

Texas Health and Human Services Commission

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 007882	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED 08/20/2020
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NAME OF PROVIDER OR SUPPLIER AUSTIN WOMENS HEALTH CENTER	STREET ADDRESS, CITY, STATE, ZIP CODE 1902 SOUTH IH 35 AUSTIN, TX 78704
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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		



TITLE *Chronic Administrator* (X6) DATE *9/9/2020*

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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 facility Office Manager the morning of 8-19-20. 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 facility Office Manager the afternoon of 8-20-20. Preliminary findings of the survey were discussed, and an opportunity given for questions.</p>	6 000		
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</p>	6 033		

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6 033	<p>Continued From page 2</p> <p>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> <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>	6 033	<p>6033 (#1)</p> <p>The Clinic Administrator will be responsible for this plan.</p> <p>The Clinic Administrator will notify all staff via memorandum on 9/8/2020 of the importance of ensuring that the Nitrous Oxide and Oxygen tanks are secured with a chain to prevent tipping at all times except during replacement of empty tanks with full tanks. We requested our Medical Gas vendor to remove tanks due to lower patient volume due to the pandemic and they had just visited. They did not adjust the chains. Therefore, Staff will also be notified that if tanks are removed and not replaced that the chain must be adjusted to accommodate for the extra space that may be created so as to not create an environment where the tanks can be leaned or tipped inadvertently. The Clinic Administrator will monitor compliance with this requirement by checking for compliance daily for a period of 3 months. Additional checks will occur randomly after this point to continue to monitor compliance.</p> <p>6 033(#2)The Clinic Administrator will be responsible for this plan.</p> <p>The Clinic Administrator contacted our Equipment Service Vendor and scheduled a preventative maintenance check of the Centrifuge to occur on 8/24/2020. The centrifuge passed inspection. The Clinic Administrator will ensure that future Equipment Inspections are scheduled at a time in the day when the Clinic Administrator is available to accompany the service representative throughout the entire office and unlock doors that DSHS has stated must remain locked so that the service representative can access rarely used equipment. And so that a brief review of all equipment will occur to ensure that no items were overlooked.</p>	<p>9/8/2020</p> <p>8/27/2020</p>
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6 033	<p>Continued From page 3</p> <p>(1) 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 did not present a safe and sanitary environment, equipped and maintained to protect the health and safety of patients and staff at all times.</p> <p>Findings were:</p> <p>During a tour of the facility on 8-20-20, the following observations were made:</p> <ul style="list-style-type: none"> * 4 large nitrous oxide tanks and 4 large oxygen tanks were found unsecured in an outside closet. A chain lay on the floor. * 2 small oxygen tanks and 1 small nitrous oxide tank were found against a wall with a very loose, low-lying chain across them. The bottles were easily leaned/tipped by the surveyor. 	6 033	<p>6 033(#3) The Clinic Administrator will be responsible for this plan.</p> <p>The Clinic Administrator will notify all staff via memorandum on 9/8/2020 that feeding stray animals is prohibited and that the Administrator is to be notified should stray animals be observed on the property. The Clinic Administrator will monitor compliance during periodic inspection of the facility's property. Any containers used to supply food or water will be removed promptly.</p> <p>Although the Clinic will implement the above plan as a courtesy to the Department, we do not agree that we are out of compliance with this regulation. As we explained during our inspection, the Clinic has repeatedly attempted to follow city guidelines for stray cats but has been frustrated in these efforts due to the ongoing pandemic.</p> <p>The Clinic contacted known community organizations over the last several months that help with re-homing cats and kittens, but we were told they were unable to help during the Pandemic. The Clinic further attempted to maintain compliance with the City of Austin's recommendations for cats during the COVID Pandemic. See https://www.austintexas.gov/page/community-cats.</p>	9/8/2020

