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 _____	03/16/2016

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 onsite, unannounced state licensure survey to determine compliance with 19 CSR 30-30.050 through 19 CSR 30-30.070 for Abortion Facilities was conducted from 03/14/16 to 03/16/16. See below for findings:	L 000		
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: - Follow the manufacturer's instructions for cleaning two of two autoclaves (sterilizers); - Follow the manufacturer's instructions for biological testing (used to monitor steam sterilizers); - Have a procedure in place to prevent cross contamination and separation of contaminated instruments by space; - Follow the manufacturer's instructions for packaging instruments for sterilization; - Restrict multi-dose vials to a centralized	L1128		

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L1128	Continued From page 1 medication area separate from the procedure room; - Restrict single-dose vials/ampoules to single patient use; - Ensure a sanitary environment was preserved in the sterilization rooms and sterile supply room; - Ensure expired supplies were not available for use; - Ensure the glucometer (instrument for testing the blood sugar level) was approved by the manufacturer for clinical use (use on multiple patients); - Ensure medication refrigerators temperatures were maintained to provide stable medication; and - Ensure equipment used for patient care was approved for use in healthcare facilities. The Abortion Facility does an average of 424 cases per month. On the first day of the survey, there were 32 cases. Findings included: 1. Review of the American National Standards Institute (ANSI)/Association of the Advancement of Medical Instrumentation (AAMI) document titled, "Comprehensive Guide to Steam Sterilization and Sterility Assurance in Healthcare Facilities, ST79," dated 2010, showed: - 9.4 Routine Care: Sterilizers should be inspected and cleaned daily according the manufacturer's written instructions. Weekly or other prescribed inspection and cleaning should be performed as specified in the manufacturer's written instructions. 2. Review of the Tuttnauer (manufacturer) undated document titled, "Operation & Maintenance Manual," showed:	L1128		

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L1128	Continued From page 2 - If the autoclave is not cleaned regularly, dirt and debris will build up and clog the tubing and valves. This dirt can also be transmitted to the instruments during sterilization. In addition, a layer of dirt on the stainless steel chamber traps moisture against the metal and will lead to the chamber becoming porous and failing. - It is recommended that your autoclave be cleaned with Chamber Brite (brand) once per week. - It is required that the air jet be cleaned once per week or more often if necessary, to remove any accumulated dirt and debris. 3. Review of the facility's Affiliate Risk Management Services (ARMS) Infection Prevention Manual, dated 08/15, showed infection prevention resources included AAMI and Association of PeriOperative Registered Nurses (AORN). 4. Review of the facility's document titled, "Sterilization Room Humidity, Temperature and Autoclave Maintenance Log," dated 02/16, showed staff failed to clean the chamber of Autoclave #1 the week of 02/23/16 through 02/27/16. 5. Review of the facility's document titled, "Sterilization Room Humidity, Temperature and Autoclave Maintenance Log," dated 03/16, showed: - Staff failed to clean the chamber of Autoclave #1 the week of 03/01/16 through 03/05/16. - Staff failed to clean the air jet of Autoclave #1 the week of 03/08/16 through 03/12/16. - Staff failed to clean the air jet of Autoclave #2 the week of 03/08/16 through 03/12/16.	L1128		

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L1128	Continued From page 3 6. Observation on 03/14/16 at 2:01 PM in the sterile processing room showed two Tuttnauer 3870M (model) autoclaves. The inside of the autoclaves was discolored with shades of brown spots. 7. During an interview on 03/14/16 at 2:04 PM, Staff B, Registered Nurse (RN), Vice President of Patient Services, confirmed the discoloration but stated that she thought the discoloration was due to the age of the sterilizers. 8. Review of the product insert for 3M (manufacturer) Attest (brand) Biological Indicator, dated 09/05, showed: - Attest biological indicators should be placed in an appropriate test tray or package, and be used to monitor every load. - Record the sterilized and control biological indicator results. 9. Review of the facility's ARMS Infection Prevention Manual, dated 08/15, showed: - Affiliates must check state/local requirements and manufacturer's recommendations. - For affiliates, a biological indicator process challenge device must be conducted every week in a health center providing family planning services and daily in a health center providing abortion/surgical services. - The results of the bacteriological test must be documented in a log book or file and maintained for three years (check state/local requirement). 10. Review of the facility's undated policy titled, "Spore Testing Biological Indicator," showed: - Attest biological indicators should be placed in an appropriate test tray or package, and be used to monitor weekly loads of autoclaves.	L1128		

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L1128	Continued From page 4 - Record the sterilized and control biological indicator results in quality management binder. 11. Review of the facility's biological indicator log dated 02/16 showed staff performed a biological indicator weekly and failed to perform a biological indicator with every load. 12. During an interview on 03/15/16 at 3:42 PM, Staff H stated that: - The biological indicator was normally run on Wednesday. - They never ran the biological indicator with every sterilization load. 13. Review of the ANSI and AAMI document titled, "ANSI/AAMI ST79:2010," Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities, dated 09/24/10, showed: - 3.2.3. The sterile processing department should be designed to separate areas in which contaminated items are received and processed from areas in which clean items are packaged, sterilized, and stored. Functional work areas should be physically separated by walls or partitions to control contaminants generated during the phases of reprocessing. 14. Observation on 03/15/16 at 3:00 PM in the decontamination room showed Staff H cleaned instruments. The pass-through window was opened to the instrument processing room during the cleaning process and a tray of previously cleaned instruments were setting on the ledge of the opened window. A blue wrap (used to wrap surgical instruments for sterilization) and gauze (included in sterilization packs) were setting on the counter on the other side of the window.	L1128		

