

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 08/04/2015
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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
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 entrance conference was held with the facility Administrator in the morning of 08/04/15. The purpose and process of the licensure resurvey were discussed, and an opportunity given for questions.</p> <p>Continued licensure is recommended, with an approved plan of correction.</p> <p>An exit conference was held with the facility Administrator the afternoon of 08/04/15. Preliminary findings of the survey were discussed, and an opportunity given for questions.</p> <p>Texas House Bill 15 states in part, "SECTION 2. Section 171.012, Health and Safety Code, is amended by amending Subsections (a), (b), and (c) and adding Subsection (a-1) to read as follows: ...</p> <p>(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:"</p>	A 000	<p>REVIEWED</p> <p>SEP 04 2015</p> 	

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(X6) DATE

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A 000	Continued From page 1 Facility based policy entitled, "Sonograms" stated in part, "The physician who is to perform the abortion, or an agent of that physician who is a also a certified sonographer on a pregnant women at least 24 hours before an abortion, or at least two hours before the abortion if the pregnant woman waives this requirement by certifying on the sonogram/abortion election form (Attachment A) that she currently lives 100 miles or more from the nearest abortion provider. This must be completed prior to receiving a sonogram and before any sedative or anesthesia is administered ..." According to documentation, 2 of 4 medical records of patients (living more than 100 miles or more from the nearest abortion provider) receiving an abortion did not wait two hours before the abortion, per House Bill 15. - Patient T3 was initially counseled and medically assessed on 01/20/15 at 09:50 AM. The initial surgical abortion was performed on 01/20/15 at 11:32 AM. Staff member # 1 confirmed the time indicated on the Operation Note. - Patient T4 was initially counseled and medically assessed on 05/23/15 at 07:00 AM. The initial medication was administered on 05/23/15 at 8:37. Texas House Bill 15 Section 171.0122 states in part, "VIEWING PRINTED MATERIALS AND SONOGRAM IMAGE; HEARING HEART AUSCULTATION OR VERBAL EXPLANATION. (a) A pregnant woman may choose not to view the printed materials provided under Section 171.012(a)(3) after she has been provided the materials.	A 000	A000 THB 15 Section 2, Section 171.012 Health and Safety Code 1. The Clinical Record Checklist was updated to include: a) Sonogram and Abortion Election form r/t patients living 100 miles or more: • Date/time initial consult: • Date/time of anesthesia: • Date/time of initial surgical abortion: 2. Staff meeting was held 8/6/15 that included an inservice on the regulation and expectations 3. Staff given additional education re: [REDACTED] What to Do When You Have a Bowie-Dick Test Problem, <u>Managing Infection Control</u> , January 2005, pp 74-79 on 8/31/15. 4. Implementation began 8/6/15 5. Compliance will be validated via MR review • 100% MR review/audit • Numerator= # MR with documentation of the minimum 2 hour wait per HB 15 • Denominator= total # MR audited	

Texas Department of State Health Services

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A 000	<p>Continued From page 2</p> <p>(b) A pregnant woman may choose not to view the sonogram images required to be provided to and reviewed with the pregnant woman under Section 171.012(a)(4).</p> <p>(c) A pregnant woman may choose not to hear the heart auscultation required to be provided to and reviewed with the pregnant woman under Section 171.012(a)(4).</p> <p>(d) A pregnant woman may choose not to receive the verbal explanation of the results of the sonogram images under Section 171.012(a)(4) (C) if:</p> <p>(1) the woman's pregnancy is a result of a sexual assault, incest, or other violation of the Penal Code that has been reported to law enforcement authorities or that has not been reported because she has a reason that she declines to reveal because she reasonably believes that to do so would put her at risk of retaliation resulting in serious bodily injury;</p> <p>(2) the woman is a minor and obtaining an abortion in accordance with judicial bypass procedures under Chapter 33, Family Code; or</p> <p>(3) the fetus has an irreversible medical condition or abnormality, as previously identified by reliable diagnostic procedures and documented in the woman's medical file.</p> <p>(e) The physician and the pregnant woman are not subject to a penalty under this chapter solely because the pregnant woman chooses not to view the printed materials or the sonogram images, hear the heart auscultation, or receive the verbal explanation, if waived as provided by this section."</p> <p>Facility based policy entitled, "Sonograms" stated in part, "The pregnant woman may choose not to receive the verbal explanation of the results of the sonogram images only if she certifies in writing on the sonogram/abortion</p>	A 000		

