

Texas Health and Human Services Commission

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 140016	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 09/09/2020
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NAME OF PROVIDER OR SUPPLIER PLANNED PARENTHOOD	STREET ADDRESS, CITY, STATE, ZIP CODE 920 SAN PEDRO AVENUE STE 150 SAN ANTONIO, TX 78212
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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		

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

TITLE

President + Chair

(X6) DATE


10.15.20

STATE FORM NO. 6599 6S2611 If continuation sheet 1 of 18

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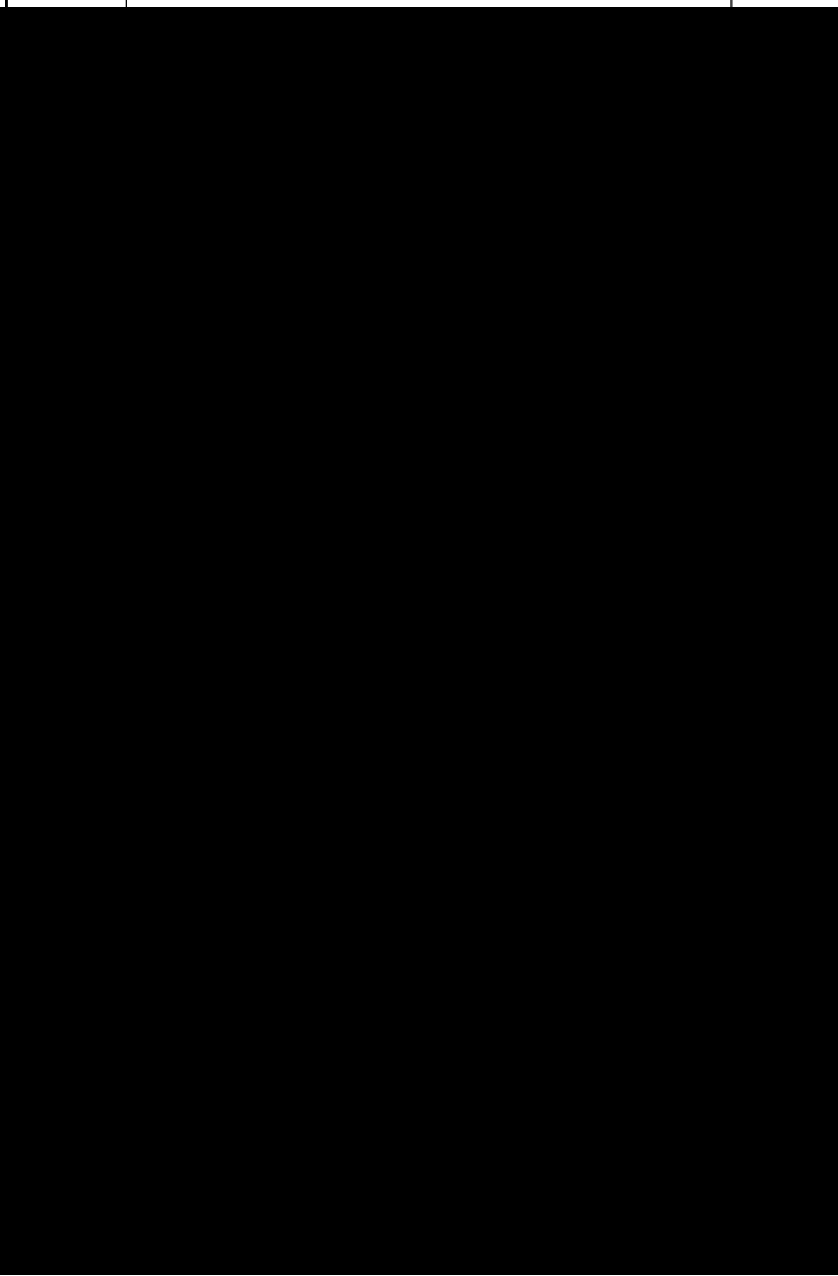
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6 000	<p>Continued From page 1</p> <p>under Health and Safety Code, Chapter 243; or</p> <p>(iii) the office of a physician licensed by the Texas Medical Board and authorized to practice medicine in the State of Texas, unless the office is used for 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).</p> <p>An onsite inital licensure survey was conducted using the Texas Administrative Code Title 25, Chapter 139 Abortion Facility Licensing Regulations. An entrance conference was held with the Facility Administrator on 09/09/20. The purpose and process of the survey was discussed, and an opportunity was given for questions.</p> <p>An exit conference was held the afternoon of 09/09/20 with the Facility Administrator and other members of management onsite. Preliminary findings of the survey were discussed, and an opportunity given for questions and discussion.</p> <p>Recommend licensure based on an approved plan of correction.</p>	6 000		09/21/2020