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L1128	Continued From page 5 15. During an interview on 03/15/16 at 3:25 PM, Staff H stated that they left the window open all the time. 16. Review of the Chex-all II (brand) paper-plastic pouches (peel packs - used to contain instruments for sterilization) manufacturer's instructions printed on the box showed: - After placing the item into the pouch, release the liner strip covering the adhesive is peeled off, and the pouch paper is folded at the crease so that the adhesive is in contact with the plastic of the pouch. - Pressure is then applied to the folded part of the pouch to complete the sealing process. 17. Review of the manufacturer's instructions printed on the peel packs showed to insert item, peel off liner, re-fold along the crease (press down from center outward). 18. Observation on 03/14/16 at 1:43 PM in procedure room #1 showed four peel packs holding instruments to be used during the abortion procedure. The closure ends of the peel pouches were folded over past the crease and folded over multiple times. (The peel packs are made with a paper side and a plastic side so steam can penetrate and is not trapped in the pouch. When the peel packs are folded over, it makes a plastic to plastic cover that prevents the proper penetration and exhaust of the steam.) (Note: Manufacturer's instructions on these peel packs were as above.) 19. Observation on 03/14/46 at 2:00 PM in procedure room #3 of the supply cabinets	L1128		

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L1128	Continued From page 6 showed numerous peel packages containing instruments to be used during the abortion procedure. The closure ends of the peel pouches were folded over approximately two inches below the package crease and taped across the package. (Note: Manufacturer's instructions on these peel packs were as above.) 20. Observation on 03/14/15 at 2:06 PM in the sterile processing room showed shelves of instruments in peel pouches. Staff failed to fold many of these peel pouches on the crease and were folded over multiple times. (Note: Manufacturer's instructions on these peel packs were as above.) 21. During an interview on 03/15/16 at 3:12 PM, Staff H stated that she did not know why some people folded over the peel packs multiple times. 22. Review of the Centers for Disease Control and Prevention (CDC) document titled, "Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care," dated 2014, showed: - To dedicate multi-dose vials to a single patient whenever possible; and - If multi-dose vials will be used for more than one patient, they should be restricted to a centralized medication area and should not enter the immediate patient treatment area (e.g., operating room, patient room/cubicle). 23. Review of the CDC document titled, "Guide to Infection Prevention for Outpatient Settings: Minimum Expectations for Safe Care," dated 2014, showed: - Do not administer medications from single-dose or single-use vials, ampoules, or bags or bottles	L1128		

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L1128	Continued From page 7 of intravenous solution to more than one patient. 24. Review of the facility's policy titled, "Infection Prevention Program," dated 12/14/14, showed: - Do not administer medications from single-dose or single-use vials, ampules, or bags or bottles of intravenous (small catheter inserted into a vein for administering medication and fluid) solution to more than one patient. - If multi-dose vials will be used for more than one patient, the vials should be restricted to a centralized medication area. 25. Review of the facility's policy titled, "Pharmaceutical Services," dated 06/14, showed: - Multi-dose vials (once opened) shall be kept in a centralized location. - Single-dose medications are used for one client only and are discarded after use on each patient. 26. Observation on 03/14/16 at 1:30 PM in Procedure Room #1 showed an opened, multi-dose vial of Lidocaine (anesthetic - numbs an area). During an interview upon the observation, Staff D, Director of Surgical Services, stated that opened, multi-dose vials were not usually kept in the procedure rooms. 27. Observation on 03/14/16 at 1:35 PM of Procedure Room #1's emergency medication box showed an opened, single-dose vial of Dextrose (a form of sugar for injection). During an interview on 03/14/16 at 1:37 PM, Staff D stated that single-dose vials were usually thrown away.	L1128		

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L1128	Continued From page 8 28. Observation on 03/14/16 at 1:50 PM of Procedure Room #3 showed an opened multi-dose vial of Lidocaine on the counter. During an interview upon the observation Staff B stated that the opened multi-dose vial should not have been in the procedure room. 29. Observation on 03/14/16 at 4:45 PM in the laboratory showed an opened, multi-dose vial of normal saline (sterile mixture of salt and water for injection) with an expiration date of 03/01/16. During an interview upon the observation, Staff B stated that she was not sure what the normal saline was used for. 30. Review of the CDC and the Healthcare Infection Control Practices Advisory Committee, "Guidelines for Environmental Infection Control in Health-Care Facilities," dated 2003, showed: - Microorganisms proliferate in environments wherever air, dust and water are present; and - Dry conditions favor gram-positive bacteria in dust and on surfaces. 31. Review of the AORN, "Guideline for Environmental Cleaning," dated 2015, showed: - Recommendation II. * The patient should be provided a clean, safe environment. - Recommendation II.a. * The perioperative Registered Nurse should assess the perioperative environment frequently for 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	L1128		

