Texas Health and Human Services Commission

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	140008	A. BUILDING: _____ B. WING _____	10/20/2020

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

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETE DATE
6 000	TAC 139.1 Initial Comments Note: The State Form is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be referred to the Office of the Texas Attorney General (OAG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately. (a) Purpose. The purpose of this chapter is to implement the Texas Abortion Facility Reporting and Licensing Act, Health and Safety Code, Chapter 245, which provides the Health and Human Services Commission with the authority to establish rules governing the licensing and regulation of abortion facilities and to establish annual reporting requirements for each abortion performed. This chapter also implements the Woman's Right to Know Act, Health and Safety Code, Chapter 171. (b) Scope and applicability. (1) Licensing requirements. (A) A person may not establish or operate an abortion facility in Texas without a license issued under this chapter unless the person is exempt from licensing requirements. (B) The following need not be licensed under this chapter: (i) a hospital licensed under Health and Safety Code, Chapter 241; (ii) an ambulatory surgical center licensed	6 000		

SOD - State Form

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

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6 000	Continued From page 1 under Health and Safety Code, Chapter 243; or (iii) the office of a physician licensed by the Texas Medical Board and authorized to practice medicine in the State of Texas, unless the office is used for the purpose of performing more than 50 abortions in any 12-month period. (2) Reporting requirements. All licensed abortion facilities and facilities and persons exempt from licensing shall comply with §139.4 of this title (relating to Annual Reporting Requirements for All Abortions Performed). [redacted]	6 000		

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[redacted]	[redacted]	[redacted]		

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[redacted]	[redacted]	[redacted]		
[redacted]	[redacted]	6 030		

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This Requirement is not met as evidenced by:

6 033	TAC 139.48 Physical and Environmental Requirements The physical and environmental requirements for a licensed abortion facility are as follows. (1) A facility shall:	6 033		

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6 033	Continued From page 6 (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; (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; (C) have a separate recovery room if moderate sedation/analgesia, deep sedation/analgesia, or general anesthesia are administered at the facility; (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; (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 Chapter 228 of this title (relating to Retail Food); (G) provide clean hand washing facilities for patients and staff including running water, and soap;	6 033		

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6 033	Continued From page 7 (H) have two functioning sinks and a functioning toilet; and (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. (2) The equipment for vacuum aspiration shall be electrically safe and designed to prevent reverse pump action in facilities that provide vacuum aspiration. (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. This Requirement is not met as evidenced by: Based on observation, the facility failed to maintain a safe and sanitary environment, maintained to protect the health and safety of patients and staff. Findings: 1. The facility failed to ensure medical equipment testing for electrical safety was not completed on all necessary equipment in the facility. 2. The facility allowed staff to participate in care with artificial nails. Observation on 1/19/2020 at 10:30 a.m. of the	6 033		

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6 033	Continued From page 8 patient procedure room # 3 the following was observed along with Medical Assistant, Employee ID #51 no electrical safety tag was found on the suction machine. Interview on 10/19/2020 Employee ID #51 confirmed the equipment should have an electrical safety sticker and the suction machine did not have an electric safety sticker. Observation of Employee ID #51 with short, artificial nails adorned with a decorative, textured finish, creating a surface similar to chipped nail polish with multiple areas for bacteria to become lodged. According to the CDC Morbidity and Mortality Weekly Report, October 25, 2002 / Vol. 51 / No. RR-16: "Studies have documented that subungual areas of the hand harbor high concentrations of bacteria, most frequently coagulase-negative staphylococci, gram-negative rods (including Pseudomonas spp.), Corynebacteria, and yeasts (14,342,343). Freshly applied nail polish does not increase the number of bacteria recovered from periungual skin, but chipped nail polish may support the growth of larger numbers of organisms on fingernails (344,345). Even after careful handwashing or the use of surgical scrubs, personnel often harbor substantial numbers of potential pathogens in the subungual spaces (346-348) ...HCWs who wear artificial nails are more likely to harbor gram-negative pathogens on their fingertips than are those who have natural nails, both before and after handwashing." The above was confirmed in an interview with the Medical Director and office manager on the afternoon of 1/20/2020	6 033		

