State of Virginia

| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
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| | FTAF-001 | A. BUILDING _____ B. WING _____ | 05/01/2012 |

| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
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| PLANNED PARENTHOOD OF SOUTHEASTERN VIR | 515 NEWTOWN ROAD VIRGINIA BEACH, VA 23462 |

| (X4) ID PREFIX TAG | SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION) | ID PREFIX TAG | PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY) | (X5) COMPLETE DATE |
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| T 000 | 12 VAC 5- 412 Initial comments<br><br>An announced Initial Licensure Abortion Facility inspection and Complaint Investigation (#2012-AC006) was conducted at the above referenced facility on May 1. 2012 by an Acute Care Supervisor and three (3) Medical Facility Inspectors from the Virginia Department of Health's, Office of Licensure and Certification.<br><br>The complaint was not substantiated<br><br>Planned Parenthood of Southeast Virginia which is located in Virginia Beach was found out of compliance with the State Board of Health 12 VAC 5-412, Regulations for Abortion Facility's effective December 29, 2011. Deficiencies were identified and cited, and will follow in this report. | T 000 | | |
| T 035 | 12 VAC 5-412-150 Policy and procedure manual.<br><br>Each abortion facility shall develop, implement and maintain an appropriate policy and procedures manual. The manual shall be reviewed annually and updated as necessary by the licensee. The manual shall include provisions covering at a minimum, the following topics:<br>1 Personnel;<br>2. Types of elective and emergency procedures that may be performed in the facility;<br>3. Types of anesthesia that may be used;<br>4. Admissions and discharges, including criteria for evaluating the patient before admission and before discharge;<br>5. Obtaining written informed consent of the patient prior to the initiation of any procedures;<br>6. When to use ultrasound to determine gestational age and when indicated to assess patient risk;<br>7. Infection prevention; | T 035 | T 035 PPSEV personnel policies amended to state that in addition to the nationwide criminal background check conducted on all employees, employees not licensed by the Board of Pharmacy and whose job duties provides them access to controlled substances within our abortion facility will also have a criminal record report from the Virginia State Police. See Background Check Policy, Exhibit (A). The New Hire Checklist for All Employees was revised to include a provision for employees not licensed by the Board of Pharmacy and whose job duties provide them with access to controlled substances within our abortion facility needing a criminal | 6/4/12 |

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| LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE |
|---|---|---|
| Patrick J. Hurd, Esq. | CEO | 6/4/12 |

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| T 035 | Continued From Page 1<br>8. Risk and quality management;<br>9. Management and effective response to medical and/or surgical emergency;<br>10. Management and effective response to fire;<br>11. Ensuring compliance with all applicable federal, state and local laws;<br>12. Facility security;<br>13. Disaster preparedness;<br>14. Patient rights;<br>15. Functional safety and facility maintenance; and<br>16. Identification of the person to whom responsibility for operation and maintenance of the facility is delegated and methods established by the licensee for holding such individual responsible and accountable. These policies and procedures shall be based on recognized standards and guidelines. | T 035 | T 035 continued.<br>record report from the Virginia State Police, in addition to the nationwide criminal background check performed on all new employees. For quality control of this policy, the Personnel File Maintenance Report has been revised to include the confirmation of the receipt of the criminal record report from the Virginia State Police for these specific employees, in addition to the nationwide criminal background check already included on the Report. | |

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| T 035 | Continued From Page 2 | T 035 | | |

This RULE: is not met as evidenced by:
Based on interview, review of 15 personnel files and policies, it was determined that the facility's personnel policies failed to include a statement about any compensated employee(s) not licensed by the Board of Pharmacy and whose job duties provides them access to controlled substances within the abortion facility must have a criminal record report form the Virginia State Police.

The findings include:
A) On May 1, 2012 between 2:45 PM and 4:36 PM, six (6) personnel files for employees whose job duties provide them access to controlled substances within the facility were reviewed in the facility's conference room. Employee's #9 and #14's personnel files failed to contain a criminal record report from the Virginia State Police.
B) On May 1, 2012 between 2:45 PM and 4:36 PM, an interview was conducted with employee #1 (Vice President of Operations), in the facility's conference room. Employee #1 acknowledged that two (2) employee's (#9 & 14) have job duties that provide access to controlled substances within the facility. Employee #1 also acknowledged that the personnel files of employee #9 and #14 failed to contain a criminal record report from the Virginia State Police
C) On May 1, 2012 between 2:00 PM and 5:30 PM the facility's polices were reviewed in the facility's conference room. The facility failed to have a personnel policy that stated any compensated employee not licensed by the Board of Pharmacy and whose job duties provide access to controlled substances within the facility are to have a criminal record report from the Virginia State Police.