Texas Department of State Health Services

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A 000	<p>Continued From page 3</p> <p>election form, one of the following:</p> <ol style="list-style-type: none"> 1. The pregnancy is a result of sexual assault, incest ... 2. The woman is a minor and obtaining an abortion in accordance with judicial bypass procedures under Chapter 33, Family Code." <p>6 out of 6 medical records of minor patients (M1, M2, M3, M4, M5, and M6) revealed improper documentation on the "Texas Department of State Health Services Sonogram and Abortion Election Form".</p> <ul style="list-style-type: none"> These 6 minor patients all initialed beside the area on the form stating, "I am a minor and obtaining an abortion in accordance with judicial bypass procedures under Chapter 33, Texas Family Code " None of these patients had any documentation of judicial bypass. All 6 had "Parental Affidavit" signed by a parent or legal guardian with supporting documentation provided (birth certificates, licenses). There was no documentation in the medical record to indicate these patients received the verbal explanation of the results of the sonogram images per the requirements of House Bill 15. <p>Texas House Bill 2 states in part, "SECTION 2. Subchapter A, Chapter 171, Health and Safety Code, is amended by adding Section 171.0031 to read as follows: Sec. 171.0031. REQUIREMENTS OF PHYSICIAN; OFFENSE. (a) A physician performing or inducing an abortion:...</p> <p>(2) shall provide the pregnant woman with: (A) Provide a telephone number by which the pregnant woman may reach the physician or other health care personnel employed by the physician or by the facility with access to the</p>	A 000	<p>A000 THB 15 Section 171.0122</p> <ol style="list-style-type: none"> 1. The Clinical Record Checklist was updated to include: <ul style="list-style-type: none"> a) Minor patients with parent/legal guardian: <ul style="list-style-type: none"> MR reflects parent/legal guardian received verbal explanation of the results of the sonogram images per requirements of HB 15 2. Staff meeting was held 8/6/15 that included an inservice on the regulation and expectations 3. Implementation began 8/6/15 4. Compliance will be validated via MR review <ul style="list-style-type: none"> 100% MR review/audit Numerator= # MR with documentation of verbal explanation of the results of the sonogram images by parents/guardians as appropriate Denominator= total # MR audited 	

Texas Department of State Health Services

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A 000	Continued From page 4 woman ' s relevant medical records 24 hours a day, to request assistance for any complications that arise from the performance or induction of the abortion or ask health-related questions regarding the abortion, AND (B) The name and telephone number of the nearest hospital to the home of the pregnant woman at which an emergency arising from the abortion could be treated. " Based on review of documentation, it was determined the facility failed to provide patients with the name and telephone number of the nearest hospital to the home of the pregnant woman at which an emergency arising from the abortion could be treated. 4 of 4 (T1, T2, T3, and T4) medical records for patients that live in areas outside of El Paso received lists with the name and telephone number of hospitals in the El Paso area. These 4 patients did not receive the name and telephone number of the nearest hospital to the home of the pregnant woman. These four patients lived in Kansas, Colorado, and cities outside of El Paso. The above findings were confirmed in an interview with staff member # 1 on 08/04/15.	A 000	A000 THB 2 Section 2. Subchapter A, Chapter 171, Health and Safety Code 1. The Emergency Contact list was updated to include a space for the staff to write in the name and telephone numbers of hospitals nearest to their homes where emergency services can be provided in case of complications 2. The Clinical Record Checklist was updated to include: a) Patients living outside the El Paso area: 1. Documentation of name/telephone number of the nearest hospital to the home of pregnant woman (includes outside El Paso as applicable) 3. Staff meeting was held 8/6/15 that included an inservice on the regulation and expectations 4. Implementation began 8/6/15 5. Compliance will be validated via MR review a. 100% MR review/audit b. Numerator= # MR with documentation of name and telephone numbers of hospitals nearest to their homes where emergency services can be provided in case of complications c. Denominator= total # MR audited		
A 283	139.48(1)(A) Physical & Environmental Requirements The physical and environmental requirements for a licensed abortion facility are as follows. (1) A facility shall: (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;	A 283			

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A 283	Continued From page 5 This Requirement is not met as evidenced by: Based on tour and interview, the facility failed to ensure a safe and sanitary environment, properly maintained to protect the health and safety of patients and staff at all times. Findings included: During a tour of the facility on 08/04/15, it was observed in the sonogram room that a probe had black electrical tape around the handle, preventing effective cleaning of the instrument. The probe also was stored in a slot that held a paper towel that was visibly soggy with ultrasound gel. This moist paper towel could provide an environment for potential bacteria growth. The above findings were confirmed in an interview with staff member # 1 on 08/04/15.	A 283	A283 139.48(1)(A) Physical & Environmental Requirements 1. A new sonogram probe was ordered and delivered 8/6/15 2. The old probe was disposed 3. New probe implemented 8/6/15. 4. Staff meeting was held 8/6/15 that included an inservice on the regulation and expectations Infection control compliance and storage of the probe • Inspection & Testing of Surgical Instruments • Surgical Instrument Decontamination 3. Implementation began 8/6/15 4. Compliance will be validated via daily observation/documentation of compliance a. 100% review/audit when used b. Numerator= # days 100% compliance of correct storage c. Denominator= total # days audited		
A 320	139.49(d)(5)(A) Infection Control Standards (d) Policies and procedures for decontamination, disinfection, sterilization, and storage of sterile supplies. (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 provide sterilization equipment adequate to meet the requirements of this paragraph for sterilization of critical items. Equipment shall be maintained and operated to	A 320			

