EXHIBIT 7

Business Records Affidavit

State of Missouri

County of Cole.

1. I, William Koebel, am over the age of 18 and competent to make this affidavit.

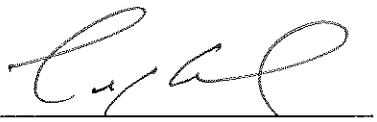
2. I am employed by the Missouri Department of Health and Senior Services, and in that role have personal knowledge about the documents listed below.

3. It is the regular practice of said Department to inspect medical facilities licensed in Missouri or seeking to be licensed in Missouri, and to create a contemporaneous record of that inspection.

4. Attached are the full, true, and complete copies of the following documents as they appear on file and of record in this office:

   a. Statement of Deficiencies, Comprehensive Health (June 11, 2013)
   b. Findings Letter, Comprehensive Health (April 3, 3015)
   c. Statement of Deficiencies, Comprehensive Health (Oct. 11, 2016)
   d. Statement of Deficiencies, Comprehensive Health (Aug. 14, 2018)
   e. Statement of Deficiencies, Comprehensive Health (Sept. 26, 2018)
   f. Statement of Deficiencies, Reproductive Health Serv. (Apr. 4, 2001)
   g. Statement of Deficiencies, Reproductive Health Serv. (Jan. 31, 2013)
   h. Statement of Deficiencies, Reproductive Health Serv. (Mar. 31, 2015)
   i. Statement of Deficiencies, Reproductive Health Serv. (Mar. 16, 2016)
   j. Statement of Deficiencies, Reproductive Health Serv. (May 25, 2017)
   k. Statement of Deficiencies, Reproductive Health Serv. (Mar. 7, 2018)

January 11, 2019



[signature]

EXHIBIT A

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	06/11/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH OF PLANNED PAR	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(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 unannounced on-site state licensure survey was conducted at this facility on 06/10/13 through 06/11/13. See below for findings. UPDATE 02/25/2014. This facility was found to be NOT performing abortion procedures. As they were not performing the procedure that required a license (and had no immediate plans to do so), a new license was not provided. Discussions were started between PP and DHSS regarding this process, with PP wishing to retain some semblance of the license, if for no other reason, so that if and when they ever reopened the facilty to perform abortions, the 2010 settlement agreement on the physical standards would still be in place. In general, DHSS was OK with this, and discussion about an additional amendment to the settlement agreement continued (we "close" the license with the agreement that a future provider [at the same location] would still have the relaxed construction standards in place from 2010. However, as of Feb 2014, there seems to have been no further movement toward an additional settlement agreement. A license has NOT been generated, nor will it be for the foreseeable future. An SOD for the June 2013 survey was never issued. This SOD and related survey processes have been held up since that time. After discussion with Section Administrator Dean Linneman, it was decided to officially close the file on both the facility and the 2013 survey of PP. (Pending a later reversal by OGC). --BAC Admin John Langston--02/25/14.	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.	L1106		

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L1106	Continued From page 1 of this rule shall be in charge in the absence of the administrator. This regulation is not met as evidenced by: Based on interview and policy review the facility failed to ensure that a policy was in place to designate the responsibilities and qualifications of an administrative designee when the administrator was absent from the facility. The facility did not conduct procedures at the time of the survey. Findings included: 1. During an interview on 06/11/13 at 10:30 AM Staff B, Director of Quality and Risk Management, stated that there is no policy which designated that a qualified person shall be in charge when the administrator is absent from the facility. 2. Review of the facility policy manual showed that no policy was in place to designate an individual to be in charge when the administrator was absent.	L1106		
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 interview, and review of the Drug Enforcement Administration (DEA) and Bureau of Narcotics and Dangerous Drugs (BNDD) websites, the facility failed to maintain a DEA and a BNDD license. The facility did not conduct	L1111		

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STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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L1111	Continued From page 2 procedures at the time of the survey. Findings included: 1. Review of the DEA website, http://www.deadiversion.usdoj.gov/drugreg/faq.htm#4 showed: - A separate registration is required for each principal place of business or professional practice where controlled substances are stored, administered, or dispensed by a person. 2. Review of the Missouri BNDD website, http://health.mo.gov/safety/bndd/faqs.php#1 showed: - Any person, business, or entity in Missouri that wants to conduct any activities with controlled substances must have a registration. - A separate registration is required at each separate location where controlled substances are stocked and stored. 3. During an interview on 06/10/13 at 2:00 PM, Staff C, Heath Center Manager, stated that patients were prescribed and/or administered Valium (a controlled substance > a drug or chemical whose manufacture, possession, or use is regulated by a government) prior to surgical abortions when the procedures had been conducted at 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	L1128		

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COMPREHENSIVE HEALTH OF PLANNED PAR	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

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L1128	Continued From page 3 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 interview, the facility failed to maintain an instruction manual from the manufacturer for the sterilizer used in the facility. The facility did not conduct procedures at the time of the survey. Findings included: During an interview on 06/11/13 at 3:00 PM, Staff G, Acting Administrator, Director of Health Center Operations, stated: - The facility did not have the original instruction manual for the sterilizer used at the facility, due to the age of the sterilizer; and - She had requested an instruction manual from the manufacturer following the surveyor's request to review the manual on 06/10/13.	L1128		
L1130	19 CSR 30-30.060(1)(B)(10) The facility shall have policies The facility shall have policies and procedures for the handling, processing, storing and transporting of clean and dirty laundry. The facility may provide laundry services at the facility or utilize contract services. This regulation is not met as evidenced by: Based on interview and observation the facility	L1130		

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L1130	Continued From page 4 failed to ensure that clean linens were processed and stored separately from the processing of soiled linens. The facility did not conduct procedures at the time of the survey. Findings included: 1. Observation on 06/11/13 at 10:00 AM showed that in a room next to the laboratory were a clothes washer and dryer next to each other. On an open shelf in this room were an uncovered stack of approximately six patient gowns and three blankets. 2. During an interview on 06/11/13 at 10:00 AM Staff A, Licensed Practical Nurse, stated that he/she processed the laundry for the facility and the patient gowns were kept on the open shelf. The soiled linen was handled in this room before being placed in the clothes washer. Staff A stated that the facility did not have patients for abortion procedures but the processing and storage of the linen remained the same as when they had patients for these procedures.	L1130		
L1169	19 CSR 30-30.060(3)(I) An emergeny tray equipped to treat An emergency tray equipped to treat seizures, bleedings, anaphylactic shock, respiratory arrest and cardiac arrest shall be immediately available to the procedure room and recovery room. This regulation is not met as evidenced by: Based on interview, the facility failed to maintain working batteries for the Automated External Defibrillator (AED) unit (a device that sends an electric shock to the heart that will restore the	L1169		

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	A004	A. BUILDING: _____ B. WING _____	06/11/2013

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH OF PLANNED PAR	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

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L1169	Continued From page 5 natural heart rhythm to the victim during a cardiac arrest) that was to be kept on the facility crash cart. The facility did not conduct procedures at the time of the survey. Findings included: During an interview on 06/11/13 at 11:00 AM, Staff G, Acting Administrator, Director of Health Center Operations, stated that the AED unit needed replacement batteries and had recently ordered batteries.	L1169		
L1241	19 CSR 30-30.070(3)(A) Smoke detectors shall be located in all Smoke detectors shall be located in all rooms and in corridors at thirty-feet (30') intervals unless the building is rated Type II (222) fire-resistive or if it is a one (1)-story building rated Type II (111) protected-noncombustible as described in Standard on Types of Building Construction 1979 published by the NFPA. If the building is multistoried and rated combustible, it shall be protected throughout by an approved automatic sprinkler system; This regulation is not met as evidenced by: Based on observation and interview the facility failed to ensure that all smoke detectors required to be installed in the facility received routine testing to ensure proper operation annually. The facility did not conduct procedures at the time of the survey. Findings included: 1. Observation on 06/10/13 and 06/11/13 of the corridors and habitable areas of the facility	L1241		

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L1241	Continued From page 6 showed that a smoke detectors were present in all areas. 2. During an interview on 06/11/13 at 12:15 PM Staff C, manager, stated that he/she knew of no test or inspection that had ever been done for the smoke detectors to ensure that they functioned properly.	L1241		

EXHIBIT B

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired 1-800-735-2966 VOICE 1-800-735-2466
Gail Vasterling
Director

Jeremiah W. (Jay) Nixon
Governor

April 3, 2015

Vicki Casey (Vicki.Casey@ppkm.org)
Columbia Center, Planned Parenthood of Kansas and Mid-Missouri
711 N. Providence Rd
Columbia, MO 65203

Re: Initial Licensure Survey

Dear Ms. Casey:

An onsite initial licensure survey for your facility to provide abortion services began on 04/02/2015. The facility was found **not** to be in compliance with all regulatory requirements as described in 19 CSR 30-30.060 and 19 CSR 30-30.070. As a result, a license will **not** be issued until the following items have each been adequately addressed:

1. A check of all current employees to ensure that none appear on the Employee Disqualification List (EDL) maintained by the Department of Health and Senior Services as required for all facilities licensed under chapter 197 must be completed. Further, a method and policy to ensure that any new employee has this check done before hire and that the facility periodically checks the EDL for all employees must be in place.

2. Ensure that all physicians on the medical staff providing abortion services have received a complete credentialing packet to include: a)appointment and approval by the Governing Body; b)appropriate certificates for medications; c)approval of privileges; and d)a completed application to be on staff at the facility.

3. The facility will need appropriate certificates for medications via registration for Controlled Substances from the Bureau of Narcotics & Dangerous Drugs and the Drug Enforcement Agency (DEA).

4. The facility will need to submit a waiver/variance request for the provision of 19 CSR 30-30.070 (2)(N) which requires to be sized to accommodate at least four (4) recovery beds or recliners for each procedure room. Required space necessary is not available and facility staff indicated two (2) is sufficient for planned licensed services and workload.

5. The Facility initially plans to offer only medication-induced procedures, but to expand to surgical procedures later in the summer. As the equipment for surgical procedures has not been purchased and is not onsite, the facility is not currently prepared to provide the surgical services. BAC will need to revisit prior to permitting surgical procedures. Therefore, the license, when issued, will only approve the facility for medication-induced procedures. Please acknowledge in your written response your facility understands this limitation placed on your license.