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6 033	Continued From page 9 The above was cited previously in a survey of the facility performed on 01/09/2019 and 09/13/16.	6 033		
6 034	TAC 139.49 Infection Control Standards (a) Written policies. A licensed abortion facility shall develop, implement, and enforce infection control policies and procedures to minimize the 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,	6 034		

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6 034	Continued From page 10 regardless of their diagnosis or presumed infection status. (I) Universal/standard precautions apply to: (-a-) blood; (-b-) body fluids, secretions, and excretions except sweat, regardless of whether or not they contain visible blood; (-c-) nonintact skin; and (-d-) mucous membranes. (II) Universal/standard precautions are designed to reduce the risk of transmission of microorganisms from both recognized and unrecognized sources of infection in facilities. (B) A licensed abortion facility shall establish procedures for monitoring compliance with universal/standard precautions described in subparagraph (A) of this paragraph. (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. (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	6 034		

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6 034	Continued From page 11 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: (A) HIV infection prevention; and (B) HBV, HCV, TB, and S. spp. infection prevention based on universal/standard precautions as defined in paragraph (1) of this subsection; (C) bidirectional aspect of disease transmission; and (D) epidemic control. (c) Cleaning and laundry policies and procedures. (1) A licensed abortion facility shall develop, implement, and enforce written policies and procedures on cleaning the procedure room(s). (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. (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.	6 034		

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6 034	Continued From page 12 (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 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. (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. (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. (3) Inspection of surgical instruments. (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. (B) Inspection procedures shall be thorough and include visual and manual inspection for condition and function. (i) Cutting edges shall be checked for	6 034		

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6 034	Continued From page 13 sharpness; tips shall be properly aligned, and box locks shall be clean and free from buildup of soap, detergent, dried blood, or tissue. (ii) There shall be no evident cracks or fissures in the box locks, and the hinges shall work freely. (iii) Ratchets shall hold and be routinely tested. (iv) There shall be no corrosion or pitting of the finish. (C) Instruments needing maintenance shall be taken out of service and repaired by someone qualified to repair surgical instruments. (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. (4) Items to be disinfected and sterilized. (A) Critical items. (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. (ii) All items that come in contact with the sterile field during the operative procedure shall be sterile.	6 034		

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6 034	Continued From page 14 (B) Semicritical items. (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 equipment, anesthesia equipment, bronchoscopes, and thermometers. (ii) High-level disinfection shall be used for semicritical items. (C) Noncritical items. (i) Noncritical items include items that come in contact with intact skin. (ii) Intermediate-level or low-level disinfection shall be used for noncritical items. (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. (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. (B) Environmental requirements. Where	6 034		

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6 034	Continued From page 15 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. (i) A facility shall have a sink for hand washing. This sink shall not be used for cleaning instruments or disposal of liquid waste. (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. (C) Preparation for sterilization. (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. (ii) One of the following methods of cleaning and decontamination shall be used as appropriate. (I) Manual cleaning. Manual cleaning of instruments at the sink is permitted. (II) Ultrasonic cleaning. Ultrasonic cleaning of instruments cleans by cavitation and reduces the need for hand scrubbing. When grossly soiled	6 034		

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6 034	Continued From page 16 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. (III) Washer-sterilizers. Washer-sterilizers clean by using rotating spray arms to create water jets that clean by impingement and appropriate soap and disinfectant. These machines shall reach a temperature of 140 degrees Celsius (285 degrees Fahrenheit). (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. (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. (D) Packaging. (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. (ii) All items shall be labeled for each sterilizer	6 034		

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WOMEN'S CENTER HOUSTON	8200 WEDNESBURY LANE, SUITE 230 HOUSTON, TX 77074