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L1128	Continued From page 9	L1128		

responsibility for verifying a clean surgical environment before the start of an operative or invasive procedure rests with perioperative nurses.
- Recommendation II.b.
* Dust is known to contain human skin and hair, fabric fibers, pollens, mold, fungi, insect parts, glove powder, and paper fibers, among other components.
- Recommendation IV.
* Perioperative areas should be terminally cleaned.
* Terminal cleaning and disinfection of the perioperative environment decreases the number of pathogens and the amount of dust and debris.
- Recommendation IV.a.
* Terminal cleaning and disinfection of perioperative areas, including sterile processing areas, should be performed daily when the areas are being used.
- Recommendation IV.e..
* Sterile processing areas should be terminally cleaned.
* Sterile processing personnel conduct critical processes, such as decontaminating, assembling, and sterilizing surgical instrumentation, in support of operating and invasive procedure rooms. As such, the recommendations for terminal cleaning apply in sterile processing areas as in areas where surgical and other invasive procedures are performed. Furthermore, sterile processing areas where decontamination occurs have some of the highest risks for environmental contamination of all perioperative areas. Environmental cleaning in sterile processing areas is critical for reducing the risk of disease transmission from reservoirs of bloodborne pathogens and microorganisms in the decontamination environment.

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L1128	Continued From page 10 - Recommendation IV.e.2. * All horizontal surfaces (e.g., sterilizers, countertops, furniture, shelving) should be damp dusted daily with an Environmental Protection Agency (EPA) registered disinfectant and a clean, low-linting cloth. - Recommendation V. * All areas and equipment that are not terminally cleaned should be cleaned according to an established schedule. * A clean environment will reduce the number of micro-organisms present. - Recommendation V.a.1. * Areas and items that should be cleaned on a schedule include clean and soiled storage areas, sterile storage areas, shelving and storage bins; corridors, including stairwells and elevators, walls and ceilings, privacy curtains, pneumatic tubes and carriers, sterilizers and loading carts, sterilizer service access rooms, unrestricted areas (e.g., lounges, waiting rooms, offices), and environmental services closets. 32. Review of the facility's policy titled, "Infection Prevention Manual," dated 12/14/14, showed as part of the infection prevention plan, (facility) has policies and procedures for routine cleaning and disinfection of environmental surfaces. 33. Review of the facility's undated policy titled, "Environmental Cleaning of Clinical Care Areas: Policy and Procedure," showed: - At the beginning of each day or prior to the first patient interaction, all environmental clinical care areas will be cleaned and disinfected. - Reprocessing and other sterile storage areas are to be cleaned according to the following schedule: * Clean all counters and floors daily.	L1128		

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L1128	Continued From page 11 (Note: The facility's policy referenced CDC.) 34. Observation on 03/14/16 at 11:28 AM of the shelving units in the sterile supply room showed: - Two blue plastic storage bins that contained oxygen masks. Dust and loose particles were observed in the bottom of the bins. - One blue plastic storage bin that contained nasal cannulas. Dust and loose particles were observed in the bottom of the bin. - One blue plastic storage bin that contained sterile IV tubing. Dust and loose particles were observed in the bottom of the bin. - One empty blue plastic storage bin. Dust and loose particles were observed in the bottom of the bin. 35. Observation on 03/14/16 at 2:25 PM in the sterile processing room showed stacks of peel pouches on the counter with off-white flecks over the pouches. Some of the flecks fell off when the peel pouches were moved. During an interview upon the observation, Staff D stated that once they go through the sterilization process, it would kill everything. 36. Observation on 03/14/16 at 2:32 PM in the sterile processing room showed dust/white flecks around autoclave #1 that left a mark when a finger was pulled through. 37. Observation on 03/15/16 at 3:24 PM in the sterile processing room showed: - The stack of peel pouches on the counter with off-white flecks on the pouches. - Dust/white flecks around autoclave #1. During an interview upon the observation, Staff H	L1128		

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L1128	Continued From page 12 stated that: - She was not sure what the off-white flecks were from. - She agreed there were white flecks and dust around autoclave #1. 38. During an interview on 03/14/16 at 2:35 PM, Staff B stated that they had a housekeeper on staff that was responsible for cleaning the blue storage bins. She agreed the bins had debris in the bottom of them. 39. Review of the AORN, "Guideline for Cleaning and Care of Surgical Instruments," dated 2015, showed: - Recommendation II.e.5. * External shipping containers and web-edged cardboard boxes may collect dust, debris, and insects during transport and may carry contaminants into the facility. 40. Review of the facility's undated policy titled, "Environmental Cleaning of Clinical Care Areas," showed: - Clean all counters and floors daily in the sterile storage areas; and - The patient care environment throughout the facility will be maintained in a state of cleanliness that meets professional standards in order to protect patients and healthcare personnel from potentially infectious microorganisms. 41. Review of the facility's ARMS Infection Prevention Manual, dated 08/15, showed: - Guidelines for the storage of sterile supplies; * Store clean supplies separately from sterile supplies; and * Store supplies 8 to 10 inches from the floor.	L1128		

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L1128	Continued From page 13 42. Observation on 03/14/16 at 1:55 PM in the decontamination room showed a stack of flattened corrugated boxes. During an interview upon the observation, Staff B stated that the boxes were used for products (of the abortions) to be sent out (to pathology). 43. Observation on 03/14/16 at 2:00 PM in the sterile supply room showed: - Shelving units mounted on all walls with the following items stored next to sterile supplies: * Three corrugated boxes labeled "BD Syringes" that contained individually packaged sterile syringes; * One corrugated box that contained sterile packages of IV catheters; * Five opened corrugated boxes labeled "IPAS Cannulae" that contained individually packaged uterine cannulas (a hollow tube that can be inserted into the body, often for delivery or removal of fluid); * One corrugated box that contained formalin (a colorless solution of formaldehyde in water, used chiefly as a preservative for biological specimens) filled specimen cups; and * One corrugated box that contained business office forms; - Two corrugated boxes on the floor that contained disposable patient bed sheets; and - One corrugated box on the floor that contained condoms. 44. Observation on 03/15/16 at 3:27 PM in the sterile processing room showed corrugated boxes on the floor and propped against the wall. During an interview upon the observation, Staff H stated that the boxes contained the blue wrap	L1128		

