Missouri Department of Health and Senior Services

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 _____	05/25/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
REPRODUCTIVE HEALTH SERVICES / PLANNED PAR	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
L 000	Initial Comments An onsite, unannounced state licensure survey to determine compliance with 19 CSR 30-30.050 through 19 CSR 30-30.060 for Abortion Facilities was conducted from 05/23/17 to 05/25/17. See below for findings:	L 000		
L1106	19 CSR 30-30.060(1)(A)(3) Bylaws of the governing body shall Bylaws of the governing body shall require that an individual who complies with paragraph (1)(A)2. of this rule shall be in charge in the absence of the administrator. This regulation is not met as evidenced by: Based on record review and interview, the facility failed to include in their bylaws the person or position in charge of the facility in the absence of the administrator. The facility performs an average of 270 procedures per month. On the first day of the survey, there were 17 cases. Findings included: 1. Review of the Facility Bylaws, Article 10, Operation of Health Care Facility, dated 03/28/17 showed: - The Vice President of Patient Services and Education (VP) and her delegate shall be responsible for overseeing the day-to-day operations of the facility; and - The VP must meet one of the following qualifications: (i) a physician licensed to practice medicine within the State of Missouri; (ii) a registered nurse licensed to practice nursing within the State of Missouri; or (iii) an individual who has at least one year of administrative experience in the health care industry.	L1106		

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L1106	Continued From page 1 Note: The bylaws failed to specifically designate who would be in charge in the absence of the administrator and what qualifications that delegate must meet. 2. During an interview on 05/23/17 at 2:05 PM, Staff A, Vice President of Patient Services and Education, stated that: - Her position was equivalent to the administrators position in the regulations; - She was responsible for day-to-day operations; - She did not have a policy that indicated who would be in charge in her absence; and - She agreed the bylaws did not specify who would be in charge in her absence or the qualifications of that individual.	L1106		
L1128	19 CSR 30-30.060(1)(B)(8) The facility shall establish a program The facility shall establish a program for identifying and preventing infections and for maintaining a safe environment. Infectious and pathological wastes shall be segregated from other wastes at the point of generation and shall be placed in distinctive, clearly marked, leak-proof containers or plastic bags appropriate for the characteristics of the infectious wastes. Containers for infectious waste shall be identified with the universal biological hazard symbol. All packaging shall maintain its integrity during storage and transport. 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 followed current acceptable	L1128		

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L1128	Continued From page 2 standards of practice for hand hygiene; - Transport soiled instruments in a covered, leak-proof container labeled with a bio-hazard label to indicate potentially infectious objects; - Follow manufacturers recommendations for use of germicidal wipes; and - Ensure a sanitary environment was preserved by providing intact (free of holes) and easily cleanable surfaces (free of rust) that will not harbor bacteria and transmit infections. The facility performs an average of 270 procedures per month. On the first day of the survey, there were 17 cases. Findings included: Hand Hygiene findings 1. Review of the Centers for Disease Control and Prevention (CDC) document titled, "Guideline for Hand Hygiene in Health-Care Settings," dated 10/25/02, showed: - Indications for hand hygiene: * Contact with a patient's intact skin; * Contact with environmental surfaces in the immediate vicinity of patients; and * After glove removal. - Indications for, and limitations of, glove use: * Hand contamination may occur as a result of small, undetected holes in the examination gloves; * Contamination may occur during glove removal; * Wearing gloves does not replace the need for hand hygiene; and * Failure to remove gloves after caring for a patient may lead to transmission of microorganisms from one patient to another.	L1128		

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L1128	Continued From page 3 2. Review of the Association for Professionals in Infection Control (APIC), scientific guidelines referred to the CDC Morbidity and Mortality Weekly Report titled, "Guideline for Hand Hygiene in Health-Care Settings," dated 10/25/02, showed the following: - Indications for hand hygiene: * Contact with a patient's intact skin; * Contact with environmental surfaces in the immediate vicinity of patients; and * After glove removal. - Indications for, and limitations of, glove use: * Hand contamination may occur as a result of small, undetected holes in the examination gloves; * Contamination may occur during glove removal; and * Wearing gloves does not replace the need for hand hygiene. 3. Review of the facility's "Infection Control Manual", dated 2017, showed resources that could be used to answer infection prevention questions and review for updated information and trends included: - Association for the Advancement of Medical Instrumentation (AAMI); - APIC; -Association of Perioperative Registered Nurses (AORN); - CDC; and - Occupational Safety and Health Administration (OSHA). 4. Review of the facility's "Infection Control Manual," policy titled, "Standard Precautions, Hand Hygiene, PPE," dated 2017, showed: -Good hand hygiene, including the use of alcohol-based hand rubs and hand washing with soap and water is critical to reduce the risk of	L1128		

