

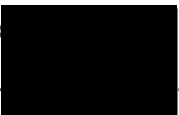
Texas Health and Human Services Commission

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 140013	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED 09/29/2021
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NAME OF PROVIDER OR SUPPLIER WHOLE WOMAN'S HEALTH ALLIANCE	STREET ADDRESS, CITY, STATE, ZIP CODE 8401 NORTH IH 35 SUITE 200 AUSTIN, TX 78753
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(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	<p>TAC 139.1 Initial Comments</p> <p>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.</p> <p>(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.</p> <p>(b) Scope and applicability.</p> <p>(1) Licensing requirements.</p> <p>(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.</p> <p>(B) The following need not be licensed under this chapter:</p> <p>(i) a hospital licensed under Health and Safety Code, Chapter 241;</p> <p>(ii) an ambulatory surgical center licensed</p>	6 000		

SOD - State Form
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE



TITLE

Clinic Manager

(X6) DATE

10/18/2021

Texas Health and Human Services Commission

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6 000	<p>Continued From page 1</p> <p>under Health and Safety Code, Chapter 243; or</p> <p>(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.</p> <p>(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 Health Center Manager on 9-29-21. The purpose and process of the licensure resurvey were discussed, and an opportunity given for questions.</p> <p>Continued licensure is recommended, with an approved plan of correction.</p> <p>An exit conference was held with the Health Center Manager on 9-29-21. Preliminary findings of the survey were discussed, and an opportunity given for questions.</p> <p>Based on a review of clinical records and an interview with staff, the facility failed to demonstrate compliance with the requirements of the Sonogram Election Form under HSC 171.012.</p> <p>Per HSC 171.012: "ABORTION AND SONOGRAM ELECTION</p> <p>(1) THE INFORMATION AND PRINTED MATERIALS DESCRIBED BY SECTIONS 171.012(a)(1)-(3), TEXAS HEALTH AND</p>	6 000		

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6 000	<p>Continued From page 2</p> <p>SAFETY CODE, HAVE BEEN PROVIDED AND EXPLAINED TO ME.</p> <p>(2) I UNDERSTAND THE NATURE AND CONSEQUENCES OF AN ABORTION.</p> <p>(3) TEXAS LAW REQUIRES THAT I RECEIVE A SONOGRAM PRIOR TO RECEIVING AN ABORTION.</p> <p>(4) I UNDERSTAND THAT I HAVE THE OPTION TO VIEW THE SONOGRAM IMAGES.</p> <p>(5) I UNDERSTAND THAT I HAVE THE OPTION TO HEAR THE HEARTBEAT.</p> <p>(6) I UNDERSTAND THAT I AM REQUIRED BY LAW TO HEAR AN EXPLANATION OF THE SONOGRAM IMAGES UNLESS I CERTIFY IN WRITING TO ONE OF THE FOLLOWING: ___ I AM PREGNANT AS A RESULT OF A SEXUAL ASSAULT, INCEST, OR OTHER VIOLATION OF THE TEXAS PENAL CODE THAT HAS BEEN REPORTED TO LAW ENFORCEMENT AUTHORITIES OR THAT HAS NOT BEEN REPORTED BECAUSE I REASONABLY BELIEVE THAT DOING SO WOULD PUT ME AT RISK OF RETALIATION RESULTING IN SERIOUS BODILY INJURY. ___ I AM A MINOR AND OBTAINING AN ABORTION IN ACCORDANCE WITH JUDICIAL BYPASS PROCEDURES UNDER CHAPTER 33, TEXAS FAMILY CODE. ___ MY UNBORN CHILD HAS AN IRREVERSIBLE MEDICAL CONDITION OR ABNORMALITY, AS IDENTIFIED BY RELIABLE DIAGNOSTIC PROCEDURES AND DOCUMENTED IN MY MEDICAL FILE.</p> <p>(7) I AM MAKING THIS ELECTION OF MY OWN FREE WILL AND WITHOUT COERCION.</p> <p>(8) FOR A WOMAN WHO LIVES 100 MILES OR MORE FROM THE NEAREST ABORTION PROVIDER THAT IS A FACILITY LICENSED UNDER CHAPTER 245, TEXAS HEALTH AND SAFETY CODE, OR A FACILITY THAT</p>	6 000		