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L1128	Continued From page 14 used for instrument wrapping (for sterilization) but were too long to be stored inside the cabinets. 45. During an interview on 03/14/16 at 2:35 PM, Staff B stated that: - They had a housekeeper on staff that was responsible for cleaning the sterile supply room, including the floors; and - The corrugated boxes should not have been in the sterile supply room. 46. Review of the bottle of Metracide (manufacturer) Cidex OPA Plus (brand - used to high-level disinfect semi-critical items that come in contact with non-intact skin or mucous membranes) test strips showed, "Use within 90 days of opening." 47. Observation on 03/14/16 at 2:15 PM showed a bottle of Metracide Cidex OPA Plus test strips with 05/16 and "11/20/15 open" written on the bottle. (Note: The test strips expired 02/20/16.) During an interview upon the observation, Staff B stated that it looked like they were expired. 48. Observation on 03/14/16 at 4:40 PM in an ultrasound room showed a container of ultrasound gel with an expiration date of 12/15. During an interview upon the observation, Staff B confirmed that the ultrasound gel had expired. 49. Observation on 03/14/16 at 4:45 PM in the laboratory showed an opened Hemocue (device used to test blood) swab (used for disinfecting the Hemocue) with an expiration date of 08/09/14.	L1128		

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L1128	Continued From page 15 During an interview upon the observation, Staff B confirmed that the Hemocue swab had expired. 50. Review of the CDC, "Infection Prevention during Blood Glucose Monitoring and Insulin Administration," dated 05/02/12, showed whenever possible, blood glucose meters should not be shared. If they must be shared, the device should be cleaned and disinfected after every use, per manufacturer's instructions. If the manufacturer does not specify how the device should be cleaned and disinfected then it should not be shared. 51. Review of the CDC, "Guideline for Disinfection and Sterilization in Healthcare Facilities," dated 2008, showed the Food and Drug Administration (FDA) had not cleared any high-level disinfectant with alcohol as the main ingredient. 52. Review of the TRUEbalance (brand) glucometer's Owner's Booklet showed: - The TRUEbalance Blood Glucose Monitoring System is for one person use ONLY; - DO NOT share your meter with anyone, including family members; and - ALL parts of the meter could carry blood-borne disease after use, even after cleaning and disinfection. 53. Review of the facility's policy titled, "Blood Glucose Testing with Glucometer," dated 06/25/15, showed: - Clean meter when visibly dirty; - Wipe meter with a clean, lint-free cloth dampened with 70% Isopropyl alcohol; and - Let meter air dry thoroughly before using to test.	L1128		

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L1128	Continued From page 16 The policy failed to list a procedure for disinfecting the glucometer. 54. During an interview on 03/15/16 at 1:30 PM, Staff B stated that: - She read the manufacturer's instructions for use manual for the glucometer; - The glucometer had not been approved for clinic use on multiple patients; and - They would purchase new multi-use glucometers. 55. Review of the facility's policy titled, "Laboratory Refrigerator," dated 05/03/15, showed: - Each site has two refrigerators for clinical operations, one for medical supplies. - The temperature should be checked and recorded twice daily. - The acceptable range is between 2 and 8 Celsius (36-46 degree Fahrenheit[F]). - If not in range, report to supervisor and document corrective action. 56. Observation on 03/14/16 at 2:00 PM in the pre-post area showed: - A refrigerator labeled patient medication refrigerator; - The refrigerator contained multiple boxes of Rhogam (a sterilized solution made from human blood used to prevent an immune response to Rh positive blood in people with an Rh negative blood type.) - The manufacturer's recommendation for storage of Rhogam showed: * Store at 2-8 degree Celsius (36-46 degree F). Do not freeze. 57. Review of the Medication Refrigerator	L1128		

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L1128	Continued From page 17 Temperature Logs for 02/16 showed direction for staff to monitor the temperatures daily. - The ideal temperature was 34-40 degrees F: - No temperature was recorded for 02/08/16, 02/11/16, 02/15/16, 02/18/16, 02/22/16, and 02/25/16; - Temperature was recorded out of range on nine of 18 recorded days based on the temperature log range of 34-40 degree F with no intervention recorded; - Temperature was outside the Rhogam manufacturer's recommended temperature range of 36-46 degree F for three of 18 recorded days; and - Temperatures were recorded below freezing (32 degree F) on three days. 58. Review of the Medication Refrigerator Temperature Logs for 03/16 showed direction for staff to monitor the temperatures daily: - No temperature was recorded for 03/03/16, 03/07/16 and 03/10/16; - Temperature was recorded out of range on six of nine recorded days based on the temperature log range of 34-40 degree F with no intervention recorded; - Temperature was outside the Rhogam manufacturer's recommended temperature range of 36-46 degree F for seven of nine recorded days; and - Temperatures were recorded at or below freezing on four days. 59. During an interview upon the observation, Staff D stated that the temperature of the refrigerator should be checked daily. She was not aware that the refrigerator was not being checked daily or that the temperature had been out of range.	L1128		

