINITIONS. In this subchapter: (1) "Core credentials data" means: (A) name and other demographic data; (B) professional education; (C) professional training; (D) licenses; and (E) Educational Commission for Foreign Medical Graduates certification. (2) "Credentials verification organization" means an organization that is certified or accredited and organized to collect, verify, maintain, store, and provide to health care entities a health care practitioner's verified credentials data, including all corrections, updates, and modifications to that data. For purposes of this subdivision, "certified" or "accredited" includes certification or accreditation by a nationally recognized accreditation organization. (3) "Health care entity" means: (A) a health care facility or other health care organization licensed or certified to provide approved medical and allied health services in	6 000		

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6 000	Continued From page 5 this state; (B) an entity licensed by the Texas Department of Insurance as a prepaid health care plan or health maintenance organization or as an insurer to provide coverage for health care services through a network of providers; or (C) a health care provider entity accepting delegated credentialing functions from a health maintenance organization. (4) "Physician" means a holder of or applicant for a license under this subtitle as a medical doctor or doctor of osteopathy. Added by Acts 2001, 77th Leg., ch. 1420, Sec. 14.033(a), eff. Sept. 1, 2001. Sec. 245.025. HUMAN TRAFFICKING SIGNS REQUIRED. (a) An abortion facility shall display separate signs, in English, Spanish, and any additional language as required by Subsection (b), side by side in accordance with this section in each restroom and patient consulting room. The signs must include the following information: (1) no person, including an individual's parents, may force any individual to have an abortion; (2) it is illegal for a person to force an individual to engage in sexual acts; (3) a woman who needs help may call or text a state or national organization that assists victims of human trafficking and forced abortions; and (4) the toll-free number of an organization described by Subdivision (3). (b) Signs required under this section must be in English and Spanish. If an abortion facility is located in a political subdivision required to provide election materials in a language other than English or Spanish under Section 272.011, Election Code, the facility shall display a separate sign in that language. (c) Signs required under this section must be at	6 000	Section 245-025 Human Trafficking Signs Required Assistant Administrator ordered Human Trafficking Signs and signs have been displayed as required. Human Trafficking Signs are displayed in both English and Spanish in each restroom and in patient consulting room. All signs will include information required by Sec. 245.025 (a)(b)(1)(2)(3)(4) Signs will be no smaller than 8 ½ by 11 inches in size and cover four-fifths of the signs and clearly visible. Both physician and Nurse Administrator shall ensure compliance has been met.	11/23/18

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6 000	Continued From page 6 least 8-1/2 by 11 inches in size and displayed in a conspicuous manner clearly visible to the public and employees of an abortion facility. The notice must cover at least four-fifths of the sign. (d) The executive commissioner shall adopt rules as necessary to implement and enforce this section. Added by Acts 2017, 85th Leg., R.S., Ch. 858 (H.B. 2552), Sec. 12, eff. September 1, 2017." Facility based policy entitled, "Medication Secutiry and Administration" stated in part, "4. Documentation i) All medications are to be documented by the person who administered the medication." During a review of clinical records for 8 medication abortion patients revealed 7 patients (#2, 5, 7, 9, 15, 16, and 18) had been administered Mifepristone (an abortion-inducing medication), the "Counseling and Medical Report" had the medication administration of Mifepristone documented, however there was no signature indicating the physician dispensed the medication to the patients. In an interview on 11/06/18, staff member #1 confirmed that the physician administered the Mifepristone to patient's for their medical abortion procedures. During a tour of the facility on 11/06/18 , no human trafficking signage was found in any of the 2 facility patient restrooms or patient consultation rooms. The above was confirmed in an interview with the facility Administrator and other administrative staff the on the afternoon of 11/06/18.	6 000	85th Leg., R.S., Ch. 858 (H.B. 2552), Sec. 12 All patients charts are to be reviewed at the end of each clinical day by physician to ensure all required signatures are properly documented showing that he administered the medication himself. Both Physician and Nurse Administrator will monitor plan of correction to ensure that compliance is meet. Nurse Administrator will be responsible for plan which was implemented as of 11/7/18.	11/07/18

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6 026	Continued From page 7	6 026		
6 026	TAC 139.44 Orientation, Training & Demonstrated Competen (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;	6 026	TAC 139.44 Orientation, Training & Demonstrated Competent On November 20, 2018 clinic conducted training session with new employees on "An Introduction to Human Trafficking" developed by the Texas Human Trafficking Prevention Task Force. Session was lead by administrative assistant. The purpose of training was to empower staff members to recognize factors related to human trafficking, identifying potential human trafficking victims and report as legally required. Administrative assistant will make certain "Human Trafficking" training is an ongoing practice at the facility. Henceforth, all staff members will have proper training on "Human Trafficking" as part of their required employment protocol.	11/20/18