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| T 070 | Continued From Page 3 | T 070 | | |
| T 070 | 12 VAC 5-412-170 C Personnel<br><br>C. Each abortion facility shall obtain a criminal history record check pursuant to 32.1-126.02 of the Code of Virginia on any compensated employee not licensed by the Board of Pharmacy, whose job duties provide access to controlled substances within the abortion facility.<br><br>This RULE: is not met as evidenced by:<br>Based on interview, review of fifteen (15) personnel files and policies, it was determined that the facility failed to have a criminal record report obtained through the Virginia State Police for two (2) out of six (6) compensated employee's whose job duties provide access to controlled substances (employee #'s 9 and 14).<br>The findings include:<br>A) On May 1, 2012 between 2:45 PM and 4.36 PM, six (6) personnel files of employees whose job duties provide access to controlled substances within the facility were reviewed in the facility's conference room. Employee's #9 and #14's personnel files failed to contain a criminal record report from the Virginia State Police.<br>B) On May 1, 2012 between 2:45 PM and 4:36 PM an interview was conducted with employee #1 (Vice President of Operations), in the facility's conference room. Employee #1 acknowledged that two (2) employees (#9 & 14) personnel files have job duties that provide access to controlled substances within the facility. Employee #1 acknowledged that the personnel files for employee #9 and #14 failed to contain a criminal record report from the Virginia State Police.<br>C) On May 1, 2012 between 2:00 PM and 5:30 PM, the facility's polices were reviewed in the facility's conference room. The facility failed to have a personnel policy that included the statement that compensated employee(s) not licensed by the Board of Pharmacy and whose job | T 070 | T 070 Employees #9 and # 14 completed the Virginia State Police criminal record application and PPSEV filed the formal requests for the criminal record reports with the Virginia State Police, adding to the nationwide criminal background check already received and placed in the personnel files for employee #'s 9 and 14 pursuant to PPSEV personnel policies. See Background Check Policy, Exhibit (A). | 6/4/12 |

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| T 070 | Continued From Page 4<br><br>duties provide access to controlled substances within the facility are to have a criminal record report Virginia State Police report. | T 070 | | |
| T 170 | 12 VAC 5-412-220 B Infection prevention<br><br>B. Written infection prevention policies and procedures shall include, but not be limited to:<br>1. Procedures for screening incoming patients and visitors for acute infectious illnesses and applying appropriate measures to prevent transmission of community acquired infection within the facility;<br>2. Training of all personnel in proper infection prevention techniques;<br>3. Correct hand-washing technique, including indications for use of soap and water and use of alcohol-based hand rubs;<br>4. Use of standard precautions;<br>5. Compliance with blood-bourne pathogen requirements of the U.S. Occupational Safety & Health Administration.<br>6. Use of personal protective equipment;<br>7. Use of safe injection practices;<br>8. Plans for annual retraining of all personnel in infection prevention methods;<br>9. Procedures for monitoring staff adherence to recommended infection prevention practices; and<br>10. Procedures for documenting annual retraining of all staff in recommended infection prevention practices.<br><br>This RULE: Is not met as evidenced by:<br>Based on observations and interviews it was determined that the facility's staff failed document refrigerator temperatures and therefore were unable to ensure the contents of the refrigerators were maintained at the correct temperature for two (2) of two (2) refrigerators observed in the | T 170 | T 170 The refrigerator Temperature Logs for both refrigerators were modified to include instructions to record temperatures daily rather than only on days when the laboratory and recovery room were in use. See Refrigerator Temperature Log, Exhibit (B). This Refrigerator Temperature Log was also placed on the refrigerator in the recovery room. Staff assigned to the laboratory and to the recovery room were instructed and trained to record temperatures daily for each of these refrigerators and to enter the temperatures in the Refrigerator Temperature Log daily rather than only on days when the laboratory and recovery room are in use. The Laboratory Manual clearly states that daily temperatures must be recorded for the refrigerators. Periodic walk-through surveys and formal audits will be conducted to assure daily recording of temperatures for refrigerators. | 6/4/12 |

