

Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 007804	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____		(X3) DATE SURVEY COMPLETED 08/30/2016
NAME OF PROVIDER OR SUPPLIER HILLTOP WOMEN'S REPRODUCTIVE CLINIC		STREET ADDRESS, CITY, STATE, ZIP CODE 600 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	
A 000	<p>TAC 139 Initial Comments</p> <p>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.</p> <p>An unannounced re-licensure survey was conducted per Title 25 TAC Chapter 139 Abortion Facility Reporting and Licensing Rules to determine the facility's compliance with the requirements.</p> <p>An entrance conference was conducted on August 30, 2016 at 9:30 AM with the Administrator. An opportunity was provided for questions and discussion.</p> <p>An exit conference was conducted on August 30, 2016 at 4:00 PM with the Administrator. The preliminary findings of the survey and the next steps in the survey process were explained. An opportunity was provided for facility to provide evidence of compliance with those requirements for which non-compliance had been found. Deficiencies were cited.</p>	A 000			
A 148	<p>TAC 139.44(b)(1)(2) Orientation/Training/Demonstrated Competency</p> <p>(b) In implementing the orientation and training program, a licensed abortion facility shall orient and train each employee to ensure, through demonstrated competency, that:</p>	A 148	<p>A148 TAC 139.44(b)(1)(2)</p> <p>Orientation and training program not documented.</p> <p>All new and current employees will be required to attend a general orientation before starting on-the-job training or orientation in their assigned departments.</p> <p>a) Orientation to facility and specific job descriptions b) Understands facility policy and procedure manual.</p>	<p>10/10/16</p> <p>10/10/16</p>	

SOD - State Form
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE Nurse Administrator

(X6) DATE 10/22/16

STATE FORM

23W11

If continuation sheet 1 of 23

SDQ - State Form
STATE FORM

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NAME OF PROVIDER OR SUPPLIER
HILLTOP WOMEN'S REPRODUCTIVE CLINIC

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

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A 156	<p>Continued From page 2</p> <p>§139.49(d) of this title (relating to Infection Control Standards) and demonstrate competency in performing the sterilization procedures at the facility.</p> <p>This Requirement is not met as evidenced by: Based on observation, record review and interview, the facility failed to ensure that 2 of 2 (#3 and #5) staff responsible for the sterilization of critical surgical instruments were trained by the facility to meet the requirements of §139.49(d) of this title (relating to Infection Control Standards) and demonstrated competency in performing the sterilization procedures.</p> <p>Findings included:</p> <p>A review of personnel records for #3 and #5 revealed no documentation of training by the facility to meet the requirements of §139.49(d) of this title (relating to Infection Control Standards) and/or demonstrating competency in performing sterilization procedures.</p> <p>During a tour of the facility on 08/30/2016 at approximately 10:00 AM observed Staff #3 was observed in the sterile processing room using Ajax, an abrasive powdered bleach cleanser, to scrub the instruments.</p> <p>According to the Association of Surgical Technologies, Standards of Practice for the Decontamination of Surgical Instruments...The cleaning agent(s) should not be corrosive and damaging to the instruments.</p> <p>An interview with Staff #2 confirmed the 2 staff members responsible for the sterilization of critical surgical instruments did not have</p>	A 156	<p>Continued From page 2</p> <p>A156 Nurse Administrator will monitor that sterilization process is being done correctly on a quarterly basis.</p>	10/10/16

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A 156	Continued From page 3 sterilization training documentation in their file to demonstrate competency in performing the sterilization procedures.	A 156		
A 185	TAC 139.47(b)(7)(8) Licensed Abortion Facility Administration (b) The administrator shall: (7) schedule employee evaluations; (8) maintain employee and patient records; This Requirement is not met as evidenced by: Based on a record review and interview, the facility Administrator failed to schedule evaluations for 2 of 4 employees working at the facility. Also, the facility failed to follow the facility policy for performance evaluations. Findings: A review of Staff #2 file revealed she had never had a evaluation since she started at the facility which was 32 years ago. A review of Staff #4 file revealed her last evaluation was in September of 2013. A review of the facility's policy titled, "Performance Evaluations" revealed the following: "Policy: Hill Top Women's Reproductive Clinic will assess competence and evaluated performance of its employees on a regularly scheduled basis as outlined below: For purposes of these guidelines, performance	A 185	A185 TAC 139.47(b)(7)(8) Facility has evaluation process in place. Not implemented on a consistent basis. A185 Nurse Administrator (you're referring to Staff #2) has been evaluated by Medical Director. The facility has no employee with a hire date of September of 2013. She is being referred to as Staff #4.	10/12/16 10/12/16