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6 026	Continued From page 8 (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, §91.002 and §91.003. (e) The facility shall document in each employee's personnel record evidence of all training and orientation received. This Requirement is not met as evidenced by: Based on record review and interview, the facility failed to ensure each employee completed required training in Human Trafficking, in that, Personnel #1 did not have training for Human Trafficking. Findings included Personnel #1's personnel file did not document training in Human Trafficking. During an interview on 11/06/18 at 2:05 PM, Personnel #1 was informed of the above finding. Personnel #1 stated, "No. I don't have that."	6 026	Continued TAC 139.44 Orientation, Training & Demonstrated Competent Nurse Administrator will be responsible for plan implementation and will review employee files for compliance on annual basis.	11/20/18

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6 026	Continued From page 9 The Acts 2015, 84th Legislature, House Bill 416 effective June 19, 2015, Health & Safety Code Subchapter E Section 171.063 Education and Training on Human Trafficking required,"applies to each person who is employed by, volunteers at, or performs services...Abortion facility...a training program to identify and assist victims of Human Trafficking...standardized curriculum..."	6 026		
6 034	TAC 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 post-procedure 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 (S. spp.); 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 S. spp. (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,	6 034	TAC 139.49 Infection Control Standards On clinical day the sterilizer is used, two biological tests indicators will be performed. A Bowie-Dick plus test which will help monitor the performance of the sterilizer by detecting potential issues which might compromise sterility. Concurrently the biological Attest will be run to determine sterilization cycle parameters were sufficient to kill the test microorganisms and sterilization process is not compromised.	11/14/18

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6 034	Continued From page 10 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 apply 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	6 034	Continued TAC 139.49 Infection Control Standards Correct Attest Biological Monitoring System Booklet & Log not to read "for dental office" was ordered by administrative assistant on November 9, 2018. Correct Monitoring booklet arrived on November 14, 2018 and was immediately implemented by nurse administrator into facilities sterilization process. Administrative assistant will be responsible for plan of correction to be an on going process and monitored correctly.	11/14/18

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6 034	Continued From page 11 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 S. spp. 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.	6 034		

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6 034	Continued From page 12 (3) A licensed abortion facility may provide cleaning and laundry services directly or by contract in accordance with Occupational Safety and Health Administration'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 if this procedure is available at the facility. (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	6 034		

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6 034	Continued From page 13 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 shall 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	6 034		

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	007804		11/06/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
HILLTOP WOMENS REPRODUCTIVE CLINIC	500 EAST SCHUSTER BUILDING B EL PASO, TX 79902

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
6 034	Continued From page 14 directly into the bloodstream or into other normally sterile areas of the body and shall be sterilized in accordance with this subsection. (ii) All items that come in contact with the sterile field during the operative procedure shall 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 subsection to provide effective sterilization measures. (A) Equipment. A licensed abortion facility shall	6 034		

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NAME OF PROVIDER OR SUPPLIER: HILLTOP WOMENS REPRODUCTIVE CLINIC

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6 034	Continued From page 15 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.	6 034		

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6 034	Continued From page 16 (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 shall 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 shall 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 shall 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	6 034		

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6 034	Continued From page 17 peel pouches, perforated metal trays, or rigid trays. Muslin packs shall be limited in size to 12 inches by 12 inches by 20 inches with a maximum weight of 12 pounds. Wrapped instrument trays shall 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 manufacturer's written instructions and indicator reaction specifications. (F) Biological indicators. (i) The efficacy of the sterilizing process shall be monitored with reliable biological indicators appropriate for the type of sterilizer used (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	6 034		

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6 034	Continued From page 18 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 shall 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 shall 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 shall be returned to sterile processing	6 034		

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6 034	Continued From page 19 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.	6 034		

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6 034	Continued From page 20 (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	6 034		

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6 034	Continued From page 21 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. This Requirement is not met as evidenced by: (F) Biological indicators. (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. Based on record review and interview, the facility failed to ensure a biological indicator was included in at least one run each day of use for steam sterilizers, in that, there was no documented biological indicator for 8 of 37 days of (October/November 2018) the sterilizer was used (11/05/18, 10/31/18, 10/25/18, 10/22/18, 10/15/18, 10/10/18, 10/08/18, 10/01/18). Findings included The October/November 2018 Sterilizer Log reflected sterilization loads ran on 11/05/18, 10/31/18, 10/25/18, 10/22/18, 10/15/18, 10/10/18, 10/08/18, 10/01/18. The Attest Biological Monitoring System Booklet and Log reflected, "for Dental Office...Use at Least Once a Week Per Sterilizer..." There were no logged Biological Testing for the	6 034		

