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
	007882	A. BUILDING: _____ B. WING _____	06/07/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
AUSTIN WOMENS HEALTH CENTER	1902 SOUTH IH 35 AUSTIN, TX 78704

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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 06/06/16. 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 other administrative staff on the afternoon of 06/07/16 Preliminary findings of the survey were discussed, and an opportunity given for questions.	A 000		
A 133	TAC 139.41(a)(7)(8)(A)(B) Policy Development and Review (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	A 133		

SOD - State Form

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

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A 133	Continued From page 1 of birth on the affidavit. Attached Graphic </fids/200902286-1.html> Figure: 25 TAC §139.41(a)(8)(A) Affidavit I, _____, swear or affirm that my date of birth is _____, _____ , and that I do not have appropriate identification that states my date of birth. Signature: _____ Printed name: _____ Witness: _____ _ Printed name of witness: _____ (B) The facility shall keep a copy of the identification presented or the affidavit in its files. This Requirement is not met as evidenced by: Based on a review of documentation the facility failed to ensure that policies for reporting suspected abuse or neglect as stipulated in Family Code, Chapter 261 were followed appropriately. Findings included: Facility based policy entitled "Minor Protocol" stated in part, "3. At the Pintail Consultation appointment the Minor patient will be screened for child abuse, and, if applicable, a report will be submitted to the Department of State Health Services and the local authorities notified	A 133		

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A 133	Continued From page 2 immediately per state law. A staff member will fill out the Child Abuse Reporting form and scan it into the patient record..." The Department of State Health Services (DSHS) Child Abuse Reporting Form" states in part, "In accordance with DSHS policy, an affirmative defense for sexual assault or indecency with a child maybe established for clients ages 14, 15, and 16 years. All instances of sexual activity of clients under 14 years of age must be reported. Check below if using the optional affirmative defense language for clients 14, 15, and 16 years of age: [ ]The actor was not more than three years older than the victim [ ]And no duress or force was used [ ]And the partner is of the opposite sex Using the criteria above or any other information provided by the client, did you determine that a report of child abuse is required? Yes___ No___" A review of the medical record for Patient # 11 revealed they were a minor at the time of the procedure (15 years old). The Child Abuse Reporting Form for this patient did not have any of the above boxes marked, however the question, "Using the criteria above or any other information provided by the client, did you determine that a report of child abuse is required?" was marked "no". Without providing answers to these question, it is unclear whether a repot should have been filed or not. The above finding were confirmed with staff members #1 and 10 and 06/07/16.	A 133		

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A 201	Continued From page 3	A 201		
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 - 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 06/07/16, it was observed the unlocked laundry room contained items including disinfectant spray, air freshener spray, germicidal wipes, all-purpose spray cleaner and bleach. Procedure room # 4 had an unlocked cabinet which contained cans of Lysol, air freshener spray, germicidal wipes, and a bottle of Acetic Acid The above was confirmed in an interview with staff #10 on 06/07/16, during a tour of the facility.	A 201		

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A 327	Continued From page 4	A 327		
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 review of documentation and interview, the facility failed to ensure that 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. Findings included: The following FDA (Food Drug Administration) references are for Historical Information on Mifepristone (marketed as Mifeprex) found at <http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm111334.htm>. These include the Mifeprex Labeling Change, July 19, 2005.	A 327		

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A 327	Continued From page 5 The FDA label for Mifeprex found at <http://www.accessdata.fda.gov/drugsatfda_docs /label/2005/020687s013lbl.pdf> stated in part, "DOSAGE AND ADMINISTRATION Treatment with Mifeprex and misoprostol for the termination of pregnancy requires three office visits by the patient. Mifeprex should be prescribed only by physicians who have read and understood the prescribing information. Mifeprex may be administered only in a clinic, medical office, or hospital, by or under the supervision of a physician, able to assess the gestational age of an embryo and to diagnose ectopic pregnancies ... Day One: Mifeprex Administration Patients must read the MEDICATION GUIDE and read and sign the PATIENT AGREEMENT before Mifeprex is administered. Three 200 mg tablets (600 mg) of Mifeprex are taken in a single oral dose. Day Three: Misoprostol Administration The patient returns to the health care provider two days after ingesting Mifeprex. Unless abortion has occurred and has been confirmed by clinical examination or ultrasonographic scan, the patient takes two 200 µg tablets (400 µg) of misoprostol orally." The FDA Medication Guide for Mifeprex® (MIF-eh-prex)(mifepristone) found at <http://www.accessdata.fda.gov/drugsatfda_docs /label/2011/020687s014lbl.pdf> stated in part, "How should I take Mifeprex? · Day 1 at your provider ' s office: - Read this MEDICATION GUIDE. - Discuss the benefits and risks of using Mifeprex to end your pregnancy. - If you decide Mifeprex is right for you, sign the PATIENT AGREEMENT. - After getting a physical exam, swallow 3 tablets	A 327		

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of Mifeprex.

· Day 3 at your provider ' s office:
-If you are still pregnant, take 2 misoprostol tablets. -Misoprostol may cause cramps, nausea, diarrhea, and other symptoms. Your provider may send you home with medicines for these symptoms."

The Patient Agreement for Mifeprex found at <http://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM162969.pdf> stated in part,

"5. I understand that I will take Mifeprex in my provider's office (Day 1).
6. I understand that I will take misoprostol in my provider's office two days after I take Mifeprex (Day 3)."

