

Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  140000	(X2) MULTIPLE CONSTRUCTION: A. BUILDING: _____  B. WING: _____	(X3) DATE SURVEY COMPLETED  03/20/2018
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NAME OF PROVIDER OR SUPPLIER  WHOLE WOMANS HEALTH OF FORT WORTH, LLC	STREET ADDRESS, CITY, STATE, ZIP CODE 3256 LACKLAND ROAD FORT WORTH, TX 76116
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A 000	<p><u>Initial Comments</u></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 Clinic Manager the morning of 3-19-18. 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 Clinic Manager the afternoon of 3-20-18. Preliminary findings of the survey were discussed, and an opportunity given for questions.</p>	A 000	<p>REVIEWED</p> <p>APR 10 2018</p> <p>BY: <i>Wanda Wilson, DO</i></p>	

30D - State Form LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE 	TITLE <i>Director of Clinical Services</i> GQMD/1	(X6) DATE 04/05/18 If continuation sheet 1 of 10
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[REDACTED]	Continued From page 1 [REDACTED]	[REDACTED]		

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A 143	Continued From page 3	A 143		
A 143	<p>TAC 139.43(2)(3)(4)(5) Personnel Policies</p> <p>(2) a requirement for orientation of all employees, volunteers, students and contractors to the policies and objectives of the facility and participation by all personnel in employee training specific to their job;</p> <p>(3) job-related training for each position;</p> <p>(4) a requirement for an annual evaluation of employee performance;</p> <p>(5) in-service and continuing education requirements;</p> <p>This Requirement is not met as evidenced by: Based on a review of documentation and an interview with staff, the facility failed to ensure that all employees received an annual evaluation of employee performance.</p> <p>Findings were:</p> <p>During a review of personnel files, it was revealed that staff #3 had not received an annual evaluation since her hire date of 5-26-16. In an interview with staff #3 on 3-19-18, she confirmed that she had not received an annual evaluation since her hire date of 5-26-16.</p> <p>The above was confirmed in an interview with the Clinic Manager on the afternoon of 3-20-18.</p>	A 143	<p>The Clinic Manager will be responsible for ensuring that all staff members receive an annual evaluation in compliance with the current Whole Woman's Health Administrative policies.</p> <p>An annual evaluation for staff member #3 will be completed on 04/11/2018. The Director of Clinical Services will also conduct an in-service with Clinic Manager to review current Whole Woman's Health Administrative Policies.</p> <p>In order to monitor compliance, the Clinic Manager will review all clinic staff files monthly.</p>	04/11/2018
A 156	<p>TAC 139.44(c) Orientation/Training/Demonstrated Competency</p> <p>(c) The facility shall ensure that staff responsible</p>	A 156		

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A 156	<p>Continued From page 4.</p> <p>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.</p> <p>This Requirement is not met as evidenced by: Based on a review of personnel records and an interview with staff, the facility failed to ensure that staff responsible for 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 demonstrate competency in performing the sterilization procedures at the facility.</p> <p>Findings were:</p> <p>During a review of personnel records, the personnel record for staff #13 (who is responsible for sterilization at the facility) contained no documentation that she had been trained in sterilization or demonstrated competency in performing the sterilization procedures at the facility. The personnel record contained an area marked "Setting up the Sterile Area" but no other training was documented. In an interview with staff #13, she stated that she had learned in medical assisting school how to pack instruments, but not how to use the specific sterilizer machine used at the facility. She stated that the clinic manager had taught her how to operate the machine used at the facility. No documentation of the above was found in the personnel file for staff #13.</p> <p>The above was confirmed in an interview with the Clinic Manager on the afternoon of 3-20-18.</p>	A 156	<p>The Clinic Manager is responsible for ensuring that staff responsible for sterilization are trained to meet facility requirements.</p> <p>All WWH staff are currently trained and have demonstrated competency on sterilization procedures. We take a proactive approach to staff training and compliance with competency in performing sterilization procedures, and so effective immediately, we will update our current competency checklist to specifically list autoclave model numbers.</p> <p>A staff in service with all trained pathology staff will be conducted on 04/11/2018 to review current autoclave model user manual and to update current training documentation.</p> <p>To monitor continued compliance, the Clinic Manager will utilize the updated competency checklist when training new staff, and will review all clinic staff files monthly.</p>	04/11/2018