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| T 170 | Continued From Page 5<br><br>facility. Specifically, the refrigerator in the laboratory did not have temperatures recorded each day the facility was open and the refrigerator in the facility's Recovery Room area, failed to have any temperatures recorded.<br><br>The findings were:<br><br>1. During the initial tour of the facility on May 1, 2012 on or about 11 AM, a "REFRIGERATOR TEMPERATURE LOG" was noted on the front of the lab's refrigerator which is located in the lab. The log was for April of 2012 and had multiple days with no temperatures recorded. Days the facility was open and had no recorded temperature readings were: 4/9; 4/11; 4/16 - 18; 4/23; 4/25; 4/28 and 4/30/12. The VP (Vice President) of Operations who accompanied this writer during the tour was asked about the missing temperatures and stated, they only record temperatures on the days the lab is actually used. She went on to clarify that even though the facility is open everyday, they don't use the lab every day.<br><br>2. Also during the tour, a refrigerator was noted to be used in the Recovery Room area . No "REFRIGERATOR TEMPERATURE LOG" was used to record refrigerator temperatures on this refrigerator. | T 170 | | |
| T 175 | 12 VAC 5-412-220 C Infection prevention<br><br>C. Written policies and procedures for the management of the facility, equipment and supplies shall address the following:<br>1. Access to hand-washing equipment and adequate supplies (e.g., soap, alcohol-based hand rubs, disposable towels or hot air dryers);<br>2. Availability of utility sinks, cleaning supplies and other materials for cleaning, disposal, | T 175 | T 175 Bins of two different colors were obtained and staff instructed to use the gray color bin for instruments to be soaked and cleaned in the Alconox solution and the gold bin to hold instruments transferred from the Alconox solution bin to be transported to the | 6/4/12 |

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| T 175 | Continued From Page 6<br><br>storage and transport of equipment and supplies;<br>3. Appropriate storage for cleaning agents (e.g., locked cabinets or rooms for chemicals used for cleaning) and product-specific instructions for use of cleaning agents (e.g., dilution, contact time, management of accidental exposures);<br>4. Procedures for handling, storing and transporting clean linens, clean/sterile supplies and equipment;<br>5. Procedures for handling/temporary storage/transport of soiled linens;<br>6. Procedures for handling, storing, processing and transporting regulated medical waste in accordance with applicable regulations;<br>7. Procedures for the processing of each type of reusable medical equipment between uses on different patients. The procedure shall address:<br>(i) the level of cleaning/disinfection/sterilization to be used for each type of equipment,<br>(ii) the process (e.g., cleaning, chemical disinfection, heat sterilization); and<br>(iii) the method for verifying that the recommended level of disinfection/sterilization has been achieved. The procedure shall reference the manufacturer's recommendations and any applicable state or national infection control guidelines;<br>8. Procedures for appropriate disposal of non-reusable equipment;<br>9. Policies and procedures for maintenance/repair of equipment in accordance with manufacturer recommendations;<br>10. Procedures for cleaning of environmental surfaces with appropriate cleaning products;<br>11. An effective pest control program, managed in accordance with local health and environmental regulations; and<br>12. Other infection prevention procedures necessary to prevent/control transmission of an infectious agent in the facility as recommended or required by the department. | T 175 | T 175 continued.<br>clean utility room for autoclaving. A Dirty Room Daily Process Flow Chart was created to appropriately display the correct flow, container usage, and proper decontamination in the dirty utility room; see Exhibit (C). This chart is visibly posted in the dirty utility room for all staff to see. Measuring containers were placed in the dirty utility room for staff access and accurate measurements. Staff members were trained in the proper measuring and use of the Alconox solution in strict adherence to the manufacturer's stated instructions and signs were posted in the dirty utility room. See Dirty Room Cleaning Agents, Exhibit (D). Periodic informal walk-through surveys will be conducted, as well as formal audits to assure that staff complies with the cleaning procedure and manufacturer's use instructions for the cleaning solution. At a minimum, annual training will be carried out or more frequently as needed based on the survey and audit results. | |

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| T 175 | Continued From Page 7 | T 175 | | |

This RULE: is not met as evidenced by:
Based on interviews and document reviews the facility staff failed to ensure they followed the manufactures directions when using a cleaning detergent that is used for the cleaning of reusable medical equipment that is used between patients.

The Findings Include:

On 5/1/12 during the initial tour of the facility at approximately 11:45 the dirty utility room was observed. There were approximately 7 gray 12 quart plastic containers sitting on the counter top in the dirty utility room. There were no measuring instruments observed on the counters. There was a cup containing brushes sitting on the counter.

The Vice President of Operations (VPO) explained the dirty utility room was where the dirty instruments used in a procedure were cleaned prior to sterilization. Employee #4 was identified by the VPO as one of the employees who would be responsible for cleaning dirty instruments.