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L1128	Continued From page 4 spreading infections in healthcare settings is recommended by the CDC and the World Health Organization because of its activity against a broad spectrum of pathogens. - Hand hygiene is the most important single procedure for preventing health-care associated infections. - Key situations where hand hygiene should be performed include: * Before touching a patient, even if gloves are worn; * Before exiting the patient's care/procedure area after touching the patient or patient's immediate environment; * After contact with blood, body fluids, excretions, or dressings; * Prior to performing an aseptic task; * If hands will be moving from a contaminated-body site to a clean-body site during patient care; and * After glove removed. 5. Observation on 05/23/17 from 10:20 AM to 10:40 AM, in the procedure room showed: - At 10:27 AM Staff JJ, Physician, and Staff LL, Physician, both donned gloves but failed to perform hand hygiene. Staff JJ performed a vaginal exam on the patient, removed her right glove, failed to perform hand hygiene, then reached into her back pocket and retrieved a glove and donned it. - Staff JJ sprayed a soap mixture in the patient's vaginal area and injected Lidocaine (numbing medication), then removed her soiled gloves, failed to perform hand hygiene, and donned sterile gloves. - At 10:37 AM, after the procedure was completed, Staff LL removed her gloves but failed to perform hand hygiene before exiting the room.	L1128		

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L1128	Continued From page 5 6. Observation on 05/23/17 from 11:00 AM to 10:15 AM, in the procedure room showed: - Staff JJ and Staff LL entered the room, performed hand hygiene and donned gloves; - At 11:02 AM, Staff LL rubbed her nose while wearing her gloves, she then failed to remove her soiled glove and perform hand hygiene. Staff JJ documented in the patient's medical record while wearing gloves, she then removed her gloves but failed to perform hand hygiene. - At 11:06 AM, Staff JJ and Staff LL donned clean gloves but failed to perform hand hygiene first. Staff JJ performed a vaginal exam, removed her soiled glove from her right hand, failed to perform hand hygiene, then reached into her back pocket and retrieved a glove and donned it. - Staff JJ sprayed a soap mixture in the patient's vaginal area and injected Lidocaine, then removed her soiled gloves, failed to perform hand hygiene, and donned sterile gloves. 7. Observation on 05/24/17 from 9:30 AM to 10:08 AM, in the procedure room showed: - At 9:34 AM Staff JJ donned gloves but failed to perform hand hygiene and Staff GG, Physician, wore gloves and attempted to restart Patient #25's intravenous (IV - small catheter inserted into a vein for administering medication and fluid) line; - At 9:38 AM Staff GG disposed of a bloody syringe and placed a dressing on the patient's arm, removed her soiled gloves and donned clean gloves. She failed to perform hand hygiene after removing her soiled gloves. She then leaned against a wall with her gloved hands behind her back, went to the electronic medical record and documented, picked up the paper medical record and reviewed it, then removed her gloves. She failed to perform hand hygiene after she removed her gloves.	L1128		

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L1128	Continued From page 6 - At 9:47 AM Staff GG stood with her gloved hands on her hips. Staff JJ removed her gloves but failed to perform hand hygiene. - At 9:47 AM Staff GG removed her gloves, handled her cell phone, and exited the room. She failed to perform hand hygiene after removing her gloves. - At 9:49 AM Staff JJ rubbed her nose and pushed her glasses up while wearing gloves. She failed to remove her gloves and perform hand hygiene. - At 9:57 AM Staff GG and Staff JJ entered the procedure room and donned gloves. They failed to perform hand hygiene before donning the gloves. - At 9:58 AM Staff JJ removed laminaria (kelp species) sticks (a thin rod of dried laminaria used to slowly dilate the cervix) from the patient's cervix. Staff GG administered additional IV medication while wearing gloves, picked up a piece of trash from the floor, stood with her gloved hands on her hips, then documented in the electronic medical record. She failed to change her gloves and perform hand hygiene. - At 10:00 AM Staff GG removed her gloves and partially stepped out of the procedure room then returned. She failed to perform hand hygiene after she removed her gloves and when she re-entered the room. She documented in the patient's electronic medical record. - At 10:01 Staff JJ removed her soiled gloves after removing the laminaria sticks and donned clean gloves. She failed to perform hand hygiene between glove changes. - At 10:02 Staff GG donned gloves. She failed to perform hand hygiene. - At 10:03 Staff JJ administered Lidocaine medication, removed her gloves, and donned sterile gloves. She failed to perform hand hygiene between glove changes.	L1128		