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L1128	Continued From page 18 60. Review of the FDA/Consumer Product Safety Commission (CPSC) document titled, "FDA/CPSC Public Health Advisory - Hazards Associated with the Use of Electric Heating Pads", dated 12/12/95, showed: - The FDA and CPSC have received many reports of injury and death from burns, electric shock and fires associated with the use of electric heating pads. - An electric heating pad can be dangerous for patients with decreased temperature sensation and patients taking medication for pain. - Prolonged use on one area of the body can cause a severe burn, even when the heating pad is at a low temperature setting. 61. FDA and CPSC recommend the following precautions be taken to avoid hazards associated with the use of electric heating pads: - Never [partial list]: * Use on a person who has skin that is not sensitive to temperature changes (e.g. sedated or medicated for pain). * Use in an oxygen enriched environment or near equipment that stores or emits oxygen. 62. Observation on 03/14/16 at 2:00 PM in the pre-post area showed: - 10 reclining chairs with electric heating pads placed across the backs; - The heating pads were labeled for Household Use Only. During an interview upon the observation, Staff D stated that: - The heating pads were used for patient comfort after their procedure. - She was not aware the facility should not use	L1128		

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L1128	Continued From page 19 electric heating pads specified for household use for patient care.	L1128		
L1137	19 CSR 30-30.060(1)(B)(13) A personnel record shall be maintained A personnel record shall be maintained on each employee and shall include documentation of each employee's orientation, health status, education and training, as well as verification of current licenses for physicians, registered nurses (RNs) and licensed practical nurses (LPNs). This regulation is not met as evidenced by: Based on state statute review, policy review, record review, and interview, the facility failed to: - Perform criminal background checks (CBCs - completion of an inquiry to the Highway Patrol for criminal records available for disclosure to a provider, to determine an individual's criminal history) prior to hire for four (Staff D, O, P, and Q) of thirteen personnel files reviewed; - Perform employee disqualification list (EDL) inquiries (to determine if the employee was placed on the EDL list maintained by the Department of Health and Senior Services, regarding employment eligibility) prior to hire for three (Staff O, P, and Q) of thirteen employees personnel files reviewed; - Provide ongoing staff education regarding infection control for five (Staff E, G, I, O, and P) of thirteen personnel files reviewed; and - Ensure orientation was completed for two (Staff O and P) of thirteen personnel files reviewed. The Abortion Facility does an average of 424 cases per month. On the first day of the survey, there were 32 cases.	L1137		

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L1137	Continued From page 20 Findings included: 1. Review of the Missouri Statute Chapter 660, showed that CBCs were required by any provider pursuant to Section 660.317.1 (that included facilities licensed under Chapter 197 - Ambulatory Surgical Centers and Abortion Facilities) prior to allowing any person who had been hired as a full-time, part-time or temporary position, to have contact with any patient. 2. Review of the Missouri Statute Chapter 660, showed that EDL checks were required by any provider pursuant to Section 660.315 (that included facilities licensed under Chapter 197 - Ambulatory Surgical Centers and Abortion Facilities) to determine employment eligibility. 3. Review of the facility's document titled, "Employee Manual," dated 07/13, showed: - The Vice President (VP) of Human Resources would be responsible for performing all "background checks" that are applicable under Federal, State and Planned Parenthood of America laws and requirements; and - All candidates prior to hire will have a criminal background check and Employee Disqualification List search completed prior to hire, per the Missouri Revised Statutes Chapter 660, Section 317. 4. Review of the personnel file for Staff D, Director of Surgical Services, showed she was hired 02/23/15. The facility failed to complete the CBC prior to hire to ensure employment eligibility. 5. Review of the personnel file for Staff O, Volunteer, showed she did not have a personnel	L1137		

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L1137	Continued From page 21 file. The facility failed to complete a CBC, and an EDL search, to ensure employment eligibility, which included volunteers, prior to having contact with any patients. 6. Review of the personnel file for Staff P, Volunteer for the Practicum Program, showed she was hired 08/06/2006. The facility failed to complete a CBC, and an EDL search, to ensure employment eligibility, which included volunteers, prior to having contact with any patients. 7. Review of the personnel file for Staff Q, Volunteer, showed no documentation of her start date. The facility failed to complete a CBC, and an EDL search, to ensure employment eligibility, which included volunteers, prior to having contact with any patients. 8. During an interview on 03/15/16 at 11:35 AM, Staff L, VP of Human Resources, stated that she had been out of the office on surgical leave, which caused Staff D's CBC to have been completed after her hire date. 9. During an interview on 03/15/16 at 1:30 PM, Staff B, Registered Nurse, VP of Patient Services, stated that: - They had not kept personnel files on volunteers that started working at Planned Parenthood until five years ago; - They had not performed EDL's on volunteers that started more than five years ago; - Staff O had been a volunteer for more than 30 years; and - They had not completed a CBC or an EDL on Staff O. 10. During an interview on 03/15/16 at 3:10 PM,	L1137		