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A 320	<p>Continued From page 6</p> <p>perform, with accuracy, the sterilization of critical items.</p> <p>This Requirement is not met as evidenced by: Based on observation, review of policy, and interview, the facility failed to ensure that sterilization equipment was maintained and operated to perform, with accuracy, the sterilization of critical items.</p> <p>Findings included:</p> <p>Facility based policy entitled, "Bowie-Dick type Test" stated in part, "The Association for the Advancement of Medical Instrumentation (AAMI) recommends that a air removal test be run on all pre-vacuum steam sterilizers on a daily basis.</p> <p>A Bowie-Dick type Test is a method of testing pre-vacuum, high speed autoclaves, such as the Ritter M 11 autoclave, to demonstrate and test the adequacy of air removal from the chamber and load, and the presence of an air leak. Presence of 'air pockets' within a sterilization chamber can lead to improper sterilization of the instrument load.</p> <p>PROCEDURE</p> <ol style="list-style-type: none"> 1. The test is made daily in the pre-vacuum sterilizer with the first sterilization run ... 5. Record sterilization number, date and operator on test sheet. Test sheets then places in the appropriate folder for record keeping ... 9. Record results in sterilizer log." <p>Facility based policy entitled, "Steam Sterilizer Documentation" stated in part,</p>	A 320	<p>A320 139.49(d)(5)(A)</p> <ol style="list-style-type: none"> 1. Bowie Dick test sheets were ordered and arrived 8/25/15 2. Logbook will specify use of Bowie Dick test and/or what method is utilized to determine mechanical integrity 3. Staff meeting was held 8/6/15 that included an inservice on the regulation and expectations of Bowie Dick test to check for air leaks in the autoclaves 4. Staff given additional education re: What to Do When You Have a Bowie-Dick Test Problem, Managing Infection Control, January 2005, pp 74-79 on 8/31/15. 5. Compliance will be validated via documentation of compliance (Log Book) <ol style="list-style-type: none"> a. 100% review/audit when used b. Numerator= # days 100% compliance of Bowie Dick tests performed c. Denominator= total # days Bowie Dick is utilized 		

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A 320	<p>Continued From page 7</p> <p>"(ii) Each sterilizer shall be monitored during operation for pressure, temperature, and time at desired temperature and pressure ...</p> <p>PROCEDURE ...</p> <p>4) Indicate (by check mark) if the run is for instruments, biological test, or mechanical test (Bowie-Dick test)."</p> <p>During a tour of the facility on 08/04/15 it was observed the facility utilizes 2 Ritter M 11 autoclaves to sterilize surgical instruments. The use of these 2 autoclaves was confirmed in an interview with staff member # 1 on 08/04/15.</p> <p>Review of facility based sterilization records revealed the following:</p> <ul style="list-style-type: none"> The Sterilization Log from 01/05/15 through 08/03/15 documented both mechanical and biological testing results with " pass/fail " indicated. This logbook did not specify the use of a Bowie Dick test or what method was utilized to determine mechanical integrity. There was detailed documentation of biological monitoring in a separate logbook that included tests results. <p>In an interview with staff member # 1 on 08/04/15 was asked if the facility utilizes the Bowie Dick test to check for air leaks in their autoclaves. Staff member # 1 initially stated that the test was documented in the Sterilization log book. This surveyor stated the logbook did not specify the method used for mechanical testing. Staff member # 1 stated they were not familiar with the Bowie Dick test after being informed the facility had a specific policy for performing the Bowie Dick test. This staff member also stated the facility did not have any test sheet for the Bowie</p>	A 320	<p>A320 139.49(d)(5)(A)</p> <ol style="list-style-type: none"> Bowie Dick test sheets were ordered and arrived 8/25/15 Logbook revised and will specify use of Bowie Dick test and/or what method is utilized to determine mechanical integrity Staff meeting was held 8/6/15 that included an inservice on the regulation and expectations of Bowie Dick test to check for air leaks in the autoclaves Staff given additional education re: [REDACTED] What to Do When You Have a Bowie-Dick Test Problem, Managing Infection Control, January 2005, pp 74-79 on 8/31/15. Compliance will be validated via documentation of compliance (Log Book) <ol style="list-style-type: none"> 100% review/audit when used Numerator= # days 100% compliance of Bowie Dick tests performed Denominator= total # days Bowie Dick is utilized 	

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A 320	Continued From page 8 Dick test or retain any such test sheets.	A 320		