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NAME OF PROVIDER OR SUPPLIER HILLTOP WOMENS REPRODUCTIVE CLINIC	STREET ADDRESS, CITY, STATE, ZIP CODE 800 EAST SCHUSTER BUILDING B EL PASO, TX 79902
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A 185	<p>Continued From page 4</p> <p>appraisal, performance review, and performance evaluation are terms used interchangeably to mean the same thing.</p> <p>Initial Employment Date - This date is the date of hire and does not change throughout the length of employment unless a break in service of greater than six months occurs. The initial employment date is used for purposes of applicable benefit accruals.</p> <p>Initial Assessment of Competency - During the pre-employment process, a candidate's credentials shall be evaluated by Administrator against the requirements for the position in question to determine if the candidate meets the minimum job related qualifications.</p> <p>Initial Employment Period - Upon completion of the initial employment period, generally following 120 days in a new position, including new hire, transfer or promotion, a competency assessment will be conducted by the immediate supervisor. It shall consist of general orientation, service specific orientation, unit or department orientation, competency skills checklist as appropriate as well as other activities as indicated.</p> <p>Annual Review - Performance reviews are scheduled annually for each employee.</p> <p>Performance evaluations and action plans as appropriate are documented in the individual's personnel record."</p> <p>In an interview with Staff #2 on 08/30/2016 at 2:00 PM confirmed the above findings.</p>	A 185	<p>Continued From page 4</p> <p>Administrator has evaluated employees and will maintain employee and patient records.</p> <p>All employee performance evaluations have been reassessed and documented in employee files.</p> <p>Performance and evaluation documentation will continue to be exercised as outlined in policy and procedure manual of facility by administrator.</p>	

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A 197	Continued From page 5	A 197		
A 197	<p>TAC 139.48(1)(A) Physical & Environmental Requirements</p> <p>The physical and environmental requirements for a licensed abortion facility are as follows:</p> <p>(1) A facility shall:</p> <p>(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;</p> <p>This Requirement is not met as evidenced by: Based on observation and interview, the facility failed to maintain a safe and sanitary environment to protect the health and safety of patients and staff at all times.</p> <p>The findings included:</p> <p>Observations on 8/30/16 at approximately 9:45 AM during the tour of the facility revealed the following:</p> <p>1. In treatment room 2, curettes x 3 were found with a brown substance on the outer package, which could contaminate the sterile supplies when opened.</p> <div style="background-color: black; width: 300px; height: 60px; margin-top: 10px;"></div> <div style="background-color: black; width: 300px; height: 40px; margin-top: 10px;"></div>	A 197	<p>A197 TAC 139.48(1)(A) See Attachment C I and J (I)(II)(III)(iv).</p> <p>Pre-sterilized curettes from manufacture were not examined properly to make sure that packages were not compromised.</p> <p>Commercially sterile packaged items will be examined for any compromised defects.</p> <div style="background-color: black; width: 250px; height: 40px; margin-top: 10px;"></div>	10/12/16

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A 197	Continued From page 6 	A 197			
A 200	<p>TAC 0139.48(1)(D) Physical & Environmental Requirements</p> <p>The physical and environmental requirements for a licensed abortion facility are as follows.</p> <p>(1) A facility shall:</p> <p>(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;</p> <p>This Requirement is not met as evidenced by: Based on observation and interview, the facility failed to conduct monthly checks for 2 of 2 fire extinguishers in the facility according to the National Fire Protection Association (NFPA) 10, Standard for Portable Fire Extinguishers. Also, the facility failed to conduct quarterly fire drills for 4 of 4 quarters of the year 2015-2016 to demonstrate the staff role and responsibility to implement the facility's emergency evacuation. The facility failed to follow their own policy for fire safety.</p> <p>A review of the NFPA 10 standards for portable fire Extinguishers revealed the following:</p> <p>7.2.4.3 At least monthly where manual inspections are conducted, the date the manual</p>	A 200	<p>A200 TAC 0139.48(1)(D)</p> <p>Fire extinguishers were being checked on a annual basis and not on a monthly basis.</p> <p>No physical fire drills were practiced, however, "Fire Safety Provisions" handout was given and reviewed with all new staff members.</p>	10/14/16	