Employee #4 was asked to explain the process of how the instruments are brought into the dirty utility room and how the instruments are then cleaned. Employee #4 stated, "The doctor brings the instruments and the medical waste in the dirty utility room in one of those containers." Employee #4 pointed to the gray 12 quart (3 gallons) containers sitting on the counter. Employee #4 stated, "He (the doctor) removes the medical waste from the container and I fill it about half way full with water. I add about 1 (one) teaspoon of the Alconox (the detergent used for cleaning medical instruments). I then used those brushes (Employee #4 pointed to the brushes in the cup on the counter) to scrub the instruments then the instruments are rinsed. I place a towel in the

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| T 175 | Continued From Page 8<br><br>bottom of another container, put the the instruments in the container, cover them with another towel and carry them to the clean utility room were they get wrapped and sterilized. I will use the same water about 3-4 times before it is changed."<br><br>Employee #4 was asked how she could tell which of the containers were dirty or clean. Employee #4 stated. "I can't I guess we need to have a different color to put the instruments in once they are clean."<br><br>The instructions on the Alconox container states "Make a fresh 1% solution (2 and 1/2 Tbsp. (tablespoons) per gal. (gallon), 1 and 1/4 oz. (ounce) or 10 grams per liter) in cold, warm or hot water. If available use warm water.... RINSE THOROUGHLY- preferably with running water. For critical cleaning, do final or all rinsing in distilled, deionzied, or purified water..." | T 175 | | |
| T 275 | 12 VAC 5-412-260 C Administration, storage and dispensing of dru<br><br>C. Drugs maintained in the facility for daily administration shall not be expired and shall be properly stored in enclosures of sufficient size with restricted access to authorized personnel only. Drugs shall be maintained at appropriate temperatures in accordance with definitions in 18 VAC 110-20-10<br><br>This RULE: is not met as evidenced by:<br>Based on observations and interviews the agency staff failed to ensure opened, accessed and available for use medications, syringes and sutures were not expired and were dated as to when they were opened. | T 275 | T 275 The items identified in the findings were immediately removed from the exam room(s) and wasted/ disposed of in accordance with applicable PPSEV disposal policies and procedures. Staff members were retrained in PPSEV policy for proper labeling and disposal of medications, multi-dose and other reusable items. This was reinforced with the establishment of a written PPSEV policy, Handling and Expiration of Multi-Dose/Reusable Medical Items Policy, | 6/4/12 |

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| T 275 | Continued From Page 9<br><br>The Findings Include:<br><br>During the initial tour of the agency on 5/1/12 between 11 A.M. and 12 P.M. with the Vice President of Operations the following rooms contained the following items:<br>Exam room #6:<br>1 container of Monocryl sutures expired 1/2011<br>Container of Baking Soda, no date<br>1 tube of Trimo San Vaginal gel expired 11/2008<br>Storage Room:<br>25 - 10 cc syringes with various expiration dates from 2006 to 2008<br>29 - 20 cc syringes with various expiration dates in 2010<br>Procedure Room #1:<br>4 - 50 ml bottles of Marcaine 0.5% had no date indicating when they were opened and accessed<br>Procedure Room #2:<br>16 oz. bottle of Betadine with the expiration date of 2/12.<br><br>The Vice President of Operations stated, "Those things should not be in here. You are correct. I know what they did with the Betadine. They poured it from the larger gallon bottle into the smaller bottle that looks like it is expired. We will have to do something else." | T 275 | T 275 continued.<br>which provides the written procedure for labeling, handling, and expiration of medications, multi-dose, and other reusable medical items. See Exhibit (E). Periodic informal and formal audits will be performed in the facility to verify compliance with this policy and procedure. | |
| T 345 | 12 VAC 5-412-320 Record storage<br><br>Provisions shall be made for the safe storage of medical records or accurate and eligible reproductions thereof according to applicable federal and state law, including the Health Insurance Portability and Accountability Act (42 USC 1320d et seq.). In the event of closure of the facility, the facility shall notify OLC concerning the location where patient medical records are stored. | T 345 | T 345 The PPSEV Medical Records Storage and Retention Policy was revised to include a statement that OLC shall be notified of the location of patient records storage if the facility were to close. See Medical Records Storage and Retention Policy, Exhibit (F). | 6/4/12 |