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L1137	Continued From page 22 staff L stated that: - They started completing EDL's on volunteers a few years ago; - They had not completed CBCs on volunteers because of the cost; - She needed to make personnel files on all volunteers to include CBCs and EDL searches; and - She agreed the CBCs and EDL's had not been completed on Staff O, P, and Q. 11. Review of the facility's document titled, "Infection Prevention Manual" dated 10/14/14, showed: - The Infection Prevention Program referenced the Centers for Disease Control and Prevention guidelines; - Training included infection prevention education and training for all staff that have the potential for exposure to patients and/or infectious materials, including body substances, contaminated medical supplies and equipment, contaminated environmental surfaces, or contaminated air. This includes persons not directly involved in patient care (e.g., volunteers, non-medical staff, contractual staff, and housekeeping) but potentially exposed to infectious agents that can be transmitted to and from staff and patients; and - Training is provided as part of staff departmental orientation and repeated regularly, at least annually, or as needed with new procedures or systems focusing on staff and patient safety. 12. Review of the personnel files for Staff E, Licensed Clinical Social Worker, and Staff I, Sonographer, showed the last infection control training date was 11/11/14.	L1137		

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L1137	Continued From page 23 13. Review of the personnel file for Staff G, Lead Health Center Assistant, showed the last infection control training date was 09/25/14. 14. Review of the personnel file for Staff O showed she did not have a personnel file and there was no documentation to show she had infection control training. 15. Review of the personnel file for Staff P showed she was hired 09/05/2006. There was no documentation to show she had infection control training. 16. Review of the personnel file for Staff Q showed the last infection control training date was 08/14. 17. During an interview on 03/15/16 at 1:30 PM, Staff B stated that Staff O had been a volunteer for more than 30 years and had not completed infection control training. 18. During an interview on 03/16/16 at 12:45 PM, Staff C, Director of Quality and Compliance, stated that: - The facility held an infection control training class on 01/28/16; and - Staff E, Staff G, and Staff I did not attend the class. 19. Review of the facility's document titled, "Employee Manual," dated 07/13, showed all employees and volunteers are required to sign an Annual Privacy Statement in compliance with this policy and the federal Health Insurance Portability and Accountability Act (HIPPA). 20. Review of the facility's undated online	L1137		

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L1137	Continued From page 24 orientation and training document titled, "Getting started with the Center for Affiliated Learning (CAL)," showed: - CAL videos are to be watched by each full-time, part-time, and per diem employee, and volunteers; and - CAL videos included: * Intimate Partner Violence 1, 2, and 3; * Blood Borne Pathogens; * Sterile Technique; * Cleaning and Disinfection; * Talking about Abortion 1, 2, and 3; * Orientation to the Abortion Pill 1, 2, and 3; and * Health Care Assistant 1 and 2. 21. Review of the personnel file for Staff O showed she did not have a personnel file. The facility failed to provide documentation of orientation or a signed confidentiality statement. 22. Review of the personnel file for Staff P showed she was hired on 09/05/06. The facility failed to provide documentation of orientation or a signed confidentiality statement. 23. During an interview on 03/15/16 at 2:50 PM, Staff D stated that anyone they chose to volunteer at the facility would complete the CAL training, the same way newly hired employees had done.	L1137		
L1153	19 CSR 30-30.060(2)(C) The medical record shall contain The medical record shall contain-a unique identifying record number, patient identifying information, name of physician, diagnosis, medical history and physical examination record, laboratory reports, tissue reports, anesthesia,	L1153		

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L1153	Continued From page 25 allergies/drug reactions, physician's orders, clinical notes, counseling notes, patient consent form, medication administration records and discharge summary. All pharmaceutical agents administered shall be timed, dated and signed by the person making the entry. This regulation is not met as evidenced by: Based on policy review, record review, and interview, the facility failed to ensure medication orders were timed, dated and signed by the ordering practitioner and medications administered to the patient were documented including dose, time, date, and signed by the person making the entry for 11 (#1, #2, #3, #4, #5, #6, #9, #10, #17, #19, and #20) of 13 patients' medical records reviewed. The Ambulatory Surgical Center does an average of 424 cases per month. On the first day of the survey, there were 32 cases. Findings included: 1. Review of the facility's policy titled, "Medical Records Documentation, and Reporting Requirements," dated 06/14, showed: - Documentation must be performed in accordance with accepted professional standards and any applicable laws/regulations. It must: *Be legible, factual, complete, concise and professional. *Be signed with the full name of the signer including credentials for licensed staff and titles for non-licensed staff. (The facility failed to give staff direction for documentation of pharmaceuticals to be timed, dated, and signed by the person making the entry.)	L1153		

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L1153	Continued From page 26 2. Review of the facility's document titled, "Registered Nurse (RN)/ Licensed Practical Nurse (LPN) Standing Orders," dated 06/19/13, showed: - RNs and LPNs may order and submit medication(s) in the electronic health record (EHR) per these standing orders. - Physician will review as part of patient care process. - All assessments, treatments and patient conditions must be fully documented in the patient record. (Note: The facility failed to include directions for completing the order set or require the standing orders to be timed, dated, and signed by the physician.) 3. Review of Patient #1's medical record for 01/30/16 showed: - Eight medication orders not timed, dated or signed by the physician. - No order for Lactate Ringers (solution for fluid and electrolyte replacement) administered intravenously (IV- small catheter inserted into a vein for administering medication and fluid). - Five medications documented as administered by nursing staff with no dose, and not timed, dated or signed by the nurse. - A narrative note by Staff T, RN, documenting that Methergine (medication that increases uterine contractions) 0.2 milligram (mg, unit of measure) was administered at 4:46 PM; the patient was discharged from the facility at 12:55 PM. - A notation on the record that the document was electronically signed by Staff F, LPN, on 02/05/16 on behalf of Staff GG, Physician.	L1153		

