Texas Health and Human Services Commission

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	140007	A. BUILDING: _____ B. WING _____	10/16/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WHOLE WOMANS HEALTH OF SAN ANTONIO	4025 E SOUTHCROSS BLVED BLDG 5 SUITE 30 SAN ANTONIO, TX 78222

(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
6 000	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.	6 000		

[redacted]

SOD - State Form

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

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[redacted]				
6 023	TAC 139.40 Policy Development and Review (a) The licensee shall be responsible for the conduct of the licensed abortion facility and shall assume full legal responsibility for developing, implementing, enforcing, and monitoring written policies governing the facility's total operation, and for ensuring that these policies comply with the Act and the applicable provisions of this chapter and are administered so as to provide	6 023		

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6 023	Continued From page 2 health care in a safe and professionally acceptable environment. These written policies shall include at a minimum the following: (1) administrative policies governing the administration of the facility, covering at a minimum: (A) personnel; (B) employee orientation, training, and evaluation; (C) employee and patient record system; (D) auditing system for monitoring state or federal funds; (E) advertisements for the facility; (F) accuracy of public education information materials and activities in relation to abortion, birth control, and sexually-transmitted diseases; (G) patient education/information services and referral services; (H) reporting requirements; and (I) procedures for the resolution of complaints regarding care or services rendered by licensed health professionals and other members of the facility staff, including contract services or staff. The facility shall document the receipt and the disposition of the complaint. The investigation and documentation shall be completed within 30 calendar days after the facility receives the complaint, unless the facility has and documents reasonable cause for a delay.	6 023		

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6 023	Continued From page 3 (2) clinical policies governing medical and clinical practices and procedures of the facility, covering at a minimum: (A) the provision of medical and clinical services; (B) the provision of laboratory services; (C) examination of fetal tissue; (D) disposition of medical waste; (E) emergency services; (F) condition on discharge procedures; (G) clinical records; (H) reporting and filing requirements; and (I) monitoring post-procedure infection(s). (3) a policy to ensure that the facility is in compliance with fire safety provisions as required by the local codes; (4) policies on decontamination, disinfection, and sterilization, and storage of sterile supplies; (5) policies for parental notice for unemancipated pregnant minors as stipulated in Family Code, Chapter 33; (6) policies for informed consent as stipulated in Health and Safety Code, Chapter 171, the Woman's Right to Know Act;	6 023		

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6 023	Continued From page 4 (7) policies for reporting suspected abuse or neglect as stipulated in Family Code, Chapter 261; and (8) policies to ensure all women who present to obtain an abortion provide identification that includes the woman's date of birth. (A) If the woman does not have identification stating her date of birth, she shall be required to execute an affidavit on a form published by the department indicating that she does not have appropriate identification and indicating her date of birth on the affidavit. Attached Graphic (B) The facility shall keep a copy of the identification presented or the affidavit in its files. (b) The licensee, in fulfilling its responsibility under subsection (a) of this section, shall review the facility's written policies and procedures periodically, but no less than once every two years; date to indicate time of last review; revise as necessary; and enforce. This Requirement is not met as evidenced by: Based on a review of documentation and an interview with staff, the licensee failed to be responsible for implementing and enforcing written policies governing the facility's total operation and for ensuring that these policies are administered so as to provide health care in a safe and professionally acceptable environment. Findings were: During a tour of the facility on 10/16/18, a random count of Midazolam (a Schedule IV controlled)	6 023		

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6 023	Continued From page 5	6 023		

was performed. 100 ml of Midazolam was present in boxed vials. 20 ml of Midazolam was present in an unopened vials (not in a box). 1 open multi use vial of Midazolam was observed with markings on the side to count the amount in the vial. The surveyor observed 7 ml of Midazolam in the open via, for a total of 127 ml . The Midazolam count on 10/16/18 was verified by staff #1, present during the tour and the narcotic count. The narcotic count sheet indicated that 126 ml of had been present during the closing count conducted on 10/16/18 (which had been verified and signed off on by two staff members).

According to https://www.deadiversion.usdoj.gov/schedules/, a Schedule IV drug is described as follows:

"Schedule IV Controlled Substances
Substances in this schedule have a low potential for abuse relative to substances in Schedule III.