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6 034	Continued From page 17 load as to the date and time of sterilization, the sterilizing load number, and the autoclave. (E) External chemical indicators. (i) External chemical indicators, also known as sterilization process indicators, shall be used on each package to be sterilized, including items being flash sterilized to indicate that items have been exposed to the sterilization process. (ii) The indicator results shall be interpreted according to the manufacturer's written instructions and indicator reaction specifications. (F) Biological indicators. (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). (ii) Biological indicators shall be included in at least one run each day of use for steam sterilizers. (iii) A log shall be maintained with the load identification, biological indicator results, and identification of the contents of the load. (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. (v) All available items shall be recalled and reprocessed if a sterilizer malfunction is found. A	6 034		

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6 034	Continued From page 18 list of all items which were used after the last negative biological indicator test shall be submitted to the administrator. (G) Sterilizers. (i) Steam sterilizers (saturated steam under pressure) shall be utilized for sterilization of heat and moisture stable items. Steam sterilizers shall be used according to manufacturer's written instructions. (ii) Other sterilizers shall be used in accordance with the manufacturer's instructions. (H) Maintenance of sterility. (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. (ii) Medication or materials within a package that deteriorate with the passage of time shall be dated according to the manufacturer's recommendations. (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. (I) Commercially packaged items. Commercially packaged items are considered sterile according to the manufacturer's instructions.	6 034		

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6 034	Continued From page 19 (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. (i) Sterilized items shall be transported so as to maintain cleanliness and sterility and to prevent physical damage. (ii) Sterilized items shall be stored in well-ventilated, limited access areas with controlled temperature and humidity. (iii) Sterilized items shall be positioned so that the packaging is not crushed, bent, compressed, or punctured so that their sterility is not compromised. (iv) Storage of supplies shall be in areas that are designated for storage. (K) Disinfection. (i) The manufacturer's written instructions for the use of disinfectants shall be followed. (ii) An expiration date, determined according to manufacturer's written recommendations, shall be marked on the container of disinfection solution currently in use. (iii) Disinfectant solutions shall be kept covered and used in well-ventilated areas. (L) Performance records. (i) Performance records for all sterilizers shall be maintained for each cycle. These records shall	6 034		

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6 034	Continued From page 20 be retained and available for review for a minimum of two years. (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: (I) the sterilizer identification; (II) sterilization date and time; (III) load number; (IV) duration and temperature of exposure phase (if not provided on sterilizer recording charts); (V) identification of operator(s); (VI) results of biological tests and dates performed; and (VII) time-temperature recording charts from each sterilizer (if not provided on sterilizer recording charts). (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 at least two years and shall be available for review to the facility within two hours of request by the department.	6 034		

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6 034	Continued From page 21 This Requirement is not met as evidenced by: Based on observation, interview and record the facility failed to implement their infection control policies and procedures to minimize the transmission of infection. Findings included: 1. The facility failed to ensure that expired medical supplies were not available for use. 2. The facility failed to ensure that medications were labeled appropriately and in the original container. 3. The facility failed to ensure the contents of the medication refrigerator did not contain blood specimens. 4. The facility failed to ensure patient treatment rooms and equipment were cleaned between patient use. 5. The facility failed to ensure the conditions of patient equipment was a solid surface and able to be disinfected. Reference Reviewed: Review of manufacturer's web site; Transeptic Cleaning Solution Multi-purpose spray for professional use in cleaning ultrasound transducer/probe surfaces. Solution is a 70% alcohol (Isopropyl Alcohol) for cleaning ultrasound transducer/probe surfaces. Retrieved from web site. https://bio-medical.com/transeptic-cleaning-solution.html Review on 10/19/2020 of the CDC website. Guideline for Disinfection and Sterilization in Healthcare Facilities (2008). Review of Center for Disease Control (CDC) Guidelines for infection control guidelines for disinfection; CDC guideline for vaginal probe disinfection: Retrieved from: https://www.cdc.gov/infectioncontrol/guidelines/di	6 034		