Sincerely,

John Langston

John Langston, MBA
Administrator
Bureau of Ambulatory Care
Phone: 573-751-6083
Fax: 573-751-6158

EXHIBIT C

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	10/11/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH OF PLANNED PAR	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(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 A full licensure survey was conducted at the facility on 10/11/16 to determine compliance with state requirements for Abortion Providers, which includes state rules 19 CSR 30-30.050-30.070, applicable portions of Chapter 197 and 188, as well as the 2010 settlement agreement between DHSS and the facility. The survey was conducted prior to issuing a license for the facility to resume providing abortion services at this location. A Statement of Deficiencies (SOD) in the form of a findings letter was sent to the facility instead of a Form 2567 in early November 2016. Following receipt of this findings letter, in early December 2016, the facility filed suit against DHSS in federal court (Case No. 2:16-cv-04313-HFS), primarily regarding DHSS ' s ongoing enforcement of Missouri requirements for ASC standards and physician privileges, following the SCOTUS decision in Whole Woman ' s Health v. Hellerstedt. As of 1/6/17, no formal response to the SOD has been received, no license has been issued. This survey process will be suspended/closed, and no further licensure activity planned pending the outcome of the federal case. This entry is being made for record-keeping and historical purposes, and should not be considered part of the formal SOD. Addendum: October 2017: After multiple court proceedings, DHSS did receive an SOD and conducted sufficient follow up activities to ensure that all requirements were eventually determined to be met. The Columbia location was eventually granted an Abortion Facility license effective date 10/3/2017.	L 000		

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	A004	A. BUILDING: _____ B. WING _____	10/11/2016

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L 000	Continued From page 1 Survey process closed. BAC Admin.	L 000		

EXHIBIT D

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	08/14/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH OF PLANNED PAR	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(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 state licensure survey was conducted from 08/13/18 to 08/14/18 in order to determine compliance with applicable statutes and regulations governing abortion facilities, including 19 CSR 30-30.050, 060, and 061 and Chapter 188, RSMo (Regulation of Abortions). See below for findings:	L 000		
L1081	19 CSR 30-30.060(1)(B)(3) The administrator shall be responsible, plan The administrator shall be responsible for developing a written plan for evacuation of patients and personnel in the event of fire, explosion, active shooter, or other disaster. The plan shall be kept current and all personnel shall be knowledgeable of the plan. Disaster drills with participation of all staff shall be conducted and documented at least annually. This regulation is not met as evidenced by: Based on record review and interview, the facility failed to ensure that all staff participated in drills and were knowledgeable about the plan. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four cases. Findings included: 1. Review of the facility's document titled, "Quarterly Fire Drill Report," dated 02/18/18, showed that the facility had a fire drill on that date. The previous fire drill was held on 04/05/17. 2. During an interview on 08/14/18 at 2:33 PM, Staff C, Health Center Manager, stated that: - She had been employed at the facility since	L1081		

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L1081	Continued From page 1 March. - She had not participated in a fire drill or emergency drill since starting at the facility. - The facility was to have fire drills or emergency drills twice per year. 3. During an interview on 08/14/18 at 2:50 PM, Staff F, Licensed Practical Nurse, stated that: - She was from a staffing agency but worked full time hours at the facility and had done so since 07/19/18. - She had not participated in a fire or emergency drill since starting at the facility. - When asked if she knew where the designated safe spot during a tornado was she replied she did not know. - When asked if she knew how to activate the fire alarm she stated she did not know.	L1081		
L1084	19 CSR 30-30.060(1)(B)(6) The admin shall be responsible for, programs The administrator shall be responsible for establishing, implementing, enforcing, and maintaining comprehensive programs for identifying and preventing infections as further detailed in this regulation and for maintaining a safe environment. This regulation is not met as evidenced by: Based on nationally-recognized standards, policy review, observation, and interview, the facility failed to: - Ensure a sanitary environment was preserved by providing easily cleanable surfaces that will not harbor bacteria and transmit infections; - Ensure a clean and sanitary environment in the exam rooms; and - Ensure expired supplies were not available for	L1084		

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L1084	Continued From page 2	L1084		

use.
The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four cases.

Findings included:

1. Review of the Association of PeriOperative Registered Nurses (AORN), "Guideline for Environmental Cleaning," dated 2017, showed:
- Recommendation II.
  * The patient should be provided with a clean, safe environment.
- Recommendation II.a.
  * The perioperative Registered Nurse (RN) 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 responsibility for verifying a clean surgical environment before the start of an operative or invasive procedure rests with perioperative nurses.
- Recommendation II.b.
  * All horizontal surfaces in the operating room (OR) (e.g., furniture, surgical lights, booms, equipment) should be damp dusted before the first scheduled surgical or other invasive procedure of the day.
  * Dust is known to contain human skin and hair, fabric fibers, pollens, mold, fungi, insect parts, glove powder, and paper fibers, among other components.

49. Review of the CDC and HICPAC, "Guidelines for Environmental Infection Control in Health-Care Facilities," dated 2003, showed:
- Microorganisms proliferate in environments

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L1084	Continued From page 3	L1084		

wherever air, dust and water are present; and
- Dry conditions favor gram-positive bacteria in dust and on surfaces.

2. Review of the facility's "Infection Prevention Manual," dated 08/15, showed infection control resources included:
- Centers for Disease Control (CDC);
- Association for Professionals in Infection Control and Epidemiology (APIC); and
- AORN.

3. Review of the facility's "Infection Prevention Manual" policy titled, "Housekeeping Services," dated 08/15, showed:
- Thoroughly clean all surfaces that are used in patient care areas.
- Avoid cleaning methods and machines that re-suspend dust from surfaces, especially in patient care areas.
- All areas of the clinic should be kept clean and free from excess clutter.
- The routine housekeeping schedule is followed and should include exam tables, counters, chairs, desks, floors, and patient care equipment.

4. Observation on 08/13/18 at 10:40 AM of the procedure room showed the metal suction machine cabinet had numerous rusted areas (uncleanable surface).

During an interview on 08/14/18 at 1:25 PM, Staff C, Health Center Manager, stated that she had cleaned the metal suction cabinet and confirmed it was rusted.

5. Observation on 08/13/18 at 10:45 AM of the recovery room medication supply room showed:
- A metal shelf unit with five pressed wood shelves, the shelves were dusty;

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L1084	Continued From page 4 - A pressed wood shelf leaning against the wall; - The floor under the shelf unit was dusty; and - There was a box containing 25 expired hCG Urine Cassette Cultures (urine pregnancy test) expiration 03/18, on the floor behind the shelving unit. During an interview upon the observation, Staff A, Nurse Practitioner (NP- a nurse who is qualified to treat certain medical conditions without the direct supervision of a doctor) stated that housekeeping staff did not have access to the room and confirmed that the urine pregnancy tests were expired. 6. Observation on 08/13/18 at 2:10 PM of exam room 1 showed: - The door facing the hallway had a plastic chart holder with a peeling label and adhesive residue which created a noncleanable surface; - Dust and debris and a brown stained area in the cabinet under the sink ; - A pressed wood table with chipped paint exposing the pressed wood; - The bottom edges below the drawers of the bed had a heavy layer of dust that left a visible mark when a finger was pulled through; and - The gooseneck lamp had a dried peeling label and adhesive residue. 7. Observation on 08/13/18 at 2:15 PM of exam room 2 showed: - The door facing the hallway had a plastic chart holder with a peeling label and adhesive residue; - Dust and debris and a grayish black discolored area in the cabinet under the sink and an area where the base of the cabinet was peeling; - A pressed wood table with chipped paint exposing the pressed wood; - The bottom edges below the drawers of the bed	L1084		

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L1084	Continued From page 5 had a heavy layer of dust that left a visible mark when a finger was pulled through; - A plastic glove box holder had dust on the top that left a visible mark when a finger was drawn through; and - The cabinet under the sink had peeling and/or missing laminate at the bottom outer corner. 8. Observation on 08/13/18 at 2:20 PM of exam room 3 showed the top edges of two picture frames were dusty. 9. During an interview on 08/13/18 at 2:25 PM, Staff C stated that: - The housekeeper did not go into the recovery room supply cabinet; - Peeling laminate could not be disinfected; and - They planned to purchase new tables for the exam rooms. 10. Observation on 08/13/18 at 2:30 PM of the soiled area showed the cabinet under the sink had a large area of dried white residue and an area of dried yellowish brown residue.	L1084		
L1090	19 CSR 30-30.060(1)(B)(7)(E) Provisions for licensed personnel to have cur Provisions for licensed personnel to have current cardiopulmonary (CPR) training so that at least one (1) licensed and trained personnel is at the facility at all times when patients are present for abortions; and This regulation is not met as evidenced by: Based on record review and interview, the facility failed to ensure that licensed personnel maintained current cardiopulmonary (CPR) training for one (B) of two licensed staff personnel	L1090		

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L1090	Continued From page 6 records reviewed. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four procedures. Findings included: 1. Review of the facility's policy titled, "Personnel Files," dated 05/15, showed personnel information collected by the facility included first aid/CPR cards. 2. Review of Staff B, Registered Nurse (RN), Nurse Practitioner's (NP- a nurse who is qualified to treat certain medical conditions without the direct supervision of a doctor) personnel file showed her CPR training had expired 04/20/18. 3. During an interview on 08/14/18 at 1:30 PM, Staff B stated that: - She was required to maintain current CPR. - She was not aware her CPR certification had expired.	L1090		
L1101	19 CSR 30-30.060(2)(B) Each patient shall be given all the informati Each patient shall be given all the information required by sections 188.027 and 188.039, RSMo, in the formats and timeframes required, by the type of professional required. This regulation is not met as evidenced by: Based on record review, observation, and interview, the facility failed to ensure that the physician who was to perform or induce the abortion or a qualified professional as required by law (Section 188.027.1(1), RSMO, a physician, physician assistant, registered nurse, licensed practical nurse, psychologist, licensed	L1101		

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professional counselor or licensed social worker licensed or registered and working under the supervision of the physician performing or inducing the abortion) informed the woman of the gestational age of the fetus at the time of abortion for ten (#1, #2, #3, #4, #5, #6, #7 #8, #9, and #10) of ten patients' medical records reviewed. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four procedures.

Findings included:

1. Review of Missouri law 188.027 RSMo, showed consent to an abortion is voluntary and informed and given freely and without coercion if, and only if, at least seventy-two hours prior to the abortion:
(1) The physician who is to perform or induce the abortion, a qualified professional, or the referring physician has informed the woman orally, reduced to writing, and in person, of the following:
(f) The gestational age (term used during pregnancy to describe how far along the pregnancy is) of the unborn child at the time the abortion is to be performed or induced; and
(g) The anatomical (relating to bodily structure) and physiological (relating to organs and functions of the body) characteristics of the unborn child at the time the abortion is to be performed or induced.

2. Review of the facility's policy titled, "Patient Consent Policy," dated 06/18, showed:
- It is the policy of the Abortion Facility to comply with all applicable federal, state, and local laws and regulation in providing abortion care.
- The physician who will perform the abortion is required to provide the following information to a patient orally and in person at least seventy-two

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hours before the abortion procedure:
* The unborn child's gestational age.
(Note: The policy failed to specify the gestational age at the time of the abortion.)

