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 _____	01/31/2013

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
L 000	Initial Comments An on-site, unannounced allegation survey was conducted at this facility from 01/30/13 - 01/31/13. Complaint MO00082879. A state licensure inspection was conducted in conjunction with the allegation survey. The complaint (MO00082879) was found to be unsubstantiated. Deficiencies as a result of the licensing inspection are as follows:	L 000		
L1111	19 CSR 30-30.060(1)(A)(8) The governing body shall ensure that The governing body shall ensure that the abortion facility abides by all applicable state and federal laws. This regulation is not met as evidenced by: Based on employee personnel file review, and review of the state statute, the facility failed to perform periodic Employee Disqualification List (EDL) checks on three of three employee personnel files reviewed. The facility does an average of 340 cases per month. On the first day of the inspection there were 25 scheduled cases. Findings included: 1. EDL checking requirements are as follows: Section 660.315, RSMo Entities required to check the EDL: 1. Licensed as operator under Chapter 198; 2. Provides in-home services under contract with the department; 3. Temporary nurse staffing agencies;	L1111		

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L1111	Continued From page 1 4. Licensed under Chapter 197 (hospitals, ambulatory surgical centers, hospices, home health agencies); and 5. Public or private facility, day program, residential facility or specialized service operated, funded or licensed by the department of mental health. Under Section 660.315, these entities are prohibited from knowingly hiring a person, for any type of position, whose name appears on the EDL. These entities must, at a minimum, check the latest EDL (on the website after September of 2005) with updates before hiring any person for any job. 2. During an interview on 01/31/13 at 10:05 AM, Staff C, Vice President of Human Resources, stated that the facility did not do EDL checks for any of the staff currently working in the facility.	L1111		
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 observation, interview, policy review,	L1128		

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L1128	Continued From page 2 and review of nationally recognized standards of practice, the facility failed to: -Ensure single use medications were discarded after use on each patient (used for multiple patients); -Ensure expired medications were available for patient use; -Date multi-dose vials when they are opened; -Ensure expired items were not available for patient use; -Ensure a sanitary environment was preserved by failure to replace worn, rusted or deteriorating equipment with functional easily cleanable surfaces that will not harbor and transmit infections in three of three Procedure Rooms; and -Ensure the facility was free of dust/debris in three of three Procedure Rooms, the storage room and supply room. The facility does an average of 340 cases per month. On the first day of the survey there were 25 scheduled cases. Findings included: 1. Record review of the Centers for Disease Control and Prevention (CDC) Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care, dated 05/11, showed the following: - Do not administer medications from single-dose or single-use vials, ampoules, or bags or bottles of intravenous solution to more than one patient. 2. Observation on 01/30/13 at 11:05 AM of the narcotic cabinet showed one opened 50 millimeter (ml) single dose vial of Fentanyl (pain medication) dated as opened on 01/27/13 with initials of the nurse who had opened the vial. The label on the medication stated, "single dose -	L1128		

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L1128	Continued From page 3 destroy unused contents, preservative free". 3. During an interview on 01/30/13, at the time of the observation, Staff K, Clinical Manager stated that the vials were used for more than one patient due to a shortage of the medication and the amount of waste that would result if the vial was disposed of after one use. 4. During an interview on 01/30/13 at 4:00 PM, Staff A, Vice President of Patient Services stated that the facility did not have a policy specific to single dose medication. 5. Review of the facility's policy titled, "Pharmaceutical Services", revised 12/12/12 shows: -At least monthly, supervisory staff should review the inventory to ensure that stock was being properly rotated and had not expired in all pharmaceutical storage areas; -Expired inventory must be removed from active stock. 6. Observation on 01/30/13 at 9:30 AM of emergency supplies in Procedure Room #1 showed: -One bag of Lactated Ringer (IV solution), expired 12/12. 7. During an interview on 01/30/13 at 9:45 AM, Physician D, Medical Director stated that medications and supplies were checked monthly by facility staff. 8. Observation on 01/30/13 at 10:11 AM of a cabinet in Procedure Room #2 showed: -One box of ammonia inhalant (used to prevent or treat fainting), three count, expired 05/10.	L1128		