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A 200	<p>Continued From page 7</p> <p>Inspection was performed and the initials of the person performing the inspection shall be recorded.</p> <p>7.2.4.4 Where manual inspections are conducted, records for manual inspections shall be kept on a tag or label attached to the fire extinguisher, on an inspection checklist maintained on file, or by an electronic method.</p> <p>7.2.4.5 Records shall be kept to demonstrate at least the last 12 monthly inspections have been performed."</p> <p>During the tour of the facility 2 fire extinguishers were observed that were not checked and initialed to know if the extinguishers were being maintained on a monthly basis. The staff would not know if a fire extinguisher was in its designated place, that it had not been actuated or tampered with, and that there was no obvious physical damage or condition to prevent its operation.</p> <p>A review of the fire drill documentation revealed that the facility had never conducted fire drills in the facility.</p> <p>A review of the facility's policy titled, "Fire safety Provisions" revealed the following: "TRAINING The Administrator shall present basic fire prevention training to all employees upon employment, and shall maintain documentation of the training, which includes: A. review of 29 CFR 1910.38, including how it can be accessed; B. this fire Prevention Plan, including how can be accessed; C. good housekeeping practices; D. proper response and notification in the event of a fire; E. instruction on the use of portable fire</p>	A 200	<p>Continued From page 7</p> <p>A200 Location of fire extinguishers reviewed with all staff members.</p> <p>Fire extinguishers have been examined for physical damage and condition.</p> <p>Fire extinguishers have been tagged by Henderson Fire Services.</p> <p>Nurse administrator has designated a staff member to document monthly inspection of fire extinguishers.</p>		

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A 200	Continued From page 8 extinguishers (as determined by company policy in the Emergency Action Plan); and F. recognition of potential fire hazards. Supervisors shall train employees about the fire hazards associated with the specific materials and processes to which they are exposed, and will maintain documentation of the training. Employees will receive this training: A. at their initial assignment; B. annually; and C. when changes in work processes necessitate additional training." An interview with Staff #2 on 08/30/2016 at 11:00 AM confirmed the above observations and findings. Also, Staff #2 confirmed they failed to follow their own policy.	A 200	Continued From Page 8 A200 Supervisors have trained and reviewed Fire Safety Provision training with all staff members to adhere with facilities policy. Use of portable fire extinguishers reviewed. Fire drill was conducted and documented. Supervisors to conduct quarterly fire drills. Supervisor to review documentation of fire drill on a quarterly basis.	10/14/16
A 217	TAC 139.49(b)(3)(A)(B)(C)(D) Infection Control Standards (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	A 217		

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A217	<p>Continued From page 9</p> <p>precautions as defined in paragraph (1) of this subsection; (C) bidirectional aspect of disease transmission; and (D) epidemic control.</p> <p>This Requirement is not met as evidenced by: Based on record review and interview, the facility failed to provide infection control training and current vaccines for Tuberculosis and Hepatitis B for 4 of 4 (#2-#5) staff members. Also, the facility failed to follow their own policy.</p> <p>Findings:</p> <p>A review of the personnel records for Staff members (#2-#5) revealed no infection control training. Also, review of the personnel files revealed no current Tuberculosis vaccines and there was no Hepatitis status of the staff members.</p> <p>A review of the record titled, "Hepatitis B Positive Employees" revealed the following:</p> <p>"PURPOSE: To establish guidelines to minimize the potential for exposure of patients and other personnel to Hepatitis B.</p> <p>POLICY:</p> <p>A. Personnel with acute or chronic hepatitis B surface antigen who do perform exposure-prone procedures have no restrictions unless epidemiologically linked to transmission of the infection.</p> <p>B. Personnel with acute or chronic hepatitis B e antigenemia who perform exposure-prone</p>	A217	<p>A217 139.49(b)(3)(A)(B)(C)(D)</p> <p>Continued From page 9</p> <p>A217 Staff members had no recent proper documentation of TB or Hepatitis vaccines.</p> <p>All staff members have been referred to Immunize El Paso for their Hepatitis and TB vaccinations.</p> <p>Follow-up will consist of Nurse Administrator reviewing staff members files annually to make sure TB and Hep vaccinations are current, and infection control training has been reinforced to all staff members.</p> <p>All new hires must present vaccination records and that they are current with their vaccinations prior to their orientation.</p>	<p>09/10/16</p> <p>09/10/16</p>