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6 034	Continued From page 22 sinfection/disinfection-methods/chemical.html Review of Transeptic ultrasound Transducer/Probe Cleaning solution Alcohol: Overview "In the healthcare setting, "alcohol" refers to two water-soluble chemical compounds-ethyl alcohol and isopropyl alcohol-that have generally underrated germicidal characteristics 482. FDA has not cleared any liquid chemical sterilant or high-level disinfectant with alcohol as the main active ingredient. These alcohols are rapidly bactericidal rather than bacteriostatic against vegetative forms of bacteria; they also are tuberculocidal, fungicidal, and viricidal but do not destroy bacterial spores." CDC Website review: 10/19/2020; https://www.cdc.gov/infectioncontrol/guidelines/disinfection/ Indications for Sterilization, high-Level Disinfection, and Low-level Disinfection Indications for sterilization and disinfection. 3.b. Provide, at a minimum, high-level disinfection for semicritical patient-care equipment (e.g., gastrointestinal endoscopes, endotracheal tubes, anesthesia breathing circuits, and respiratory therapy equipment) that touches either mucous membranes or nonintact skin. 3.c. Perform low-level disinfection for noncritical patient-care surfaces (e.g., bedrails, over-the-bed table) and equipment (e.g., blood pressure cuff) that touch intact skin 10. Disinfection Strategies for Other Semicritical Devices. Recommendations from Disinfection strategies for other semicritical devices: 10.a. Even if probe covers have been used, clean and high-level disinfect other semicritical devices such as rectal probes, vaginal probes, and cryosurgical probes with a product that is not toxic to staff, patients, probes, and retrieved germ cells (if applicable). Use a high-level disinfectant at the FDA-cleared exposure time.	6 034		

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6 034	Continued From page 23 10.b When probe covers are available, use a probe cover or condom to reduce the level of microbial contamination. Do not use a lower category of disinfection or cease to follow the appropriate disinfectant recommendations when using probe covers because these sheaths and condoms can fail. 10.c. After high-level disinfection, rinse all items. Use sterile water, filtered water or tap water followed by an alcohol rinse for semicritical equipment that will have contact with mucous membranes of the upper respiratory tract (e.g., nose, pharynx esophagus). 10.d. There is no recommendation t use sterile or filtered water rather than tap water for rinsing semicritical equipment that contact the mucous membranes of the rectum (e.g., rectal probes, anoscope) or vagina (e.g., vaginal probes). Observation on the morning of 10/19/2020 included: Patient Exam Room # 1 the following was observed along with Medical Assistant, Employee ID # 51 1 - Container Henry Schein Plain Packing Strips, Sterile, ¼" x 5 yards/0.64 cm x 4.5 cm, Lot # 04755, Expired 2020-04 1 - Container Henry Schein Plain Packing Strips, Sterile, ¼" x 5 yards/0.64 cm x 4.5 cm, Lot # 08745, Expired 2020-08 1 - Container Henry Schein Plain Packing Strips, Sterile, ¼" x 5 yards/0.64 cm x 4.5 cm, Lot # 04763, Expired 2020-04 Patient Recovery Room # 1 the following was observed along with Medical Assistant, Employee	6 034		

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6 034	Continued From page 24 ID #51 4- pleather reclining chairs were observed with cracked areas noted on the arms and the backs of each of the chairs impending cleaning and disinfection of the chairs. 3 - 23-gauge ¾ inch Terumo Sureflow Winged Infusion Set, Expired 2013-8 2 - 23-gauge ¾ inch Terumo Sureflow Winged Infusion Set, Expired 2013-10 2- Terumo Syringes3cc/ml, Expired 2011-01 Patient Treatment Room #2 the following was observed along with Medical Assistant, Employee ID #51 Ultrasound Machine GE, Voluson 730 Pro was identified with dust and dubrie along with splatter stains on top lateral panel and base area of machines. Patient Recovery Room # 3 the following was observed along with Medical Assistant, Employee ID #51 and and Medical Director# 52 A 16-ounce spray bottle containing approximately 8 ounces of dark brown liquid solution. A white label was observed on the container and labeled with only Betadine 100% and a date of 1/8/20. Under the white attached label, the bottled was observed to be labeled as a cleaning lemon scent for use on hard, non-porous environment. See Cetylcide II concentrate. Rust, paint chips and visible dust and debris was observed on the lateral surfaces of the patient exam table and the patient feet stirrups were to have rusty areas. Corometrics Medical Systems, Aloka 620 Ultrasound machine was observed to have visible dust and stains on top control panel, with loose buttons on the top surface and dust and debris on the bottom lateral surface. Gomo Surgical Suction machine was observed to have visible dust, debris, and paint chips, no	6 034		

