

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  10/15/2018
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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**

(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
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[REDACTED]

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.

[REDACTED]

[REDACTED]

SOD - State Form  
LABORATORY DIRECTOR'S

[REDACTED]

...ER REPRESENTATIVE'S SIGNATURE

Clinic Manager

TITLE

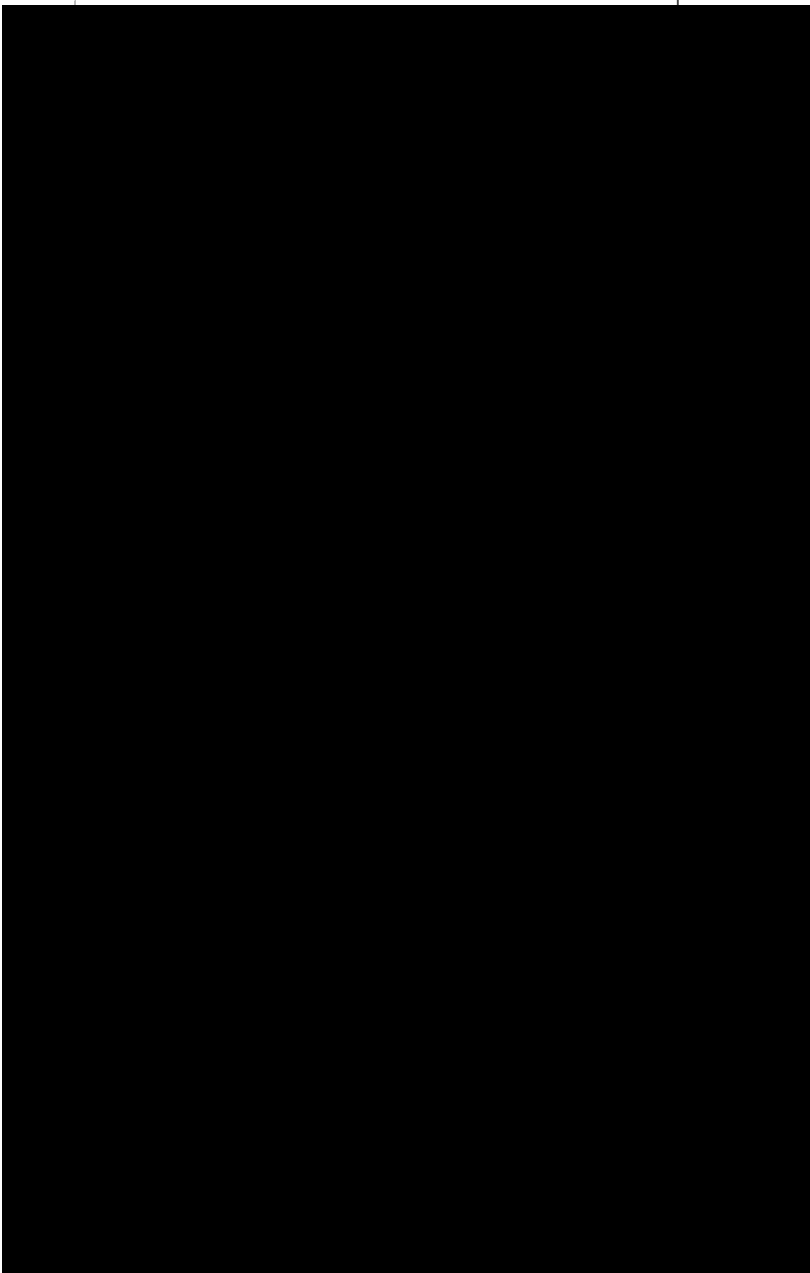
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11/21/2018