3. Review of medical records showed:
- The Seventy-two Hour Informed Consent was documented on 04/16/18 for Patient #1, #2, and #3 and the abortion was performed on 04/30/18, 14 days after the ultrasound was performed.
- The Seventy-two Hour Informed Consent was documented on 4/30/18 for Patient #4, #5, and #6 and the abortion was performed on 05/14/18, 14 days after the ultrasound was performed.
- The Seventy-two Hour Informed Consent was documented on 06/04/18 for Patient #8 and #9 and the abortion was performed on 06/18/18, 14 days after the ultrasound was performed.
- The Seventy-two Hour Informed Consent was documented on 05/14/18 for Patient #8 and the abortion was performed on 05/21/18, 7 days after the ultrasound was performed..
- The Seventy-two Hour Informed Consent was documented on 07/23/18 for Patient #10 and the abortion was performed on 07/30/18, 7 days after the ultrasound was performed.
(Note: The gestational age presented to the pregnant woman at the time of the seventy-two hour consent visit was based on the determination of gestational age by ultrasound on that day and not the gestational age of the unborn child at the time of abortion.)

4. During an interview on 08/14/18 at approximately 1:30 PM, Staff B, Registered Nurse (RN), Nurse Practitioner (NP- a nurse who is qualified to treat certain medical conditions without the direct supervision of a doctor), stated that:
- During the abortion education at the seventy-two

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L1101	Continued From page 9 hour informed consent visit the woman is given the gestational age of the embryo (a human offspring during the period from approximately the second to the eighth week after fertilization) based on her last menstrual period and told the gestational age would be confirmed by ultrasound. - The gestational age that is discussed is based on the ultrasound results at the time of the seventy-two hour visit, not the procedure date. - The day of procedure they go over gestational age again and discuss it but they do not use the Missouri Informed Consent Booklet or show them pictures of the gestational age of the unborn infant.	L1101		
L1119	19 CSR 30-30.060(3)(B) The facility shall maintain a medical record The facility shall maintain a medical record according to professional standards for each patient. This regulation is not met as evidenced by: Based on policy review, record review, and interview, the facility failed to ensure discharge instructions were included in the medical record for 10 (#1, #2, #3, #4, #5, #6, #7, #8, #9, and #10) of 10 patients' medical records reviewed. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four cases. Findings included: 1. Review of the facility's policy titled, "Medical Records, Documentation, and Reporting Requirements," dated 03/31/17, showed: - 5.1.1 Required components:	L1119		

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L1119	Continued From page 10 * Affiliates must maintain a complete medical record for each patient in accordance with acceptable professional standards and any applicable laws/regulations. * The medical record must include documentation of all services and information provided. 2. Review of medical records for Patient #1, #2, #3, #4, #5, #6, #7, #8, #9, and #10 with admission dates ranging from 04/30/18 through 07/30/18 for surgical abortion procedures showed the facility failed to ensure the medical record contained documentation of the discharge instructions provided to the patient. 3. During an interview on 08/13/18 at 1:30 PM, Staff D, Vice President of Patient Services, stated that: - Discharge instructions were provided in the form of written instructions given to the patient: * "Surgical Abortion Discharge Instructions" including what was normal and what was abnormal, and staff contact numbers in the event of questions, concerns or an emergency; * "How Much Am I Bleeding," and * Instructions for taking prescribed medications. - The facility did not retain a copy of the instructions or include them in the medical record.	L1119		
L1120	19 CSR 30-30.060(3)(C) All medical record entries shall be timed All medical record entries shall be timed, dated, and signed or authenticated by the person making the entry. This regulation is not met as evidenced by: Based on policy review, record review, and	L1120		

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L1120	Continued From page 11	L1120		

interview, the facility failed to ensure medication orders were timed, dated and signed by the ordering practitioner for 10 (#1, #2, #3, #4, #5, #6, #7, #8, #9, and #10) of 10 patients' medical records reviewed. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four cases.

Findings included:

1. Review of the facility's policy titled, "Medical Records, Documentation, and Reporting Requirements," dated 03/31/17, showed:
- 5.1.1 Required components:
  * II.J
    The medical record shall contain physician orders.
    All pharmaceutical agents administered shall be timed, dated and signed by the person making the entry.
(Note: The policy failed to address the need for medication orders, to be dated, timed and signed or authenticated by the person ordering the medications.)

2. Review of medical records for Patient #1, #2, #3, #4, #5, #6, #7, #8, #9, and #10 with admission dates ranging from 04/30/18 to 07/30/18 for surgical abortion procedures showed the facility failed to ensure medication orders were signed, dated and timed by the ordering physician.

3. During an interview on 08/13/18 at 1:30 PM, Staff D, Vice President of Patient Services, stated that:
- She was aware the medication orders should be timed, dated and signed by the physician when they were ordered.
- The facility had developed a standard order set

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L1120	Continued From page 12 for medications but it had not been approved to be implemented.	L1120		
L1122	19 CSR 30-30.060(3)(D)(1) Documentation with a unique identifying recor Documentation with a unique identifying record number; patient identifying information; name of physician; diagnosis; medical history and physical examination record; laboratory reports; anesthesia administered; allergies/drug reactions; physician's orders; clinical notes; counseling notes; patient consent form; medication administration records; and discharge summary; This regulation is not met as evidenced by: Based on policy review, record review, and interview, the facility failed to ensure that the physician documented the abortion counseling notes in the medical record for three (#3, #9, and #10) of ten patients' medical records reviewed. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four procedures. Findings included: 1. Review of the facility's policy titled, "Medical Standards and Guidelines," dated 06/16 showed: - 1.2 Surgical Abortion: * 1.2.1 Patient Education and Informed Consent: All written materials given to the patient must be documented in record. 2. Review of the medical records for Patient #3, #9, and #10 with admission dates ranging from 04/30/18 to 07/30/18 showed the records did not contain the physician counseling notes.	L1122		

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L1122	Continued From page 13 3. During an interview on 04/13/18 at 1:30 PM, Staff D, Vice President of Patient Services, stated that: - The physician was responsible for documenting the abortion counseling that was performed during the initial patient visit in the medical record. - The medical records for Patients #3, #9, and #10 did not contain the required abortion counseling documentation.	L1122		
L1124	19 CSR 30-30.060(3)(D)(3) Method used to determine gestational age Method used to determine gestational age; gestational age; informed consent checklist required by section 188.027.3, RSMo; copy of abortion report required by section 188.052, RSMo, and 19 CSR 10-15.010; for surgical abortions, copy of tissue report required by section 188.047, RSMo, and 19 CSR 10-15.030; where applicable, copy of complication report required by section 188.052, RSMo, and 19 CSR 10-15.020; and This regulation is not met as evidenced by: Based on policy review, record review, and interview, the facility failed to ensure a copy of the abortion report was included in the medical record for two (#4 and #6) of 10 patients' medical records reviewed. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four cases. Findings included: 1. Review of Missouri law 188.052 RSMo, showed: - 1. An individual abortion report for each abortion performed or induced upon a woman shall be	L1124		

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L1124	Continued From page 14 completed by her attending physician. - 4. A copy of the abortion report shall be made a part of the medical record of the patient of the facility or hospital in which the abortion was performed. 2. Review of the facility's policy titled, "Medical Records, Documentation, and Reporting Requirements," dated 03/31/17, showed: - 5.1.1 Required components: * Affiliates must maintain a complete medical record for each patient in accordance with acceptable professional standards and any applicable laws/regulations. * The medical record must include documentation of all services and information provided. 3. Review of the medical records for Patient #4, and #6 with an admission date of 05/14/18 for surgical abortion procedures showed the facility failed to ensure the medical record contained a copy of the abortion report. 4. During an interview on 08/13/18 at 1:30 PM, Staff D, Vice President of Patient Services, stated that: - The medical records for Patient #4 and #6 did not contain an abortion report. - Facility staff had failed to ensure a copy of the abortion report was included in the medical records for Patient #4 and #6.	L1124		
L1130	19 CSR 30-30.060(4) Infection Control Program Infection Control Program. The facility shall establish a comprehensive program for identifying and preventing infections. The infection control program shall be appropriate for	L1130		

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L1130	Continued From page 15 scope and type of abortion procedures performed at the facility. This regulation is not met as evidenced by: Based on nationally-recognized standards, policy review, observation, and interview, the facility failed to ensure staff followed acceptable standards of practice for hand hygiene. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were four procedures. Findings included: 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; and * Wearing gloves does not replace the need for hand hygiene. 2. Review of the Association for Professionals in Infection Control and Epidemiology (APIC) scientific guidelines referred to in 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;	L1130		

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L1130	Continued From page 16 * 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 Association of PeriOperative Registered Nurses (AORN), "Guideline for Hand Hygiene," dated 2017, showed: - Recommendation I.d.4. * In the absence of visible soil, hands should be disinfected with an alcohol-based hand rub rather than washed with soap and water. - Recommendation III. * Perioperative team members should perform hand hygiene. - Recommendation III.a. * Personnel should perform hand hygiene: Before and after patient contact; Before performing a clean or sterile task; After risk for blood or body fluid exposure; After contact with patient surroundings; and When hands are visibly soiled. - Recommendation III.a.1. * Hand hygiene should be performed before and after patient contact, including: Performing a physical exam; Marking the site; Transferring or positioning the patient; Assessing an invasive device (e.g., vascular catheter [peripheral, arterial, central], urinary catheter); and Assessing wound dressing. - Recommendation III.a.2.	L1130		

