EXHIBIT A-A

EXHIBIT A

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	03/13/2019

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REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

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L 000	Initial Comments An on-site, unannounced state licensure survey was conducted from 03/11/19 to 03/13/19 in order to determine compliance with applicable statutes and regulations governing abortion facilities, including 19 CSR 30-30.050, 060, and 061 and Chapter 188, RSMo (Regulation of Abortions). See below for findings:	L 000		
L 069	19 CSR 30-30.020(1)(A)(6) A written plan shall provide A written plan shall provide for the evacuation of patients, visitors and personnel in the event of fire or other disaster within the facility and for an alarm system to notify personnel. Personnel are to be acquainted with the evacuation plan to properly perform their duties in the event of a fire or disaster. This regulation is not met as evidenced by: Based on policy review, record review, and interview, the facility failed to ensure that all employees participated in a fire drill at least annually. The Abortion Facility does an average of 216 cases per month. On the first day of the survey, there were 21 procedures. Findings included: 1. Review of the facility's policy titled, "Natural Disasters, Chemical Attacks, and Physical Actions," dated 04/18, showed that fire drills are performed at least annually. All staff should be involved. The drill is to familiarize staff with assigned emergency duties.	L 069		

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L 069	Continued From page 1 2. Review of the facility's records of fire drills showed that the most recent fire drill occurred on 11/30/18 and the previous drill occurred on 06/02/17. (Note: The time between drills was more than 12 months). The list of staff on the drill from 11/30/18 showed 30 names and 10 were indicated as having been part of the drill. 3. During an interview on 03/11/19 at 4:15 PM, Staff N, Clinical Quality Improvement Manager, stated that she did not know why the fire drills were more than 12 months apart and that no physicians were listed as participating as there were none onsite that day.	L 069		
L1069	19 CSR 30-30.060(1)(A)(1) The governing body shall have full legal The governing body shall have full legal responsibility for determining, implementing, and monitoring policies governing a facility's total operation and for ensuring that the policies are administered in a manner to provide acceptable care in a safe environment and in accordance with all legal requirements and standards of care. This regulation is not met as evidenced by: Based on record review the facility failed to ensure all policies were written to maintain compliance with all regulatory requirements for obtaining a complete medical history to include a pelvic examination. Findings included: 1. Licensure regulations at 19 CSR 30-30.060 (2)(D) require a written medical history shall be obtained for each patient. A health assessment	L1069		

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L1069	Continued From page 2 including a pelvic examination shall be performed. Pregnancy shall be confirmed by clinical evidence and laboratory tests. This information shall be used in determining the duration of gestation, identifying preexisting medical or other complications, and detecting any factors which could influence the choice of the procedure, anesthesia, or preoperative and postoperative management. If the physician determines gestation is beyond the first trimester, an ultrasound examination shall be performed and results shall be recorded in the patient's medical record. 2. Review of the facility's document titled, "Minutes from RHS (Reproductive Health Services) Provider Training's Regarding SB (Senate Bill) 5 and Corrections for DHSS (Department of Health and Senior Services) Inspection," dated 04/26/18, showed: - Pelvic exams done prior to surgical abortion will continue and should be documented in the surgical abortion template as has been required - current practice. - Pelvic exams will only be done for medical abortion when medically indicated - current practice.	L1069		
L1076	19 CSR 30-30.060(1)(A)(8) The governing body, ensure abortion facility The governing body, through the administrator, shall ensure that the abortion facility abides by all applicable state and federal laws and regulations. This shall include, but not be limited to, compliance with Chapter 188, RSMo. This regulation is not met as evidenced by:	L1076		

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L1076	Continued From page 3 Based on policy review, record review and interview, the facility failed to ensure the physician who obtained the informed consent was the physician who performed or induced the abortion for two (#7 and #10) of 10 patients' abortion medical records reviewed. The Abortion Facility does an average of 216 cases per month. On the first day of the survey, there were 21 procedures. Findings included: 1. The physician who is to perform or induce the abortion shall provide the information required in section 188.027.6, RSMo, orally and in person to the patient at least seventy-two (72) hours before the abortion. 2. Review of the facility's policy titled, "Consent and Informed Consent," dated 06/16, showed per Missouri SB (Senate Bill) 793 and SB5 ALL women who request an abortion in Missouri must meet with a Qualified Health Professional and the physician who will provide the abortion procedure for consultation at least 72 hours prior to an abortion procedure (or informed consent may be given by physician only). 3. Review of Patient #7's medical record showed: - On 11/15/18, Staff GG, Medical Doctor (MD), signed the facility's document titled, "State of Missouri Department of Health and Senior Services Informed Consent Checklist - Abortion." - On 11/20/18, Staff AA, MD, administered Mifepristone (stops the pregnancy from growing and is the first of two medications administered in a medication-induced abortion). 4. During an interview on 03/12/19 at 1:04 PM,	L1076		