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6 000	<p>Continued From page 3</p> <p>PERFORMS MORE THAN 50 ABORTIONS IN ANY 12-MONTH PERIOD ONLY: I CERTIFY THAT, BECAUSE I CURRENTLY LIVE 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, I WAIVE THE REQUIREMENT TO WAIT 24 HOURS AFTER THE SONOGRAM IS PERFORMED BEFORE RECEIVING THE ABORTION PROCEDURE. MY PLACE OF RESIDENCE IS: _____.</p> <p>_____ SIGNATURE DATE";</p> <p>(6) before the abortion is performed or induced, the physician who is to perform or induce the abortion receives a copy of the signed, written certification required by Subdivision (5); and</p> <p>(7) the pregnant woman is provided the name of each person who provides or explains the information required under this subsection.</p> <p>(a-1) During a visit made to a facility to fulfill the requirements of Subsection (a), the facility and any person at the facility may not accept any form of payment, deposit, or exchange or make any financial agreement for an abortion or abortion-related services other than for payment of a service required by Subsection (a). The amount charged for a service required by Subsection (a) may not exceed the reimbursement rate established for the service by the executive commissioner for statewide medical reimbursement programs.</p> <p>(b) The information required to be provided under Subsections (a)(1) and (2) may not be provided by audio or video recording and must be provided at least 24 hours before the abortion is to be performed:</p>	6 000		

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6 000	<p>Continued From page 4</p> <p>(1) orally and in person in a private and confidential setting if the pregnant woman currently lives less than 100 miles 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; or</p> <p>(2) orally by telephone on a private call or in person in a private and confidential setting if the pregnant woman certifies that the woman 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.</p> <p>(c) When providing the information under Subsection (a)(3), the physician or the physician's agent must provide the pregnant woman with the address of the Internet website on which the printed materials described by Section 171.014 may be viewed as required by Section 171.014(e).</p> <p>(d) The information provided to the woman under Subsection (a)(2)(B) must include, based on information available from the Office of the Attorney General and the United States Department of Health and Human Services Office of Child Support Enforcement for the three-year period preceding the publication of the information, information regarding the statistical likelihood of collecting child support.</p> <p>(e) The department is not required to republish informational materials described by Subsection (a)(2)(B) because of a change in information described by Subsection (d) unless the statistical information in the materials changes by five percent or more.</p> <p>(f) The physician who is to perform the abortion, or the physician's designee, shall in person hand to the pregnant woman a copy of the informational materials described by Section</p>	6 000		