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L1130	Continued From page 17 * Hand hygiene should be performed before a clean or sterile task, including: Inserting an invasive device (e.g., vascular catheter [peripheral, arterial, central] urinary catheter); Assessing a vascular device (e.g., port, stopcock, IV tubing); Moving from a contaminated body site (e.g., perineum) to a clean body site (e.g., face) on the same patient; Opening sterile supplies; and Performing patient skin antisepsis. - Recommendation III.a.3. * Hand hygiene should be performed after risk for blood or body fluid exposure, including: Removing personal protective equipment (e.g., gloves, mask); Having contact with blood, body fluids, excretions, mucous membranes, non-intact skin, or wound dressings; - Recommendation III.a.4. * Hand hygiene should be performed after contact with patient surroundings, including: Inanimate surfaces and objects, including medical equipment, in the immediate vicinity of the patient; Operating room (OR) bed controls; and Patient bed and linens. - Recommendation III.a.5. * The use of gloves does not replace the need for hand hygiene. - Recommendation III.d. * When hands are not visibly soiled or dirty, hand hygiene should be performed using an alcohol-based hand rub according to the manufacturer's instructions for use. 4. Review of the facility's "Infection Prevention Manual," dated 08/15, showed infection control resources included:	L1130		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	08/14/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH OF PLANNED PAR	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(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
L1130	Continued From page 18 - CDC; - APIC; and - AORN. 5. Review of the facility's "Infection Prevention Manual" policy titled, "Standard Precautions, Hand Hygiene, Personal Protective Equipment (PPE)," dated 08/15, showed: - Hand hygiene should be performed when hands are visibly soiled with blood or other body fluids, wash hands with water and soap. Wash hands even prior to donning gloves. - If hands are not visibly soiled, use an alcohol-based hand rub for routinely decontaminating hands in all clinical situations other than those listed under "hand hygiene" above. 6. Observation on 08/13/18 from approximately 10:12 AM to 10:30 AM of Patient #11's abortion procedure showed Staff BB, Physician: - Entered the room, donned gloves and performed a manual vaginal exam; - Changed her gloves, did not perform hand hygiene, and performed a speculum (medical tool inserted into the vagina to dilate it for examination of the vagina and cervix) exam; - Picked up a bottle of spray vinegar solution and sprayed the solution in the patient's vaginal area; - Picked up a syringe of Lidocaine (numbing medication) and injected it into the patient's vaginal/cervix area; - Disposed of the medication syringe, removed her soiled gloves, and donned sterile gloves without performing hand hygiene; - Completed the abortion, cleansed the patient's vaginal area, removed her bloody gloves, failed to perform hand hygiene, and donned nonsterile gloves; - Exited the room; and	L1130		

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	A004	A. BUILDING: _____ B. WING _____	08/14/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH OF PLANNED PAR	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(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
L1130	Continued From page 19 - Carried the product of conception to the soiled area, examined the product of conception, removed her gloves, and performed hand hygiene. 7. Observation on 08/13/18 from approximately 11:10 AM to 11:35 AM of Patient #12's procedure showed Staff BB, Physician: - Entered the room, examined the patient's medical record and donned a single glove, she failed to perform hand hygiene before donning the glove; - Performed an abdominal ultrasound (test that uses sound waves to make images within the abdomen to determine the size/age of the fetus) on the patient, removed the glove, and failed to perform hand hygiene; - Wiped the ultrasound gel off the patient's abdomen and had the patient sign paperwork; and - Picked up the patient's medical record, reviewed the consent with the patient, had the patient sign the consent, Staff BB signed the consent, and exited the room without performing hand hygiene. 8. Observation on 08/13/18 from approximately 11:53 AM to 12:05 PM of Patient #13's lab visit for blood and urine testing showed Staff F, Licensed Practical Nurse: - Performed hand hygiene and donned gloves, moved a urine specimen cup from the wall cabinet to the sink, removed her gloves, and donned clean gloves. She failed to perform hand hygiene between gloves changes; - Tested the urine, removed her gloves and performed hand hygiene and documented in the medical record; and - Donned clean gloves without performing hand hygiene, obtained a blood sample, checked the blood sample and removed her gloves. She failed	L1130		

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	A004	A. BUILDING: _____ B. WING _____	08/14/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH OF PLANNED PAR	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(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
L1130	Continued From page 20 to perform hand hygiene after removing her gloves. 9. Observation on 08/13/18 at 2:00 PM showed: - Staff A, Nurse Practitioner (NP- a nurse who is qualified to treat certain medical conditions without the direct supervision of a doctor) performed hand hygiene upon entering the room, obtained lab supplies to obtained a blood specimen; - Donned gloves, failed to perform hand hygiene prior to donning the gloves; - Drew blood from Patient #13, removed her gloves, failed to perform hand hygiene; - Escorted the patient to the door; and - Took the patient's medical record to the lab.	L1130		

EXHIBIT E

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	R 09/26/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH OF PLANNED PAR	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

(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 state licensure revisit was conducted on 09/26/18 to determine compliance with applicable statutes and regulations governing abortion facilities, including 19 CSR 30-30.050, 060, and 061 and Chapter 188, RSMo (Regulation of Abortions). See below for findings:	{L 000}		
{L1084}	19 CSR 30-30.060(1)(B)(6) The admin shall be responsible for, programs The administrator shall be responsible for establishing, implementing, enforcing, and maintaining comprehensive programs for identifying and preventing infections as further detailed in this regulation and for maintaining a safe environment. This regulation is not met as evidenced by: Based on nationally-recognized standards, policy review, observation, and interview, the Abortion Facility failed to: - Ensure a sanitary environment was preserved by providing easily cleanable surfaces that will not harbor bacteria and transmit infections; - Ensure a clean and sanitary environment in the soiled room; - Dispose of used, soiled single-use suction tubing; - Dispose of a soiled reusable series connecting hose (clear secondary suction tubing); and - Clean and disinfect a reusable glass suction bottle. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were no cases. Findings included:	{L1084}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	R 09/26/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH OF PLANNED PAR	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

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{L1084}	Continued From page 1 1. Review of the Association of PeriOperative Registered Nurses (AORN), "Guideline for Environmental Cleaning," dated 2017, showed: - Recommendation II. * The patient should be provided with a clean, safe environment. - Recommendation II.a. * The perioperative Registered Nurse (RN) 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 responsibility for verifying a clean surgical environment before the start of an operative or invasive procedure rests with perioperative nurses. * 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 III.c. * Operating and procedure rooms must be cleaned after each patient. - Recommendation V.a.1. * Areas and items that should be cleaned on a schedule include clean and soiled storage areas and sterile storage areas. 2. Review of the facility's "Infection Prevention Manual," dated 08/15, showed infection control resources included: - Centers for Disease Control and Prevention (CDC); - Association for Professionals in Infection Control and Epidemiology (APIC); - Association for the Advancement of Medical Instrumentation (AAMI); and	{L1084}		

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	A004	A. BUILDING: _____ B. WING _____	R 09/26/2018

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{L1084}	Continued From page 2 - AORN. 3. Review of the facility's "Infection Prevention Manual" policy titled, "Housekeeping Services," dated 08/15, showed: - The routine housekeeping schedule is followed and should include exam tables, counters, chairs, desks, floors, and patient care equipment. 4. Review of the facility's "Infection Prevention Manual" policy titled, "Directions for Cleaning and Disinfection - Abortion Procedure Suction Tubing," dated 08/15, showed: - Single-use suction tubing must be disposed of as an infectious waste after each patient use. - Multi-use suction tubing is first cleaned by running water through the tube, removing all blood and bioburden immediately after the procedure. Then soak tubing in chemical disinfectant ad per manufacturer's instructions for semi-critical devices. 5. Observation on 09/26/18 at 9:40 AM of the procedure room showed: - The metal suction machine cabinet had numerous rusted areas (uncleanable surface); - There was a used, single-use suction tubing connected to a plastic suction canister. The single-use tubing contained reddish colored fluid; - A reusable series connecting hose on the top of the machine had a blackish-gray substance on the inside the length of the tubing; and - The reusable series connecting hose was connected to a reusable glass suction bottle. There was a layer of dried black substance in the bottom of the bottle. During an interview upon the observation Staff C, Health Center Manager, stated that the replacement reusable series connecting hose	{L1084}		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	A004	A. BUILDING: _____ B. WING _____	R 09/26/2018

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COMPREHENSIVE HEALTH OF PLANNED PAR	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

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{L1084}	Continued From page 3 was on back order. 6. Observation on 09/26/18 at 9:50 AM of the storage room showed the metal cabinet of a second suction machine had numerous rusted areas, old peeling tape, dried adhesive residue on the front surface, (uncleanable surfaces) and a dried brown spill down the side of the machine that was approximately six-inches long. 7. During an interview on 09/26/18 at 9:55 AM, Staff C stated that: - The substance in the single-use suction tubing was most likely bodily fluid; - Their last procedure had been the previous Friday (09/21/18); - She did not think they had used the suction machine that day; and - The blackish gray substance in the secondary reusable series connecting hose was mold. 8. During an interview on 09/26/18 at 12:00 PM, Staff I, Maintenance, stated that the replacement for the reusable series connecting hose was located inside the suction machine cabinet. Staff C stated that she was not aware that the secondary replacement reusable series connecting hose was inside the suction cabinet. 9. During an interview on 09/26/18 at 2:10 PM, Staff C stated that: - She identified the problem (blackish gray residue) inside the reusable series connecting hose a couple of months previously (probably July) and began trying to find replacement tubing; - They continued to use the machine (with the reusable series connecting hose that had blackish gray residue inside) on patients after they identified the issue; and - She had talked with other people about the	{L1084}		

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	A004	A. BUILDING: _____ B. WING _____	R 09/26/2018

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COMPREHENSIVE HEALTH OF PLANNED PAR	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

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{L1084}	Continued From page 4 issue with the reusable series connecting hose and it was not an infection control issue. 10. Review of the American National Standards Institute (ANSI) and AAMI document titled, "ANSI/AAMI ST79:2017," Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities, dated 2017, showed: - 3.3.6.4 Sterile storage: * Open or wire shelving is suitable for confined storage areas, provided that proper attention is given to traffic control, area ventilation, and housekeeping. * Storage areas should be designed to protect sterile items and their packaging from damage. - 11.1.1 Storage Facilities: * The bottom shelf of storage carts or shelving should be solid. 11. Observation on 09/26/18 at 10:00 AM of the recovery room medication supply room showed a metal storage shelving unit. There was no bottom barrier on the bottom shelf. The shelf was placed over a submersible sump pump (used to remove water that has accumulated in a water-collecting sump basin) installed in the floor. 12. Observation on 09/26/18 from 10:05 AM to 10:10 AM of exam room #1 and #2 showed each room contained a pressed wood table with chipped paint exposing the pressed wood (uncleanable surface). 13. Observation on 09/26/18 at 10:10 AM of the soiled room showed the cabinet under the sink had a large area of dried white residue and an area of dried yellowish brown residue. During an interview upon the observation, Staff C stated that housekeeping staff were responsible	{L1084}		

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	A004	A. BUILDING: _____ B. WING _____	R 09/26/2018

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COMPREHENSIVE HEALTH OF PLANNED PAR	711 N PROVIDENCE ROAD COLUMBIA, MO 65203

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{L1084}	Continued From page 5 to clean and confirmed the cabinet was not clean.	{L1084}		
L1113	19 CSR 30-30.060(2)(K) The facility shall ensure, each patient prep The facility shall ensure that each patient is prepared for the abortion in a manner that facilitates her safety and comfort. 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 equipment used for patient care was approved for use in healthcare facilities. The Abortion Facility does an average of 14 cases per month. On the first day of the survey, there were no cases. Findings included: 1. 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. FDA and CPSC recommend the following precautions be taken to avoid hazards associated with the use of electric heating pads:	L1113		