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L1076	Continued From page 4 Staff A, Director of Surgical Services, stated that: - Staff AA was a fellow (physician who has completed their residency and elects to complete further training in a specialty) who worked with Staff GG. - The Mifepristone agreement (medication agreement form signed by the patient and provider [physician] that explains that the medications will end the pregnancy, what to expect, and directions) was signed by the patient and Staff AA. 5. Review of Patient #10's medical record showed: - On 08/29/18, Staff FF, Doctor of Osteopathic Medicine (physician whose training focused on emphasizing a whole-person approach to treatment and care), signed the facility's document titled, "State of Missouri Department of Health and Senior Services Informed Consent Checklist - Abortion." - On 09/05/18, Staff AA attempted a surgical abortion, which was unsuccessful. - On 09/05/18, Staff AA administered Mifepristone. - A separate document generated by Staff FF that included: * "I was present for the procedure and agree with the treatment and follow up plan(s)." * "TV (Trans-vaginal) U/S (ultrasound) was able to confirm the path, but given the unique position of the uterus and patient's discomfort, coupled with early gestational age, we opted to stop the SAB (surgical abortion) and proceed with MAB (medical abortion)." 6. During an interview on 03/13/19 at 1:24 PM, Staff EE, MD, stated that: - The supervising physician was responsible for	L1076		

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L1076	Continued From page 5 care of the patient; - The supervising physician for Patient #7 was Staff GG; - Staff GG did not complete a supervisory note for Patient #7; - Staff AA could administer the Mifepristone without the supervisory physician in the room; - Staff GG was in the room during the surgical abortion attempt on Patient #7 (performed by Staff AA); and - The supervising physician for Patient #10 was Staff FF.	L1076		
L1103	19 CSR 30-30.060(2)(D) A written medical history shall be obtained A written medical history shall be obtained for each patient. A health assessment including a pelvic examination shall be performed. Pregnancy shall be confirmed by clinical evidence and laboratory tests. This information shall be used in determining the duration of gestation, identifying preexisting medical or other complications, and detecting any factors which could influence the choice of the procedure, anesthesia, or preoperative and postoperative management. If the physician determines gestation is beyond the first trimester, an ultrasound examination shall be performed and results shall be recorded in the patient's medical record. This regulation is not met as evidenced by: Based on record review and interview, the facility failed to perform the pelvic examination at a time that could influence the choice of the planned procedure and pre-operative management for nine (#1, #2, #3, #4, #5, #6, #7, #8, and #10) of nine patients' abortion medical records reviewed.	L1103		

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L1103	Continued From page 6 The Abortion Facility does an average of 216 cases per month. On the first day of the survey, there were 21 procedures. Findings included: 1. 188.027 states that Consent to an abortion is voluntary and informed and given freely and without coercion if, and only if, at least seventy-two hours prior to the abortion: 1(f)- the physician who is to perform or induce the abortion, a qualified professional, or the referring physician informs the woman of the gestational age of the unborn child at the time the abortion is to be performed or induced. 30-30.060 (D) A written medical history shall be obtained for each patient. A health assessment including a pelvic examination shall be performed. Pregnancy shall be confirmed by clinical evidence and laboratory tests. This information shall be used in determining the duration of gestation, identifying preexisting medical or other complications, and detecting any factors which could influence the choice of the procedure, anesthesia, or preoperative and postoperative management. 2. Review of the facility's document titled, "Minutes from RHS (Reproductive Health Services) Provider Trainings Regarding SB (Senate Bill) 5 and Corrections for DHSS (Department of Health and Senior Services) Inspection," dated 04/26/18, showed: - Pelvic exams done prior to surgical abortion will continue and should be documented in the surgical abortion template as has been required - current practice. - Pelvic exams will only be done for medical	L1103		

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L1103	Continued From page 7 abortion when medically indicated - current practice. 3. Review of medical records for Patient #1, #2, #3, #4, #5, #6, and #8 with admission dates ranging from 11/17/18 to 02/23/19 for a surgical abortion showed documentation included findings from a pelvic examination, but the date and time of the pelvic examination were not documented. 4. Review of Patient #7's medical record, dated 11/20/18, showed the patient was admitted for a surgical abortion. The physician's undated and untimed note of the pelvic examination included, "Exam limited by body habitus." A medical record entry, dated 11/20/18 at 1:40 PM, showed Staff B, Registered Nurse, documented, "Per (Staff GG, Medical Doctor [MD]) they were unable to perform in clinic procedure (surgical abortion) so patient will proceed with medication abortion." 5. Review of Patient #10's medical record, dated 09/05/18, showed the patient was admitted for a surgical abortion. Documentation included findings from a pelvic examination, but the date and time of the pelvic examination were not documented. (Note: The surgical abortion was unsuccessful so the plan changed to a medication-induced abortion.) 6. During an interview on 03/13/19 at 11:50 AM, Staff A, Director of Surgical Services, stated that: - The pelvic exam was done after the consenting process and pre-operative phase; - Pelvic exams were done right after the time out (intentional pause immediately before starting the surgical procedure when a final verification is made to confirm the correct patient, surgery, side, implant, and any special requirements);	L1103		

