Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROV DER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULT PLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	140000	A. BUILDING: _____ B. WING _____	10/06/2015

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WHOLE WOMANS HEALTH OF FORT WORTH, LLC	3256 LACKLAND ROAD FORT WORTH, TX 76116

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFIC ENCIES (EACH DEFIC ENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENT FY NG 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	TAC 139 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. An entrance conference was held with the facility Administrator in the morning of 10/05/15. The purpose and process of the licensure resurvey were discussed, and an opportunity given for questions. Continued licensure is recommended, with an approved plan of correction. An exit conference was held with the facility Administrator and another staff member on the afternoon of 10/06/15. Preliminary findings of the survey were discussed, and an opportunity given for questions. 0000 House Bill 15 HEALTH AND SAFETY CODE TITLE 2. HEALTH SUBTITLE H. PUBLIC HEALTH PROVISIONS CHAPTER 171. ABORTION SUBCHAPTER A. GENERAL PROVISIONS Sec. 171.012. VOLUNTARY AND INFORMED CONSENT. (a) Consent to an abortion is voluntary and informed only if: (1) the physician who is to perform the abortion informs the pregnant woman on whom the abortion is to be performed of:	A 000		

SOD - State Form

LABORATORY D RECTOR'S OR PROV DER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

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A 000	Continued From page 1	A 000		

(A) the physician's name;
(B) the particular medical risks associated with the particular abortion procedure to be employed, including, when medically accurate:
(i) the risks of infection and hemorrhage;
(ii) the potential danger to a subsequent pregnancy and of infertility; and
(iii) the possibility of increased risk of breast cancer following an induced abortion and the natural protective effect of a completed pregnancy in avoiding breast cancer;
(C) the probable gestational age of the unborn child at the time the abortion is to be performed; and
(D) the medical risks associated with carrying the child to term;
(2) the physician who is to perform the abortion or the physician's agent informs the pregnant woman that:
(A) medical assistance benefits may be available for prenatal care, childbirth, and neonatal care;
(B) the father is liable for assistance in the support of the child without regard to whether the father has offered to pay for the abortion; and
(C) public and private agencies provide pregnancy prevention counseling and medical referrals for obtaining pregnancy prevention medications or devices, including emergency contraception for victims of rape or incest;
(3) the physician who is to perform the abortion or the physician's agent:
(A) provides the pregnant woman with the printed materials described by Section 171.014 <http://www.statutes.legis.state.tx.us/GetStatute.aspx?Code=HS&Value=171.014&Date=7/18/2015>; and
(B) informs the pregnant woman that those materials:
(i) have been provided by the Department of State Health Services;

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A 000	Continued From page 2 (ii) are accessible on an Internet website sponsored by the department; (iii) describe the unborn child and list agencies that offer alternatives to abortion; and (iv) include a list of agencies that offer sonogram services at no cost to the pregnant woman; (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: (A) the physician who is to perform the abortion or an agent of the physician who is also a sonographer certified by a national registry of medical sonographers performs a sonogram on the pregnant woman on whom the abortion is to be performed; (B) the physician who is to perform the abortion displays the sonogram images in a quality consistent with current medical practice in a manner that the pregnant woman may view them; (C) the physician who is to perform the abortion provides, in a manner understandable to a layperson, a verbal explanation of the results of the sonogram images, including a medical description of the dimensions of the embryo or fetus, the presence of cardiac activity, and the presence of external members and internal organs; and (D) the physician who is to perform the abortion or an agent of the physician who is also a sonographer certified by a national registry of medical sonographers makes audible the heart auscultation for the pregnant woman to hear, if present, in a quality consistent with current medical practice and provides, in a manner	A 000		

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A 000	Continued From page 3 understandable to a layperson, a simultaneous verbal explanation of the heart auscultation; Based on a review of documentation, personnel records and an interview with staff, patients did not receive a sonogram performed by a sonographer certified by a national registry of medical sonographers. Findings were: In a review of 16 clinical records, 14 of the 16 patients (patients #1 - #6, #8 and #10 - #16) received their sonogram from a sonographer who was not certified by a national registry of medical sonographers. The personnel record for staff #5 contained no evidence of certification, and staff #6 confirmed verbally that staff #5 was not certified by a national regustry of medical sonographers.	A 000		
A 197	TAC 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; This Requirement is not met as evidenced by: Based on observation and an interview with staff, the facility failed to have a safe and sanitary environment that was maintained to protect the health and safety of patients and staff at all times.	A 197		