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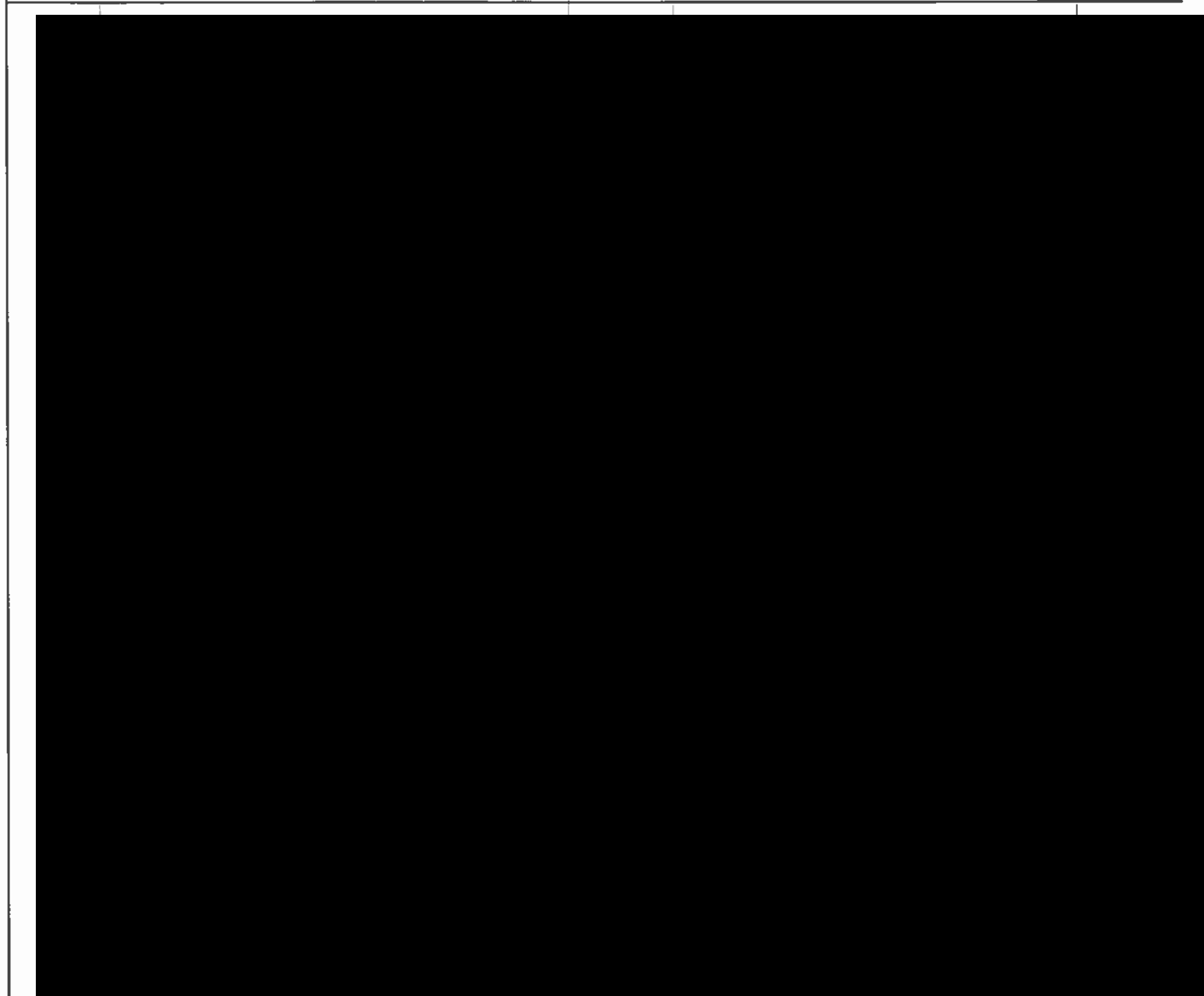


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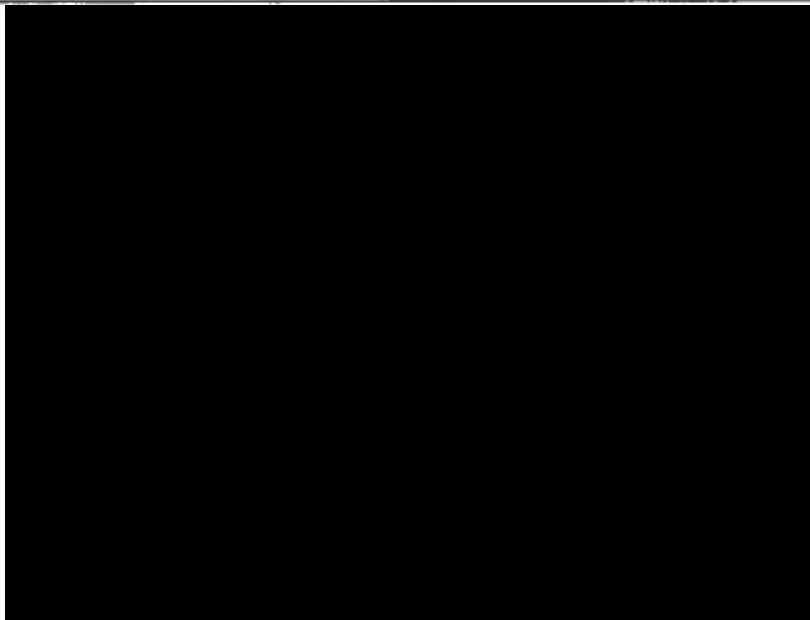


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6 023	<p>TAC 139.40 Policy Development and Review</p> <p>Continued licensure is recommended with an approved Plan of Correction.</p> <p>An exit conference was conducted on the evening of 10-15-2018 with the Director of Clinical Services. The preliminary findings of the survey were discussed, and an opportunity was given for facility staff to ask question. All questions were answered.</p> <p>(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</p>	6 023		
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6 023	<p>Continued From page 4</p> <p>health care in a safe and professionally acceptable environment. These written policies shall include at a minimum the following:</p> <p>(1) administrative policies governing the administration of the facility, covering at a minimum:</p> <p>(A) personnel;</p> <p>(B) employee orientation, training, and evaluation;</p> <p>(C) employee and patient record system;</p> <p>(D) auditing system for monitoring state or federal funds;</p> <p>(E) advertisements for the facility;</p> <p>(F) accuracy of public education information materials and activities in relation to abortion, birth control, and sexually-transmitted diseases;</p> <p>(G) patient education/information services and referral services;</p> <p>(H) reporting requirements; and</p> <p>(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.</p>	6 023		