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L1103	Continued From page 8 - Right after the pelvic exam, medications were given and then the procedure was completed; and - The medical records did not include the date and time of the pelvic exam. 7. During an interview on 03/13/19 at 1:24 PM, Staff EE, MD, stated that: - Routinely, they performed the time out, the pelvic exam, administered the medication, and then performed the procedure. - They did the pelvic exam before going into the uterus.	L1103		
L1116	19 CSR 30-30.060(2)(N) Facilities performing surgical,emergency drug Facilities performing surgical procedures shall have emergency drugs, oxygen, and intravenous fluids in the procedure room to stabilize the patient's condition when necessary. A manual breathing bag, suction machine, and endotracheal equipment shall be located in the clinical area for immediate access. This regulation is not met as evidenced by: Based on state statute, nationally-recognized standards, policy review, record review, observation, and interview, the facility failed to ensure: - Staff maintained the necessary endotracheal equipment (equipment used to provide respiration when the patient is unable to breath for themselves) readily available to manage a respiratory emergency; - Staff were familiar with the location and operation of emergency equipment; and - Policies were developed to ensure staff orientation and knowledge validation for the	L1116		

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L1116	Continued From page 9 location and use of emergency supplies; The Abortion Facility does an average of 216 procedures per month. On the first day of the survey, there were 21 procedures. Findings included: 1. Review of the 2011 Missouri Revised Statutes TITLE XII PUBLIC HEALTH AND WELFARE Chapter 197 Medical Treatment Facility Licenses Section 197.230 showed: - The department of health and senior services shall make, or cause to be made, such inspections and investigations as it deems necessary. The department may delegate its powers and duties to investigate and inspect ambulatory surgical centers or abortion facilities to an official of a political subdivision having a population of at least four hundred fifty thousand if such political subdivision is deemed qualified by the department to inspect and investigate ambulatory surgical centers. The official so designated shall submit a written report of his or her findings to the department and the department may accept the recommendations of such official if it determines that the facility inspected meets minimum standards established pursuant to sections 197.200 to 197.240. - In the case of any abortion facility, the department shall make or cause to be made an unannounced on-site inspection and investigation at least annually. Such on-site inspection and investigation shall include, but not be limited to, the following areas: (1) Compliance with all statutory and regulatory requirements for an abortion facility, including requirements that the facility maintain adequate staffing and equipment to respond to medical emergencies.	L1116		

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L1116	Continued From page 10 2. Review of the Association of PeriOperative Registered Nurses "Guideline for Care of the Patient Receiving Moderate Sedation/Analgesia (a condition in which the patient exhibits a mildly depressed level of consciousness and an altered perception of pain but retains the ability to respond appropriately to verbal or tactile stimulation)," dated 2018, showed: - Recommendation III.c.4. * Monitoring equipment (e.g., pulse oximetry (device that measures the oxygen saturation of arterial blood), Electrocardiogram (ECG - measures electrical activity all over the heart), capnography (the monitoring of the concentration carbon dioxide in the respiratory gases), blood pressure measurement devices, oxygen source, masks and cannulas, suction source, tubing, and tips, and oral and nasal [through the nose] airways) should be working properly, and immediately available in the room where the procedure is being performed. - Recommendation III.e. * Emergency resuscitation equipment and supplies should be immediately available in every location in which moderate sedation is administered. - Recommendation III.e.1. * Emergency equipment and supplies should include: Airway and ventilatory equipment (e.g., laryngoscopes (a diagnostic tool with a blade, light, and mirrors, used to examine the larynx [hollow organ in the throat that forms an air passage to the lungs]), endotracheal tubes (ETT- a breathing tube inserted into the airway to keep the airway open), laryngeal mask airway (LMA - a medical device that keeps a patient's airway open during anesthesia or unconsciousness),	L1116		