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6 034	Continued From page 25 electrical safety sticker was identified. A wall mounted dispenser containing hand sanitizer expired 3/2020. Laboratory area the following was observed along with the Medical Director# 52 The following was identified: 2 - Boxes of 30 each Sureflow Winged Infusion set 23-gauge x ¾", Expired 2019 - 01 1 - Box 100 23-gauge Monojet Standard Hypodermic Needles, Expired 2018-1 1 - Box 1- ml syringe - BD 1 ml syringe, Lot # 0324764 Expired 2015 - 11 1 - Box Arriva Medical Lancets 100 count one-time use, Lot # 122709U, Expiration 09/2017 1 - Above sink hand soap dispenser contained hand soap the expired 6/20 Dirty Utility Area area was observed along with Medical Assistant, Employee ID #51 and Medical Director # 52 the following was identified: 4 containers of blood in the medication refrigerator used as control samples for Rh testing Clean supply area/sterilization area was observed along with Employee ID #51 and #52, the following was identified: 6 - MedGyn Disposable Rigid Curette, 16 mm curved, Lot # 051166, Expired 2011-04 1 - MedGyn Disposable Rigid Curette, 12 mm curved, lot # 070946, Expired 2019-06 4 - MedGyn Disposable Rigid Curette, 12 mm curved, Lot # 070946, Expired 2017-09 50 - MedGyn Disposable Rigid Curette, 12 mm curved, lot # 1000226 Expired 2017-09 Interview on 10/19 at: 10:15 am with Medical Assistant ID #51 confirmed the expired items should not be available for use. Employee ID #51 stated we are all responsible for checking for expired items daily and once a month at least.	6 034		

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6 034	Continued From page 26 Employee ID #51 also confirmed the patient treatment rooms should be cleaned and wiped down after each patient use and opened bottles should be labeled with open date and the expiration date. When ask about disinfecting of the vaginal probe used for ultrasound she confirmed the facility sprays the wand with Transeptic cleaning solution and leaves it on for a few seconds then wipes the disinfection off and they do not rinse the probe after the disinfection has been applied. Employee ID #51 also confirmed there was no electrical safety inspection sticker on suction equipment. Employee ID #51 confirmed she was trained by Employee ID #52 on the cleaning of the ultrasound vaginal wands. Interview on 10/19/2020 at 11:30 a.m. with Medical Director, Employee ID #52 confirmed the staff should be monitoring and checking for expired supplies and confirmed the expired supplies should have been removed from the facility. Employee ID #52 also confirmed the storage of blood samples in the medication refrigerator and stated he was unaware that blood samples could not be stored there. Employee ID #52 also confirmed the accumulation of dust, visible rust and chipping of medical equipment and stated he would have it repaired along with the patient's recliners in the recovery room reupholstered. Employee ID #52 confirmed the facility followed CDC guidelines for infection control. Medical Director confirmed the ultrasound vaginal wand was cleaned with Transeptic Cleaning Solution that contained 70% alcohol and was not followed with a disinfection process.	6 034		
6 045	TAC 139.60 Other State and Federal Compliance Requiremen	6 045		