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6 033	<p>Continued From page 4</p> <p>According to https://www.usasafety.com/regulations.php, "1926.350(a)(9) Compressed gas cylinders shall be secured in an upright position at all times except, if necessary, for short periods of time while cylinders are actually being hoisted or carried."</p> <p>A centrifuge found on the counter of the laundry room bore 3 tags, each stating that it was due for inspection next in 2018. No documentation of a more recent inspection could be found. In an interview with staff #1 on 8-20-20, staff #1 confirmed that the centrifuge had not been inspected since 2017.</p> <p>Outside the facility (in an area accessible to staff and patients), a cat was observed, eating and drinking from bowls on the ground. Staff #1 was asked if facility personnel were feeding the cat and she stated that they were. When asked if the facility was providing veterinary care (to include required vaccinations) for the cat, staff #1 stated that they were not. Encouraging the company of a feral/stray animal poses an infection control issue to staff and patients of the clinic, as the cat could bite a staff member or a patient or carry other diseases and spread them through contact.</p> <p>The above was confirmed in an interview with staff #1 on the afternoon of 8-20-20.</p>	6 033	<p>(cont)</p> <p>After the Clinic was unable to receive assistance from the City or community organizations, staff members personally rehomed two of the cats. The remaining cat has only been seen occasionally and staff were not feeding the cat on a regular basis. While a staff member put out food and water for the cat on the day of the inspection, the food and water were in an area neither frequented by staff nor accessible by patients.</p> <p>For the reasons stated above we do not believe the facility was out of compliance and Austin Women's Health Center requests that this statement regarding this statement as a part of the citation be rescinded.</p>	
6 034	<p>TAC 139.49 Infection Control Standards</p> <p>(a) Written policies. A licensed abortion facility shall develop, implement, and enforce infection control policies and procedures to minimize the</p>	6 034		

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6 034	Continued From page 5 transmission of post-procedure infections. These policies shall include, but not be limited to, the prevention of the transmission of human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV), Mycobacterium tuberculosis (TB), and Streptococcus species (S. spp.); educational course requirements; cleaning and laundry requirements; and decontamination, disinfection, sterilization, and storage of sterile supplies. (b) Prevention and control of the transmission of HIV, HBV, HCV, TB, and S. spp. (1) Universal/standard precautions. (A) An abortion facility shall ensure that all staff comply with universal/standard precautions as defined in this paragraph. (i) Universal/standard precautions includes procedures for disinfection and sterilization of reusable medical devices and the appropriate use of infection control, including hand washing, the use of protective barriers, and the use and disposal of needles and other sharp instruments. (ii) Universal/standard precautions synthesize the major points of universal precautions with the points of body substance precautions and apply them to all patients receiving care in facilities, regardless of their diagnosis or presumed infection status. (I) Universal/standard precautions apply to: (-a-) blood; (-b-) body fluids, secretions, and excretions	6 034	6 034 The Clinic Administrator will be responsible for this plan. The Clinic Administrator will facilitate staff training to address proper completion of the Autoclave load logs. The Clinic Administrator will monitor compliance with this requirement by reviewing the daily Autoclave load logs for a period of 3 months. Additional checks will occur randomly after this point to continue to monitor compliance.	9/8/2020

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6 034	<p>Continued From page 6</p> <p>except sweat, regardless of whether or not they contain visible blood;</p> <p>(-c-) nonintact skin; and</p> <p>(-d-) mucous membranes.</p> <p>(II) Universal/standard precautions are designed to reduce the risk of transmission of microorganisms from both recognized and unrecognized sources of infection in facilities.</p> <p>(B) A licensed abortion facility shall establish procedures for monitoring compliance with universal/standard precautions described in subparagraph (A) of this paragraph.</p> <p>(2) Health care workers infected with the HIV or HBV. A licensed abortion facility shall adopt, implement, and enforce a written policy to ensure compliance of the facility and all of the health care workers within the facility with the Health and Safety Code, Chapter 85, Subchapter I, concerning the prevention of the transmission of HIV and HBV by infected health care workers.</p> <p>(3) Educational course work and training. A licensed abortion facility shall require its health care workers to complete educational course work or training in infection control and barrier precautions, including basic concepts of disease transmission, scientifically accepted principles and practices for infection control and engineering and work practice controls. To fulfill the requirements of this paragraph, course work and training may include formal education courses or in-house training or workshops provided by the facility. The course work and training shall include, but not be limited to:</p>	6 034		