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6 034	Continued From page 3	6 034		
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 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.</p> <p>(b) Prevention and control of the transmission of HIV, HBV, HCV, TB, and S. spp.</p> <p>(1) Universal/standard precautions.</p> <p>(A) An abortion facility shall ensure that all staff comply with universal/standard precautions as defined in this paragraph.</p> <p>(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.</p> <p>(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.</p>	6 034	<p>RE: TAC 139.49</p> <p>Immediately following survey, on 09/10 the Center Manager in coordination with the Director of Nursing was held a mandatory staff training (see attached, Tac139.49 Staff Trng) to review and discuss corrective measures for all identified survey findings with facility staff. Items reveiwed included:</p> <ol style="list-style-type: none"> 1. Clear dilineation from Clean & Dirty areas; 2. Proper Sterilization & Storage processes of instruments; 3. Proper cleaning process for the vaginal probe Gus System; and 4. Disiposible pillow cases. <p>(see attachments, TAC139.49)</p> <p>Additionally, the Center Manager will continue to monitor for compliance within 30/60 days to ensure all corrections are maintained. This audit will be reported and recorded at the scheduled Quality Assurance and Risk Management group meeting, on 10/29/2020.</p>	<p>09/10/2020</p> <p>09/10/2020</p> <p>09/10/2020</p> <p>09/17/2020</p>

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6 034	<p>Continued From page 4</p> <p>(I) Universal/standard precautions apply to:</p> <p>(-a-) blood;</p> <p>(-b-) body fluids, secretions, and excretions 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</p>	6 034		

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6 034	<p>Continued From page 5</p> <p>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> <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</p>	6 034		

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6 034	<p>Continued From page 6</p> <p>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.</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>	6 034		

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6 034	<p>Continued From page 7</p> <p>(ii) There shall be no evident cracks or fissures in the box locks, and the hinges shall work freely.</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>	6 034		

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6 034	<p>Continued From page 8</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 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</p>	6 034		

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6 034	<p>Continued From page 9</p> <p>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> <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</p>	6 034		

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6 034	<p>Continued From page 10</p> <p>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 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>	6 034		

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6 034	<p>Continued From page 11</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 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>	6 034		

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6 034	<p>Continued From page 12</p> <p>(G) Sterilizers.</p> <p>(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.</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</p>	6 034		

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6 034	<p>Continued From page 13</p> <p>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 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>	6 034		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 140016	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED 09/09/2020
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NAME OF PROVIDER OR SUPPLIER PLANNED PARENTHOOD	STREET ADDRESS CITY STATE ZIP CODE 920 SAN PEDRO AVENUE STE 150 SAN ANTONIO, TX 78212
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6 034	<p>Continued From page 14</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> <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 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 observations and interview, the facility failed to ensure the following:</p>	6 034		

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6 034	<p>Continued From page 15</p> <ol style="list-style-type: none"> All Items were properly packaged and sterilized, and articles to be sterilized were arranged so all surfaces were to be directly exposed to the sterilizing agent for the prescribed time and temperature utilizing chemical indicators on each package to be sterilized. Ensure universal/standard precautions includes procedures for disinfection and sterilization of reusable medical devices and the appropriate use of protective barriers was in place. Provide a separate clean sink for hand washing in the surgical instrument sterilization and decontamination area. Ensure that the sterilization solution for the vaginal ultrasound probes was free from dust and debris. <p>The findings were:</p> <ol style="list-style-type: none"> Observation on 9/9/20 in the facility instrument storage room revealed the peel pouches were stored folded, resulting in open gaps exposed to air which made the instruments no longer sterile. <p>Further observations of the peel pouches revealed 16 peel pouches of clamps and scissors were sterilized and stored in a closed position, resulting in all areas not being exposed to the sterilization agent. 2 of the peel pouches of scissors revealed the closed scissors had poked through the pouch and created an open hole.</p> <p>Continued observation revealed a single peel</p>	6 034		

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6 034	<p>Continued From page 16</p> <p>pouch containing approximately 10 scissors all in a closed position, the peel pouch had a hole and there was no indicator to confirm whether the instruments were sterile or not.</p> <p>Interview on 9/9/20 with the facility director confirmed the above findings.</p> <p>2. Observations in the recovery room revealed there were 4 recovery chairs. All 4 chairs had a heating pad. There was no protective barrier covering the heating pads. 2 of the heating pads was covered in a cloth like substance</p> <p>Interview on 9/9/20 with the facility Registered Nurse revealed they didn't use protective barriers on the heating pads for each patient, and only wiped down the heating pads between patient use. Even the cloth like heating pads.</p> <p>3. Observations in the combined facility sterilization and decontamination area revealed only one sink was available for use and was location on the "dirty" decontamination side of the room where biologically contaminated surgical instruments and products of conception were processed. This sink also contained the only eye wash station in the facility. Further observations revealed that there was no demarcation between the "clean" and "dirty" sides of the processing area, with cross over contamination occurring.</p> <p>4. 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.</p>	6 034		

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6 034	Continued From page 17 In an interview conducted on 09/09/2020 at the time of observation, the Registered Nurse confirmed the above findings and the facility's deficient practice.	6 034		