Examples of Schedule IV substances include: alprazolam (Xanax®), carisoprodol (Soma®), clonazepam (Klonopin®), clorazepate (Tranxene®), diazepam (Valium®), lorazepam (Ativan®), midazolam (Versed®), temazepam (Restoril®), and triazolam (Halcion®).

Facility policy titled "Procedure for Handling Controlled Medications" stated, in part:
"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.
...
7. Any discrepancies between the actual closing count and the anticipated closing count should be resolved and reported to the clinical manager.

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6 023	Continued From page 6	6 023		

Discrepancies that cannot be resolved should generate a Narcotics Deviation Report (see sample attached). Deviation reports of concern, i.e. that indicate missing drugs or careless handling, should be shared with the Medical Director/Consultant and and Director of Clinical Services included in the Quarterly QA Review... 9. The closing count will be documented in red ink on the Controlled Medication Log."

The above was confirmed in an interview with staff #1 on the afternoon of 10/16/18.

Based on a review of performance records and interview, the facility failed ensue that policies on decontamination, disinfection, and sterilization, and storage of sterile supplies were implemented. As evidence by failing to ensure that each sterilizer was monitored during operation for pressure, temperature, and time at desired temperature and pressure, as evidenced by the fact that a record was not maintained that included: duration and temperature of exposure phase (if not provided on sterilizer recording charts).

Finding included:

Review of the autoclave logs for August, September, and October 2018 revealed that pressure, temperature, and/or duration of exposure at desired temperature and pressure of the sterilized logs were not appropriately documented on the following dates/loads: 08/07/18 (load #080705 and 080706), load #100401 (no date indicated), 10/04/18 (load 100405),

With no documentation of these elements it is unknown if these loads and instruments were

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6 023	Continued From page 7 effectively sterilized. Facility policy titled "Decontamination, Disinfection, Sterilization, and Storage of Sterile Supplies" states, in part: "Performance Records Performance records for all sterilizers will be maintained for each cycle. And will be retained for two years.(sic) These records will be available for review within two hours during the specified two-year period. All sterilizers will be monitored during operation for pressure, temperature, and time at desired temperature and pressure. The performance record will include: -Sterilizer identification number -Sterilization date -Sterilization time -Load number -Pack ID# -Duration and temperature of exposed phase -Identification of operator -Results of biological tests and dates performed -Time/temperature recording charts from each sterilizer" The above findings we confirmed on 10/1618 in an interview with staff member #1.	6 023		
6 041	TAC 139.56 Emergency Services (a) A licensed abortion facility shall have a readily accessible written protocol for managing medical emergencies and the transfer of patients requiring further emergency care to a hospital. The facility shall ensure that the physicians who practice at the facility:	6 041		

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6 041	Continued From page 8 (1) have active admitting privileges at a hospital that provides obstetrical or gynecological health care services and is located not further than 30 miles from the abortion facility; (2) provide the pregnant woman with: (A) a telephone number by which the pregnant woman may reach the physician, or other health care personnel employed by the physician or the facility at which the abortion was performed or induced with access to the 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 would be treated. (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 required in their job description or job responsibilities. This Requirement is not met as evidenced by: Based on a review of documentation and staff	6 041		

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6 041	Continued From page 9 interview, the licensee failed to provide a patient 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 would be treated. Findings included: In 1 (patient #8) out of 20 clinical records reviewed the patients drivers license listed their place of residence to be in Mesquite, Texas and the facility provided the name and telephone number of Odessa Regional Medical Center as the hospital located nearest to her home of the patient. The information provided to the patient was not the nearest hospital to the home of the patient's residence. The above was confirmed in an interview with the Clinical Manager on the evening of October 16, 2018.	6 041		
6 045	TAC 139.60 Other State and Federal Compliance Requiremen (a) A licensed abortion facility shall be in compliance with all state and federal laws pertaining to handling of drugs. (b) A licensed abortion facility that provides laboratory services shall meet the Clinical Laboratory Improvement Amendments of 1988, 42 United States Code, §263a, Certification of Laboratories (CLIA 1988). CLIA 1988 applies to all facilities with laboratories that examine human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.	6 045		