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6 034	<p>Continued From page 7</p> <p>(A) HIV infection prevention; and</p> <p>(B) HBV, HCV, TB, and S. spp. infection prevention based on universal/standard precautions as defined in paragraph (1) of this subsection;</p> <p>(C) bidirectional aspect of disease transmission; and</p> <p>(D) epidemic control.</p> <p>(c) Cleaning and laundry policies and procedures.</p> <p>(1) A licensed abortion facility shall develop, implement, and enforce written policies and procedures on cleaning the procedure room(s).</p> <p>(2) A licensed abortion facility shall develop, implement, and enforce written policies and procedures for the handling, processing, storing, and transporting of clean and dirty laundry.</p> <p>(3) A licensed abortion facility may provide cleaning and laundry services directly or by contract in accordance with Occupational Safety and Health Administration's Standards, 29 Code of Federal Regulations, Subpart Z. Bloodborne Pathogens.</p> <p>(d) Policies and procedures for decontamination, disinfection, sterilization, and storage of sterile supplies. A licensed abortion facility shall have written policies covering its procedures for the decontamination and sterilization activities performed. Policies shall include, but not be limited to, the receiving, cleaning, decontaminating, disinfecting, preparing and</p>	6 034		

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6 034	<p>Continued From page 8</p> <p>sterilization of critical items (reusable items), as well as those for the assembly, wrapping, storage, distribution, and the monitoring and control of sterile items and equipment.</p> <p>(1) Supervision. The decontamination, disinfection, and sterilization of all supplies and equipment shall be under the supervision of a person qualified by education, training, or experience.</p> <p>(2) Quantity of sterile surgical instruments. The facility shall ensure that surgical instruments are sufficient in number to permit sterilization of the instrument(s) used for each procedure and adequate to perform conventional cervical dilatation and curettage if this procedure is available at the facility.</p> <p>(3) Inspection of surgical instruments.</p> <p>(A) All instruments shall undergo inspection before being packaged for reuse or storage. Routine inspection of instruments shall be made to assure clean locks, crevices, and serrations.</p> <p>(B) Inspection procedures shall be thorough and include visual and manual inspection for condition and function.</p> <p>(i) Cutting edges shall be checked for sharpness; tips shall be properly aligned, and box locks shall be clean and free from buildup of soap, detergent, dried blood, or tissue.</p> <p>(ii) There shall be no evident cracks or fissures in the box locks, and the hinges shall work freely.</p>	6 034		

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6 034	<p>Continued From page 9</p> <p>(iii) Ratchets shall hold and be routinely tested.</p> <p>(iv) There shall be no corrosion or pitting of the finish.</p> <p>(C) Instruments needing maintenance shall be taken out of service and repaired by someone qualified to repair surgical instruments.</p> <p>(D) To protect the instrument and its protective finish, impact markers or electric engravers shall not be used for instrument identification. Instrument identification shall be accomplished by the instrument manufacturer, employing methods which shall not damage the instrument or its protective finish.</p> <p>(4) Items to be disinfected and sterilized.</p> <p>(A) Critical items.</p> <p>(i) Critical items include all surgical instruments and objects that are introduced directly into the bloodstream or into other normally sterile areas of the body and shall be sterilized in accordance with this subsection.</p> <p>(ii) All items that come in contact with the sterile field during the operative procedure shall be sterile.</p> <p>(B) Semicritical items.</p> <p>(i) Semicritical items include items that come in contact with nonintact skin or mucous membranes. Semicritical items shall be free of microorganisms, except bacterial spores. Semicritical items may include respiratory therapy</p>	6 034		

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6 034	<p>Continued From page 10</p> <p>equipment, anesthesia equipment, bronchoscopes, and thermometers.</p> <p>(ii) High-level disinfection shall be used for semicritical items.</p> <p>(C) Noncritical items.</p> <p>(i) Noncritical items include items that come in contact with intact skin.</p> <p>(ii) Intermediate-level or low-level disinfection shall be used for noncritical items.</p> <p>(5) Equipment and sterilization procedures. Effective sterilization of instruments depends on performing correct methods of cleaning, packaging, arrangement of items in the sterilizer, and storage. The following procedures shall be included in the written policies as required in this subsection to provide effective sterilization measures.</p> <p>(A) Equipment. A licensed abortion facility shall provide sterilization equipment adequate to meet the requirements of this paragraph for sterilization of critical items. Equipment shall be maintained and operated to perform, with accuracy, the sterilization of critical items.</p> <p>(B) Environmental requirements. Where cleaning, preparation, and sterilization functions are performed in the same room or unit, the physical facilities, equipment, and the written policies and procedures for their use shall be such as to effectively separate soiled or contaminated supplies and equipment from the clean or sterilized supplies and equipment.</p>	6 034		