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A217	<p>Continued From page 10</p> <p>procedures may not perform exposure-prone invasive procedures until counsel from an ID (Infectious Disease) specialist has been received.</p> <p>1. The ID specialist will review and recommend procedures the worker can perform, taking into account specific procedures as well as skill and technique of the worker.</p> <p>C. Employees who are Hepatitis B surface antigen (HBsAg) positive will utilize appropriate standard and transmission based precautions when providing patient care.</p> <p>1. Personnel will wear gloves during high-risk procedures in which their blood/body fluids may contact patients or other personnel.</p> <p>2. Double-gloving during complex surgery will be utilized.</p> <p>D. Known/newly diagnosed carriers of Hepatitis B will be counseled regarding the practice of good personal hygiene and preventing blood/body fluid contact.</p> <p>E. Documentation will be made in the Employee Health File including the counseling of the employee.</p> <p>F. CDC guidelines and recommendations will be utilized to evaluate employees who are antigen positive."</p> <p>A review of the staff members files revealed no Hepatitis B status, so there was no way to know if the staff members or patients were being exposed to Hepatitis B.</p> <p>An interview with Staff #3 on 08/30/2016 at 12:30 PM confirmed the above findings.</p>	A217	<p>Inservice was provided to staff members on Hepatitis, TB and HIV testing and the importance of having proper vaccinations. Referring staff members to Immunize El Paso for vaccinations.</p>	09/10/16	

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A 220	Continued From page 11	A 220	A220 TAC 139.49(d)(1)		
A 220	TAC 139.49(d)(1) Infection Control Standards 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. This Requirement is not met as evidenced by: Based on observation, record review, and interview, the facility failed to ensure they had a policy for decontamination of surgical instruments. Findings include: Observations on 8/30/16 at approximately 10:00 AM during a tour of the facility sterile processing room revealed facility Staff #3 was using Ajax, an abrasive powdered bleach cleanser, to scrub the instruments. According to the Association of Surgical	A 220	Decontamination and disinfection of surgical instruments policy of the facility not being implemented by staff member. Decontamination and disinfection of surgical instruments policy has been made readily available and is being implemented under the supervision of a qualified staff member. Nurse administrator to follow-up with adherence to policy on a quarterly basis.	10/10/16 10/10/16	

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A 220	Continued From page 12 Technologies, Standards of Practice for the Decontamination of Surgical Instruments...The cleaning agent(s) should not be corrosive and damaging to the instruments. Interview on 8/30/16 at approximately 10:05 AM, with Staff #3, revealed she always uses the abrasive powdered cleanser to clean the instruments. Interview on 8/30/16 with facility Staff #2 confirmed the above findings and revealed the facility did not have a policy on the decontamination of instruments.	A 220	Continued From Page 12 A220 Documentation of sterilized instruments in place.	10/13/16
A 242	TAC 139.49(d)(5)(D)(i)(ii) Infection Control Standards 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 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. This Requirement is not met as evidenced by: Based on observation, record review, and interview, the facility failed to document on the	A 242	A242 TAC 139.49(d)(5)(D)(i)(ii) Facilities policy on decontamination of instruments not being followed by staff member. A242 All wrapped articles to be sterilized are being packaged in materials recommended for the specific type of sterilizer being used. Acceptable packing are perforated metal trays. Wrapped instruments are not exceeding 17 pounds.	10/13//16