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A 197	<p>TAC 139.48(1)(A) Physical &amp; Environmental Requirements</p> <p>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;</p> <p>This Requirement is not met as evidenced by: Based on a tour of the facility and a review of documentation, the facility failed to maintain 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>Findings were:</p> <p>An unlocked medication refrigerator was found in an unsecured laboratory area, adjacent to patient procedure and consultation rooms. The refrigerator contained medications such as Pitocin®, Methergine®, Engerix-B® (Hepatitis B vaccine), Depo-Provera® and RhoGAM®.</p> <p>External shipping boxes were found on the floor of the clean instrument/sterilization preparation area. A box of instrument wrapping cloth was being stored (open) on the floor.</p> <p>A count of the Versed® single-dose vials (2 milliliters per vial) by the surveyor revealed a quantity of 63 vials. A review of the narcotic count for the same medication revealed that there</p>	A 197	<p>The Clinic Manager is responsible for ensuring the physical and environmental requirements are met.</p> <p>Whole Woman's Health of Fort Worth maintains a safe and sanitary environment for our patients. The refrigerator in question was in a non-patient care area, with posted staff only signs. In order to further secure the area, a lock will be placed on the door to completely seal the laboratory area from patients.</p> <p>An in-service will be held on 04/11/2018 with all staff to review ensuring that the above mentioned lock is secured when patients are in the building</p>	04/11/2018

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A.197	<p>Continued From page 6</p> <p>should be 64 vials. The quantity on the narcotic count sheet had been performed by staff #11 and verified by staff #13. In an interview with staff #11, staff #11 was questioned about the discrepancy. Staff #11 stated that a vial of Versed® had been drawn into a syringe on 3-17-18 but that the patient had refused the medication and it had been wasted. Staff #11 stated that [staff #11] had failed to document the waste in the controlled medication log.</p> <p>Facility policy titled "Medication Therapy Practices" states, in part: "Controlled Medications Opening Count 1) Each day, prior to drawing up or administering any medications, two staff will open the safe and count each drug on the Controlled Medication Log.</p> <p>... Logging Controlled Medications Administered 1. Each patient administered controlled medication will be logged in the Controlled Medications Log. The patient name and amount of medication administered will be recorded.</p> <p>... Controlled Medications Closing Count 1. Each day that Controlled Medications are administered, at the end of the day, two staff will open the safe and count each drug on the Controlled Medication Log.</p> <p>... 6. The second staff person will verify the reported count."</p> <p>The above was confirmed in an interview with the Clinic Manager on the afternoon of 3-20-18.</p>	<p>A.197</p> <p>A.197</p> <p>A.201</p>	<p>Whole Woman's Health of Fort Worth will purchase air tight containers to store "instrument wrapping cloth" (CSR wrap)</p> <p>An in-service will be held on 04/11/2018 with all staff to review receiving, unpacking and storing clinic supplies.</p> <p>In order to monitor compliance, the Clinic Manager will check monthly to ensure that clinic supplies are stored correctly.</p> <p>The narcotic count was verified by the Clinic Manager and the clinic nurse. The narcotic log was corrected and a narcotic count deviation was completed.</p> <p>The Director of Clinical Services will conduct an ins-service with all clinic management and nursing staff to review the current Whole Woman's Health Medication Therapy Practice policy on 04/12/2018.</p> <p>In order to monitor continued compliance, the Clinic Manager will complete a monthly audit of the Narcotic Log and count.</p>	<p>04/11/2018</p> <p>04/12/2018</p>
A.201	TAC 139.48(1)(E)(F) Physical & Environmental Requirements			

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A 201	<p>Continued From page 7</p> <p>The physical and environmental requirements for a licensed abortion facility are as follows: (1) A facility shall: (E) store hazardous cleaning solutions and compounds in a secure manner and label substances; (F) have the capacity to provide patients with liquids. The facility may provide commercially packaged food to patients in individual servings. If other food is provided by the facility, it shall be subject to the requirements of §§229.161 - 229.171 of this title (relating to Texas Food Establishments);</p> <p>This Requirement is not met as evidenced by: Based on a tour of the facility, the facility failed to store hazardous cleaning solutions and compounds in a secure manner.</p> <p>Findings were: During a tour of the facility on 3-19-18, hazardous cleaning solutions and compounds were found in patient care areas, unsecured, throughout the facility.</p> <p>The above was confirmed in an interview with the Clinic Manager on the afternoon of 3-19-18.</p>	A 201	<p>The Clinic Manager is responsible for ensuring the physical and ensuring the physical and environmental requirements are met.</p> <p>Cabinet locks will be installed in all patient care areas. An in-service will be held on 04/11/2018 to review procedures to ensure that all cleaning solutions are stored in locked cabinets during patient care hours.</p> <p>To ensure continued compliance, the Clinic Manager will ensure that all locks are working properly during monthly site inspection.</p>	04/11/2018
A 328	<p>HSC Code, D173.063(d)((1)(2)(e)(1)(2)(f): Abortion-inducing Drugs</p> <p>(d) The physician who gives, sells, dispenses, administers, provides, or prescribes an abortion-inducing drug shall provide the pregnant woman with: (1) a copy of the final printed label of that</p>	A 328		