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L1116	Continued From page 11 oral and nasal airways; 3. Review of the facility's policy titled, "Emergency Response Protocol and Procedure for Emergency Transfer of Patients in Life Threatening Situations," dated 02/19, showed: - When an emergency is recognized by staff they will respond to the patient in crisis and notify physician and Registered Nurse (RN)/Licensed Practical Nurse (LPN). - Basic Life Support (BLS - a level of medical care which is used for victims of life-threatening illnesses or injuries until they can be given full medical care) services and supportive care will be started as indicated. - Treating physician will direct patient care and designate team members to carry out tasks as necessary. * Be sure to start with the ABCs (Airway, Breathing, Circulation). - RN/LPN who comes to the room should assess ABCs and should ask treating physician for report regarding any other equipment (e.g. intravenous (small catheter inserted into a vein for administering medication and fluid) access, oxygen, and ultrasound) or medications needed. (Note: The policy failed to identify the emergency equipment necessary to treat seizures, bleedings, anaphylactic shock, respiratory arrest, and cardiac arrest and other life threatening emergencies and failed to address the need for staff orientation and training on the locations and operation of emergency equipment.) 4. Review of the facility's undated document titled, "Emergency Box: Medication and Supplies," showed the emergency box checklist failed to include suction equipment, i.e., suction device (plastic suction tip used to suction	L1116		

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L1116	Continued From page 12 secretions from the mouth and throat) and endotracheal equipment (equipment used to manage an open airway, i.e., endotracheal tubes, endotracheal tube introducers [device used to assist in obtaining an airway] and laryngoscope handle and blades). 5. Review of the facility's undated checklist titled, "Quality Management (QM) Site System Review," showed: - The document was to be completed monthly by the Surgical Services Manager/Delegate and included: - Emergency Equipment * Audited by nursing supervisor (blank for initials). * Resuscitative equipment; and * Cart with emergency supplies & weekly checklist current. (Note: The checklist failed to contain a list of specific emergency or resuscitative equipment to be checked.) 6. Observation on 03/11/19 at approximately 1:45 PM showed: - A portable suction machine in supply storage room #2; - No suction equipment in three of three procedure rooms; and - No suction equipment in the pre/post procedure area. 7. During an interview on 03/12/19 at 9:25 AM in the pre/post procedure area, Staff O, Advanced Practice Registered Nurse (APRN), Clinical Manager, stated that: - There was no suction in the procedure rooms or pre/post procedure area. - She did not know where the suction machine	L1116		

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L1116	Continued From page 13 was located. - Staff needed an in-service on location of emergency equipment. 8. Observation on 03/12/19 at 9:30 AM in the pre/post procedure area showed: - An emergency box with emergency medications and supplies. * The emergency box did not contain suction supplies (suction tips or cannulas) or endotracheal equipment. During an interview upon the observation, Staff B, Registered Nurse (RN), stated that: - There was no suction supplies or endotracheal equipment in the pre/post area. - She did not know what emergency supplies were in the procedure rooms, she was only responsible for the pre/post procedure area. - She had worked at the facility for approximately three years. - She did not know where the suction machine was located. During an interview upon the observation, Staff O stated that she did not know where the endotracheal tubes were located. 9. During an interview on 03/12/19 at 10:05 AM, Staff EE, Physician, stated that: - If they had a patient that needed intubation he would use a LMA. - The LMA's were with the emergency supplies in the procedure rooms. - The facility had LMAs, oxygen, and suction for endotracheal equipment. - Given the facility's proximity to a hospital and EMS response time he had determined those supplies were sufficient for the facility.	L1116		

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L1116	Continued From page 14 10. During an interview on 03/12/19 at 10:10 AM, Staff H, Surgical Scrub Technician (staff member who performs multiple duties including providing the surgeon with the instruments needed to perform a surgery), Patient Flow Coordinator, stated that: - The suction machine was in the sterile supply storage room. - They did not have suction tips or catheters for oral suction of the patient. - She did not know if the facility had laryngoscope handles and blades. - They did not have LMAs. 12. During an interview on 03/12/19 at 10:15 AM, Staff A, Director of Surgical Services, stated that she did not know where the suction tips or laryngoscope handles and blades were located or if they had them. 13. Observation on 03/12/19 at 10:20 AM of procedure room #3 and two sterile supplies closet showed there were no LMA or suction tips available for the facility. 14. Observation on 03/12/19 at 10:35 AM of sterile storage room #2 showed: - The laryngoscope handles and blades were stored together in a factory storage container on the top shelf. - The handles and blades had not been cleaned, high level disinfected, or packaged to prevent cross-contamination. (Note: The handles and blades were not ready for patient use.) During an interview upon the observation, Staff EE, stated that:	L1116		