On March 30, 2016, the Food and Drug Administration (FDA) "approved a supplemental application for Mifeprex based on data and information submitted by the drug manufacturer. After reviewing the supplemental application, the agency determined that Mifeprex is safe and effective when used to terminate a pregnancy in accordance with the revised labeling.

FDA-Approved Regimen (2016)

Mifeprex is approved, in a regimen with misoprostol, to end a pregnancy through 70 days gestation (70 days or less since the first day of a woman's last menstrual period). The approved Mifeprex dosing regimen is:
· On Day One: 200 mg of Mifeprex taken by mouth
· 24 to 48 hours after taking Mifeprex: 800 mcg of misoprostol taken buccally (in the cheek

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A 327	Continued From page 7	A 327		

pouch), at a location appropriate for the patient
· About seven to fourteen days after taking Mifeprex: follow-up with the healthcare provider "

Review of medical abortions performed at the facility revealed that 3 of 4 medical abortions were performed prior to March 2016 change in regimen to the administration of Mifeprex and Misoprostol. Patient #9 (December 2015), Patient # 16 (October 2015), and Patient # 20 (February 2016). The medical records for these three patients revealed the following:
· 3 of 3 medical abortion records prior to March 2016 contained signed Patient Agreements for Mifeprex tablets which included the statements: "5. I understand that I will take Mifeprex in my provider ' s office (Day 1).
6. I understand that I will take misoprostol in my provider ' s office two days after I take Mifeprex (Day 3)."
· The physician documented the administration of Mifepristone per FDA guidelines in 3 of 3 records.
· The physician visit following the administration of Mifepristone included the following documentation in 3 of 3 records, " Start Misoprostol, 200 mcg, as directed, BUCCAL , 4 tabs
Notes:MD ADVISED PATIENT TO USE PREVIOUSLY PRESCRIBED MEDICATIONS AS NEEDED. COUNSELED PATIENT ON HOW TO ADMINISTER MISOPROSTOL. [Lot# Expiration date]."

In an interview on 06/06/16, staff member # 1 was asked if these 3 patients were administered the Misoprostol at the facility during the physician visit following the administration of the Mifepristone. Staff member #1 stated that the patients were provided the Misoprostol tablets to

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A 327	Continued From page 8 administer themselves and the facility felt this was the appropriate method of providing the medication. The staff member add the FDA language says the Mifeprex must be swallowed at the office and the Misoprostol "taken" at the office. The staff member stated the facility did not interpret that to mean the Misoprostol was to be administer at the facility, despite the language in the patient agreement to "take misoprostol in my provider's office two days after I take Mifeprex". Based on review of documentation and interview, the facility failed to ensure that the Misoprostol portion of the medical abortion was administered or taken in the provider office, per FDA regulations in effect at the time the medical abortions were performed.	A 327		
A 362	TAC 139.57(a)(2)(A)(B)(C)(D)(3) Discharge and Follow-up Referrals (a) A licensed abortion facility shall develop and implement written discharge instructions which shall include: (2) a statement of the facility's plan to respond to the patient in the event the patient experiences any of the complications listed in the discharge instructions to include: (A) a telephone number by which the patient may reach the physician, or other health care personnel employed by the physician or by 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; (B) the name and telephone number of the	A 362		

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A 362	Continued From page 9 nearest hospital to the home of the patient at which an emergency arising from the abortion would be treated; (C) assurance that the responding individual shall be a physician, advanced practice registered nurse, physician assistant, registered nurse, or licensed vocational nurse; and (D) information that the patient may also contact the emergency medical service or present for care at the emergency room of a hospital in addition to contacting the facility; and (3) information concerning the need for a post-abortion examination. This Requirement is not met as evidenced by: Based on a review of medical records and interview, the facility failed to implement written discharge instructions which included the name and telephone number of the nearest hospital to the home of the patient at which an emergency arising from the abortion would be treated. Findings included: Review of medical records revealed the following: * Paper documentation included a statement on the "Operative Report" which read in part, "PHYSICAL EXAMINATION AND PROCEDURE ....Patient given information regarding nearest hospital to her current home address..." * Electronic Medical Record Documentation included the following statement, "All state regulations have been addresses and complied with Patient given information regarding nearest hospital to her current home address.." * The Discharge Summary form provided to all patients included the following statement, "By	A 362		

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A 362	Continued From page 10 signing below, I attest I have received a copy of the Aftercare Instructions and I have been given information regarding the location of the nearest hospital." * Staff member # 1 and 10 confirmed the above statements on the forms reflected the expectation was that patients are provided this information. * The facility provided the surveyors with a copy of a form listing all the local hospital in Austin and the surrounding areas including the phone numbers of the facilities with boxes beside to check the one located closest to the patient's address. An area for "other" hospitals and phone number was provided on this form. Staff member #10 confirmed this form is provided to patients post discharge, however a copy is not kept the medical record. The wording of the above documentation indicated that patients were proved information regarding the hospital closest to their current address. The forms do not state this information included the telephone number of the nearest hospital. * 20 of 20 medical records reviewed did not contain documentation of the name and telephone number of the nearest hospital to the home of the patient at which an emergency arising from the abortion would be treated. Without the inclusion of the form listing all the local hospital in Austin and the surrounding areas including the phone numbers of the facilities, it cannot be established that the facility provided the patients with the name and telephone number of the nearest hospital to the home of the patient at which an emergency arising from the abortion would be treated;	A 362		

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