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L1128	Continued From page 4 9. Observation on 01/30/13 at 10:45 AM of the narcotic cabinet behind the nursing station showed: -Nine vials of Valium (medication used for sedation), expired 12/01/12; -Eighteen vials of Naloxone Hydrochloride (used to counter the effects of a narcotic overdose), expired 10/12; and -Two 50% Dextrose (glucose) injectables, expired 08/12. 10. Observation on 01/30/13 at 11:10 AM of the emergency medications located in the pre-operative area showed: -One bag of Lactated Ringer expired 12/12. 11. During an interview on 01/30/13 at 11:15 AM, Staff K stated that nursing staff checked for expired medications weekly. (Note that this conflicts with Physician D's interview above, in regard to how frequently medications are checked). 12. During an interview on 01/31/13 at 10:45 AM, Staff A stated that nursing staff were responsible for checking monthly for expired medications. 13. Record review of the Centers of Disease Control and Prevention (CDC) recommendations for multi-dose vials, dated 02/09/11 showed: - When should multi-dose vials be discarded? Medication vials should always be discarded whenever sterility is compromised or questionable. In addition, the United States Pharmacopeia (USP) General Chapter 797 [16] recommends the following for multi-dose vials of sterile pharmaceuticals: - If a multi-dose has been opened or accessed (e.g., needle-punctured) the vial should be dated	L1128		

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L1128	Continued From page 5 and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial. - If a multi-dose vial has not been opened or accessed (e.g., needle-punctured), it should be discarded according to the manufacturer's expiration date. The manufacturer's expiration date refers to the date after which an unopened multi-dose vial should not be used. The beyond-use-date refers to the date after which an opened multi-dose vial should not be used. The beyond-use-date should never exceed the manufacturer's original expiration date. 14. Review of the facility's policy titled, "Pharmaceutical Services", revised 12/12/12 showed: -If a multi-dose vial has been opened or accessed (e.g., needle-punctured) the vial must be dated and discarded in accordance with manufacturer's instructions and state/local regulations. 15. Observation on 01/30/13 at 9:25 AM of Procedure Room #1 showed one opened multi-dose vial of Lidocaine with no date to show when the vial was opened. During an interview on 01/30/13, at the time of the observation, Staff L, Registered Nurse (RN) stated that she had just opened the vial that morning and she would discard it at the end of the day. 16. Review of the facility's policy titled, "Medical Equipment and Supplies", showed: -Supplies are checked regularly by the assigned staff, rotated to ensure oldest used first, and; -Expired supplies were removed from the active	L1128		

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L1128	Continued From page 6 stock. 17. Observation on 01/30/13 at 10:35 AM of the supply room showed: -Three boxes of surgical gloves, expired 11/05; -One box of surgical gloves, expired 01/07, and; -Three postpartum balloons (used to control or reduce postpartum [occurring in the period shortly after childbirth] hemorrhage), expired 12/10, 12/11, and 01/12. 18. During an interview on 01/31/13 at 10:45 AM, Staff A stated that the policy needed to include the frequency that supplies were checked. 19. Review of the Association of Perioperative Registered Nurses (AORN) Standards and Recommended Practices, "Environmental Cleaning", dated 2012, Recommendation II showed, "A safe, clean environment should be reestablished after each surgical procedure. Routine cleaning and disinfection reduces the amount of dust, organic debris (debris in the environment) and microbial load (number and type of microorganisms contaminating an object) in the environment. Following scientifically based recommendations for cleaning and disinfection practice in health care organizations helps to reduce infections associated with contaminated items". 20. Review of the facility's policy titled, "Cleaning, Disinfection and Sterilization", revised 04/08 showed: -Thoroughly clean all surfaces that are being used in patient care areas. and; -All areas of the clinic should be kept clean and free from excess clutter. 21. Observation on 01/30/13 at 9:30 AM of	L1128		