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L1116	Continued From page 15 - The facility purchased laryngoscope handles and blades approximately one year ago. - They were stored on the top shelf in the supply room, still in the original case. - They would never use the laryngoscope handles and blades or the ET tubes. - He did not know the facility did not have any suction tips for oral suctioning. 15. During an interview on 03/13/19 at 11:00 AM, Staff N, Clinical Quality Implementation Manager, stated that: - The only checklist for staff to validate emergency supplies was the document, "Emergency Box," which was used for the pre/post procedure monitoring area. - The facility did not have an inclusive list of unit emergency supplies and equipment. - The monitoring tool for emergency supplies, "QM Monthly Site System Review Worksheet," did not include a list of emergency supplies and was not a tool to validate staff knowledge of emergency supplies. - The facility did not have a policy that outlined the required emergency supplies to be maintained by the unit; and - The facility did not have a policy that directed staff orientation and knowledge validation for the location and use of emergency supplies.	L1116		
L1131	19 CSR 30-30.060(4)(A) Infection control standards of the facility Infection control standards of the facility must be identified in writing, in compliance with generally-agreed upon national standards such as those of the Centers for Disease Control and Prevention (CDC), Association for Professionals in Infection Control and Epidemiology (APIC),	L1131		

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L1131	Continued From page 16 Association of peri-Operative Registered Nurses (AORN), or other standards determined acceptable by the department. This regulation is not met as evidenced by: Based on nationally-recognized standards, policy review, record review, observation, and interview, the facility failed to ensure: - Staff maintained a controlled environment to prevent cross-contamination in sterile processing and decontamination; - Staff followed acceptable sterilization standards and manufacturers instructions for use (IFU) for the monitoring of chemicals used for High-Level Disinfection (HLD) of instruments; - Staff followed acceptable sterilization standards for the maintenance of logs to document the required monitoring controls for HLD of instruments; - Staff followed acceptable sterilization standards for the maintenance of logs to document the required monitoring controls for steam sterilization; - Staff followed acceptable sterilization standards and facility policy for the labeling of sterile instruments and packages; and - Ensure expired supplies were not available for use. The Abortion Facility does an average of 216 procedures per month. On the first day of the survey, there were 21 procedures. Findings included: 1. Review of the facility's policy titled, "Managing Infection Prevention at Affiliates," dated 07/09/18, showed: - All staff is responsible for adhering to and incorporating infection prevention practices with	L1131		

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service provision.
- The facility uses as a reference:
  * The Affiliate Risk Management Services infection Prevention Manual;
  * Centers for Disease Control and Prevention;
  * HealthCare Infection Control Practices Advisory Committee Guidelines;
- Other resources are listed in the attachment section of this manual:
  * Association for the Advancement of Medical Instrumentation (AAMI);
  * Association of PeriOperative Registered Nurses (AORN);
  * Association of Professionals in Infection and Epidemiology (branch of medicine which deals with the incidence, distribution, and possible control of diseases and other factors relating to health); and
  * Occupational Safety and Health Administration.

2. Review of the AORN "Perioperative Standards and Recommended Practices for Instrument Cleaning," dated 2018, showed:
- Recommendation V.
  * Instruments should be cleaned and decontaminated in an area separate from locations where clean items are handled.
  * Physical separation of decontamination areas (area of a health care facility designated for collection, retention, and cleaning of soiled and/or contaminated items) from areas where clean items are handled minimized the risk of cross-contamination.
  * Droplets and aerosols created during cleaning of soiled instruments can cause cross-contamination of any nearby clean items or surfaces.
- Recommendation V.a.

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L1131	Continued From page 18 * The sterile processing area should have: - Separate clean and decontamination spaces, which may be rooms or areas; - Decontamination and clean spaces that are separated by one of three methods: A wall with a door or pass-through, a partial wall or partition that is at least 4 feet high and at least the width of the counter, or a distance of 4 feet between the instrument washing sink and the area where the instruments are prepared for sterilization. - Recommendation VI. * Contaminated instruments are a potential source of transmissible pathogens. 3. Review of the American National Standards Institute (ANSI) and AAMI document titled, "ANSI/AAMI ST79:2017, Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities," dated 2017, showed: 3.3.6.1.1 Design considerations: The decontamination area/room should be physically separate from all other processing areas and from areas in which clean or sterilization procedures are carried out, with any connecting doors and pass-through windows remaining closed. 4. Observation on 03/11/19 at 1:30 PM of the sterile processing area showed: - The pass through window between sterile processing and decontamination was open. - Staff F, Surgical Scrub Technician (ST, staff member who performs multiple duties including providing the surgeon with the instruments needed to perform a surgery), was cleaning contaminated instruments in the decontamination room in direct proximity to the pass through window. - The door to the sterile processing room was	L1131		