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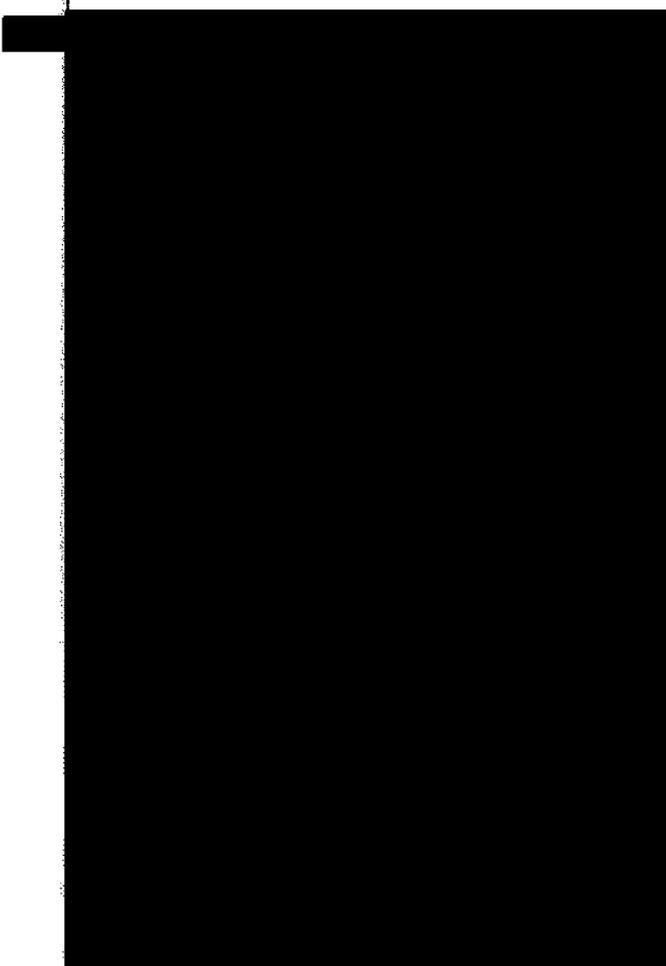
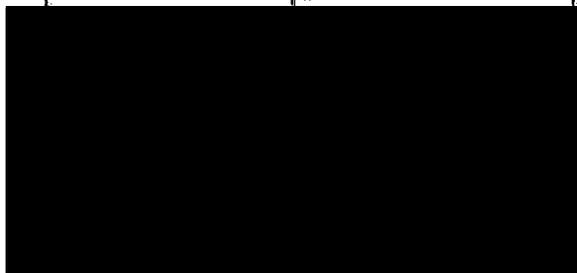
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A 328	<p>Continued From page 8</p> <p>abortion-inducing drug; and</p> <p>(2) a telephone number by which the pregnant woman may reach the physician, or other health care personnel employed by the physician or by the facility at which the abortion was performed with access to the woman's relevant medical records, 24 hours a day to request assistance for any complications that arise from the administration or use of the drug or ask health-related questions regarding the administration or use of the drug.</p> <p>(e) The physician who gives, sells, dispenses, administers, provides, or prescribes the abortion-inducing drug, or the physician's agent, must schedule a follow-up visit for the woman to occur not more than 14 days after the administration or use of the drug. At the follow-up visit, the physician must:</p> <p>(1) confirm that the pregnancy is completely terminated; and</p> <p>(2) assess the degree of bleeding.</p> <p>(f) The physician who gives, sells, dispenses, administers, provides, or prescribes the abortion-inducing drug, or the physician's agent, shall make a reasonable effort to ensure that the woman returns for the scheduled follow-up visit under Subsection (e). The physician or the physician's agent shall document a brief description of any effort made to comply with this subsection, including the date, time, and name of the person making the effort, in the woman's medical record.</p>	A 328		



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A-328	Continued From page 10 Clinic Manager on the afternoon of 3-20-18. 	A-328 		04/12/2018
A-356	TAC 139.56(b)(c) Emergency Services  (b) The facility shall have the necessary equipment and personnel for cardiopulmonary resuscitation as described in §139.59 of this title (relating to Anesthesia Services).	A-356		



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A 356	<p>Continued From page 12.</p> <p>in the United States endorses certification without practice and evaluation of hands-on skills. According to the Occupational Safety and Health Administration (OSHA) online training alone does not meet OSHA first aid and CPR training requirements." Further guidance can be found at <a href="https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&amp;p_id=28541">https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&amp;p_id=28541</a>.</p> <p>The above was confirmed in an interview with the Clinic Manager on the afternoon of 3-20-18.</p>	A 356		