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

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6 023	<p>Continued From page 6</p> <p>(7) policies for reporting suspected abuse or neglect as stipulated in Family Code, Chapter 261; and</p> <p>(8) policies to ensure all women who present to obtain an abortion provide identification that includes the woman's date of birth.</p> <p>(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.</p> <p>Attached Graphic</p> <p>(B) The facility shall keep a copy of the identification presented or the affidavit in its files.</p> <p>(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.</p> <p>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.</p> <p>Findings were:</p> <p>During a tour of the facility on 10/15/18, a random count of Midazolam (a Schedule IV controlled)</p>	6 023		

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6 023	<p>Continued From page 7</p> <p>was performed. 400 ml of Midazolam was present in boxed vials. 4 ml of Midazolam was present in an 2 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 411 ml . The vial had a label indicating that 6 ml were counted of Midazolam, for a total of 410 ml of Midazolam. The Midazolam count on 10/15/18 was verified by staff #2, present during the tour and the narcotic count. The narcotic count sheet indicated that 410 ml of had been present during the closing count conducted on 10/15/18 (which had been verified and signed off on by staff #2 and a second staff member). In an interview with staff member #2 they were unable to explain the 1 ml Midazolam discrepancy.</p> <p>According to <a href="https://www.deadiversion.usdoj.gov/schedules/">https://www.deadiversion.usdoj.gov/schedules/</a>, a Schedule IV drug is described as follows:</p> <p>"Schedule IV Controlled Substances Substances in this schedule have a low potential for abuse relative to substances in Schedule III.</p> <p>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®).</p> <p>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</p>	6 023	<p><b>6 023</b></p> <ul style="list-style-type: none"> <li>The Clinic Manager is responsible for ensuring that staff members will complete an accurate narcotic count at the opening and closing of each session.</li> <li>Multi-use vials are pre-prepared by the manufacturer with a slight overage (approximate 1 cc volume) to account for regular waste when drawing up individual doses. The 1 cc overage is considered to be part of the manufacturers' supplied volume that had not been wasted when drawing up the 4 cc out of the 10 cc vial.</li> <li>The Clinic Manager will direct the order of single use vials for purchase when available by the manufacturer.</li> <li>The narcotic count was verified on 10/16/2018 by the Clinic Manager and the Clinic Coordinator. A narcotic deviation was created for the additional 1cc of Midazolam. The deviation documentation was signed and placed in the narcotic log on 10/16/2018.</li> <li>The Director of Clinical Services conducted a re-training of Whole Woman's Health Handling Controlled Medications Protocol with the Clinic Manager, Clinic Coordinator, and all clinical staff on 10/18/2018. Staff are aware to notify Clinic Manager and Medical Director of any narcotic deviations.</li> <li>In order to monitor continued compliance, the Clinic Manager will randomly observe staff open and</li> </ul>	10/18/18



close narcotic count during session for a one month duration. The Clinic Manager will also complete a monthly audit of the narcotic log. This will enable the Clinic Manager will be able to determine whether Controlled Medications policies are being followed.

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6 023	<p>Continued From page 8</p> <p>Controlled Medication log.</p> <p>...</p> <p>7. 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 (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...</p> <p>9. The closing count will be documented in red ink on the Controlled Medication Log."</p> <p>The above was confirmed in an interview with staff #1 and 2 on the afternoon of 10/15/18.</p>	6 023		
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</p>	6 033		

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6 033	<p>Continued From page 9</p> <p>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> <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>	6 033		
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6 033	<p>Continued From page 10</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 tour and interview, the facility failed to ensure a safe and sanitary environment, properly maintained to protect the health and safety of patients and staff at all times.</p> <p>Findings included:</p> <p>During a tour of the facility on 10/15/18, it was observed that there was large water stain approximately 3 feet X 10 inches in size observed on the ceiling of the recovery room. The presence of a water stain presents the risk for bacteria growth and contamination.</p> <p>The an interview with staff member # 1 on 10/15/18 they confirmed the above findings, stating the leak had been repaired previously by the facility, but that the building owner had not repaired the roof outside the building and the leak continued to be an issue.</p>	6 033	<p>6 033</p> <ul style="list-style-type: none"> <li>The Clinic Manager is responsible for ensuring the physical and environmental safety for all patients that come to WWHA.</li> <li>The Clinic Manager is responsible for contracting a vendor to assess interior ceiling to assess the risk for bacteria growth and contamination. The clinic manager has contacted the property owner regarding the need for an evaluation of the exterior roof.</li> <li>The Clinic Manager contacted the property owner on 05/10/2018 and again on 06/15/18 to provide notice that the exterior roof needs to be evaluated.</li> <li>The clinic manager contacted a vendor to assess the interior ceiling on 11/15/2018 who came out for evaluation on 11/16/18. Upon evaluation, it was discovered that</li> </ul>	
6 041	<p>TAC 139.56 Emergency Services</p> <p>(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.</p>	6 041		