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L1153	Continued From page 27 4. Review of Patient #2's medical record for 02/23/16 showed: - Five medication orders not timed, dated or signed by the physician. - Four medications documented as administered by nursing staff with no dose administered, and not timed, dated or signed by the nurse. - Provider: Staff DD, Physician, not dated, timed or electronically signed. Review of Patient #2's medical record for 02/24/16 showed: - Six medication orders not timed, dated or signed by the physician. - No order for Lactate Ringers administered IV. - Three medications documented as administered by nursing staff with no dose and not timed, dated or signed by the nurse. - Provider: Staff DD, not dated, timed or electronically signed. - Document generated by Staff S, Health Center Assistant. 5. Review of Patient #3's medical record for 03/11/16 showed: - Five medication orders not timed, dated or signed by the physician. - Four medications documented as administered by nursing staff with no dose administered, and not timed, dated or signed by the nurse. - Provider: Staff GG, not dated, timed or electronically signed. - Document generated by Staff S. Review of Patient #3's medical record for 03/12/16 showed: - Seven medication orders not timed, dated or signed by the physician. - No order for Lactate Ringers administered IV. - Three medications documented as administered by nursing staff with no dose and	L1153		

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	MOA-0014	A. BUILDING: _____ B. WING _____	03/16/2016

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L1153	Continued From page 28 not timed, dated or signed by the nurse. - Provider: Staff GG, not dated, timed or electronically signed. - Document generated by Staff T. 6. Review of Patient #4's medical record for 03/08/16 showed: - Five medication orders not timed, dated or signed by the physician. - Four medications documented as administered by nursing staff with no dose and not timed, dated or signed by the nurse. - Provider and document generated by Staff JJ, Physician, not dated, timed or electronically signed. Review of Patient #4's medical record for 03/09/16 showed: - Seven medication orders not timed, dated or signed by the physician. - No order for Lactate Ringers administered IV. - Three medications documented as administered by nursing staff with no dose and not timed, dated or signed by the nurse. - Provider and document generated by Staff JJ, not dated, timed or electronically signed. 7. Review of Patient #5's medical record for 02/12/16 showed: - Six medication orders not timed, dated or signed by the physician. - No order for Lactate Ringers administered IV. - Four medications documented as administered by nursing staff with no dose and not timed, dated or signed by the nurse. - Provider: Staff GG, not dated, timed or electronically signed. - Document generated by Staff J, RN. 8. Review of Patient #6's medical record for	L1153		

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L1153	Continued From page 29 02/05/16 showed: - Four medication orders not timed, dated or signed by the physician. - No order for Lactate Ringers administered IV. - Two medications documented as administered by nursing staff with no dose and not timed, dated or signed by the nurse. - Provider: Staff GG, not dated, timed or electronically signed. - Document generated by Staff R, Advanced Practice Registered Nurse (APRN), Lead Clinician. 9. Review of Patient #9's medical record for 01/06/16 showed: - Six medication orders not timed, dated or signed by the physician. - One medication with no dose documented, administered by a physician. - Three medications documented as administered by nursing staff with no dose and not timed, dated or signed by the nurse. - Provider: Staff JJ, not dated, timed or electronically signed. - Document generated by Staff S. 10. Review of Patient #10's medical record for 12/24/15 showed: - Seven medication orders not timed, dated or signed by the physician. - One medication with no dose documented, administered by a physician. - Three medications documented as administered by nursing staff with no dose and not timed, dated or signed by the nurse. - Provider: Staff JJ, not dated, timed or electronically signed. Review of Patient #10's medical record for 12/30/15 showed:	L1153		

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L1153	Continued From page 30 - Six medication orders not timed, dated or signed by the physician. - No order for Lactate Ringers administered IV. - Six medications documented as administered by nursing staff with no dose and not timed, dated or signed by the nurse. - Provider: Staff DD, not dated, timed or electronically signed. - Document generated by: Staff S. 11. Review of Patient #17's medical record for 02/27/16 showed "oral sedation" administered at 10:30 AM. Staff failed to document what medication was administered and signature of person who administered the medication. 12. Review of Patient #19's medical record for 06/19/15 showed no order for Lactate Ringers administered IV. During an interview on 03/16/16 at 1:25 PM, Staff JJ stated that there were standing orders to give IV fluid for dehydration. 13. Review of Patient #20's medical record for 07/10/15 showed three medications documented as administered by nursing staff but staff failed to time, date or sign. 14. During an interview on 03/15/16 at 8:30 AM, Staff R stated that: - There was not a place in the medical record for the nurse to document who administered the medication. - Medications were not associated with times in the EMR. - The facility had a set of pre-printed orders used by the nursing staff. - The pre-printed orders were not scanned into	L1153		