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L1128	Continued From page 7 Procedure Room #1 showed: -One ceiling air vent that had copious amounts of visible dust/dirt; -One table with rusted castors (uncleanable surface); -One stool with rust which was covered with clear tape (uncleanable surface); -One plastic bin which contained emergency supplies was covered with dust; -One plastic bin which contained intravenous (IV/inserted into a blood vein) solution was covered with dust; and -One oxygen tank with adhesive residue (uncleanable surface). During an interview on 01/30/13 at 9:40 AM, Physician D, Medical Director acknowledged the dust on the plastic bins and stated that staff should have noticed when checking the emergency supplies. 22. Observation on 01/30/13 at 10:11 AM of Procedure Room #2 showed: -One ceiling air vent that had copious amounts of visible dust/dirt; -One IV pole with rusted castors; -One table with rusted castors; -One oxygen tank with rust and tape residue; -One suction machine with rust on the kick plates; -One plastic bin containing emergency supplies was covered with dust; and -One stool with rust which was covered with clear tape. 23. Observation on 01/30/13 at 10:25 AM of Procedure Room #3 showed: -Rust on the base of the procedure table; -One IV pole with rusted castors; -One table with rusted castors; -One oxygen tank with tape residue;	L1128		

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L1128	Continued From page 8 -One suction machine with rust on the sides; and -Two plastic bins containing emergency supplies were covered with dust. 24. Observation on 01/30/13 at 10:35 AM of the storage room showed: -One ceiling air vent with visible dust; and -The floor in the room which contained eight oxygen canisters had visible dirt and dust. 25. Observation on 01/30/13 at 10:45 AM of the supply room showed: -One suction machine with visible dust. 26. During an interview on 01/31/13 at 10:45 AM, Staff A stated that the management team was responsible for spot audits and for checking for environmental issues.	L1128		
L1170	19 CSR 30-30.060(3)(J) Each abortion facility shall develop Each abortion facility shall develop a quality assurance program that includes all health and safety aspects of patient care and shall include a review of appropriateness of care. Results of the quality assurance program shall be reviewed at least quarterly by the administrator, director of patient care, a representative of the medical staff and the governing body. The quality assurance program shall include a review of at least the following: 1. Completeness of clinical records; 2. Incidence of morbidity and mortality; 3. Intraoperative and postoperative complications; 4. All cases transferred to a hospital; 5. All cases that resulted in a length of stay of more than twelve (12) hours; 6. Errors in diagnosis;	L1170		

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L1170	Continued From page 9 7. Problems in compliance with state and local laws and regulations; and 8. All cases in which the gestational age was determined to be beyond eighteen (18) weeks. This regulation is not met as evidenced by: Based on interview and record review, the facility failed to adequately include in the Quality Assurance program all cases in which the gestational age was determined to be beyond eighteen (18) weeks. The facility does an average of 340 cases per month. On the first day of the survey there were 25 scheduled cases. Findings included: 1. Review of the facility's quarterly Quality Assurance (QA) log of complications and occurrences included the gestational age of the fetus as part of the data, but not all cases greater than 18 weeks were placed on the report. 2. During an interview on 01/30/13 at 4:45 PM, Staff A, Vice President of Patient Services confirmed that a gestational age of 18 weeks is not by itself considered a complication or occurrence, and therefore not all of those cases are routinely reviewed as part of the QA activities, only if there were also a complication and/or occurrence.	L1170		
L1171	19 CSR 30-30.060(3)(K) The quality assurance program must show The quality assurance program must show evidence of action taken as a result of the identification of the problems. This regulation is not met as evidenced by:	L1171		