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6 034	<p>Continued From page 11</p> <p>(i) A facility shall have a sink for hand washing. This sink shall not be used for cleaning instruments or disposal of liquid waste.</p> <p>(ii) A facility shall have a separate sink for cleaning instruments and disposal of liquid waste. Hand washing shall only be performed at this sink after it has been disinfected.</p> <p>(C) Preparation for sterilization.</p> <p>(i) All items to be sterilized shall be prepared to reduce the bioburden. All items shall be thoroughly cleaned, decontaminated and prepared in a clean, controlled environment. Cleaning is the removal of all adherent visible soil from the surfaces, crevices, joints, and lumens of instruments. Decontamination is the physical/chemical process that renders an inanimate object safe for further handling.</p> <p>(ii) One of the following methods of cleaning and decontamination shall be used as appropriate.</p> <p>(I) Manual cleaning. Manual cleaning of instruments at the sink is permitted.</p> <p>(II) Ultrasonic cleaning. Ultrasonic cleaning of instruments cleans by cavitation and reduces the need for hand scrubbing. When grossly soiled items are placed in the ultrasonic cleaner the water shall be changed more than once a shift. If using this method for cleaning, chambers shall be covered to prevent potential hazards to personnel from aerosolization of the contents.</p> <p>(III) Washer-sterilizers. Washer-sterilizers clean by using rotating spray arms to create</p>	6 034		

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6 034	<p>Continued From page 12</p> <p>water jets that clean by impingement and appropriate soap and disinfectant. These machines shall reach a temperature of 140 degrees Celsius (285 degrees Fahrenheit).</p> <p>(IV) Washer-decontaminator machines. Washer-decontaminator machines clean by numerous water jets and a high pH of detergent even if instruments are grossly soiled. The thorough cleaning is followed by a neutralizing rinse to quickly restore the pH to neutral.</p> <p>(iii) All articles to be sterilized shall be arranged so all surfaces shall be directly exposed to the sterilizing agent for the prescribed time and temperature.</p> <p>(D) Packaging.</p> <p>(i) All wrapped articles to be sterilized shall be packaged in materials recommended for the specific type of sterilizer and material to be sterilized, and to provide an effective barrier to microorganisms. Acceptable packaging includes peel pouches, perforated metal trays, or rigid trays. Muslin packs shall be limited in size to 12 inches by 12 inches by 20 inches with a maximum weight of 12 pounds. Wrapped instrument trays shall not exceed 17 pounds.</p> <p>(ii) All items shall be labeled for each sterilizer load as to the date and time of sterilization, the sterilizing load number, and the autoclave.</p> <p>(E) External chemical indicators.</p> <p>(i) External chemical indicators, also known as sterilization process indicators, shall be used on each package to be sterilized, including items</p>	6 034		

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NAME OF PROVIDER OR SUPPLIER AUSTIN WOMENS HEALTH CENTER	STREET ADDRESS, CITY, STATE, ZIP CODE 1902 SOUTH IH 35 AUSTIN, TX 78704
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6 034	<p>Continued From page 13</p> <p>being flash sterilized to indicate that items have been exposed to the sterilization process.</p> <p>(ii) The indicator results shall be interpreted according to the manufacturer's written instructions and indicator reaction specifications.</p> <p>(F) Biological indicators.</p> <p>(i) The efficacy of the sterilizing process shall be monitored with reliable biological indicators appropriate for the type of sterilizer used (e.g., Bacillus stearothermophilus for steam sterilizers).</p> <p>(ii) Biological indicators shall be included in at least one run each day of use for steam sterilizers.</p> <p>(iii) A log shall be maintained with the load identification, biological indicator results, and identification of the contents of the load.</p> <p>(iv) If a test is positive, the sterilizer shall immediately be taken out of service. A malfunctioning sterilizer shall not be put back into use until it has been serviced and successfully tested according to the manufacturer's recommendations.</p> <p>(v) All available items shall be recalled and reprocessed if a sterilizer malfunction is found. A list of all items which were used after the last negative biological indicator test shall be submitted to the administrator.</p> <p>(G) Sterilizers.</p> <p>(i) Steam sterilizers (saturated steam under pressure) shall be utilized for sterilization of heat</p>	6 034		