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L1128	Continued From page 7 8. During an interview on 05/25/17 at 11:50 AM, Staff CC, Medical Director, Physician,: - Questioned if hand hygiene between glove changes was a new standard; - Wanted to know whose standard it was; - Stated that the procedures they performed were not "sterile"; and - Questioned if it was facility policy to perform hand hygiene after glove removal. Instrument transport findings 9. Review of the AORN, "Guideline for Cleaning and Care of Surgical Instruments," dated 2016, showed: - Recommendation IV.b. * Soiled instruments must be transported to the decontamination area in a closed container or enclosed transport cart. The container or cart must be: Leak proof; Puncture resistant; Large enough to contain all contents; and Labeled with a fluorescent orange or orange-red label containing a bio-hazard legend. * Labeling the transport containment device communicates to others that the contents are potentially infectious. - Recommendation IV.b.1. * Bio-hazard labels should be affixed so as to prevent separation from the contents. When appropriate to the configuration of the contents, a red bag or red container may be used instead of a label to indicate contaminated waste. 10. Review of the (AAMI document titled, "Comprehensive Guide to Steam Sterilization and Sterility Assurance in Healthcare Facilities, ST79," dated 2010, showed:	L1128		

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L1128	Continued From page 8 - N.2.2.5 Transport of instruments to the decontamination area: * During transport of instruments from the point of use to the decontamination area, appropriate precautions (e.g., use of a closed transport container) should be taken to avoid personnel exposure to blood-borne pathogens, contamination of the work environment, and further contamination of the instruments. 11. Review of the facility's "Infection Prevention Manual", policy titled, "Handling of Contaminated Furniture/Equipment/Linen/Instruments/Supplies," dated 2017, showed contaminated instruments should be transported covered. 12.Observation on 05/23/17 at approximately 10:37 AM after Patient #20's procedure showed Staff M, HCA, partially wrapped the soiled instruments in the disposable sterilization wrap and a disposable pad, then removed the soiled instruments from the procedure room. She failed to transport the instruments to the decontamination room in a closed, leak-proof container with a biohazard label affixed to the container. 13. Observation on 05/23/17 at 11:16 AM after Patient #19's procedure showed Staff M partially wrapped the soiled instruments in the disposable sterilization wrap and a disposable pad then removed the soiled instruments from the procedure room. She failed to transport the instruments to the decontamination room in a closed, leak-proof container with a biohazard label affixed to the container. 14. During an interview on 05/24/17 at 10:25 AM, Staff G, Health Center Manager, stated that they did not use closed leak-proof containers with a	L1128		

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L1128	Continued From page 9 biohazard label but thought it would be a good idea. Germicidal Wipes findings 15. Review of the manufacturers instructions for use for the McKesson (brand) Disposable Germicidal Surface Wipes showed: - Cleaning and Disinfection Instructions * Use a fresh wipe to pre-clean surfaces of all gross filth and heavy soil. * Repeat as necessary until all surfaces are visibly clean. * To effectively disinfect the pre-cleaned surfaces, use a fresh wipe or turn the wipe over to the clean side to thoroughly wet the surfaces and allow surface to remain wet for the appropriate time indicated for the purpose intended. * Effectively kills the multiple microorganisms at room temperature with a two minute contact time when used as directed. * Used in surgical centers and rooms and areas/facilities concerned with the hazards of cross contamination from infectious microorganisms. 16. Review of the facility's "Infection Prevention Manual", policy titled, "Cleaning, Disinfection, and Sterilization," dated 2017, showed: -Procedure Room Practices: Disposable paper coverings may eliminate the need to disinfect between clients. Disinfection must be done if paper covering becomes torn, wet, or visibly soiled. - If paper covering is used, change the paper covering and disinfect the surface as needed (i.e., when the paper covering becomes saturated with blood or body fluids.) -Spray on disinfectant. Leave on surface for	L1128		