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L1131	Continued From page 19 propped open. - Two sterilizers along the wall adjacent to the door that protruded past the door frame and prevented the door from being closed. During an interview upon the observation, Staff A, Director of Surgical Services, stated that the sterilizers blocked the door to sterile processing from closing. 5. Observation on 03/12/19 at 9:28 AM showed the doors to sterile processing and decontamination and the pass through window were open. 6. Observation on 03/12/19 at 11:25 AM showed the door to sterile processing and the pass through window was open. 7. During an interview on 03/13/19 at 9:15 AM, Staff A stated that the door to decontamination and the pass through window were to remain closed at all times. 8. Review of the ANSI/AAMI document titled, "ANSI/AAMI ST79:2017, Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities," dated 2017, showed: - E.6 Quality control in chemical disinfection (chemical substances which are used to kill or deactivate pathogenic microorganisms [capable of causing illness in humans]) * Dilution and minimum effective recommendation (MEC) / minimum recommended concentration (MRC) monitoring: The disinfectant is diluted by water remaining on surfaces and in the lumens of devices immersed in the disinfectant. Dilution can be very significant in the	L1131		

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L1131	Continued From page 20 long-term use and reuse of a chemical disinfectant and can potentially reduce the concentration of the chemical agent to a level too low to be effective in killing a sufficient number of certain microorganisms in the recommended exposure time. To avoid dilution of the disinfectant, excess moisture should be removed after cleaning. Disinfectant solutions must not be used at concentrations below the MEC or MRC stated on the label. As part of a health care facility's quality control program, Liquid Chemical Sterilants (LCS)/HLD solutions such as glutaraldehyde (Cidex OPA [brand] - high level disinfectant for semi-critical medical devices) solution should be monitored upon activation and before each use in order to detect unexpected dilution of the solution. 9. Review of the AORN "Guideline for Manual Chemical High-Level Disinfection," dated 2018, showed: - Recommendation IV.d. * High-level disinfection should occur in a designated clean area that is separate from the decontamination area. * Separating the clean area from the area where devices are cleaned and prepared for high-level disinfection reduces the risk of device contamination that might occur when both clean and contaminated processing activities are performed in a single area. - Recommendation VI.c.1. * A test strip or other Food and Drug Administration-cleared testing device specific to the disinfectant and the active ingredient in the disinfectant should be used before each use of the HLD solution. - Recommendation VI.d.1.	L1131		

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L1131	Continued From page 21 * The temperature of the HLD solution should be verified before each use with a thermometer calibrated within the applicable range. - Recommendation IX: * Documentation should be completed to enable the identification of trends and demonstrate compliance with regulatory and accrediting agency requirements. - Recommendation IX.a. * Records related to manual chemical high-level disinfection should include: The date and time of high-level disinfection; HLD solution lot number; HLD solution shelf-life date; HLD solution activation date; HLD solution reuse-life date; Results of solution test strip testing; Results of MRC or MEC testing, if applicable; HLD solution temperature; HLD solution exposure time; Quantity and description of the device or item; and Identity of the person performing high-level disinfection. 10. Review of the facility's policy titled, "Cleaning, Disinfection, and Sterilization," dated 07/09/18, showed to ensure integrity, visually inspect previously used solution before use, test and record results in appropriate testing log daily. 11. Review of the manufacturer's IFU for Cidex OPA showed: - Reuse for Disinfection: * The concentration of Cidex OPA Solution during its use-life (time between activation of the solution and last date to be used) must be verified by the test strips prior to each use. * This is to ensure the minimum effective	L1131		

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concentration is present.
* Cidex OPA Solution may be used for up to a maximum of 14 days provided the required conditions of concentration and temperature exist.

12. Review of the facility's documents titled, "Cidex OPA Solution MEC test log showed:
- The document was used to record the following information:
* Date the solution was poured into the secondary container (a soaking pan);
* Staff initials;
* MEC test strip results; and
* Comments/resolution.
- Review of the monthly logs showed:
* 11/18 - entries on three days;
* 12/18 - entries on three days;
* 01/19 - entries on four days;
* 02/19 - entries on seven days; and
* 03/01/19 - 03/11/19 - entries on four days:
* Staff documented that the solution was changed four times in 19 weeks.
- Staff failed to document:
* The date and time of high-level disinfection;
* HLD solution lot number;
* HLD solution reuse-life date;
* HLD solution exposure time; and
* Quantity and description of the devices or items disinfected.