			<p>the external structure needed to be repaired and the internal structure needed cosmetic repairs. The contractor is unable to complete internal cosmetic repair and has referred to another company. The landlord was notified regarding repairs needed. Repairs to be determined pending contractor availability</p> <ul style="list-style-type: none"><li>• In order to monitor continued compliance, the Clinic Manager will communicate with the property owner every 30 days regarding the progress of obtaining quotes, assessment, and or repair if needed of the exterior roof.</li><li>• Currently in progress as of November 18,2018</li></ul>	
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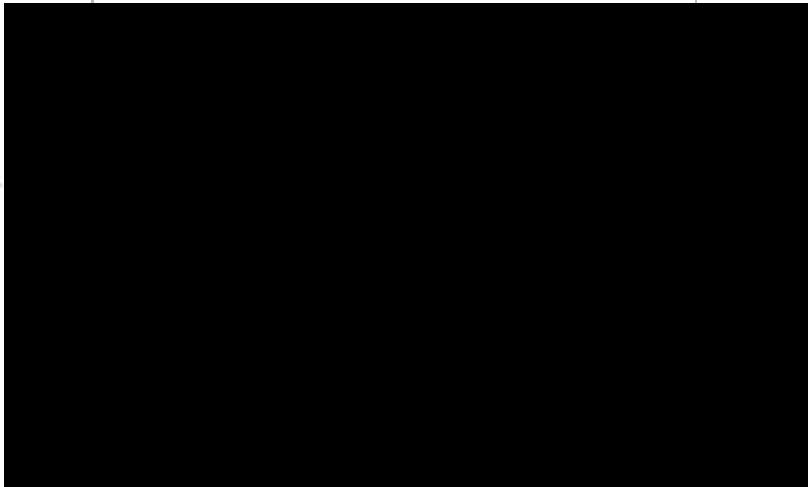
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6 041	<p>Continued From page 11</p> <p>The facility shall ensure that the physicians who practice at the facility:</p> <p>(1) have active admitting privileges at a hospital that provides obstetrical or gynecological health care services and is located not further than 30 miles from the abortion facility;</p> <p>(2) provide the pregnant woman with:</p> <p>(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</p> <p>(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.</p> <p>(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).</p> <p>(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.</p>	6 041		