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(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
A 242	<p>Continued From page 13</p> <p>Instrument packages the following: the date and time of sterilizing, sterilizing load number, and the identification of the autoclave used. Also, the facility failed to follow their own policy.</p> <p>During a tour of the facility's exam room and sterilization room on 08/30/2016 at 10:00 AM observed the instruments in the exam room were not labeled with date or time sterilized, sterilizing load number, and the identification of the autoclave used. The wrapped instruments that were being removed from the autoclave were not labeled with date or time sterilized, sterilizing load number, and the identification of the autoclave used.</p> <p>A review of the facility policy titled, "Infection Control Program" revealed the following:</p> <p>"PURPOSE: The intent of Hill Top Women's Reproductive Center's Infection Control Program is to meet all of the prerequisites listed in TAC Title 25 Rule §139.49 - Infection Control Standards.</p> <p>(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 (SP); educational course requirements; cleaning and laundry requirements; and decontamination, disinfection, sterilization, and storage of sterile supplies.</p> <p>(ii) All items shall be labeled for each sterilizer</p>	A 242	<p>Continued From page 13</p> <p>A242 During the inspection, staff member was in the process of sterilizing instruments and had not yet labeled the instruments tray with time, date and load number.</p> <p>All items sterilized are being identified as being sterilized by autoclave #1. Two sterilizers are no longer being used.</p> <p>Labeling includes date and time of sterilization including sterilizing load number.</p> <p>On a monthly basis nurse administrator or assistant administrator will review sterilization process and log records.</p>	

Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 007804	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____		(X3) DATE SURVEY COMPLETED 08/30/2016
NAME OF PROVIDER OR SUPPLIER HILLTOP WOMENS REPRODUCTIVE CLINIC		STREET ADDRESS, CITY, STATE, ZIP CODE 500 EAST SCHUSTER BUILDING B EL PASO, TX 79902			
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A 242	Continued From page 14 load as to the date and time of sterilization, the sterilizing load number, and the autoclave," etc. An interview with the Staff #3 on 08/30/2016 at 11:00 AM confirmed the above findings.	A 242			
A 245	TAC 139.49(d)(5)(F)(iii)(iv)(v) Infection Control Standards (F) Biological Indicators. (ii) 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. This Requirement is not met as evidenced by: Based on observation, record review, and interview, the facility failed to perform biological testing for the bacterial growth and possible sterilization failure and document the results on a log for 2 of 2 sterilizers being used in the facility. Also, the facility failed to follow their own policy. Findings: A review of the log records revealed that the	A 245	A245 TAC 139.49(d)(5)(iii)(iv)(v) As per last years inspection, the choice of using either Bowie-dick type test or Attest was given. Facility selected to use the Bowie-dick type test and not Attest. Bowie-dick type test will continue to be run and Attest has been implemented.	08/19/16	

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NAME OF PROVIDER OR SUPPLIER HILLTOP WOMENS REPRODUCTIVE CLINIC	STREET ADDRESS, CITY, STATE, ZIP CODE 500 EAST SCHUSTER BUILDING B EL PASO, TX 79902
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A 245	<p>Continued From page 15</p> <p>facility had no biological testing log. Therefore there were no readings documented after 48 hours to know if the biological indicator had any bacterial growth and possible sterilization failure.</p> <p>A review of the policy titled, "Infection Control Program" revealed the following:</p> <p>"PURPOSE: The intent of Hill Top Women's Reproductive Center's Infection Control Program is to meet all of the prerequisites listed in TAC Title 25 Rule §139.49 - Infection Control Standards.</p> <p>(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 (SP); educational course requirements; cleaning and laundry requirements; and decontamination, disinfection, sterilization, and storage of sterile supplies.</p> <p>(F) Biological indicators.</p> <p>(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).</p> <p>(ii) Biological indicators shall be included in at least one run each day of use for steam sterilizers.</p> <p>(iii) A log shall be maintained with the load identification, biological indicator results, and</p>	A 245	<p>Continued From page 15</p> <p>A245 Attest biological testing log has been implemented.</p> <p>Assistant Administrator to review on a monthly basis that biological testing is being run up to par and logged accordingly.</p>	