13. During an interview on 03/13/19 at 8:35 AM, Staff F stated that:
- Staff checked the Cidex daily;
- They only checked the Cidex on days they had procedures that required HLD.
- The Cidex expired 14 days after it was mixed regardless of the MEC.
- The number of HLD loads disinfected averaged

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L1131	Continued From page 23 between 12 and 15 HLD loads per day on procedure days. - She did not check the Cidex MEC prior to disinfection of each load. 14. During an interview on 03/13/19 at 9:30 AM, Staff A stated that: - She did not know the Cidex MEC should be validated prior to each HLD load of instruments; and - She was not aware the time of high-level disinfection, solution lot number, reuse-life date, exposure time, quantity, and description of the device or item disinfected should be documented. 15. Review of the ANSI/ AAMI document titled, "ANSI/AAMI ST79:2017, Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities," dated 2018, showed: - 13.3.3 Sterilizer records * The process critical parameters (time and temperature) provided on the recording chart, printer, or tape should be reviewed, signed, and dated by the operator to indicate an acceptable cycle. * For each sterilization cycle, the following information should be recorded: (a) The load number; (b) The specific contents of the lot or load, including quantity, department, and a specific description of the items(e.g., towel packs, type/name of instrument sets); (c) The exposure time and temperature, if not provided on the sterilizer recording chart; and (d) Operator identification. 16. Review of the facility's policy titled, "Cleaning, Disinfection, and Sterilization," dated 07/09/18,	L1131		

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L1131	Continued From page 24 showed: - Information that should be recorded and maintained for each sterilization cycle includes guidance from Consolidated Test of American National Standard/Advancing Safety in Medical Technology: * Specific contents of the lot or load, including quantity, department, and specific description of the items (e.g. towels, type/name of instrument sets); * Exposure time and temperature, if not provided on the sterilizer recording chart; * Name or initials of operator; and * Results of biological testing, if applicable. 17. During an interview on 03/12/19 at 9:15 AM in the sterile processing room, Staff D, ST, stated that: - They did not maintain a sterilization log. - She never had any training on the sterilization process; she just continued to do what she had seen was done in the past. - She only logged sterilizer cleaning and results of the biologicals. - Each instrument package and set should be labeled with a load number and autoclave number. - She did not know they should keep a record of the content, time and temperature for each sterilizer load. 18. During an interview on 03/12/19 at 9:30 AM in the sterile processing room, Staff A stated that: - They tested the Cidex OPA solution daily. - She did not know they were supposed to test the Cidex OPA solution before every load of instruments processed. - They did not have a log to document load content, time, and temperature for the Cidex OPA	L1131		

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L1131	Continued From page 25 solution or the steam sterilizers. 19. Review of the ANSI/AAMI document titled, "ANSI/AAMI ST79:2017, Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities," dated 2017, showed: - 13.3.1 General considerations * Each item or package intended for use as a sterile product should be labeled with a lot control identifier to allow full traceability of that item to the patient. * Each load should have a load control record that includes a detailed content list, including specific identification of sets and the contents of sealable pouches. - 13.3.2 Package labeling * Each item or package intended for use as a sterile product should be labeled with a lot control identifier prior to sterilization. The lot control identifier should identify: a) The sterilizer identification number or code; b) A detailed list of the contents (e.g., identification of multiple sets and the contents of paper-plastic pouches); c) The person who assembled the package; d) The date of sterilization; e) The cycle number (cycle run of the sterilizer); and f) The patient, if applicable. - Rationale: Labeling items with a lot control number and an expiration statement or (when applicable) expiration date is necessary for proper stock rotation. Lot identification enables personnel to retrieve items in the event of a recall and to trace problems (e.g., wet packs) to the source. Pre-sterilization labeling can be done after sterilizer and cycle assignment is determined and as the cart is loaded. Accountability to the patient and surgeon for the	L1131		

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L1131	Continued From page 26 sterility of a reprocessed device requires documentation that can be traced to the patient. Traceability is especially important as the consequences of infection can result in increased morbidity and mortality. 20. Review of the facility's policy titled, "Cleaning, Disinfection and Sterilization," dated 07/09/18, showed: - Documentation establishes accountability by documenting what instruments have been processed and provides evidence of monitoring controls for those items. * In the event of a sterilization process failure, good records will help the staff trace each package back to the event itself. * Each item or pack should be labeled with a lot identifier that designates the sterilizer identification number or code, the date of sterilization, and the cycle number (cycle run of the sterilizer). *Lot identification enables retrieval of items in the event of a recall, tracing problems to their source and facilitates proper stock rotation. 21. Observation on 03/11/19 at 3:00 PM in the sterile processing room showed 13 of 26 sterile instrument packages observed did not have a sterilizer or load number identified on the package. During an interview upon the observation, Staff O, Clinical Manager, stated that she did not know the sterilizer and load number should have been identified on the packages of sterilized instruments. Staff F stated that she did not know she was supposed to label every instrument package with the sterilizer number and load number.	L1131		