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A 197	Continued From page 4 Findings were: During a tour of the facility on 10-6-15, the following observations were made: - The vinyl cover on the exam table in the small procedure room contained rips and tears, which can harbor bacteria and prevent the exam table from being completely cleaned. - The vinyl cover on the exam table in the large procedure room contained cracks along the edge, which can harbor bacteria and prevent the item from being completely cleaned. - Examination of the medications in the emergency cart revealed 2 of 4 500 milliliter bags of intravenous solution of 5% dextrose and 0.9% normal saline that had expired at the end of 8-15 but were still available for patient use. The above was confirmed in an interview with staff #6 during a tour of the facility on 10-6-15.	A 197		
A 201	TAC 139.48(1)(E)(F) Physical & Environmental Requirements 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 -	A 201		

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A 201	Continued From page 5 229.171 of this title (relating to Texas Food Establishments); 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. Failure to do so increases the risk of harm to patients. Findings were: During a tour of the facility on 10-6-15, the unlocked laundry room contained items including disinfectant spray, air freshener spray, germicidal wipes, plant feeder spikes, all-purpose spray cleaner and bleach. The above was confirmed in an interview with staff #6 on 10-6-15 during a tour of the facility.	A 201		
A 244	TAC 139.49(d)(5)(F)(i)(ii) Infection Control Standards (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. This Requirement is not met as evidenced by: Based on a review of facility provided documentation and interview, it was determined the facility failed to ensure that log for biological indicators was maintained with the load	A 244		

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A 244	Continued From page 6 identification, biological indicator results, and identification of the contents Findings included: The "Whole Woman's Health Procedures for Pathology" included a section entitled, "Procedure for Decontamination, Disinfection, Sterilization, and Storage of Sterile Supplies" which stated in part, "Biological Indicators: The efficacy of the sterilizing process will be monitored with reliable biological indicators ... B. A log will be maintained with the load identification, biological indicator results, and identification of the contents of the load". The "Whole Woman's Health Procedures for Pathology" included a section entitled, "Procedure for Administering and Recording Results of Biological Indicators" which stated in part, "1. After placing the indicators in the incubator, the staff member will begin a Biological Indicator Performance Log. He or she will record his or her initials and the date and start time of the incubation for each Autoclave that has an indicator... 3. If the processed indicator has a yellow color, this demonstrates bacterial growth and a failure in the sterilization process. If the processed indicator stays purple color, this demonstrates a satisfactory sterilization process. The positive control indicator should turn a yellow color; this demonstrates that the processed indicator results are valid. 4. The staff member will record results on the Biological Indicator Performance Log at 24 hours." The Autoclave Load Log (from 04/07/15 through	A 244		

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A 244	Continued From page 7 10/06/15) contained documentation of the load identification number, the contents of the load per facility based procedure. This log has an area to indicate "Bio indicator in load", there was no documentation of the biological indicator results on this form. The Biological Indicator Log did not contain the results of the biological indictor tests for the 2 autoclaves used at the facility. The area to document the results for the two sterilizers (1 and 2) contained initials and the date and start time of the incubation for each Autoclave for the 24 hour and 48 hour check, but the positive or negative results for the tests were not documented. The only results indicated were for the control. The area to document the control from 04/07/15 through 10/05/15 would indicate for the 24 hour check "no growth" and for the 48 hour reading "growth". In an interview on 10/06/15, staff member # 10 confirmed that the results of the biological indicators were not appropriately documented in the facility logs to indicate positive or negative results.	A 244		
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). (c) Personnel providing direct patient care shall be currently certified in basic life support by the American Heart Association, the American Red Cross, or the American Safety and Health Institute, or in accordance with their individual professional licensure requirements, and if	A 356		

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A 356	Continued From page 8 required in their job description or job responsibilities. This Requirement is not met as evidenced by: Based on a review of personnel files and an interview with staff, the facility failed to ensure that all direct care personnel were competent in and maintained current certification in cardiopulmonary resuscitation (CPR), as there was no documented evidence of hands-on skills practice and in-person assessment and demonstration of CPR skills. This presents a risk, as staff may not be competent to respond in a medical emergency. Findings included: A review of personnel files revealed that 7 of 8 direct staff members at facility (#4-10)obtained cardiopulmonary resuscitation (CPR) through an online resource that contained a "National Cognitive Evaluation" with no evidence of hands-on skills practice and in-person assessment and demonstration of CPR skills. Review of the Health & Safety Institute and the National Safety Council website found at http://news.hsi.com/onlineonlycpr reveals that, "No major nationally recognized training program 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."	A 356		