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L1113	Continued From page 6 - 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. 2. Observation 09/26/18 at 9:30 AM in the recovery room showed: - Four recovery chairs with heating pads draped across the backs. - Three of the four heating pads were labeled "For Household Use Only" and the fourth heating pad was not labeled. - The fourth heating pad cover showed a one inch streak of clear, hard surface matter with a small circular bead of clear material at the top on the heating pad cover. 3. During an interview on 09/26/18 at 1:45 PM, Staff C, Health Center Manager, stated that: - The heating pads were for household use and needed to be removed. - She did not believe the facility had a policy for the use of heating pads.	L1113		

EXHIBIT F

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 _____	04/04/2001

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 022	30.060(1)(B)8. 8. THE FACILITY SHALL BE 8. 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:	L 022		
L 079	.060(3)(K) (K) THE QUALITY ASSURANCE PROGRAM (K) 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:	L 079		
L 084	.060(4)(C) (C) ALL TISSUE OBTAINED FROM (C) All tissue obtained from abortions, except tissue submitted to a pathologist for analysis, shall be submerged in a preservative solution and shall be transported in a	L 084		

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 _____	04/04/2001

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 084	Continued From page 1 leakproof container to a facility with a waste sterilizer or an incinerator approved by the Department of Natural Resources. If kept for more than twelve (12) hours, all tissue shall be refrigerated. This regulation is not met as evidenced by:	L 084		
L 087	.060(5) (5) COMPLAINTS. ANY PERSON HAVING (5) Complaints. Any persons having a complaint 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:	L 087		

EXHIBIT G

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		3/15/13

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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

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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:	L1128		3/15/13

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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L1128	Continued From page 2 Based on observation, interview, policy review, 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	L1128		

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L1128	Continued From page 3 label on the medication stated, "single dose - 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	L1128		

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L1128	Continued From page 5	L1128		

(e.g., needle-punctured) the vial should be dated 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;

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L1128	Continued From page 6 -Expired supplies were removed from the active 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.	L1128		

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L1128	Continued From page 7 21. Observation on 01/30/13 at 9:30 AM of 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;	L1128		

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L1128	Continued From page 8 -One oxygen tank with tape residue; -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	L1170		3/15/13

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L1170	Continued From page 9 more than twelve (12) hours; 6. Errors in diagnosis; 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	L1171		3/15/13

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L1171	Continued From page 10 identification of the problems. This regulation is not met as evidenced by: 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		

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L1190	Continued From page 11	L1190		
L1190	19 CSR 30-30.060(5) Complaints, Any person having a complaint Complaints. Any persons having a complaint 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	L1190		3/15/13

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L1190	Continued From page 12 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 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	L1252		3/15/13

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L1252	Continued From page 13 scheduled cases. Findings included: 1. Observation during a tour of the facility 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		

EXHIBIT H

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L 000	Initial Comments An on-site, unannounced, state licensure survey was conducted from 03/30/15 to 03/31/15. An onsite complaint investigation for complaint MO00100367 was also conducted and the complaint was found to be unsubstantiated. See below for findings related to the licensure survey:	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, observation, and interview, the facility failed to: - Restrict multi-dose vials to a centralized medication area separate from the patient treatment area; - Ensure expired medications were not available for patient use; - Have accessible and follow manufacturer's instructions for use; - Monitor the humidity in the clean and dirty instrument processing area; - Protect sterile items from dust and moisture by	L1128		5/31/15

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L1128	Continued From page 1	L1128		

placing a solid barrier on the bottom shelves;
- Ensure staff wore personal protective equipment (PPE) appropriate to the task performed;
- Replace worn or deteriorating patient-care items with functional, easily cleanable surfaces that would not harbor and transmit infections; and
- Clean dirty/dusty surfaces.
The Abortion Facility does an average of 462 cases per month. On the first day of the survey, there were 40 cases.

Findings included:

1. Review of the facility's, "Infection Prevention Manual," dated 09/09/13, showed the Infection Prevention Committee responsibilities and program components included:
- Surveillance, investigation, control and prevention of infection;
- Review, revision, and approval of infection prevention policies and procedures;
- Take appropriate action to correct deficiencies relating to infection prevention as they are reported;
- Use of standard precautions including Personal Protective Equipment (PPE);
- Injection safety (i.e., if multi-dose vials will be used for more than one patient, the vials should be restricted to a centralized medication area);
- Environmental cleaning;
- Handling of contaminated furniture/equipment/linen/instruments/ supplies;
- Medical equipment; and
- Ongoing program evaluation of program.
(Note: The facility's policy titled, "Pharmaceutical Services," dated 07/01/13, did not address that multi-dose medications should be restricted to a centralized medication area as shown in the facility's, Infection Prevention Manual .)

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L1128	Continued From page 2 2. 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. 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., OR, patient room/cubicle). 3. Review of the facility's policy titled, "Pharmaceutical Services," dated 07/01/13, showed: - On the first clinic session of each month, a delegated staff reviews the inventory to ensure that stock is being properly rotated and has not expired. - Expired inventory must be removed from active stock and marked as expired to ensure it is not available to patient care. - Controlled substances must be destroyed by two nurses and documented on the Controlled Substance Dispensing or Administration Log Sheet. - A daily count at the beginning and at the end of the clinic day must be taken on days when controlled substances are administered or prescribed. - Syringes taken from multi-dose vials must be labeled with date, time, and staff initials. If not used within 24-hours, it must be discarded no later than 24-hours. - Manufacturer's recommendations for storage of opened and unopened multi-dose vials must be followed. (Note: The policy did not address that multi-dose medications should be restricted to a centralized medication area as shown in the facility's Infection Prevention Manual.)	L1128		

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L1128	Continued From page 3 4. Observation of the pre-operative medication area on 03/30/15 at 2:15 PM showed: - An expired EpiPen ([brand] epinephrine autoinjector-medical device used to inject a measured dose or doses of epinephrine used for the treatment of allergic reaction), expiration 02/15. - A pre-drawn syringe labeled Fentanyl (narcotic pain medication) 50 micrograms, dated 03/28/15. Staff failed to dispose of the Fentanyl within 24-hours. - Staff failed to count the syringe of Fentanyl at the end of the day on 03/28/15. During an interview upon the observations, Staff C, Registered Nurse, Clinical Manager confirmed the EpiPen was expired. 5. Observation on 03/30/15 at 2:35 PM of procedure room #2 showed an opened, multi-dose vial of Lidocaine (numbing medication). 6. Observation on 03/30/15 at 2:40 PM of procedure room #3 showed an opened, multi-dose vial of Lidocaine. 7. Observation on 03/30/15 at 2:50 PM, of the clean side of the sterilization area showed two, Tuttnauer 3870-M autoclaves. Staff were unable to find the manufacturer's instructions for use (IFU). 8. Review of requested information on 03/31/15 at approximately 9:30 AM, showed the facility failed to provide the autoclave manufacturer's IFU. The information was requested again. 9. During an interview on 03/31/15 at 10:40 AM,	L1128		

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L1128	Continued From page 4 Staff H, Health Center Assistant (HCA), explained the cleaning and sterilization process. She stated that she could not locate the autoclave manufacturer's IFU. 10. During an interview on 03/31/15 at 1:40 PM, Staff I, Practim Coordinator, stated they were still looking for the autoclave manufacturer's IFU. 11. During an interview on 03/31/15 at 1:45 PM, Staff J, Training and Quality Systems Coordinator, provided a copy of the autoclave manufacturer's IFU and stated they had just printed them off the Internet as they had not been able to locate the facility copy. 12. Review of the newly printed autoclave manufacturer's IFU showed: - Clean the door gasket daily; - Clean the autoclave airjet weekly; - Once every month, clean and check the safety valve; - Replace the door gasket every 12 months, or as needed; and - Once a year, inspect the locking device for excessive wear. Note: The facility failed to provide documentation they or the biomedical company performed these required services. 13. Review of a document provided by the facility titled, "PSS Biomedical Service," dated 08/07/14, showed documentation noting the manufacturer, model, and serial number for the autoclaves, but failed to document what service was provided. 14. Review of the CDC, "Guideline for Disinfection and Sterilization in Healthcare Facilities," dated 2008, showed: - The American Institute of Architects 959	L1128		

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L1128	Continued From page 5 recommends the sterile storage area should be a limited access area with a controlled temperature (may be as high as 75° Fahrenheit (F) and relative humidity (30-60% in all work areas except sterile storage, where the relative humidity should not exceed 70%). 15. Review of the facility's document titled, "Affiliate Risk Management Services (ARMS) Infection Prevention Manual," (a corporate document) dated 2010 showed : - Guidelines for the storage of sterile supplies: *Store supplies 8 to 10 inches from the floor; and *Relative humidity must be controlled at 35-50%. 16. Review of the facility documentation log for the sterilization area showed staff failed to document the humidity levels of the clean and dirty side of the sterilization area. 17. Observation on 03/30/15 and 03/31/15 of the clean and dirty side of the sterilization area showed there was no humidistat to monitor the humidity level. 18. During an interview on 03/31/15 at approximately 10:30 AM, Staff H stated that they monitored the temperature but did not monitor the humidity. 19. Review of the American National Standards Institute (ANSI) and Association for the Advancement of Medical Instrumentation (AAMI) document titled, "ANSI/AAMI ST79:2010," Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities," dated 09/24/10, showed: - Sterile items should be stored in a manner that	L1128		

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reduces the potential for contamination.
- Shelving or carts used for sterile storage should be maintained in a clean and dry condition.
- For sterile or clean supplies stored on the bottom shelf of an open-shelf (wire) cart, there should be a physical barrier between the shelf and traffic or housekeeping activities.

20. Observation on 03/31/15 at approximately 10:15 AM of the clean room showed a metal storage rack for sterile instrument sets. There was no protective barrier on the bottom shelf. (Note: There is a potential risk for splash onto the sterile items on the lower shelves without a barrier.)

During an interview upon the observation, Staff H stated that they did not store instruments on the bottom shelf.

21. Review of the Occupational Health and Safety Administration standards titled, "Bloodborne Pathogens," dated 04/03/12, showed:
- The employer shall ensure that the employee uses appropriate Personal Protective Equipment (PPE); and
- Masks, Eye Protection, and Face Shields. Masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin-length face shields, shall be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated.

22. Review of the facility's document titled, "ARMS Infection Prevention Manual," dated 2010 showed:
- PPE is the clinic workers last line of defense

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against blood borne pathogens. PPE included face shields/masks, goggles, and safety glasses.
- Masks, Eye Protection, Face Shields shall be worn whenever splashes, spray splatter, or droplets of blood or other potentially infectious material may be generated and eye, nose, or mouth contamination can be reasonably anticipated. Examples included washing soiled instruments. References for the document included CDC.