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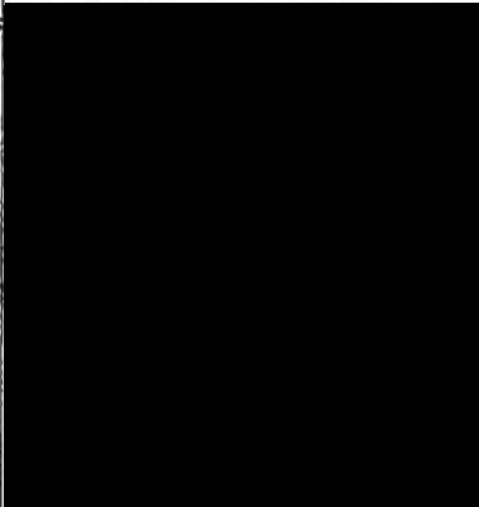

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HILLTOP WOMEN'S REPRODUCTIVE CLINIC

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A 245	Continued From page 16 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. An interview with Staff #2 on 08/30/2016 at 11:30 AM confirmed there were no biological testing logs and the facility failed to follow their own policy for biological testing.	A 245		
A 266		A 266		

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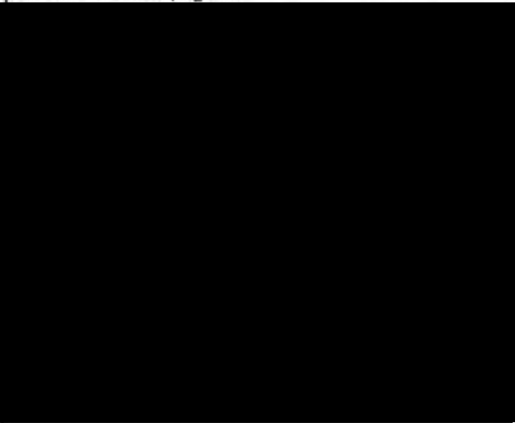
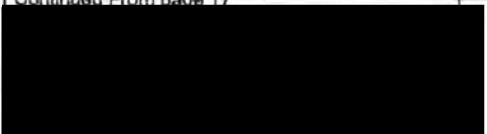
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A 286	Continued From page 17 	A 286	Continued From page 17 	
A 322	<p>TAC 139.54(b)(2) Health Care Services</p> <p>(b) Licensed health care professionals, (2) A licensed abortion facility may allow physicians to train nonlicensed personnel, age 18 years or above, to extract blood for laboratory testing and to administer intravenous fluids.</p> <p>This Requirement is not met as evidenced by: Based on record review and interview, the facility failed to provide training by a physician for 2 of 2 (#3 and #5) nonlicensed personnel that were extracting blood from patients for laboratory testing.</p> <p>A review of the personal files for Staff #3 and #5 revealed no training by the physician to the nonlicensed personnel for extracting blood from patients for laboratory testing.</p> <p>An interview with Staff #2 on 08/30/2016 at 1:00</p>	A 322	<p>A322 Nurse did train non-licensed personnel on procedure to draw blood but not the doctor.</p> <p>Will implement from now on that all non-licensed personnel will be trained on how to draw blood by doctor.</p> <p>Nurse will follow-up with training policy and that there is proper documentation.</p>	10/10/16

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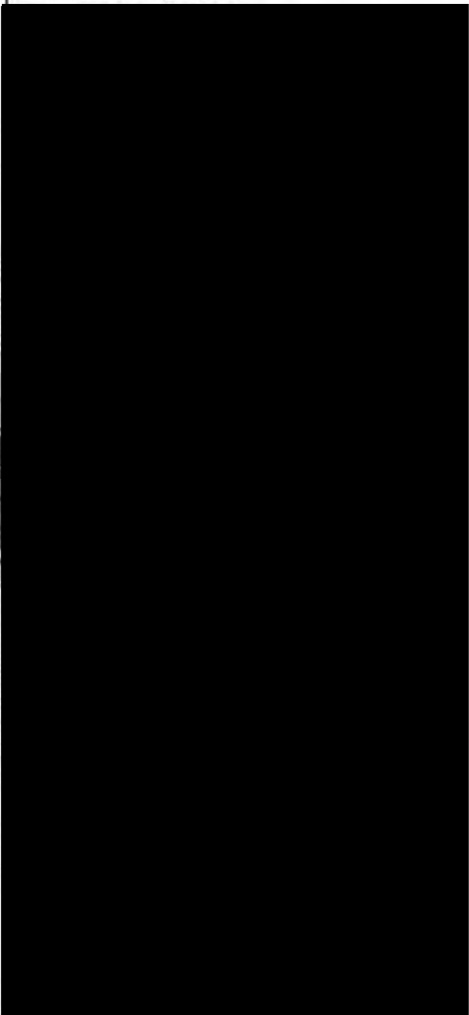