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6 034	Continued From page 22 dates of 11/05/18, 10/31/18, 10/25/18, 10/22/18, 10/15/18, 10/10/18, 10/08/18, 10/01/18. During an interview on 11/06/18 at 2:05 PM, Personnel #1 was informed of the above findings. Personnel #1 agreed with the findings and stated, "We are doing (them) weekly." The 1/2008 effective date, "Biological Monitoring of the Ritter M11 Steam Sterilizer" policy required, "To document proper performance of the Ritter M11 Steam Sterilizer...A biological indicator test will be processed daily...for the first sterilizer run of the day..."	6 034		
6 038	TAC 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, shall 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 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	6 038		

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6 038	Continued From page 23 Disclosure of Specific Risks and Hazards--List A), §601.4 of this title (relating to Disclosure and Consent Form), and Health and Safety Code, §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, advanced practice registered nurse, or physician assistant 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 shall 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, advanced practice registered nurse, physician assistant, registered nurse, or licensed vocational nurse shall 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.	6 038		

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6 038	Continued From page 24 (9) The recovery room(s) at the facility shall be supervised by a physician, advanced practice registered nurse, physician assistant, or registered nurse. This supervisor shall 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 shall 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 shall 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.	6 038		

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6 038	Continued From page 25 (2) All medical and clinical services of the facility, with the exception of the abortion procedure, shall 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, advanced practice registered nurse, or physician assistant 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	6 038		

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6 038	Continued From page 27 Findings included: HEALTH AND SAFETY CODE, TITLE 2. HEALTH, SUBTITLE H. PUBLIC HEALTH PROVISIONS, CHAPTER 171. ABORTION, SUBCHAPTER A. GENERAL PROVISIONS stated in part, "Sec. 171.012. VOLUNTARY AND INFORMED CONSENT. (a) Consent to an abortion is voluntary and informed only if:... 4) before any sedative or anesthesia is administered to the pregnant woman and at least 24 hours before the abortion or at least two hours before the abortion if the pregnant woman waives this requirement by certifying that she currently lives 100 miles or more from the nearest abortion provider that is a facility licensed under Chapter 245 or a facility that performs more than 50 abortions in any 12-month period..." Based on a review of documentation and interview, the facility failed to ensure that A physician must perform a sonogram on a woman seeking an abortion at least 24 hours prior to performing the abortion, unless the woman lives 100 miles from the closest abortion provider in which case the sonogram must be performed at least 2 hours prior to the abortion. Findings included: 2 of 11 same-day procedure patients had undergone same-day procedures, although they did not qualify to do so (did not live 100 miles or more from the nearest abortion provider). Online search engines www.google.com and www.bing.com were used to calculate distance from the patients' residences to the provider.	6 038	"Sec. 171.012. Voluntary and Informed Consent To comply with "Sec. 171.012 patients from more than 100 miles and HAVE NOT by passed other abortion providers will wait 2 hours from the time of ultrasound before abortion procedure is performed. Patients from more than 100 miles and HAVE passed a closer abortion facility will automatically wait 24 hours from time of ultrasound for abortion procedure. Facility will do a google search to verify distance traveled was more than 100 miles and no other abortion facilities were by passed from city traveled to clinic. Physician and Nurse Administrator will be responsible for plan of correction to be implemented and monitored on each clinical day to verify mileage requirement is meet.	11/08/18

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6 038	Continued From page 26 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, §601.4 of this title, and Health and Safety Code, §171.011 and §171.012. (7) A licensed abortion facility shall provide the patient with written discharge instructions including a direct referral to a physician who shall accept the patient for surgical abortion. (c) Requirements of a physician. A physician performing or inducing an abortion must, on the date the abortion is performed or induced, have active admitting privileges at a hospital that: (1) is located not further than 30 miles from the location at which the abortion is performed or induced; and (2) provides obstetrical or gynecological health care services. This Requirement is not met as evidenced by: The facility failed to comply with the requirements of Health and Safety Code, Chapter 171.012 related to Voluntary and Informed Consent".	6 038		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION A. BUILDING: B. WING	(X3) DATE SURVEY COMPLETED
	007804		11/06/2018

NAME OF PROVIDER OR SUPPLIER: HILLTOP WOMENS REPRODUCTIVE CLINIC

STREET ADDRESS, CITY, STATE, ZIP CODE: 500 EAST SCHUSTER BUILDING B, EL PASO, TX 79902

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
6 038	Continued From page 28 * Patient #1 lived only 84 miles from the provider, according to her address in Alamagordo, NM. Patient #7 lived only 46 miles from the provider, according to her address in Las Cruces, NM. * Patient #13 lived within 100 miles of multiple other abortion providers based her address in Ft. Hood, Texas. There are providers in Waco and Austin, as well as other areas within 100 miles of their home address. - 1 of 11 same-day procedure patients ("same-day" patient #4) received her ultrasound on 07/16/17 at 8:02 am but her surgical procedure started at 9:22 AM on 07/16/18, thus this did not undergo the required, 2 hour wait between the ultrasound and the start of the procedure. The above findings were confirmed on 11/06/18 in an interview with staff members #1 and 2.	6 038		