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6 000	<p>Continued From page 5</p> <p>171.014: (1) on the day of the consultation required under Subsection (a)(4) for a pregnant woman who lives less than 100 miles from the nearest abortion provider that is a facility licensed under Chapter 245 or a facility in which more than 50 abortions are performed in any 12-month period; or (2) before any sedative or anesthesia is administered to the pregnant woman on the day of the abortion and at least two hours before the abortion if the woman lives 100 miles or more from the nearest abortion provider that is a facility licensed under Chapter 245 or a facility in which more than 50 abortions are performed in any 12-month period.</p> <p>Added by Acts 2003, 78th Leg., ch. 999, Sec. 1, eff. Sept. 1, 2003. Amended by: Acts 2011, 82nd Leg., R.S., Ch. 73 (H.B. 15), Sec. 2, eff. September 1, 2011. Acts 2015, 84th Leg., R.S., Ch. 1 (S.B. 219), Sec. 3.0518, eff. April 2, 2015. Acts 2019, 86th Leg., R.S., Ch. 502 (S.B. 24), Sec. 1, eff. September 1, 2019. Acts 2021, 87th Leg., R.S., Ch. 62 (S.B. 8), Sec. 8, eff. September 1, 2021.</p> <p>Findings were:</p> <p>A review of clinical records for 4 patients (medication patients #1 - #4) who received services after 9-1-21 (the effective date of SB 8) revealed that the sonogram election form had not been changed from the word "fetus" to the words "unborn child". This was verified in an interview with staff #1 on 9-29-21.</p>	6 000	<p>The Clinic Manager is responsible for ensuring compliance with DSHS regulation and Whole Woman's Health Alliance policies and procedures.</p> <p>Whole Woman's Health Alliance received notice of the required language changes to HB15 Sonogram and Abortion Election Form on September 15, 2021. After researching the DSHS website for printed resources and reaching out to our local DSHS office, we found that the HB15 Sonogram Election Form was not updated with the newly required language. Whole Woman's Health Alliance Austin amended the provided form internally to reflect these changes. The updated forms were implemented on September 20, 2021, and Whole Woman's Health Alliance has remained compliant since implementation.</p> <p>The provided HB15 Sonogram and Abortion Election Form on the DSHS website remains unchanged in accordance with the updated language at the time of submission of plan of correction.</p> <p>The Clinic Manager will continue to monitor the DSHS website for updated forms and will continue to monitor compliance.</p>	