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L1131	Continued From page 27 22. Observation on 03/11/19 at 1:30 PM in the sterile supply storage room showed: - A box of 50 infusion sets (small tubing with needle inserted into a vein for administering medication and fluid) that had expired 08/18. - Staff A removed the box of expired supplies. During an interview upon the observation, Staff A stated that Staff H, Patient Flow Coordinator and Staff T, Shipping and Receiving Coordinator, were responsible for checking for expired supplies at least monthly. 23. Observation on 03/11/19 from 1:50 PM through 2:45 PM during tour of the patient care areas, showed seven expired cans of alcohol-based hand sanitizer with expiration dates ranging from 08/18 through 12/18. 24. During an interview on 03/13/19 at 11:02 AM, Staff O stated that she did not know who was responsible to monitor the expiration dates of the alcohol-based hand sanitizer. 25. During an interview on 03/13/19 at 11:10 AM, Staff H stated that she did not know who was responsible to monitor the expiration dates of the alcohol-based hand sanitizer.	L1131		
L1146	19 CSR 30-30.060(5)(F) The facility shall follow all applicable laws The facility shall follow all applicable laws and regulations pertaining to controlled substances. This regulation is not met as evidenced by: Based on state statute, policy review, record review, and interview, the facility failed to:	L1146		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	MOA-0014	A. BUILDING: _____ B. WING _____	03/13/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNI	4251 FOREST PARK AVENUE SAINT LOUIS, MO 63108

(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
L1146	Continued From page 28 - Ensure controlled substance logs were maintained to include the addresses of patients who received controlled substances; and - Ensure controlled substance logs were maintained to include the reason for the destruction or wastage of controlled substances not administered. The Abortion Facility does an average of 216 cases per month. On the first day of the survey, there were 21 cases. Findings included: 1. Review of Missouri's 19 Code of State Regulations (CSR) 30-1.048(1)(3), dated 04/30/17, showed: - Each individual practitioner, institutional practitioner, and pharmacy shall maintain records with the following information for each controlled substance received, maintained, dispensed, or disposed: * The name of the substance; * Each finished form (for example, ten milligram (10 mg) tablet or ten milligram (10 mg) concentration per fluid ounce or milliliter) and the number of units or volume of finished form in each commercial container (for example, one hundred (100) tablet bottle or three milliliter (3 ml) vial); * The number of commercial containers of each finished form received from other persons, including the date of and number of containers in each receipt and the name, address and registration number of the person from whom the containers were received; * The number of units or volume of the finished form dispensed including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume	L1146		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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L1146	Continued From page 29	L1146		

dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance; and
* The number of units or volume of the finished forms, commercial containers, or both, disposed of in any other manner by the registrant, including the date and manner of disposal and the quantity of the substance in finished form disposed.
- Individual practitioners shall maintain the records listed in subsections (1)(A)-(E) of this rule separately from patient medical records.

2. Review of Missouri's 19 CSR 30-1.078(5) showed the following shall be entered in the controlled substance administration record or a separate controlled substance destruction record when the controlled substance is destroyed in the patient care area: the date and hour of destruction, the drug name and strength, the amount destroyed, the reason for destruction and the patient's name and room number. The nurse, pharmacist or physician and the witnessing hospital employee shall sign the entry.

3. Review of the facility's policy titled, "Policy Statement & Work Practices for Management of Controlled Substances," dated 04/30/18, showed:
- The dispensing log must include the date dispensed, patient name, patient address, drug name, strength, dosage form and quantity dispensed, and the name/initials of the person performing the dispensing.
- The chief circumstances for disposal of unwanted controlled substances are:
* The drug has been contaminated by patient contact, left over injectable drugs in a syringe, or a tablet that has fallen out of a patient's hand or mouth. In these cases the drug may be

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L1146	Continued From page 30 destroyed by two employees. The drug must be destroyed beyond reclamation and documented as described below. * When practitioners administer injectable controlled substances, there will be a small amount remaining in the hub of the syringe. These are considered insignificant in the course of normal practice. These amounts are not considered lost. They should be documented on the logs so they are accounted for and records balance. (Note: The facility did not include documenting the reason for wastage in their list of required documentation.) 4. Review of the facility's documents titled, "Controlled Substance Dispensing Or Administration Log," dated 01/30/19 through 03/13/19, showed: - Staff did not include the patients' addresses on the log; and - Staff did not document the reason controlled substances were wasted. 5. During an interview on 03/12/19 at 9:00 AM, Staff B, Registered Nurse, stated that: - They did not document the patient's address on the "Controlled Substance Dispensing Or Administration Log;" and - Staff did not document the reason controlled substances were wasted unless the reason for wastage was something "weird."	L1146		