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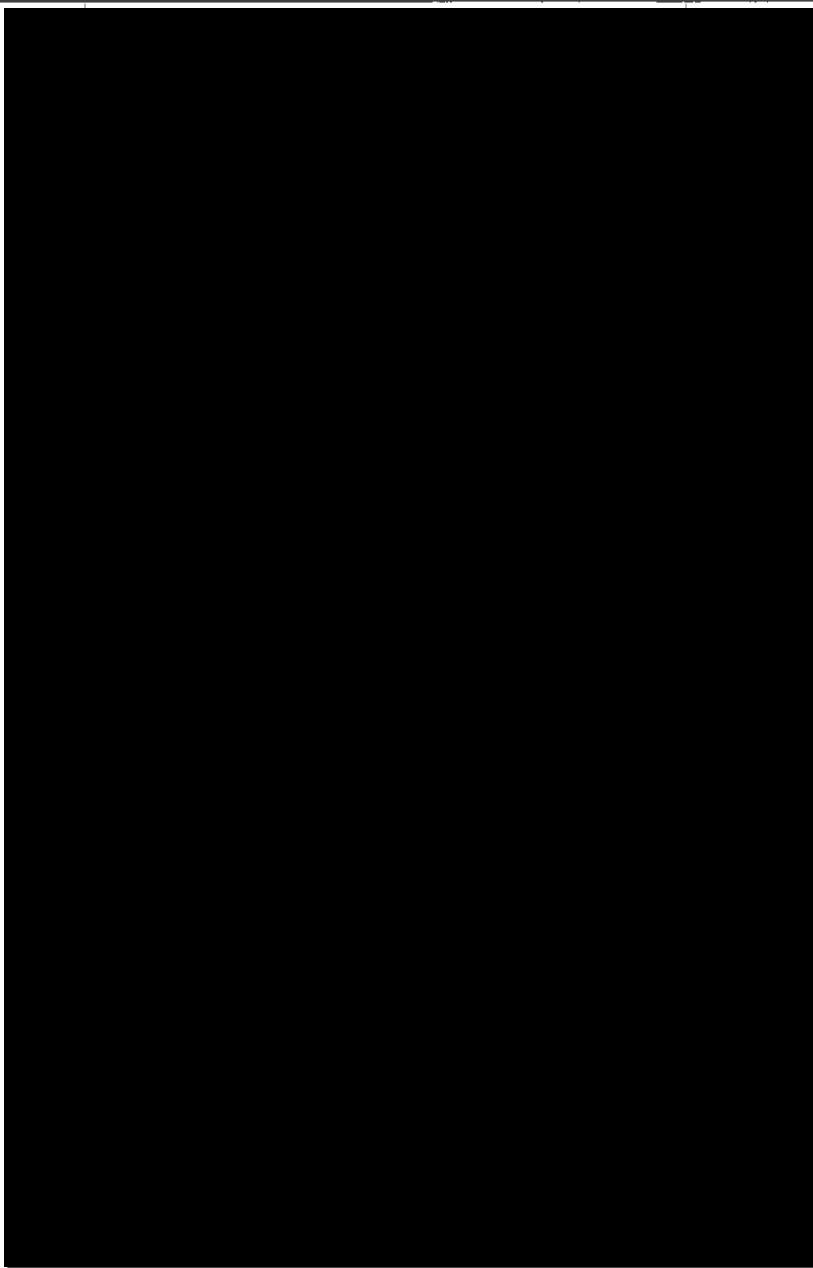
6 041	<p>Continued From page 12</p> <p>This Requirement is not met as evidenced by: Based on a review of documentation and staff interview, the licensee failed to provide a patient with the name and telephone number of the nearest hospital to the home of the pregnant woman at which an emergency arising from the abortion would be treated.</p> <p>Findings include:</p> <p>In 1 (patient #3) out of 20 clinical records reviewed the patients residence was listed in Houston, Texas and the facility provided the patient with the name and telephone number to a hospital located in Austin, Texas. The information provided to the patient was not the nearest hospital to the home of the patient's residence.</p> <p>The above was confirmed in an interview with the Director of Clinical Services on the evening of 10-15-2018.</p> 	6 041	<p>6 041</p> <ul style="list-style-type: none"> <li>The Clinic Manager is responsible for ensuring compliance with all policies regarding medical and clinical services.</li> <li>WWHA complies with the requirement that patients shall be provided with the name and telephone number of both the nearest hospital to her physical location and hospital nearest to where the patient might be residing during her recovery time.</li> <li>An in-service was conducted with all staff on 10/18/2018 to review WWHA policy for Management of Medical Abortion and documentation of hospital nearest to the patient's physical residence during recovery.</li> <li>In order to monitor compliance, the Clinic Manager will complete a monthly chart audit.</li> </ul>	10/18/18
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Texas Health and Human Services Commission

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>140013</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____  B. WING _____	(X3) DATE SURVEY COMPLETED  <b>10/15/2018</b>
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NAME OF PROVIDER OR SUPPLIER  <b>WHOLE WOMAN'S HEALTH ALLIANCE</b>	STREET ADDRESS, CITY, STATE, ZIP CODE <b>8401 NORTH IH 35 SUITE 200 AUSTIN, TX 78753</b>
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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
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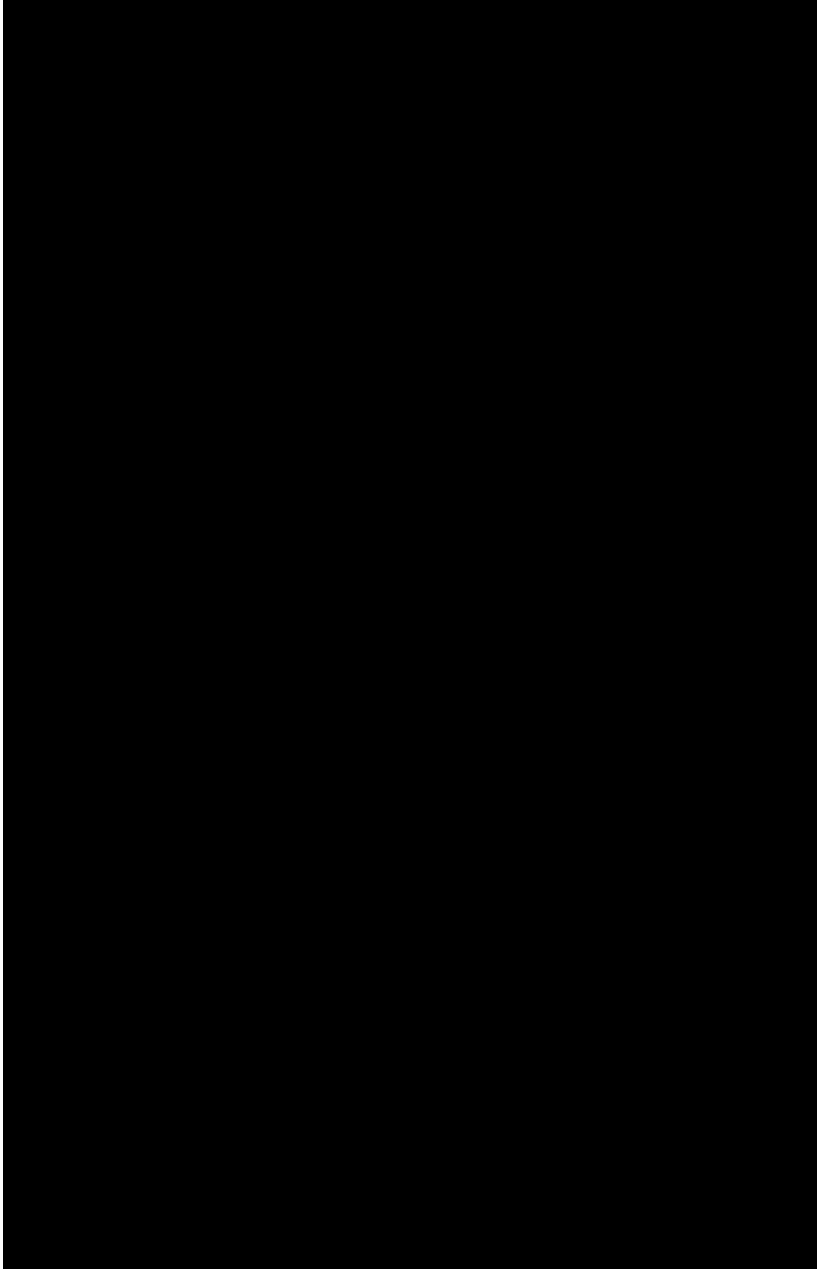