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6 034	<p>Continued From page 14</p> <p>and moisture stable items. Steam sterilizers shall be used according to manufacturer's written instructions.</p> <p>(ii) Other sterilizers shall be used in accordance with the manufacturer's instructions.</p> <p>(H) Maintenance of sterility.</p> <p>(i) Items that are properly packaged and sterilized shall remain sterile indefinitely unless the package becomes wet or torn, has a broken seal, is damaged in some way, or is suspected of being compromised.</p> <p>(ii) Medication or materials within a package that deteriorate with the passage of time shall be dated according to the manufacturer's recommendations.</p> <p>(iii) All packages shall be inspected before use. If a package is torn, wet, discolored, has a broken seal, or is damaged, the item may not be used. The item shall be returned to sterile processing for reprocessing.</p> <p>(I) Commercially packaged items. Commercially packaged items are considered sterile according to the manufacturer's instructions.</p> <p>(J) Storage of sterilized items. The loss of sterility is event related, not time related. The facility shall ensure proper storage and handling of items in a manner that does not compromise the packaging of the product.</p> <p>(i) Sterilized items shall be transported so as to maintain cleanliness and sterility and to</p>	6 034		

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6 034	<p>Continued From page 15</p> <p>prevent physical damage.</p> <p>(ii) Sterilized items shall be stored in well-ventilated, limited access areas with controlled temperature and humidity.</p> <p>(iii) Sterilized items shall be positioned so that the packaging is not crushed, bent, compressed, or punctured so that their sterility is not compromised.</p> <p>(iv) Storage of supplies shall be in areas that are designated for storage.</p> <p>(K) Disinfection.</p> <p>(i) The manufacturer's written instructions for the use of disinfectants shall be followed.</p> <p>(ii) An expiration date, determined according to manufacturer's written recommendations, shall be marked on the container of disinfection solution currently in use.</p> <p>(iii) Disinfectant solutions shall be kept covered and used in well-ventilated areas.</p> <p>(L) Performance records.</p> <p>(i) Performance records for all sterilizers shall be maintained for each cycle. These records shall be retained and available for review for a minimum of two years.</p> <p>(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:</p>	6 034		

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6 034	<p>Continued From page 16</p> <p>(I) the sterilizer identification;</p> <p>(II) sterilization date and time;</p> <p>(III) load number;</p> <p>(IV) duration and temperature of exposure phase (if not provided on sterilizer recording charts);</p> <p>(V) identification of operator(s);</p> <p>(VI) results of biological tests and dates performed; and</p> <p>(VII) time-temperature recording charts from each sterilizer (if not provided on sterilizer recording charts).</p> <p>(M) Preventive maintenance. Preventive maintenance of all sterilizers shall be performed according to individual policy on a scheduled basis by qualified personnel, using the sterilizer manufacturer's service manual as a reference. A preventive maintenance record shall be maintained for each sterilizer. These records shall be retained for at least two years and shall be available for review to the facility within two hours of request by the department.</p> <p>This Requirement is not met as evidenced by: Based on a review of documentation and interview, the facility failed to ensure that Each sterilizer shall be monitored during operation for time at desired temperature and pressure. A record shall be maintained either manually or machine generated and shall include: (IV) duration and temperature of exposure phase (if</p>	6 034		