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L1171	Continued From page 10 Based on interview and record review, the facility failed to adequately document action taken as a result of ongoing Quality Assurance activities. The facility does an average of 340 cases per month. On the first day of the survey there were 25 scheduled cases. Findings included: 1. Review of facility's quarterly Quality Assurance (QA) committee meeting notes indicated that while various improvement topics were discussed, there was no formal evidence presented to consistently indicate what actions were taken by the committee as a result of identification of problems. 2. During an interview on 01/30/13 at 3:50 PM Staff A, Vice President of Patient Services stated that the QA staff had many years of experience working together, knew each other well, and regularly talked about what issues were ongoing, but formal documentation of action items and the outcome could be improved. 3. During an interview on 01/30/13 at 4:25 PM, Staff G, Training and Quality Systems Coordinator stated that the facility had a corrective action tracking form that was in report format that the laboratory staff used for quality improvement, and the facility was considering using the same format for non-laboratory problems, but stated that she could not find any specific example of the form being used outside the laboratory.	L1171		
L1190	19 CSR 30-30.060(5) Complaints, Any person having a complaint Complaints. Any persons having a complaint	L1190		

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L1190	Continued From page 11 pertaining to the care of a patient rendered by an abortion facility shall direct the complaint in writing to the Missouri Department of Health, Bureau of Hospital Licensing and Certification, P.O. Box 570, Jefferson City, MO 65102. The person making the complaint shall be contacted by the Department of Health within five (5) working days of receipt of the complaint and the complaint shall be investigated by the Department of Health within twenty (20) working days of receipt of the complaint. This regulation is not met as evidenced by: Based on interview, policy review, and review of the facility's patient rights document, the facility failed to provide accurate written notice of patient rights to inform patients or their representatives of their options of who to contact to file a grievance/complaint as required. The Ambulatory Surgical Center does an average of 340 cases per month. On the first day of the survey there were 25 scheduled cases. Findings included: 1. Review of the facility's policy titled, "Client Services", revised 12/12/12 stated: -A bill of rights is available, either framed and hanging on the wall, or on the clipboards; -This specified client's rights and the facility's obligations; -For any concerns, it gives a managerial contact for clients to call; -Clients with grievances will be given to the supervisor or manager on duty; -Should this person not be available or be unable to resolve the client's issue, the client will be offered the option to talk with the next managerial level, and; -They can do this by calling that person's number	L1190		

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L1190	Continued From page 12 and extension directly or staff can take the client's name and number and forward it. 2. Review of the facility's "Bill of Rights" that patients are given prior to a procedure, gave direction for the patient to contact the Health Center Coordinator or the Director of Surgical Services, and provided the facility telephone number. (Note that the notice of rights failed to state that patients could report their complaint to the state agency, failed to include the state agency address, and telephone number). 3. During an interview on 01/31/13 at 11:00 AM, Staff A, Vice President of Patient Services stated that the facility had not been including/providing the state agency information (address and telephone number) in the "Bill of Rights" document that was presented to patients.	L1190		
L1252	19 CSR 30-30.070(3)(L) At least two (2) ABC-type fire extinguishers At least two (2) ABC-type fire extinguishers shall be located in the facility, one (1) in the clinical area; This regulation is not met as evidenced by: Based on observation and interview, the facility failed to conduct a monthly inspection of the portable fire extinguishers. This deficient practice affects all occupants in the facility. The facility does an average of 340cases per month. On the first day of the inspection there were 25 scheduled cases. Findings included: 1. Observation during a tour of the facility	L1252		

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L1252	Continued From page 13 conducted on the morning of 01/30/13, showed the monthly inspection tags on all of the portable fire extinguishers were blank indicating a monthly inspection had not been conducted. 2. During an interview on 01/30/13 at 2:20 PM, Staff A, Director of Patient Services stated the facility staff did not conduct monthly inspections of the portable fire extinguishers.	L1252		