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
	140008	A. BUILDING: _____ B. WING _____	10/14/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WOMENS CENTER HOUSTON	8200 WEDNESBURY LANE SUITE 230 HOUSTON, TX 77074

(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. (a) Purpose. The purpose of this chapter is to implement the Texas Abortion Facility Reporting and Licensing Act, Health and Safety Code, Chapter 245, which provides the Health and Human Services Commission with the authority to establish rules governing the licensing and regulation of abortion facilities and to establish annual reporting requirements for each abortion performed. This chapter also implements the Woman's Right to Know Act, Health and Safety Code, Chapter 171. (b) Scope and applicability. (1) Licensing requirements. (A) A person may not establish or operate an abortion facility in Texas without a license issued under this chapter unless the person is exempt from licensing requirements. (B) The following need not be licensed under this chapter: (i) a hospital licensed under Health and Safety Code, Chapter 241; (ii) an ambulatory surgical [redacted]	6 000		

SOD - State Form

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER R[redacted] TITLE (X6) DATE 14.17. 10/20/21

STATE FORM WNBT11 If continuation sheet 1 of 8

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6 000	Continued From page 1 under Health and Safety Code, Chapter 243; or (iii) the office of a physician licensed by the Texas Medical Board and authorized to practice medicine in the State of Texas, unless the office is used for the purpose of performing more than 50 abortions in any 12-month period. (2) Reporting requirements. All licensed abortion facilities and facilities and persons exempt from licensing shall comply with §139.4 of this title (relating to Annual Reporting Requirements for All Abortions Performed). An entrance conference was held with the facility staff the morning of 10-13-2021. 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 nurse and medical assistant the afternoon of 10-14-2021. Preliminary findings of the survey were discussed, and an opportunity given for questions.	6 000		
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	6 045		

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6 045	Continued From page 2 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. (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	6 045		

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6 045	Continued From page 3 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; (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.	6 045		

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6 045	Continued From page 4 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 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 interview, review of documentation and observation the facility failed to: 1.Make a reasonable effort to ensure that the woman returns for the scheduled follow-up after a procedure. 2.Ensure staff conducted physical counts and kept accurate records of the disposition of drugs listed in schedules II, III, IV and V of the Comprehensive Drug Abuse Prevention and Control Act. This deficient practice placed the facility at increased risk of experiencing drug diversions. Review of federal government laws:	6 045	The office administrator will provide a daily follow-up after surgical procedure/ abortion pill form with the date, patient's name, date of birth and the date of the patient's scheduled follow-up appointment. If a patient fails to return for the scheduled follow-up appointment the registered nurse will contact the patient by phone, explain the importance of their follow-up appointment and offer the patient to reschedule the appointment. The registered nurse will document notes. Will be monitored by the physician. The daily follow-up form (surgical and abortion pill) will be presented at the quarterly quality assurance meeting, will be continuously monitored by the physician.	10/28/2021

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6 045	Continued From page 5 The Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub.L. 91-513, 84 Stat. 1236, enacted October 27, 1970, is a United States federal law that, with subsequent modifications, requires the pharmaceutical industry to maintain physical security and strict record keeping for certain types of drugs.[1] Controlled substances are divided into five schedules (or classes) on the basis of their potential for abuse, accepted medical use, and accepted safety under medical supervision. Substances in Schedule I have a high potential for abuse, no accredited medical use, and a lack of accepted safety. From Schedules II to V, substances decrease in potential for abuse. The Controlled Substances Act (CSA), Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, is the legal foundation of the government's fight against the abuse of drugs and other substances. The CSA also creates a closed system of distribution for those authorized to handle controlled substances. The cornerstone of this system is the registration of all those authorized by the DEA to handle controlled substances. All individuals and firms that are registered are required to maintain complete and accurate inventories and records of all transactions involving controlled substances, as well as security for the storage of controlled substances.[3] Review of https://www.dea.gov/sites list the medications Lorazepam and Diazepam as Scheduled IV controlled drugs for potential for abuse. Findings were:	6 045	The office administrator will provide a daily controlled substance distribution form with the date, patient name, date of birth, medication, expiration date, lot number, amount of dosage, waste amount and the total amount dispensed. All medications open or unopened will be recorded in inventory. This will be monitored by the physician. The daily controlled substance distribution form will be presented at the quarterly quality assurance meeting, will be continuously monitored by the physician.	10/28/2021

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6 045	Continued From page 6 Record review of twenty clinical records were reviewed for follow-up appointments. All patients were given appointments for follow-up however, six medical patients ((10,16, 17,18, 19, 20) and seven surgical patients (3, 4, 11, 12, 13, 14, 15) failed to show up for follow-up appointments. Review of the above patient records had no documentation that included the date, time, and name of the person making the effort in the woman's medical record of an attempt to follow-up from the clinic. The medical record for all medical and surgical abortion patients revealed the patient had a follow up appointment scheduled and did not show up for their appointments. There were no documented attempts by the facility to contact the patient regarding missing their follow-up appointment after their abortion. The above findings were confirmed in an interview with staff member #55 on the afternoon of 10/13//2021 Observation conducted on 10/14/2021 at 1430 of the facility medication storage area revealed that scheduled medications were being stored and locked in pharmacy stock bottles. Record review of the facility drug records for August 2021 had no date noted on latest drug record for 2021 revealed that facility staff were not conducting a full count of scheduled medications. Further review revealed that the facility staff only counted medications that were open and did not include unopened bottles of medications. The facility had on hand Lorazepam (2 mg tablets), and six (6) unopened bottles of	6 045		

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6 045	Continued From page 7 100 tablets, and Diazepam (5 mg tablets), and four (4) unopened bottles, of 100 tablets in the cabinet. In an interview conducted on 10/15/2021 at 1351 with facility staff (ID #55) and the Physician (ID#52) who both confirmed that daily counts were not being conducted for scheduled drugs unless they were dispensed.	6 045		

WOMEN'S CENTER OF HOUSTON
8200 Wednesbury Ln. ste 230
Houston, TX 77074
Tel: 713-995-1264
Fax: 281-974-1190

SURGICAL PROCEDURE: 1
ABORTION PILL : 2

FOLLOW-UP APPOINTMENT
SURGICAL/ABORTION PILL

DATE	NAME	D.O.B	PH#:	F/U APPT (SCHEDULED)	AB TYPE	NOTES:	INT.

Women's Center of Houston
8200 Wednesbury Ln. Ste. 230
Houston, Tx 77074
Office:713-981-1972
Fax:281-974-1190

DATE:_____

CONTROLLED SUBSTANCE
DAILY MEDICATION DISTRIBUTION FORM

NAME:	MEDICATION DOSAGE	LOT# & EXP.	DOSAGE AMT.	WASTE AMT.	TOTAL DISP.
DOB:					
	Lorazepam 2mg				
	Diazepam 2mg				
	Tylenol #3 300mg/30mg				
	Promethazine 25MG				
NAME:					
DOB:					
	Lorazepam 2mg				
	Diazepam 2mg				
	Tylenol #3 300mg/30mg				
	Promethazine 25MG				

PHYSICIAN:_____ DATE:_____