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L1128	Continued From page 10 number of minutes as per product directions ("contact time"). 17. Observation on 05/23/17 at 10:40 AM, after Patient #20's procedure showed Staff J, Environmental Services, wiped the bed with McKesson germicidal wipes. She failed to allow for two minutes of contact time. During an interview immediately after the observation, Staff K, Flow Facilitator, stated that the germicidal wipes dried in 30 seconds and agreed that Staff J did not allow two minutes of contact time. 18. Observation on 05/23/17 at 10:45 AM in the recovery area showed Staff N, Registered Nurse, cleaned a chair with a germicidal wipe but failed to allow two minutes of contact time. 19. Observation on 05/23/17 at 11:20 AM, after Patient #19's procedure showed the paper liner covering the bed was partially saturated with blood in several spots, and there was additional blood on the procedure table that had leaked through the paper liner. Staff L, MA, removed the paper liner and wiped the bed with a germicidal wipe. She failed to allow two minutes of contact time. During an interview immediately after the observation, Staff L stated that the contact time was 15 seconds. Oxygen Tanks findings 21. Review of the AORN, "Guideline for Environmental Cleaning," dated 2016, showed: - Recommendation II. * The patient should be provided with a clean, safe environment. - Recommendation II.a. * The perioperative RN should assess the perioperative environment frequently for	L1128		

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L1128	Continued From page 11 cleanliness and take action to implement cleaning and disinfection procedures. Environmental cleaning and disinfection is a team effort involving perioperative personnel and environmental services personnel. The responsibility for verifying a clean surgical environment before the start of an operative or invasive procedure rests with perioperative nurses. 22. Observation on 05/23/17 from 9:30 to 9:40 AM of procedure rooms #1, #2, and #3 showed each had an oxygen tank in the room. The tanks were soiled and had adhesive residue with dirt stuck on the tanks. 23. During an interview on 05/24/17 at 10:25 AM, Staff G agreed the oxygen tanks were not clean and stated that staff did wipe the tanks down when they got new tanks but the residue did not come off with routine wiping.	L1128		
L1136	19 CSR 30-30.060(1)(B)(12) The administrator shall be responsible The administrator shall be responsible for ensuring that the provisions of Chapter 188, Regulation of Abortions, RSMo 1986 are adhered to. This regulation is not met as evidenced by: Based on record review and interview, the facility failed to submit complication reports to the Missouri Department of Health and Senior Services (Department) as required by statute. The facility performs an average of 270 procedures per month. On the first day of the survey, there were 17 cases. Findings included:	L1136		

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L1136	Continued From page 12 1. Review of Missouri law 188.052(2);(3) RSMo, showed: - An individual complication report for any post-abortion care performed upon a woman shall be completed by the physician providing such post-abortion care. This report shall include: (1) The date of the abortion; (2) The name and address of the abortion facility or hospital where the abortion was performed; (3) The nature of the abortion complication diagnosed or treated. 3. All complication reports shall be signed by the physician providing the post-abortion care and submitted to the department of health and senior services within forty-five days from the date of the post-abortion care. 2. Review of 19 CSR 30-30.050(1)(D) showed "complication" to be defined in the regulation as: "Complication-includes, but is not limited to, hemorrhage, infection, uterine perforation, cervical lacerations and retained products." 3. Review of the facility's "Complication and incident log"-an internal database report dated 05/24/17 and used by facility staff to follow up on patients who sought post-abortion care, showed multiple patients being treated at the facility for issues that met the regulatory definition of complication. Follow up care was documented in the complication log, but there was no evidence of any associated complication reports being submitted to the Department. 4. Review of the facility's "QA Manual" dated 2017, showed policies regarding various reports sent to the state: - "CVR reports are state reports that are submitted [to the Department] by the 10th of the month before for all abortion procedures	L1136		

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L1136	Continued From page 13 performed." This report corresponds to the mandatory "Induced Termination of Pregnancy" reports required to be submitted to the Department. - "Board of Healing Arts report is a state report that is required by the State for all Abortion procedures for over 20 weeks [gestational age]." The report corresponds to the mandatory viability determination report. - However, there was no facility policy specific to the submission of post-abortion complication reports to the Department. 5. During an interview on 05/24/17 at 3:05 PM, Staff D, Director of Quality, stated: - The facility and the physicians were not sending any complication reports at this time. - The facility had become fully aware of the complication report requirement in the last few months, and had discussed the issue internally, but wanted a clearer definition of complication before they would comply. 6. During an interview on 05/25/17 at 10:23 AM, Staff B, President and CEO stated: - The facility had become aware of the complication reporting requirement after communications with the Department "several months ago." - The facility had not sent in any complication reports even once they became fully aware of the requirement. - The facility had requested a formal meeting with the Department and other stakeholders several times to seek clarification on the requirement, but so far no such meeting was planned, and the facility was waiting for this meeting before they believed they could adequately comply with the requirement.	L1136		