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
	140016	A. BUILDING: _____ B. WING _____	09/30/2021

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
PLANNED PARENTHOOD	920 SAN PEDRO AVENUE STE 150 SAN ANTONIO, TX 78212

(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
6 034	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, regardless of their diagnosis or presumed infection status. (I) Universal/standard precautions apply to:	6 034		

SOD - State Form

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

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6 034	Continued From page 1 (-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 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	6 034		

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6 034	Continued From page 2 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. (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	6 034		

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6 034	Continued From page 3 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 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	6 034		

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6 034	Continued From page 4 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. (B) Semicritical items. (i) Semicritical items include items that come in contact with nonintact skin or mucous	6 034		

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6 034	Continued From page 5 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 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	6 034		

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6 034	Continued From page 6 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 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.	6 034		

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6 034	Continued From page 7 (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 load as to the date and time of sterilization, the sterilizing load number, and the autoclave. (E) External chemical indicators.	6 034		

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6 034	Continued From page 8 (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 list of all items which were used after the last negative biological indicator test shall be submitted to the administrator. (G) Sterilizers.	6 034		

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6 034	Continued From page 9 (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. (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.	6 034		

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6 034	Continued From page 10 (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 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	6 034		

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6 034	Continued From page 11 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. This Requirement is not met as evidenced by: Based on observations and interview, the facility failed to ensure the following:	6 034		

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6 034	Continued From page 12 1. Treatment rooms and equipment were terminally cleaned, or cleaned after patients were seen. 2. Ensure that the sterilization solution for the vaginal ultrasound probes was free from dust and debris. The findings were: Observations on 9/30/21 at 11:15 a.m. of all the treatment rooms revealed there was an unindenitified pinkish/red stain on the floors and walls. Further observations revealed the rolling cart which held the sonogram machine and probes were dusty and had an unidentified pinkish/red substance dried on it. Interview on 9/30/21 with the facility director revealed the facility did not have a terminal cleaning schedule for the treatment rooms nor a checklist to ensure the rooms were cleaned after patients. 2. Observations in the patient treatment rooms revealed that the vaginal ultrasound probe decontamination solution, which was contained in a box on the wall, was found to have dust and unidentified debris in the containers. Interview on 9/30/21 at the time of observation, the facility director confirmed the above findings and the facility's deficient practice.	6 034		

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6 045	TAC 139.60 Other State and Federal Compliance Requiremen (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	6 045		

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6 045	Continued From page 14 Practice Act, Occupations Code, Chapters 301 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	6 045		

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6 045	Continued From page 15 (8) 29 Code of Federal Regulations, Subpart Z, §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:	6 045		