23. Review of the facility's documents titled, "Infection Prevention Compliance Audit," (tool) dated 01/09/14, showed staff identified eye protection/face shields were not consistently used in the decontamination area. Review of the audit tools dated 04/10/14, 07/10/14, 10/09/14 , and 01/08/15, showed staff failed to identify any issues with eye protection/face shields.

24. Review of the facility's, "Infection Prevention Surgical Ad Hoc Committee Meeting," minutes, dated 06/18/14, showed recommendations for the decontamination area included to continue with wearing PPE including face shield.

25. Observation on 03/31/15 at 10:15 AM showed Staff H cleaned surgical instruments. She did not wear protective goggles or a face mask.

During an interview upon the observation, Staff H stated that she could not see without wearing her glasses and could not wear her glasses with the goggles. Staff F, Licensed Practical Nurse, directed her to put on a face shield.

26. Review of the facility's policy titled, "Surgical Abortion Services," dated 10/10/14, showed:
- Supplies must be checked monthly to ensure adequate amount for anticipated care and to

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L1128	Continued From page 8 remove any expired supplies from active inventory. - This is done on the last day of the month or the first day of each successive month prior to the start of the clinic session. 27. Observation on 03/30/15 at 1:50 PM of the ultrasound room showed a can of hand sanitizer, expiration 12/14. 28. Observation on 03/30/15 at 2:15 PM of the medication refrigerator showed a box of Tempa-Dot (brand) thermometers, expiration 02/15. 29. During an interview on 03/30/15 at 2:28 PM, Staff C stated that the thermometers had expired. 30. Observation on 03/30/15 at 3:12 PM of the second ultrasound room showed a can of hand sanitizer, expiration 02/15. During an interview upon the observation, Staff C stated that the hand sanitizer was expired. 31. Observation on 03/30/15 at 3:15 PM of ultrasound room C showed the examination table had a T-shaped tear in the middle of the pad, on the left side of the bed, approximately 6-inches high by 5-inches wide and an approximately 7-inch long linear tear on the right side. The tears exposed the foam core of the pad in several places leaving an uncleanable surface. During an interview upon the observation, Staff C stated that she had ordered a new table top pad approximately two weeks prior. 32. During an interview on 03/31/15 at 2:15 PM, Staff C stated that:	L1128		

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L1128	Continued From page 9 - Approximately two weeks prior another staff member asked for things needed and she had requested a new table top pad. - A large patient sat on the table and the table top pad split but she did not recall when this occurred. - They had not ordered a replacement table top pad. - She could not find any documentation to show they had identified they needed to replace the table top pad. 33. Observation on 03/30/15 at 1:50 PM of the ultrasound room C showed the cloth pillow on the table was covered with a torn, unzipped plastic pillow cover and a cloth pillow case. Approximately 3 inches of the cloth pillow was exposed. The exposed edge of the pillow showed a noticable gray discoloration while the remainder of the pillow that was protected by the plastic cover was white. 34. Observation on 03/30/15 at approximately 3:20 PM of procedure room #1 showed the cloth pillow on the table was covered with an unzipped plastic pillow cover and a cloth pillow case. The exposed end of the pillow was not covered by the plastic pillow case. 35. Observation on 03/30/15 at approximately 3:25 PM of procedure room #2 showed the cloth pillow on the table was covered with a cloth pillow case, leaving an uncleanable surface. 36. During an interview on 03/30/15 at approximately 3:20 PM, Staff E, Sonographer (Ultrasound Technician), stated that she changed the pillow case covers after each patient. 37. Review of the CDC and the Healthcare	L1128		

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L1128	Continued From page 10 Infection Control Practices Advisory Committee (HICPAC), "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. 38. Review of the facility's undated policy titled, "Environmental Cleaning of Clinical 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, including: patient dressing area, recovery rooms and exam/procedure rooms. 39. Review of the facility's,"Infection Prevention Ad Hoc Committee Meeting," minutes, dated 03/13/15 showed: -Identified areas of surgical services for daily, weekly, monthly, and periodic cleaning to included ultrasound rooms, procedure rooms; and recovery area. - Need to detail items for cleaning in the ultra sound rooms (i.e., identify equipment and furniture items to clean--exam table, lamps, other furniture, and wall items). 40. Review of the facility's, "Infection Prevention Committee Meeting," minutes, dated 11/12/14, showed staff identified that they needed to include environmental cleaning expectation in the general standard requirement section of their OSHA manual. 41. Observation on 03/30/15 at approximately 2:15 PM of the pre/postoperative medication refrigerator showed the front of the refrigerator	L1128		

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L1128	Continued From page 11 was dirty and there was tape and adhesive on the refrigerator, leaving an uncleanable surface. 42. Observation on 03/30/15 at 2:21 PM of the pre/post-operative area nurses' station showed a cabinet with packages of intravenous (IV-small catheter inserted into a vein for administering medication and fluid) administration tubing. There was a layer of dust on the shelves that left a easily visible mark when a finger was pulled through. 43. During an interview on 03/30/15 at 2:27 PM, Staff C stated that the cabinet shelves were dusty. 44. Observation on 03/30/15 at 2:30 PM of the pre/postoperative area showed there was tape, adhesive, and/or peeling labels on the cabinets and clip boards on the wall, leaving an uncleanable surface. 45. Observation on 03/30/15 at 2:40 PM of procedure room #3 showed a drawer with dust and debris inside and adhesive residue and/or torn labels on the outside of the cabinets and/or drawers. 46. Observation on 03/30/15 at 2:43 PM of procedure room #1 showed adhesive residue and tape on the cabinet doors and drawers. 47. During an interview on 03/30/15 at 2:45 PM, Staff C stated that they would have to remove the tape and adhesive residue. 48. Observation on 03/30/15 at 2:50 PM of the clean side of the sterilization area showed: - Brownish residue in one cabinet and on the floor in front of the cabinet;	L1128		

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L1128	Continued From page 12 - Tape and/or adhesive residue on the cabinet doors ; and - A drawer in the corner of the room which contained nonsterile surgical instruments with dust and debris in the drawer. During an interview upon the observation, Staff C stated that it was obvious no one had been in the drawer in a long time. 49. During an interview on 03/31/15 at 10:35 AM, Staff H stated that she did not clean the drawers and the instruments in the drawer were extra instruments. 50. Observation on 03/30/15 at 3:12 PM of the ultrasound room showed: - A plastic tray holding protective bed pads. The tray had a layer of dust that left a mark when a finger was pulled through. - An ultrasound machine (used to obtain images of the fetuses) with a layer of dust on the control panel that left an easily visible mark when a finger was pulled through. - Tape on the side and base of the ultrasound machine. 51. During interviews upon the observation, Staff E stated that she had just dusted the room that morning and dusted constantly but the room got dusty again quickly. Staff A, Chief Operating Officer, stated that the tape could be removed. 52. Observation on 03/30/15 at 3:55 PM of the hallway outside the sterilization area showed there was a wheelchair with a layer of dust on the frame that left an easily visible mark when a finger was pulled through. During an interview upon the observation, Staff C	L1128		

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L1128	Continued From page 13 stated that they often used the wheelchair. 53. Review of the facility's, "OSHA and Laboratory Procedure Manual," dated 12/14/14 showed: - Each employee is responsible to disinfect and decontaminate work surfaces at the end of each shift; and - Work surfaces included countertops, exam tables, mobile medication carts, etc. (Note: There were no directions on when and/or how often to clean the laboratory refrigerator.) 54. Review of the facility's, "Quality Management Checklist," policy dated 12/14/14, showed: - Check refrigerator temperatures daily; and - Clean/disinfect laboratory equipment/furniture. (Note: There were no directions on when and/or how often to clean the laboratory refrigerator.) 55. Observation on 03/30/15 at 3:00 PM of the laboratory refrigerator, showed there were several dark strands of hair and dust on the bottom shelf of the refrigerator. During an interview upon the observation, Staff C confirmed there was hair in the refrigerator. 56. During an interview on 03/30/15 at 3:10 PM, Staff D, HCA, stated that: - He had been employed approximately 1 and 1/2 years. - He had never cleaned the refrigerator; - He did not recall if it was one of his duties; and - Maybe people that had worked there longer cleaned it.	L1128		
L1136	19 CSR 30-30.060(1)(B)(12) The administrator shall be responsible	L1136		5/31/15

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L1136	Continued From page 14 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 policy review and interview the facility failed to ensure that all provisions of Chapter 188 were adhered to regarding the reporting of pathologist's reports and the submission to the Missouri Department of Health. The abortion facility does an average of 462 cases per month. On the first day of the survey, there were 40 cases. Findings included: 1. Review of the facility's policy titled, "Surgical Abortion Services," dated 10/10/14, showed per Missouri law, all fetal tissue is sent to a pathology laboratory for evaluation. 2. Review of Missouri State Statute 188.047 showed that a representative sample of tissue removed shall be submitted to a pathologist who shall file a copy of the tissue report with the state Department of Health and Senior Services. 3. During an interview on 03/31/15 at 11:00 AM Staff A, Chief Executive Officer, stated that the pathology service utilized by the facility did not submit pathology specimen reports to the Missouri Department of Health and Senior Services.	L1136		
L1184	19 CSR 30-30.060(4)(D) The following laboratory procedures shall The following laboratory procedures shall be	L1184		5/31/15

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L1184	Continued From page 15 performed on every abortion patient: hematocrit; urinalysis, including pregnancy test; and Rh typing. This regulation is not met as evidenced by: Based on record review, observation, and interview, the facility failed to date glucometer (device used for testing the blood sugar level) test strips (used to place a drop of blood to test the blood sugar). The Abortion Facility does an average of 462 cases per month. On the first day of the survey, there were 40 cases. 1. Review of the facility's undated OneTouch UltraSmart (brand - glucometer) Owner's Booklet showed: - Write the discard date (3 months after first opening the vial) on the vial label when you first open it. Discard remaining OneTouch Ultra Test Strips after the discard date. - Do not use test strips beyond the expiration (printed on the package) or discard date, whichever comes first, because they may cause inaccurate results. 2. Review of the facility's laboratory log showed the last blood glucose test had been completed on 03/28/15. 3. Observation on 03/30/15 at 3:00 PM in the laboratory showed a OneTouch UltraSmart glucometer. Staff failed to date the bottle of test strips to show when they were to be discarded. Instructions on the bottle showed, "Discard six months after opening." There was a line on the bottle to write the discard date, which had been left blank. During an interview upon the observation, Staff D, Health Center Assistant, who was working in the	L1184		

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L1184	Continued From page 16 lab, stated that he had no idea when the test strips had been opened.	L1184		

EXHIBIT I

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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 medication area separate from the procedure	L1128		4/30/16

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L1128	Continued From page 1	L1128		

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:
- If the autoclave is not cleaned regularly, dirt and debris will build up and clog the tubing and

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L1128	Continued From page 2	L1128		

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.