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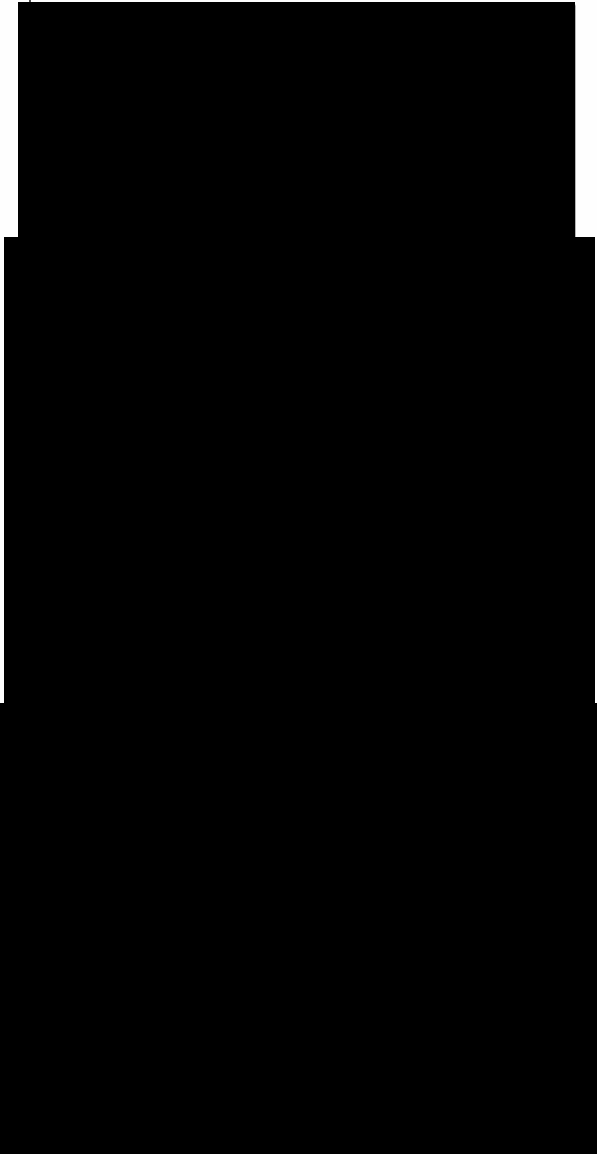
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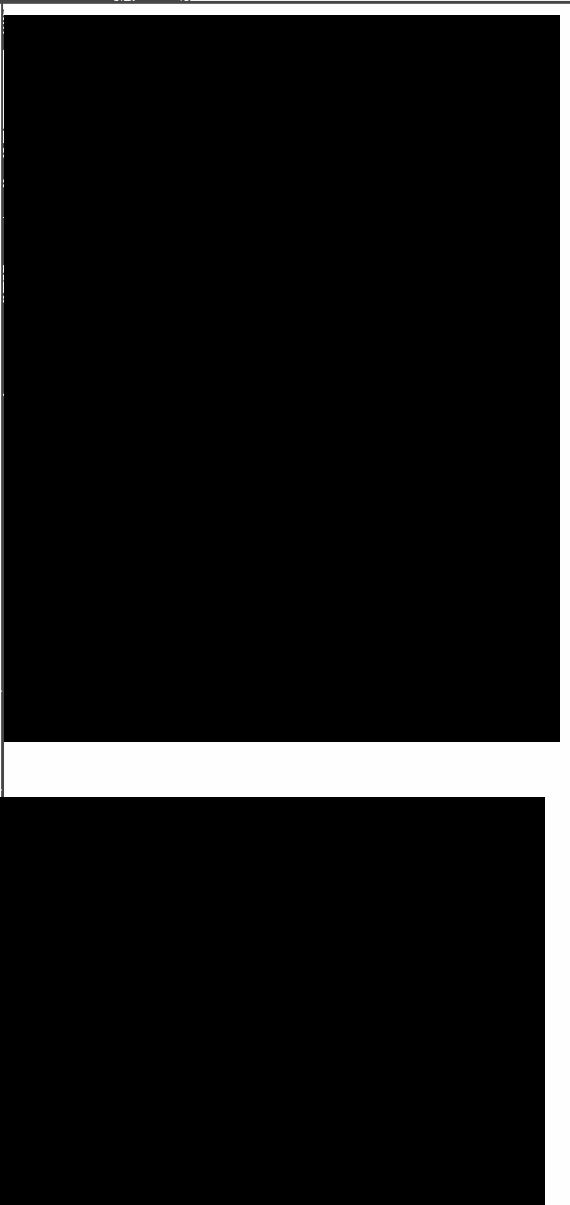
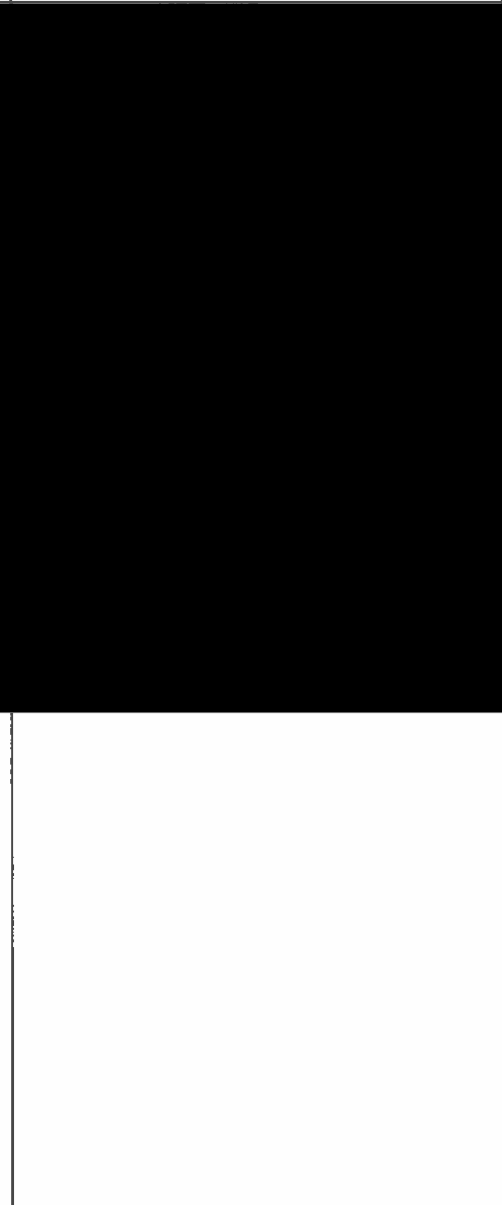
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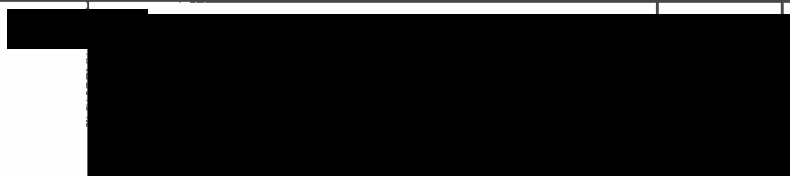
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6 033	<p>TAC 139.48 Physical and Environmental Requirements</p> <p>The physical and environmental requirements for a licensed abortion facility are as follows.</p> <p>(1) A facility shall:</p> <p>(A) have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients and staff at all times;</p> <p>(B) equip each procedure room so that procedures can be performed in a manner that assures the physical safety of all individuals in the area;</p> <p>(C) have a separate recovery room if moderate sedation/analgesia, deep sedation/analgesia, or general anesthesia are administered at the facility;</p> <p>(D) have a written protocol for emergency evacuation for fire and other disasters tailored to the facility's geographic location. Each staff member employed by or under contract with the facility shall be able to demonstrate their role or responsibility to implement the facility's emergency evacuation protocol required by this subparagraph;</p> <p>(E) store hazardous cleaning solutions and compounds in a secure manner and label substances;</p>	6 033		
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6 033	<p>Continued From page 10</p> <p>(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 Chapter 228 of this title (relating to Retail Food);</p> <p>(G) provide clean hand washing facilities for patients and staff including running water, and soap;</p> <p>(H) have two functioning sinks and a functioning toilet; and</p> <p>(I) have equipment available to sterilize instruments, equipment, and supplies in accordance with §139.49(d) of this title (relating to Infection Control Standards) before use in the facility.</p> <p>(2) The equipment for vacuum aspiration shall be electrically safe and designed to prevent reverse pump action in facilities that provide vacuum aspiration.</p> <p>(3) Projects involving alterations of and additions to existing buildings shall be programmed and phased so that on-site construction shall minimize disruptions of existing functions. Access, exit ways, and fire protection shall be maintained so that the safety of the occupants shall not be jeopardized during construction.</p> <p>This Requirement is not met as evidenced by: Based on a tour of the facility and an interview with staff, the facility failed to maintain a safe and sanitary environment, as the sonogram machine</p>	6 033		

