Texas Department of State Health Services

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	140013	A. BUILDING: _____ B. WING _____	07/24/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WHOLE WOMAN'S HEALTH ALLIANCE	8401 NORTH IH 35 SUITE 200 AUSTIN, TX 78753

(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	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 Clinic Nurse Manager the morning of 7-24-17. The purpose and process of the initial licensure survey were discussed, and an opportunity given for questions. Initial licensure is recommended, with an approved plan of correction. An exit conference was held with the Clinic Nurse Manager and the Director of Clinical Services on the afternoon of 7-24-17. Preliminary findings of the survey were discussed, and an opportunity given for questions.	A 000		
A 126	TAC 139.41(a) 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 health care in a safe and professionally acceptable environment. These written policies shall include at a minimum the following:	A 126		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	140013	A. BUILDING: _____ B. WING _____	07/24/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WHOLE WOMAN'S HEALTH ALLIANCE	8401 NORTH IH 35 SUITE 200 AUSTIN, TX 78753

(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 126	Continued From page 1 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 7-24-17, a random count of Fentanyl (a Schedule II narcotic medication) was performed. 150 ml of Fentanyl was present in boxed vials. 2 ml of Fentanyl was present in an unopened vial (not in a box). 2 syringes, each pre-filled with 0.5 ml of the drug, represented 1 ml of Fentanyl, for a total of 153 ml of Fentanyl. The Fentanyl count on 7-24-17 was verified by staff #7, present during the tour and the narcotic count. The narcotic count sheet indicated that 154 ml of Fentanyl had been present during the closing count conducted on 7-21-17 (which had been verified and signed off on by staff #6 and staff #9). In an interview with staff members #6 & #7, neither member was able to explain the 1 ml Fentanyl discrepancy and both staff stated that no patients had been seen since 7-21-17. According to https://www.deadiversion.usdoj.gov/schedules/, a Schedule II drug is described as follows: "Schedule II/IIN Controlled Substances (2/2N) Substances in this schedule have a high potential for abuse which may lead to severe psychological	A 126		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	140013	A. BUILDING: _____ B. WING _____	07/24/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WHOLE WOMAN'S HEALTH ALLIANCE	8401 NORTH IH 35 SUITE 200 AUSTIN, TX 78753

(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 126	Continued From page 2	A 126		

or physical dependence.

Examples of Schedule II narcotics include: hydromorphone (Dilaudid®), methadone (Dolophine®), meperidine (Demerol®), oxycodone (OxyContin®, Percocet®), and fentanyl (Sublimaze®, Duragesic®). Other Schedule II narcotics include: morphine, opium, codeine, and hydrocodone.

Examples of Schedule IIN stimulants include: amphetamine (Dexedrine®, Adderall®), methamphetamine (Desoxyn®), and methylphenidate (Ritalin®).

Other Schedule II substances include: amobarbital, glutethimide, and pentobarbital."

Facility policy titled "Medication Therapy Practices" stated, in part:
"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.
...
8. Any discrepancies between the actual closing count and the anticipated closing count should be resolved and reported to the clinical manager. Discrepancies that cannot be resolved should generate a Narcotics Deviation Report. Deviation reports of concern, i.e. that indicate missing drugs or careless handling, should be shared with the Medical Director/Consultant and included in the Quarterly Review."

The above was confirmed in an interview with staff #6 and staff #7 on the afternoon of 7-24-17.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	140013	A. BUILDING: _____ B. WING _____	07/24/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WHOLE WOMAN'S HEALTH ALLIANCE	8401 NORTH IH 35 SUITE 200 AUSTIN, TX 78753

(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 257	Continued From page 3	A 257		
A 257	TAC 139.49(d)(5)(L)((ii)(I - V) Infection Control Standards (L) Performance records. (ii) Each sterilizer shall be monitored during operation for pressure, temperature, and time at desired temperature and pressure. A record shall be maintained either manually or machine generated and shall include: (I) the sterilizer identification; (II) sterilization date and time; (III) load number; (IV) duration and temperature of exposure phase (if not provided on sterilizer recording charts); (V) identification of operator(s); This Requirement is not met as evidenced by: Based on a review of performance records and interview, the facility failed 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 May, June, and July 2017 revealed that pressure, temperature, and duration of exposure at desired temperature and pressure of the sterilized logs was not documented. In an interview on 07/24/17, staff member #7 stated that the new autoclave forms have an area to document the pressure and temperature,	A 257		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	140013	A. BUILDING: _____ B. WING _____	07/24/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WHOLE WOMAN'S HEALTH ALLIANCE	8401 NORTH IH 35 SUITE 200 AUSTIN, TX 78753

(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 257	Continued From page 4 however the facility was utilizing old logs that did not contain a prompt to document this information. The new forms also did not have an area to document duration of the exposure phase. With no documentation of these elements it is unknown if these loads and instruments were 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 07/24/17 in an interview with staff member #7.	A 257		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	140013	A. BUILDING: _____ B. WING _____	07/24/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WHOLE WOMAN'S HEALTH ALLIANCE	8401 NORTH IH 35 SUITE 200 AUSTIN, TX 78753

(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 315	Continued From page 5	A 315		
A 315	House Bill 2 Medical and Clinical Services A physician must provider the pregnant woman with: a) a telephone number by which the pregnant woman may reach the physician, 24 hours a day to request assistance for any complications that arise from 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. This Requirement is not met as evidenced by: Based on a review of clinical records and an interview with staff, the physician failed to provide the pregnant women 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 were: During a review of 21 clinical records, 10 of the 21 records (patients #2, #3, #4, #5, #6, #12, #13, #14, #15 and #16) contained no documentation that the patient had been furnished with the name and/or telephone number of the nearest hospital to the home of the pregnant woman at which an emergency arising from the abortion would be treated. -Patients #2, #3, #4, #5 and #6 had been provided with a hospital name but no telephone number for the hospital. -Patients #12, #13, #14, #15 and #16 had been	A 315		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	140013	A. BUILDING: _____ B. WING _____	07/24/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WHOLE WOMAN'S HEALTH ALLIANCE	8401 NORTH IH 35 SUITE 200 AUSTIN, TX 78753

(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 315	Continued From page 6 provided with neither a hospital name nor a telephone number for the hospital. The above was confirmed in an interview with staff #7 on the afternoon of 7-24-17.	A 315		
A 327	House Bill 2 Medical and Clinical Services Physicians must ensure that abortion-inducing drugs are used according to FDA regulations that require the women to visit the physician in person for each of the two doses of the abortion pill, as well as for a follow-up appointment within 14 days. The physician must provide the woman with a copy of the final printed label of the abortion-inducing drug. This Requirement is not met as evidenced by: Based on a review of clinical records and an interview with staff, the physician failed to ensure that the patient was scheduled for a follow-up appointment within 14 days. Findings were: Based on the review of 21 clinical records, 1 of 21 (patient #1) was not scheduled to return to the clinic for a follow-up visit within the required 14	A 327		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	140013	A. BUILDING: _____ B. WING _____	07/24/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WHOLE WOMAN'S HEALTH ALLIANCE	8401 NORTH IH 35 SUITE 200 AUSTIN, TX 78753

(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 327	Continued From page 7 days (appointment was scheduled for 21 days after). The above was confirmed in an interview with staff #7 on the afternoon of 7-24-17.	A 327		