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| T 345 | Continued From Page 10<br><br>This RULE: is not met as evidenced by:<br>Based on review of the facility's Policy and Procedure Manual and interview, it was determined the facility failed to have a policy that addressed, the Office of Licensure and Certification (OLC), would be notified of where records would be stored if the facility would close.<br><br>The findings were:<br><br>The facility's Policy and Procedure Manual was reviewed in the facility on May 1, 2012 between 2 and 5 PM. The manual failed to contain a specific policy that addressed the OLC being notified of the location of patient records if the facility were to close.<br><br>The VP of Operations was asked if they had a policy that addressed the OLC being notified of where records would be stored if the facility closed and she stated, they did not have a policy addressing that. | T 345 | | |
| T 375 | 12 VAC 5-412-360 A Maintenance<br><br>A. The facility's structure, its component parts, and all equipment such as elevators, heating, cooling, ventilation and emergency lighting, shall be all be kept in good repair and operating condition. Areas used by patients shall be maintained in good repair and kept free of hazards. All wooden surfaces shall be sealed with non-lead-based paint, lacquer, varnish, or shellac that will allow sanitization.<br><br>This RULE: is not met as evidenced by:<br>Based on observations made during the initial tour of the facility it was determined that the facility failed to ensure the equipment was in good repair, | T 375 | T 375 The 5 metal storage cabinets have been removed from use in the procedure rooms. Items previously stored in the cabinets have been relocated to proper storage cabinets in the abortion facility. Items for use during patient procedures on a given day in each procedure room shall be placed upon stainless steel rolling trays. | 6/4/12 |

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| NAME OF PROVIDER OR SUPPLIER | STREET ADDRESS, CITY, STATE, ZIP CODE |
|---|---|
| PLANNED PARENTHOOD OF SOUTHEASTERN VIR | 515 NEWTOWN ROAD VIRGINIA BEACH, VA 23462 |

| (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 |
|---|---|---|---|---|
| T 375 | Continued From Page 11<br><br>free of hazards or maintain infection control precautions for the cleaning and disinfection of all surfaces. More specifically, five (5) of five (5) metal cabinets used in the procedures rooms could not be completely cleaned or sanitized due to multiple chips in the paint which were found on all cabinets. One cabinet also had what appeared to be a large area of tape residue on one side of the cabinet.<br><br>The findings were:<br><br>A tour of the facility was conducted on May 1, 2012 beginning at approximately 11 AM.<br><br>The facility has two (2) procedure rooms that are used to perform procedures on patients. Procedure room #1 has three (3) green metal storage cabinets in it. All the cabinets had scratches and or chips of paint missing on the front, the sides and several legs.<br><br>Procedure room #2 had two (2) metal storage cabinets in it. Both cabinets had chips and scratches. The taller cabinet also had a large area (approximately 10 inches wide by 1 inch tall of what appears to be a tape residue. | T 375 | | |
| T 380 | 12 VAC 5-412-360 B Maintenance<br><br>B. When patient monitoring equipment is utilized, a written preventative maintenance program shall be developed and implemented. This equipment shall be checked and/or tested in accordance with manufacturer's specifications at periodic intervals, no less than annually, to ensure proper operation and a state of good repair. After repairs and/or alterations are made to any equipment, the equipment shall be thoroughly tested for proper operation before it is | T 380 | T 380 The specific equipment items delineated were inspected and safety checks performed and stickers applied with the date, technician and company performing the inspection/ safety check. In addition, the technician conducted a walk-through survey of the entire facility and performed an inspection and safety check of all | 6/4/12 |

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| T 380 | Continued From Page 12<br><br>returned to service. Records shall be maintained on each piece of equipment to indicate its history of testing and maintenance.<br><br>This RULE: is not met as evidenced by:<br>Based on observations and interview, it was determined that the facility failed to maintain a preventative maintenance program at least annually on all equipment. Specifically no preventative and or safety checks were documented for eight (8) heating pads, a microscope or a doppler. A preventative maintenance sticker was found on a blood typing machine (for Rh factors) but it was older than 12 months.<br><br>The findings were:<br><br>During a tour of the facility beginning at 11 AM on May 1, 2012 the following pieces of equipment failed to have any documented evidence of being inspected for safe use or preventative maintenance being conducted on them or, were inspected more than 12 months ago.<br><br>Eight (8) heating pads, six (6) of which were in the Recovery Room for patient use and one in each of the two (2) exam rooms. The heating pads found in the exam rooms were used to warm instruments that are used to exam patients with.<br><br>The microscope and the blood typing machine are both used in the lab to examine specimens. The microscope did not have any documented evidence of being inspected and the blood typing machine had a sticker saying it was inspected 8/20/10 which is greater than 12 months ago The lab has been in operation for greater than 12 months. | T 380 | T 380 continued.<br>equipment and affixed inspection tags to each item inspected with the date, technician and company performing the inspection. Each item has been added to the list of items to be inspected at least annually by the company. This list is inspected by staff at the abortion facility to ensure each item has received preventive maintenance following the annual inspections. New equipment purchased and leased for use in the facility shall also be inspected and a tag affixed with the date, technician and company performing the inspection/ safety check. | |

State of Virginia

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