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

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L1128	Continued From page 3 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. - Record the sterilized and control biological indicator results in quality management binder. 11. Review of the facility's biological indicator log	L1128		

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L1128	Continued From page 4 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. 15. During an interview on 03/15/16 at 3:25 PM, Staff H stated that they left the window open all the time.	L1128		

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L1128	Continued From page 5 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 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.)	L1128		

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L1128	Continued From page 6 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 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	L1128		

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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.

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

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L1128	Continued From page 8 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 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.	L1128		

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L1128	Continued From page 9 * 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. - 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	L1128		

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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.
(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

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L1128	Continued From page 11 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 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	L1128		

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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.

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

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L1128	Continued From page 13 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 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	L1128		

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L1128	Continued From page 14 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. 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	L1128		

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L1128	Continued From page 15 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. 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.	L1128		

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L1128	Continued From page 16 - 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 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:	L1128		

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L1128	Continued From page 17 - 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. 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]:	L1128		

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L1128	Continued From page 18 * 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 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	L1137		4/30/16

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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.

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

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L1137	Continued From page 20 "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 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.	L1137		

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L1137	Continued From page 21 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, 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,	L1137		

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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.

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

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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 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

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L1137	Continued From page 24 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, 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	L1153		5/6/16

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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.)

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.

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(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
L1153	Continued From page 26 - 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. 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	L1153		

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L1153	Continued From page 27	L1153		

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 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.

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L1153	Continued From page 28 - 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 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.	L1153		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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L1153	Continued From page 29 - 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: - 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	L1153		

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L1153	Continued From page 30	L1153		

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 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.

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L1153	Continued From page 31 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 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;	L1165		4/15/16

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L1165	Continued From page 32 * 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 * 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	L1165		

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L1165	Continued From page 33 minutes . - An aldrete score was not documented for the recovery period until the patient was discharged. 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	L1165		

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L1165	Continued From page 34 signs were recorded at 12:50 PM. - Vital signs were not taken every 15 minutes. - An aldrete score was not documented for the 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		

EXHIBIT J

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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		5/30/17

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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		6/30/17

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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.

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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		5/31/17

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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		

EXHIBIT K

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L 000	Initial Comments An on-site, unannounced state licensure survey was conducted from 03/05/18 to 03/07/18 in order to determine compliance with applicable statutes and regulations governing abortion facilities, including 19 CSR 30-30.050, 060, and 061 and Chapter 188, RSMo (Regulation of Abortions). See below for findings:	L 000		
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 federal regulations, state statute, policy review, record review, and interview, the facility failed to: - Reconcile controlled substances ordered with controlled substances received; - Conduct an annual inventory of controlled substances; and - Ensure a Power of Attorney (POA) was obtained authorizing the person designated to order narcotics for the facility and ensure the POA was readily available for inspection. The Abortion Facility does an average of 315 cases per month. On the first day of the survey, there were no procedures. Findings included: 1. Review of the Drug Enforcement Administration (DEA) Regulation 21 Code of Federal Regulations (CFR) 1301.71(a) showed: - All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled	L1111		5/1/18

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L1111	Continued From page 1 substances. 2. Review of the DEA Title 21 CFR, Controlled Substance Act, Part 1305, Subpart B, dated 10/27/70, showed: - §1305.13 Procedure for filing DEA Forms 222. * A purchaser must submit Copy 1 and Copy 2 of the DEA Form 222 to the supplier and retain Copy 3 in the purchaser's files. * The purchaser must record on Copy 3 of the DEA Form 222 the number of commercial or bulk containers furnished on each item and the dates on which the containers are received by the purchaser. - §1305.17 Preservation of DEA Forms 222. * The purchaser must retain Copy 3 of each executed DEA Form 222 and all copies of unaccepted or defective forms with each statement attached. 3. Review of Missouri's 19 CSR 30-1.048(1)(A)-(C), dated 04/30/17, showed: 1) Each individual practitioner, institutional practitioner, and pharmacy shall maintain records with the following information for each controlled substance received, maintained, dispensed, or disposed: (A) The name of the substance; (B) Each finished form (for example, ten milligram (10 mg [unit of measure]) tablet or ten milligram (10 mg) concentration per fluid ounce or milliliter [ml - unit of measure]) and the number of units or volume of finished form in each commercial container (for example, one hundred (100) tablet bottle or three milliliter (3 ml vial); and (C) The number of commercial containers of each finished form received from other persons, including the date of and number of containers in each receipt and the name, address and registration number of the person from whom the	L1111		

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L1111	Continued From page 2 containers were received. 4. Review of the Control Substance Act of 1970 (Public Law 91-513) requires that complete and accurate records of all receiving and dispensing transactions must be maintained for a period of two years. 5. Review of the facility's copies of completed DEA Forms 222 showed: - The DEA Forms 222 did not have an invoice or packing slip attached to them to reconcile what was ordered with what was received or to track who received the controlled substances; - The DEA Forms 222 did not have an invoice or packing slip attached to them to document the name, address and registration number of the person from whom the containers of controlled substances were received; and - The facility failed to record on Copy 3 of the DEA Form 222 the number of packages received and the dates on which the controlled substances were received. 6. During an interview on 03/07/18 at 3:35PM, Staff A, Vice President Patient Care and Clinical Services, stated that Staff C, Nurse Practitioner (advanced registered nurse), Lead Clinician, and Staff CC, Physician, Medical Director, ordered the narcotics (controlled substances) for the facility. 7. During a telephone interview on 03/07/18 at 3:55 PM, Staff C stated that: - She ordered all Schedule II narcotics but did not receive them when they were delivered to the facility; - After she filled out the DEA Form 222 and placed the order, she gave Staff R, Financial Officer, the DEA Form 222 to file in her office; - When the narcotics were delivered to the facility,	L1111		

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L1111	Continued From page 3 Staff S, Maintenance and Receiving, received the narcotics and put them in a double-locked narcotic box located in a cage downstairs; - Once the narcotics were delivered to the facility, she did not fill in the number of packages received or the date the packages were received on copy 3 of the DEA Form 222; - She did not reconcile what was ordered with what was received; and - She was not sure where the packing slips for the controlled substances were. 8. During an interview on 03/07/18 at 4:08 PM, Staff A stated that she was unaware the DEA Form 222 should have been reconciled with the packing slip to show that what was ordered was received. 9. Review of the Missouri State Statue RSMo, Chapter 195, dated 08/28/15, showed: - 195.050.6: Every person registered to manufacture, distribute or dispense controlled substances under sections 195.005 to 195.425 shall keep records and inventories of all such drugs in conformance with the record keeping and inventory requirements of federal law, and in accordance with any additional regulations of the Department of Health and Senior Services. 10. Review of Missouri's 19 CSR 30 - 1.041(3) (A)-(B), dated 04/30/17, showed: - Records Requirements. Each registered individual practitioner, institutional practitioner, manufacturer, distributor, importer and exporter, shall maintain inventories and records of controlled substances as follows: * (A) Inventories and records of controlled substances listed in Schedules I - II shall be maintained separately from all of the records of the registrant:	L1111		

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L1111	Continued From page 4 * (B) Inventories and records of controlled substances listed in Schedules III - V shall be maintained either separately from all other records of the registrant or in a form that the information required is readily retrievable from the ordinary business records of the registrant. 11. Review of Missouri's 19 CSR 30 - 1.042(3), dated 04/30/17, showed: - Annual Inventory Date. After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least once a year. The annual inventory may be taken on any date that is within one year of the previous annual inventory date. - Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory was taken. - Controlled substances shall be deemed on hand if they are in the possession of or under the control of the registrant, including substances returned by a customer, substances ordered by a customer but not yet invoiced, and substances stored in a warehouse on behalf of the registrant. - For each controlled substance in finished form, the name of the substance (for example, ten milligram (10 mg) tablet or ten milligram (10 mg) concentration per fluid ounce or milliliter); the number of units or volume of each finished form in each commercial container (for example, four 100 tablet bottles or three milliliter (3 ml) vials); the number of commercial containers of each finished form (for example, four 100 tablet bottles or six three milliliter (3 ml) vials). (Note: Schedule IV drugs included Diazepam (used to treat muscle spasms and anxiety) and Versed (sedative). Schedule II drugs included Fentanyl (narcotic pain medication). 12. Observation on 03/05/18 at 2:20 PM of the	L1111		

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L1111	Continued From page 5 narcotic cabinet showed the facility had Diazepam, Fentanyl, and Versed. During an interview upon the observation, Staff J, RN, confirmed that these controlled substances were used by the facility. 13. On 03/06/18 at 2:10 PM staff provided an annual inventory for the facility. The annual inventory provided was not the required separate inventory for Schedule I - II and Schedule III - V controlled substances. The annual inventory list was requested again. (Note: The facility failed to provide the required annual inventory for Schedule I - II and Schedule III - V prior to exit.) 14. Review of the Title 21 Code of Federal Regulations §1305.05 Power of Attorney (POA) showed: * A registrant may authorize one or more individuals, whether or not located at his or her registered location, to issue orders for Schedule I and II controlled substances on the registrant's behalf by executing a power of attorney for each such individual, if the power of attorney is retained in the files, with executed Forms 222 where applicable, for the same period as any order bearing the signature of the attorney. - The power of attorney must be available for inspection together with other order records. 15. During an interview on 03/05/18 at approximately 2:30 PM, Staff J, RN, stated that Staff H, Health Center Manager, ordered medications. 16. During interviews on 03/06/18 at 11:35 AM and 2:10 PM, survey staff requested the POA for the person responsible for ordering controlled substances from Staff A.	L1111		

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L1111	Continued From page 6 17. During an interview on 03/07/18 at 1:30 PM, Staff H stated that she: - Did not order controlled drugs; and - Did not know who ordered the controlled drugs. 18. During an interview on 03/07/18 at 2:00 PM, Staff P, Director of Quality and Infection Control, stated that Staff C was responsible for ordering medications. 19. During an interview on 03/07/18 at 3:20 PM, Staff A stated that Staff R had the POA but they were unable to find it. 20. During an interview on 03/07/18 at 3:35PM, Staff A stated that Staff C and Staff CC ordered the narcotics (controlled substances) for the facility. 21. (Note: The annual inventory and POA were originally requested on 03/06/18 at 11:35 AM. Staff failed to provide the annual inventory and the POA by the time of exit on 03/07/18 at 5:45 PM.)	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	L1128		4/30/18