Texas Health and Human Services Commission

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>140013</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____  B. WING _____	(X3) DATE SURVEY COMPLETED  <b>10/15/2018</b>
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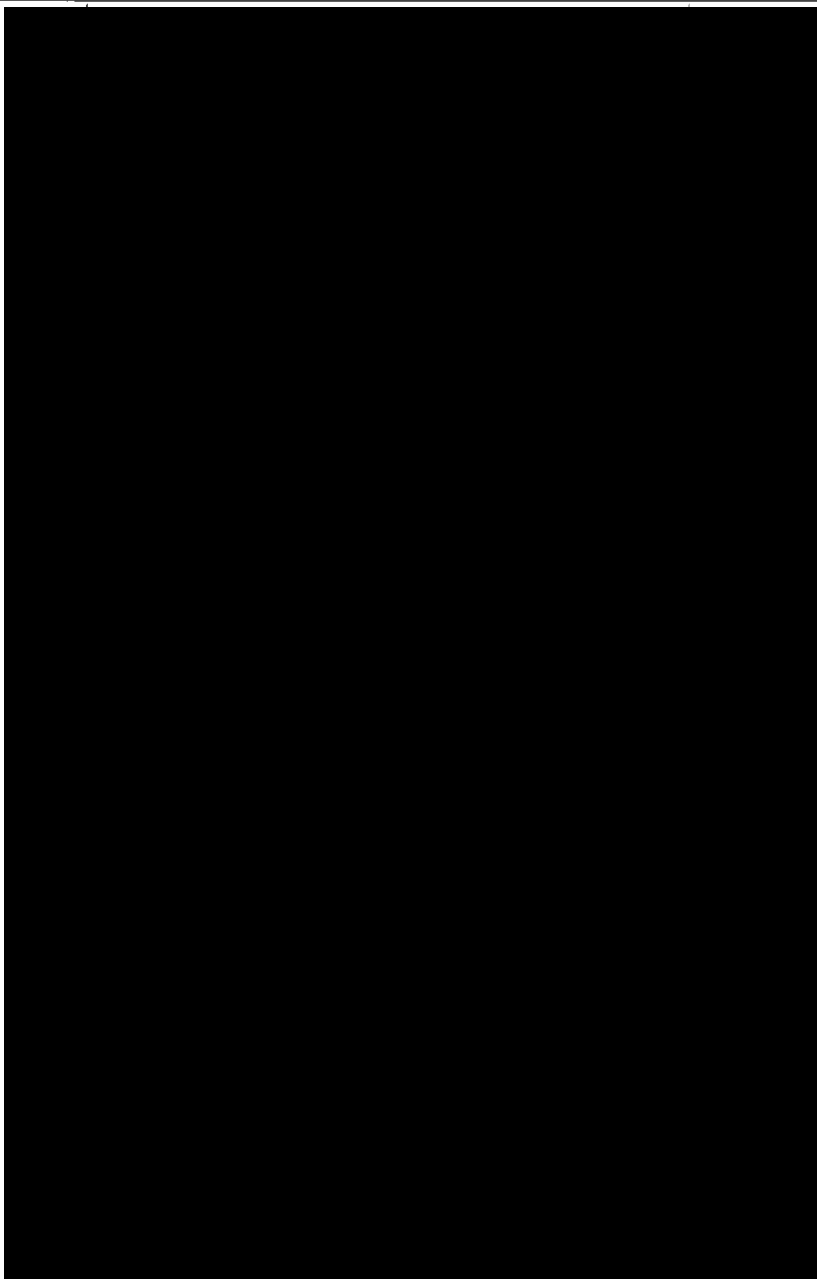