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6 033	<p>Continued From page 11</p> <p>was not properly maintained and did not display the correct time and hazardous cleaning solutions and compounds were not stored in a secure manner.</p> <p>Findings were:</p> <p>During a tour of the facility on 9-29-21, the following observations were made:</p> <ul style="list-style-type: none"> * The sonogram machine in the Amelia room displayed the time as 11:44 am, although the correct time was 12:42 pm. * In the patient bathroom, Cavicide was stored on the shelf and toilet cleaner was stored under the sink. * Under the lab sink, 2 bottles of bleach water had been stored. <p>The above was confirmed in an interview with staff #1 on 9-29-21.</p>	6 033	<p>The Clinic Manager is responsible for ensuring compliance with DSHS regulation and Whole Woman's Health Alliance policies and procedures.</p> <p>Whole Woman's Health Alliance Austin maintains a safe and sanitary environment. The Clinic Manager completed a walk-through of the physical plant to review physical plant requirements, ensure proper storage, and ensure the time is accurately displayed on all sonogram machines. The time on the sonogram machine in the Amelia room was updated by the Clinic Manager to reflect the accurate time.</p> <p>A staff in-service will be facilitated by the Clinic Manager to review proper storage and sink usage, to be completed by November 28, 2021. Daily monitoring of accurate time on sonogram machines will be completed by Clinic Manager.</p> <p>The Clinic Manager will be responsible for monitoring ongoing compliance by conducting monthly physical plant walk-throughs.</p>	