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6 034	<p>Continued From page 17</p> <p>not provided on sterilizer recording charts);</p> <p>Findings included: Facility based policy entitled, "Cleaning, Decontamination, and Sterilization of Instruments in the Path Lab" stated in part, "D. Every package intended for sterile use must be imprinted or labeled ... 1. All items place in a load will be marked with the sterilizer load #...The record will contain the load number, and will indicate the temperature and the time parameters of the cycle. E. The time required to achieve sterilization by steam under pressure varies with the method uses and the type of item to be sterilized. Time and temperature relationships indicate holding times after the specific temperature have been reached ..."</p> <p>Facility based policy entitled, "Protocol for Pathology" stated in part, "4. Running the Autoclave ... c) Run autoclave on 'Packs' at 250 for 30 mins or 'Pouches' at 270 degrees for 6 minutes for unwrapped speculums ... e) After load is run, finish filling out log." Facility based policy entitled, "Daily Routine of Autoclave and Sterilization Tasks" states in part, "10. Verify documentation in load run-logbook and biological indicator log."</p> <p>Review of the facility Autoclave Load Log for January 2020 through August 2020 revealed the following dated did not have temperature noted:</p> <p>* On 01/06/20 the instruments run on machine #2 did not have the load, temperature, or time exposure documented. * On 01/08/20 load #2 with the start time noted at 1623 had no cycle (exposure) time noted.</p>	6 034		

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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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6 034	<p>Continued From page 18</p> <ul style="list-style-type: none"> * On 01/11/20 load #1 with the start time noted at 0838 had no cycle (exposure) time noted. * On 03/13/20 load #2 with the start time noted at 1605 had no cycle (exposure) time noted. * On 05/19/20 load #1 with the start time noted at 1627 had no cycle (exposure) time noted. * On 06/17/20 load #1 with the start time noted at 1643 had no cycle (exposure) time noted. * On 06/19/20 load #1 with the start time noted at 1521 had no cycle (exposure) time noted. * On 07/07/20 load #2 with the start time noted at 0913 had no cycle (exposure) time noted. <p>In an interview on 08/20/20 staff member #1 verified that the exposure time for these loads should have been documented per policy and regulations.</p>	6 034		
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. 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</p>	6 041		

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6 041	<p>Continued From page 19</p> <p>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> <p>This Requirement is not met as evidenced by: Based on a review of clinical records and an interview with staff, the facility failed to provide the patient with the name and telephone number of the nearest hospital to the home of the pregnant woman at which an emergency may arise for 1 of 20 patients.</p> <p>Findings were:</p> <p>Surgical patient #9 provided a home address in Garden City, KS. Her discharged instructions contained no hospital name and number for a hospital near her home address but stated</p>	6 041		

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6 041	<p>Continued From page 20</p> <p>"Patient is from KS [Kansas] but is staying in Killeen, Tx. I gave hospital info for Killeen."</p> <p>The above was confirmed in an interview with staff #1 on 8-20-20.</p>	6 041	<p>6 041</p> <p>The Clinic Administrator will be responsible for this plan.</p> <p>The Clinic Administrator will notify all staff via memorandum on 9/8/2020, that it is not sufficient to give the name, address, and phone number of the nearest hospital to the location the patient will be residing for the duration of the medication abortion process. Staff will be notified that they must give the name, address, and phone number, for the nearest hospitals to both their 'home' address listed on their paperwork and to whatever other address they report they will actually be residing at for the duration of the medication abortion process.</p> <p>The Clinic Administrator will monitor compliance with this requirement through monthly audits of patient records.</p> <p>We will implement the above plan as a courtesy to the department however, as stated during our inspection, we do not believe we are out of compliance with TAC 139.56 Emergency Services (A) (2) (B). This regulation states that "the name and telephone number of the nearest hospital to the home of the <u>pregnant woman at which and emergency arising from the abortion would be treated</u>. In accordance with this regulation, the woman stated she lived in Kansas but was residing in Killeen for the period of time during which the abortion process would occur. Therefore the staff member gave the pregnant woman the name of the nearest hospital in Killeen <u>at which an emergency arising from the abortion would be treated</u> and documented the information and reason for providing the information.</p> <p>For the reasons stated above we do not believe the facility was out of compliance and Austin Women's Health Center requests that the deficiency regarding lack of compliance with TAC 139.56 Emergency Services be rescinded.</p>	9/8/2020