Texas Health and Human Services Commission

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WHOLE WOMAN'S HEALTH ALLIANCE	8401 NORTH IH 35 SUITE 200 AUSTIN, TX 78753

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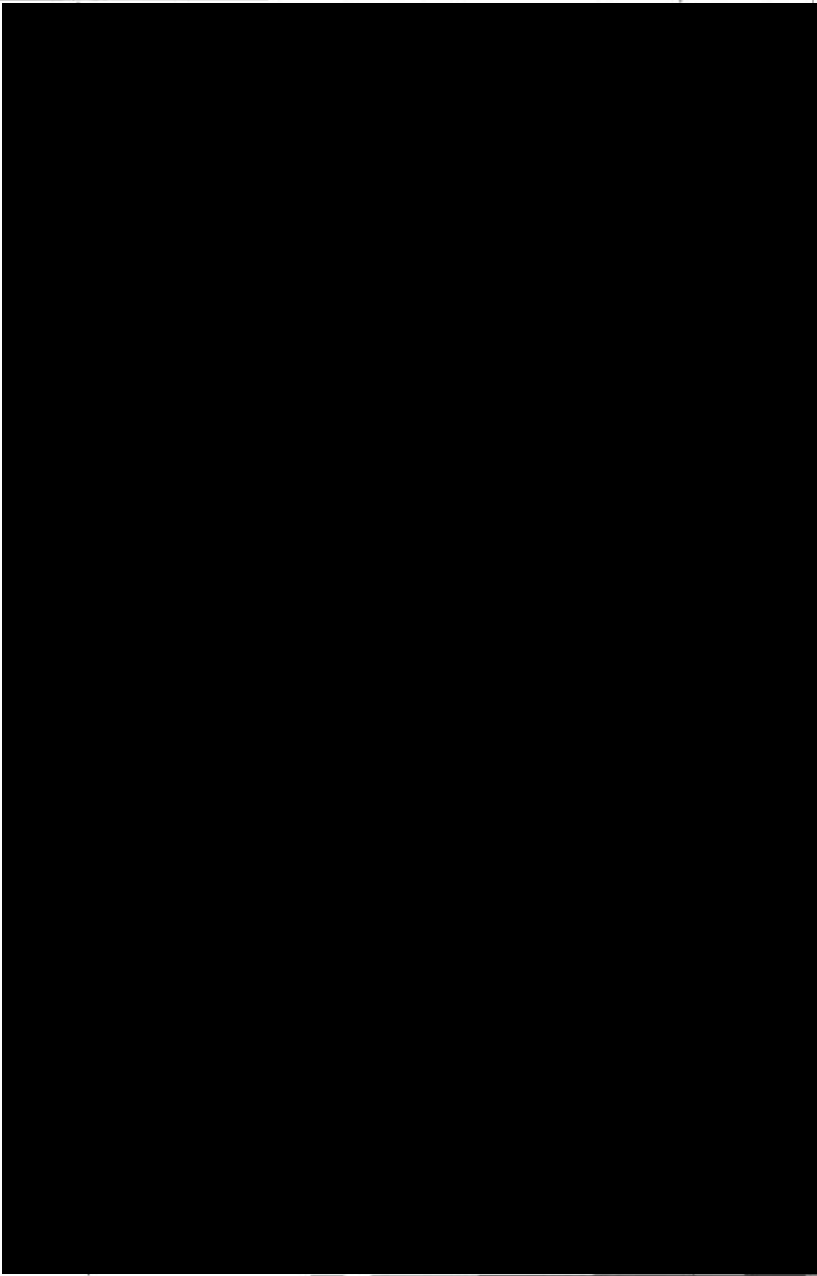