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L1153	Continued From page 31 the EMR. - The physician reviewed the entire record, including the orders. - A notation in the chart, "document generated by," with the physician's name is the equivalent of the physicians' signature. - The physician's signature was not dated or timed. 15. During an interview on 03/16/16 at 10:00 AM, Staff JJ stated that: - The medical staff had developed standing orders for the nursing staff to follow. - The standing orders included all medications that would be administered on a routine basis in the facility. - The standing orders were not signed off for each patient and were not scanned into the medical record. - The physicians reviewed the medical record and electronically signed off on the record. - The electronic medical record signature covered medication orders. 16. During an interview on 03/16/16 at 10:55 AM, Staff J stated that: - The nurses used a medical flow sheet that showed physician preference. - The nurses referred to a standing order sheet that was hung in a cabinet at the nurses' station. - The nurses used clinical judgement, the patient's pain level, and how big the patient was to determine dose when there was a dose option. 17. During an interview on 03/16/16 at 1:38 PM, Staff JJ stated that: - The standing orders populated into the medical record based on the gestational age, type of procedure the woman was having, and that	L1153		

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L1153	Continued From page 32 physician's preference. - The nurses may ask a physician if they needed to override the standing order or they could make their own clinical decision.	L1153		
L1165	19 CSR 30-30.060(3)(E) A patient shall be fully reactive A patient shall be fully reactive and her vital signs shall be stable before discharge from the facility. This regulation is not met as evidenced by: Based on policy review, record review and interview, the facility failed to ensure staff followed policy for monitoring the stability and vital signs of patients during recovery for nine (#2, #3, #4, #5, #6, #10, #17, #19, and #20) of 13 patients' medical records reviewed. The Ambulatory Surgical Center does an average of 424 cases per month. On the first day of the survey, there were 32 cases. Findings included: 1. Review of the facility's policy titled, "Recovery Area Care," dated 03/31/15, showed the following direction for staff: - 17.1.1 Sedated Clients: Must assess the following at initiation of recovery and then every 15 minutes during the recovery process until discharge: * Blood pressure (BP), respiratory rate, pulse, oxygen saturation; * Pain level; * Level of consciousness using the Aldrete Scoring System (a medical scoring system for the measurement of recovery after anesthesia which includes activity, respiration, consciousness, blood circulation and color); and	L1165		

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L1165	Continued From page 33 * Amount of bleeding, when applicable. - 17.1.2 Non-sedated clients: Must access the following at initiation of recovery and then every 15 minutes during the recovery process until discharge: * BP, respiratory rate, pulse (a minimum of 2 sets); * Pain level; and * Amount of bleeding, if applicable. - 17.2.a. Aldrete Scoring System: The client is rated a score between 0 - 2 on the following: * Activity level; * Respirations; * Circulation (BP) consciousness; and * Oxygen saturation as determined by pulse oximetry (device that measures oxygen saturation of the blood). 2. Review of Patient #2's medical record for 02/24/16 showed: - Recovery vital signs were documented as taken at 12:34 PM, 12:40 PM, 1:10 PM, 2:00PM, and 2:30 PM. - Vital signs were not taken every 15 minutes, but rather at intervals of 9, 30, 50, and 30 minutes. - An aldrete score was not documented for the recovery period until the patient was discharged. 3. Review of Patient #3's medical record for 03/12/16 showed: - Recovery vital signs were documented as taken at 11:26 AM, 11:40 AM, 11:55 AM, 12:20 PM, 12:45 PM, 1:00 PM, and 1:25 PM. - Vital signs were not taken every 15 minutes, but rather at intervals of 14, 15, 25, 25, 15, and 15 minutes . - An aldrete score was not documented for the recovery period until the patient was discharged.	L1165		

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L1165	Continued From page 34 4. Review of Patient #4's medical record for 03/09/16 showed: - Recovery vital signs were documented as taken at 12:02 PM, 12:22 PM, 1:00 PM, 1:20 PM, 1:40 PM, 2:00 PM and 2:15 PM. - Vital signs were not taken every 15 minutes, but rather at intervals of 20, 38, 20, 20, 20, and 15 minutes. - An aldrete score was not documented for the recovery period until the patient was discharged. 5. Review of Patient #5's medical record for 02/12/16 showed: - Recovery vital signs were documented as taken at 3:50 PM, 4:15 PM, 4:50 PM, 5:00PM. - Vital signs were not taken every 15 minutes, but rather at intervals of 25, 35, and 10 minutes. - An aldrete score was not documented for the recovery period until the patient was discharged. - The patient was discharged at 5:25 PM with no discharge vital signs recorded. 6. Review of Patient #6's medical record for 02/01/16 showed: - An aldrete score was notdocumented for the recovery period until the patient was discharged. 7. Review of Patient #10's medical record for 12/30/15 showed: - An aldrete score was not documented for the recovery period until the patient was discharged. 8. Review of Patient #17's medical record for 02/27/16 showed: - The patient was discharged at 1:16 PM with no discharge vital signs recorded. The previous vital signs were recorded at 12:50 PM. - Vital signs were not taken every 15 minutes. - An aldrete score was not documented for the	L1165		

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L1165	Continued From page 35 recovery period until the patient was discharged. 9. Review of Patient #19's medical record from 06/19/15 showed: - An aldrete score was not documented for the recovery period until the patient was discharged. 10. Review of Patient #20's medical record from 07/10/15 showed: - An aldrete score was not documented for the recovery period until the patient was discharged. 11. During an interview on 03/15/16, Staff R, Advanced Practice Registered Nurse, Lead Clinician, stated that: - Vital signs were to be taken and documented every 15 minutes while the patient was in recovery. - Aldrete scores should be assessed and documented every 15 minutes with vital signs. - She was not aware there was not a place to document the Aldrete scores on the recovery record.	L1165		