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6 045	Continued From page 27 (a) A licensed abortion facility shall be in compliance with all state and federal laws pertaining to handling of drugs. (b) A licensed abortion facility that provides laboratory services shall meet the Clinical Laboratory Improvement Amendments of 1988, 42 United States Code, §263a, Certification of Laboratories (CLIA 1988). CLIA 1988 applies to all facilities with laboratories that examine human specimens for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. (c) A licensed abortion facility shall ensure that its physicians comply with the Medical Practice Act, Occupations Code, Chapters 151 - 160 and 162 - 165, while functioning in his or her capacity at or for the facility. (d) A licensed abortion facility utilizing the services of a physician assistant(s) shall ensure that its physician assistants comply with the Physician Assistant Licensing Act, Occupations Code, Chapter 204, while functioning in his or her capacity at or for the facility. (e) A licensed abortion facility utilizing the services of a registered nurse shall ensure that its registered nurses comply with the Nursing Practice Act, Occupations Code, Chapters 301 and 304, while functioning in his or her capacity at or for the facility. (f) A licensed abortion facility utilizing the services of a licensed vocational nurse(s) shall ensure that its vocational nurse(s) comply with the Nursing Practice Act, Occupations Code, Chapters 301	6 045		

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6 045	Continued From page 28 and 304, while functioning in his or her capacity at or for the facility. (g) A licensed abortion facility that provides pharmacy services shall obtain a license as a pharmacy if required by the Texas Pharmacy Act, Occupations Code, Chapters 551 - 569. (h) A licensed abortion facility shall comply with the following federal Occupational Safety and Health Administration requirements: (1) 29 Code of Federal Regulations, Subpart E, §1910.38, concerning emergency action plan and §1910.39, concerning fire prevention plans; (2) 29 Code of Federal Regulations, Subpart I, §1910.132, concerning general requirements for personal protective equipment; (3) 29 Code of Federal Regulations, Subpart I, §1910.133, concerning eye and face protection; (4) 29 Code of Federal Regulations, Subpart I, §1910.138, concerning hand protection; (5) 29 Code of Federal Regulations, Subpart K, §1910.151, concerning medical services and first aid; (6) 29 Code of Federal Regulations, Subpart L, §1910.157, concerning portable fire extinguishers; (7) 29 Code of Federal Regulations, Subpart Z, §1910.1030, concerning bloodborne pathogens; and (8) 29 Code of Federal Regulations, Subpart Z,	6 045		

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6 045	Continued From page 29 §1910.1200, Appendices A - E, concerning hazard communication (hazardous use of chemicals). (i) A licensed abortion facility shall not use adulterated or misbranded drugs or devices in violation of the Health and Safety Code, §431.021. Adulterated drugs and devices are described in Health and Safety Code, §431.111. Misbranded drugs or devices are described in Health and Safety Code, §431.112. (j) A licensed abortion facility shall not commit a false, misleading, or deceptive act or practice as that term is defined in the Deceptive Trade Practices-Consumer Protection Act, Business and Commerce Code, §17.46. (k) A licensed abortion facility shall comply with the requirements of the Family Code, §33.002, relating to a Consent Form. (l) A licensed abortion facility shall comply with the requirements of Health and Safety Code, Chapter 171, the Woman's Right to Know Act. (m) A licensed abortion facility shall comply with the requirements of Occupations Code, Chapter 102, Solicitation of Patients. This Requirement is not met as evidenced by: Based on observations, record reviews and interview, the facility failed to ensure staff conducted physical counts and kept accurate records of the disposition of drugs listed in schedules II, III, IV and V of the Comprehensive Drug Abuse Prevention and Control Act. This deficient practice placed the facility at	6 045		

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6 045	Continued From page 30 increased risk of experiencing drug diversions. Findings include: Observation conducted on 10/20/2020 at 1030 am of the facility medication storage area revealed that scheduled medications were being stored in pharmacy stock bottles. Record review of the facility drug records for September 2020 and October 2020 revealed that facility staff were not conducting daily physical counts of scheduled medications. In an interview conducted on 10/20/2020 at 1100 am facility staff #51 and Physician #52 confirmed that daily counts were not being conducted for scheduled drugs. Staff #51 further stated that she did not have the counts recorded.	6 045		