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6 045	Continued From page 10 (c) A licensed abortion facility shall ensure that its physicians comply with the Medical Practice Act, Occupations Code, Chapters 151 - 160 and 162 - 165, while functioning in his or her capacity at or for the facility. (d) A licensed abortion facility utilizing the services of a physician assistant(s) shall ensure that its physician assistants comply with the Physician Assistant Licensing Act, Occupations Code, Chapter 204, while functioning in his or her capacity at or for the facility. (e) A licensed abortion facility utilizing the services of a registered nurse shall ensure that its registered nurses comply with the Nursing Practice Act, Occupations Code, Chapters 301 and 304, while functioning in his or her capacity at or for the facility. (f) A licensed abortion facility utilizing the services of a licensed vocational nurse(s) shall ensure that its vocational nurse(s) comply with the Nursing Practice Act, Occupations Code, Chapters 301 and 304, while functioning in his or her capacity at or for the facility. (g) A licensed abortion facility that provides pharmacy services shall obtain a license as a pharmacy if required by the Texas Pharmacy Act, Occupations Code, Chapters 551 - 569. (h) A licensed abortion facility shall comply with the following federal Occupational Safety and Health Administration requirements: (1) 29 Code of Federal Regulations, Subpart E, §1910.38, concerning emergency action plan and §1910.39, concerning fire prevention plans;	6 045		

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6 045	Continued From page 11 (2) 29 Code of Federal Regulations, Subpart I, §1910.132, concerning general requirements for personal protective equipment; (3) 29 Code of Federal Regulations, Subpart I, §1910.133, concerning eye and face protection; (4) 29 Code of Federal Regulations, Subpart I, §1910.138, concerning hand protection; (5) 29 Code of Federal Regulations, Subpart K, §1910.151, concerning medical services and first aid; (6) 29 Code of Federal Regulations, Subpart L, §1910.157, concerning portable fire extinguishers; (7) 29 Code of Federal Regulations, Subpart Z, §1910.1030, concerning bloodborne pathogens; and (8) 29 Code of Federal Regulations, Subpart Z, §1910.1200, Appendices A - E, concerning hazard communication (hazardous use of chemicals). (i) A licensed abortion facility shall not use adulterated or misbranded drugs or devices in violation of the Health and Safety Code, §431.021. Adulterated drugs and devices are described in Health and Safety Code, §431.111. Misbranded drugs or devices are described in Health and Safety Code, §431.112. (j) A licensed abortion facility shall not commit a false, misleading, or deceptive act or practice as that term is defined in the Deceptive Trade	6 045		

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6 045	Continued From page 12 Practices-Consumer Protection Act, Business and Commerce Code, §17.46. (k) A licensed abortion facility shall comply with the requirements of the Family Code, §33.002, relating to a Consent Form. (l) A licensed abortion facility shall comply with the requirements of Health and Safety Code, Chapter 171, the Woman's Right to Know Act. (m) A licensed abortion facility shall comply with the requirements of Occupations Code, Chapter 102, Solicitation of Patients. This Requirement is not met as evidenced by: Based on a review of documentation and staff interview, the licensee failed to schedule a follow-up appointment for 1 patient (patient #17) out of 20 patient charts reviewed and the licensee also failed to make a reasonable effort to ensure that 3 patients (patients #1, 14, and 19) out of 20 patient charts reviewed returned for their scheduled follow-up appointments post procedure. Findings were: HEALTH AND SAFETY CODE, TITLE 2. HEALTH, SUBTITLE H. PUBLIC HEALTH PROVISIONS, CHAPTER 171. ABORTION, SUBCHAPTER A. GENERAL PROVISIONS stated in part, "Sec. 171.063. DISTRIBUTION OF ABORTION-INDUCING DRUG... (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	6 045		

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6 045	Continued From page 13 occur not more than 14 days after the administration or use of the drug. At the follow-up visit, the physician must:... (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." In 1 out of the 20 clinical records reviewed, the facility staff failed to schedule a follow-up appointment for patient #17. In 3 out of the 20 clinical records reviewed the facility staff failed to make a reasonable effort to ensure that patients #1, 14, and, 19 returned for their follow-up appointments. The above was confirmed in an interview with the Clinic Manager on the evening of October 16, 2018.	6 045		