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A 322	Continued From page 18 PM confirmed that Staff #3 and #5 are the staff members that were extracting blood from patients for laboratory testing in the facility. An interview with Staff #2 on 08/30/2016 at 1:00 PM confirmed the above findings.	A 322		
A 332	[REDACTED]	A 332	[REDACTED]	
A 338	[REDACTED]	A 338	[REDACTED]	

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A 338	Continued From page 19 	A 338	Continued From page 19 		
A 341	TAC 139.55(c)(13)(14)(15)(16) Clinical Records	A 341			

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A 341	<p>Continued From page 20</p> <p>(c) The clinical record shall contain: (13) 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; (14) condition on discharge; (15) the medical examination or written referral, if obtained; (16) physician documentation of viability or nonviability of fetus(es) at a gestational age greater than 26 weeks; and</p> <p>This Requirement is not met as evidenced by: Based on record review and interview, the facility failed to ensure the name and signature of the staff administering medications was notated on the medication administration records for sampled patients 1-10 (#1-10).</p> <p>The findings were:</p> <p>Record review of the patient medical records for #1-10 revealed when a medication was given, the name of the staff administering the medication nor their signature was documented.</p> <p>Interview on 8/30/16 with the facility Staff #2 confirmed the above findings.</p>	A 341	<p>A341 TAC 139.55(c)(13)(14)(15)(16) On examination of medical records by surveyors the name and signature of staff members administering medications was not consistent.</p> <p>On clinical days medical records will be reviewed for appropriate signatures and documentation of medication being administered.</p> <p>Nurse to follow-up on a quarterly basis of 10 medical records to ensure proper documentation.</p>		
A 347	<p>TAC 139.55(c)(17)(A)(B) Clinical Records</p> <p>(c) The clinical record shall contain:</p>	A 347			

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A 347	<p>Continued From page 21</p> <p>(17) 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.</p> <p>This Requirement is not met as evidenced by: Based on record review and interviews, the facility failed to ensure the respirations were obtained and recorded before sedation, during sedation, during the procedure, during the initial recovery period, and before discharge from the facility for sampled patients #1-#10 (#1-#10).</p> <p>The findings were:</p> <p>Record review of the patient medical records for sampled patients #1-#10 revealed there was no documentation of patient respirations before, during, and after an abortion procedure.</p> <p>Interview on 8/30/16 with facility Staff#2 confirmed the above findings.</p>	A 347	<p>Continued From page 21</p> <p>A347 TAC 139.55 (c)(17)(A)(B)</p> <p>Surveyors upon reviewing medical records found that no respirations were documented.</p> <p>Respirations were recorded in patients medical chart before and after an abortion procedure, but not during procedure.</p> <p>After each clinical day patients medical record will be reviewed for proper documentation of respirations by staff members.</p>	
A 391	<p>TAC 139.80(a) Other State and Federal Compliance Rqmts</p> <p>(a) A licensed abortion facility shall be in</p>	A 391		

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A 391	<p>Continued From page 22</p> <p>compliance with all state and federal laws pertaining to handling of drugs.</p> <p>This Requirement is not met as evidenced by: Based on observation and interview, the facility failed to ensure opened multi-dose vials were dated and timed after opening.</p> <p>The findings were:</p> <p>Observations on 8/30/16 at approximately 10:10 AM during the tour of the facility medication area, revealed an opened multi-dose vial of Lidocaine 1% which had no label or documentation of when it was opened.</p> <p>Interview on 8/30/16 with the facility Staff #2 confirmed the above findings.</p>	A 391	<p>A391 Multi-dose vial of Lidocaine 1% had just been opened for that clinical day and staff members had not had a chance to label when the vial was opened.</p> <p>Multi-dose vials or any vials will be labeled immediately upon opening.</p> <p>Staff members will ensure that vials are labeled properly on a daily basis.</p>		