Texas Health and Human Services Commission

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>140013</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____  B. WING: _____	(X3) DATE SURVEY COMPLETED  <b>10/15/2018</b>
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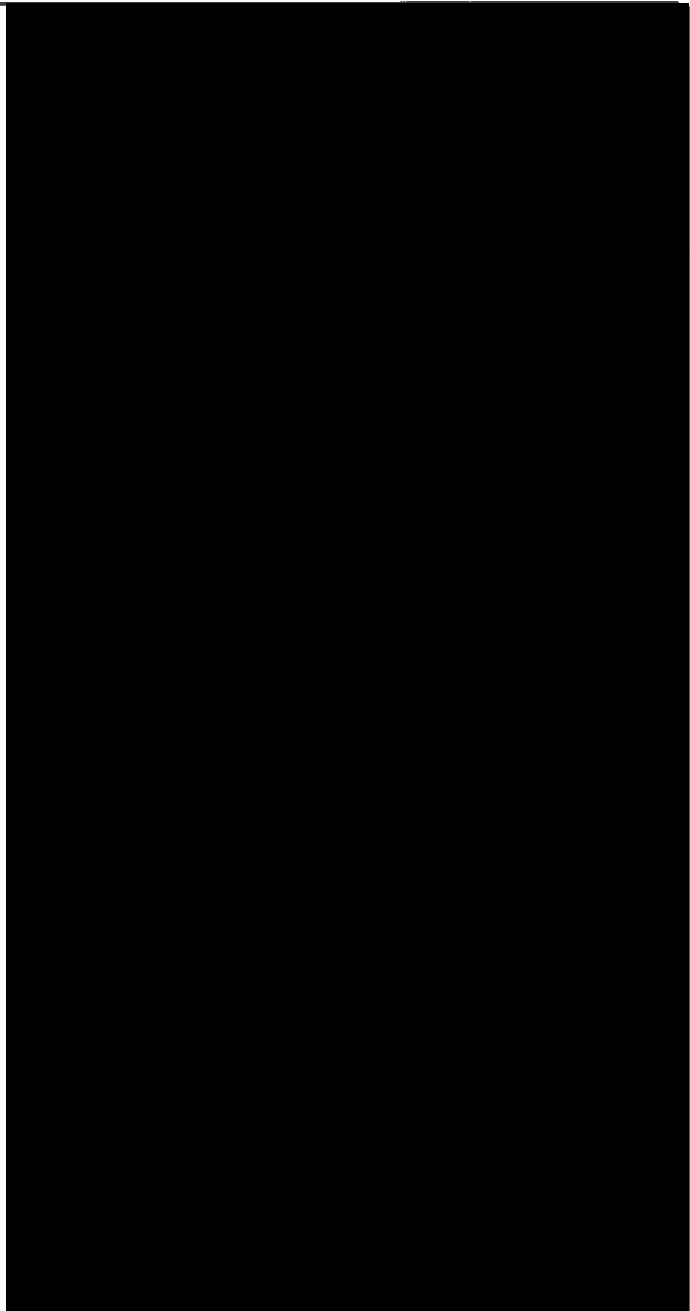
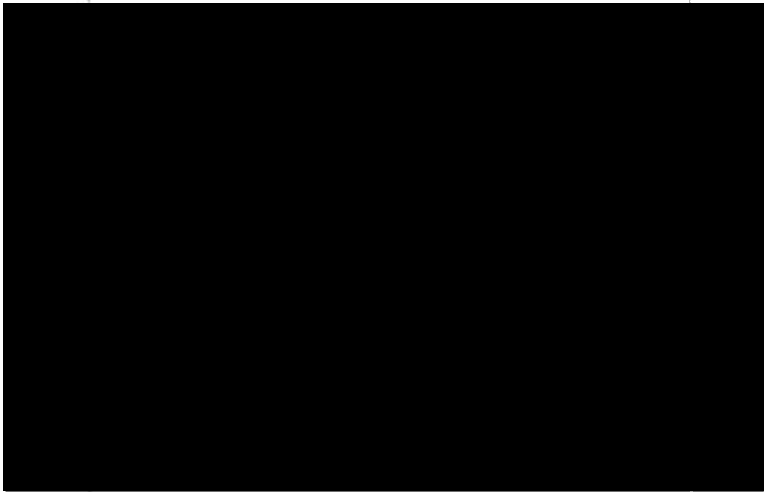


Texas Health and Human Services Commission

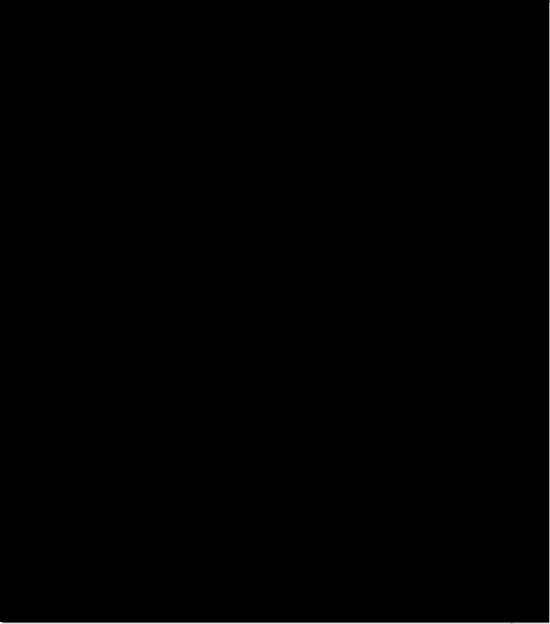
STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>140013</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____  B. WING _____	(X3) DATE SURVEY COMPLETED  <b>10/15/2018</b>
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