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L1128	Continued From page 7 packaging shall maintain its integrity during storage and transport. This regulation is not met as evidenced by: Based on nationally-recognized standards, policy review, observation, and interview, the facility failed to: - Ensure staff followed acceptable standards of practice for hand hygiene; - Follow the manufacturer's recommendations for disinfectant dry time; - Follow the manufacturer's recommendations for disinfectant storage; and - Ensure a sanitary environment was preserved by providing easily cleanable surfaces that will not harbor bacteria and transmit infections. The Abortion Facility does an average of 315 cases per month. On the first day of the survey, there were no procedures. Findings included: 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	L1128		

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L1128	Continued From page 8 * Failure to remove gloves after caring for a patient may lead to transmission of microorganisms from one patient to another. 2. Review of the facility's "Infection Prevention Manual" policy titled, "Standard Precautions, Hand Hygiene, Personal Protective Equipment (PPE)," dated 09/05/17, showed: - Key situations were [sic] hand hygiene should be performed include: * Before exiting the patient's care/procedure area after touching the patient or the patient's immediate environment; * After contact with blood, body fluids or excretions, or dressings; and * After glove removed. - Hand-rubs (alcohol-based product) should be used before and after each patient just as gloves should be changed before and after each patient. - Do not wash or try to re-use disposable (single use, exam) gloves. (Note: The facility's policy referenced the CDC document noted above.) 3. Observation on 03/06/18 at 9:20 AM showed Staff G, Sonographer (ultrasound technician), completed an ultrasound on Patient #19, wiped off the ultrasound probe with a paper towel, removed one glove, failed to remove both gloves and perform hand hygiene, and opened the door with the hand not gloved. 4. Observation on 03/06/18 at 9:44 AM showed Staff I, Sonographer, completed an ultrasound on an unidentified patient, removed the paper that covered the exam table, removed one glove, failed to remove both gloves and perform hand hygiene, rubbed her eye with the hand not gloved, donned the dirty glove, rinsed the vaginal probe with water, wiped it with gauze and placed it in the	L1128		

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L1128	Continued From page 9 high-level disinfectant, removed one glove, failed to remove both gloves and perform hand hygiene, rubbed her eye, donned the soiled glove, and cleaned the exam table. 5. During an interview on 03/07/18 at 1:55 PM, Staff H, Health Center Manager, stated that hand hygiene was expected: - Before and after patient care; - Before and after glove use; and - Even if gloves were worn. 6. Review of the CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC), "Guidelines for Environmental Infection Control in Health-Care Facilities," dated 2008, showed: - Disinfect noncritical surfaces with an EPA (Environmental Protection Agency) -registered hospital disinfectant according to the label's safety precautions and use directions. Most EPA-registered hospital disinfectants have a label contact time of 10 minutes. However, many scientific studies have demonstrated the efficacy of hospital disinfectants against pathogens with a contact time of at least 1 minute. By law, the user must follow all applicable label instructions on EPA-registered products. If the user selects exposure conditions that differ from those on the EPA-registered product label, the user assumes liability for any injuries resulting from off-label use and is potentially subject to enforcement action under FIFRA (Federal Insecticide, Fungicide, and Rodenticide Act). 7. Review of the facility's container of McKesson (manufacturer) disinfectant wipes' label instructions for contact time showed to allow the surface to remain wet for two minutes.	L1128		

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L1128	Continued From page 10 8. Review of the facility's "Infection Prevention Manual" policy titled, "Cleaning, Disinfection and Sterilization," dated 09/05/17, showed: - Germicidal wipes (disinfectant wipes): * Use: 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 to remain wet for the appropriate time indicated for the purpose intended. Allow 2 (two) minute contact time. (Note: The facility's policy referenced CDC.) 9. Observation on 03/06/18 at 9:20 AM, after Patient #19's ultrasound, showed Staff G wiped the foot end of the exam table with a McKesson disinfectant wipe, immediately pulled the roll of paper to cover the area that she had wiped, and failed to allow adequate dry time of the disinfectant. 10. During an interview on 03/07/18 at 1:55 PM, Staff H stated that the disinfectant wipes had a two minute dry time. 11. Review of the facility's container of McKesson disinfectant wipes' label showed, "When not in use, keep center cap closed to prevent evaporation." 12. Review of the facility's container of PDI-Sani Cloth (Manufacturer and brand) disinfectant wipes' label showed, "Replace lid." 13. Review of the facility's "Infection Prevention Manual" policy titled, "Cleaning, Disinfection and Sterilization," dated 09/05/17, showed: - Germicidal wipes (disinfectant wipes): * Preparation: To start feed, remove cover and discard seal. From the center of the pipe roll, pull up a wipe corner, twist it into a point and thread it	L1128		

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L1128	Continued From page 11 though [sic] the hole located on the container cover. Pull through about one inch. Replace cover. Pull out first wipe and tear off at an angle. Remaining wipes feed automatically, ready for the next use. When not in use, keep center cap closed to prevent evaporation. 14. Observation on 03/06/18 at 9:20 AM in an ultrasound room showed a container of McKesson disinfectant wipes and a container of PDI-Sani Cloth disinfectant wipes. The disinfectant wipes were not in use and Staff G had failed to close the caps of the containers. 15. Observation on 03/06/18 at 9:30 AM in an ultrasound room showed a container of McKesson disinfectant wipes and a container of PDI-Sani Cloth disinfectant wipes. The disinfectant wipes were not in use and Staff I had failed to close the caps of the containers. 16. Observation on 03/06/18 at 9:44 AM in an ultrasound room showed a container of McKesson disinfectant wipes and a container of PDI-Sani Cloth disinfectant wipes. The disinfectant wipes were not in use and Staff I had failed to close the caps of the containers. 17. Observation on 03/06/18 at 2:20 PM in an ultrasound room showed a container of McKesson disinfectant wipes and a container of PDI-Sani Cloth disinfectant wipes. The disinfectant wipes were not in use and Staff I had failed to close the caps of the containers. 18. During an interview on 03/07/18 at 1:55 PM, Staff H stated that the containers of disinfectant wipes should have been closed when not in use. 19. Review of the CDC and the HICPAC,	L1128		

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L1128	Continued From page 12 "Guidelines for Environmental Infection Control in Health-Care Facilities," dated 2008, showed: - Some items that may come in contact with nonintact skin for a brief period of time (i.e., hydrotherapy tanks, bed side rails) are usually considered noncritical surfaces and are disinfected with intermediate-level disinfectants. - Clean housekeeping surfaces (e.g., floors, tabletops) on a regular basis, when spills occur, and when these surfaces are visibly soiled. - Disinfect (or clean) environmental surfaces on a regular basis (e.g., daily, three times per week) and when surfaces are visibly soiled. - Use a one-step process and an EPA-registered hospital disinfectant designed for housekeeping purposes in patient care areas where: * Uncertainty exists about the nature of the soil on the surfaces (e.g., blood or body fluid contamination versus routine dust or dirt); or * Uncertainty exists about the presence of multidrug resistant organisms on such surfaces. 20. Review of the facility's "Infection Prevention Manual" policy titled, "Environmental Cleaning of Clinical Care Areas," dated 09/05/17, showed: - Other patient care areas and environmental surfaces that come in direct contact with patients will be cleaned with a facility-approved, EPA registered disinfectant. - Clean the exam/procedure table: * Clean from top; * Clean exposed frame; * Clean headboard, foot board, bed rails, bed attachments and bed controls; pay particular attention to areas that are visibly soiled and surfaces frequently touched by staff; and * Clean all lower parts. (Note: The facility's policy referenced CDC.) 21. Review of the facility's, "Infection Prevention	L1128		

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L1128	Continued From page 13 Manual, policy titled, "Cleaning, Disinfection, and Sterilization," dated 09/05/17, showed: - Clean and disinfect exterior of cabinets and doors; - Clean and disinfect all horizontal surfaces; - Clean all furnishings and horizontal surfaces in the room; and - Report any needed repairs. (Note: The facility's policy referenced CDC.) 22. Review of the facility's document titled, "Environmental Cleaning Schedule for Surgical Services Floor, Weekly, Monthly, Periodically Cleaning," dated 2017, showed: - Clean Medical Supply Room daily (including bins and shelves); - Procedure room cabinets vertical surfaces, tops, and shelves, and under sink cleaned two times week; -Ultrasound rooms, furniture cleaned and disinfected daily, Monday through Friday 23.. Observation on 03/05/18 at 2:00 PM of procedure room #1 showed: - The top of the emergency box was dusty and left a visible mark when a finger was dragged across the surface; and - The trays inside the emergency box were dusty which left a visible mark when a finger was dragged across the surface. 24. Observation on 03/05/18 at 2:05 PM of procedure room #2 showed: - The upper cabinets had peeling labels and adhesive residue; - The top of a plastic storage box on the counter top was dusty and left a visible mark when a finger was dragged across the surface. 25. Observation on 03/05/18 at 2:10 PM of	L1128		

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L1128	Continued From page 14 procedure room #3 showed: - A plastic storage box on the counter with a peeling label; and - The top of the emergency box was dusty and left a visible mark when a finger was dragged across the surface. 26. Observation on 03/05/18 at 2:30 PM of the pre/postoperative area showed inside the cabinet above the sink was a gouged area (approximately three centimeters deep) exposing the particle board or pressed wood, leaving an uncleanable surface. 27. Observation on 03/05/18 at 2:40 PM of the supply room showed a metal storage rack with five pressed wood shelves which were an uncleanable surface. 28. Observation on 03/06/18 at 9:07 AM of the supply room showed a metal storage rack with five pressed wood shelves. During an interview upon the observation Staff L, Flow Coordinator, stated that they cleaned the pressed wood shelves with Lysol (brand of disinfectant). 29. Observation on 03/06/18 at 2:20 PM in the ultrasound room closest to the laboratory showed the following uncleanable surfaces on the exam table: - An approximately one-inch diameter opening (manufacturer's design for the insertion of a side rail) that was full of white paper; and - Peeling tape and a business card on the side of the table. During an interview upon the observation, Staff I stated that: - She had put tissue in the hole of the exam table to fill it; and	L1128		

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L1128	Continued From page 15 - The peeling tape was uncleanable. 30. Observation on 03/06/18 at 2:30 PM of the pre/postoperative area showed inside the cabinet above the sink was a gouged area (approximately three centimeters deep) exposing the particle board or pressed wood, leaving an uncleanable surface. 31. Observation on 03/07/18 at 2:30 PM in the pre/postoperative area storage cabinet in bay #11 showed: - Dust on one side of the cabinet which left a visible mark when a finger was pulled across the surface; - Adhesive residue on the opposite side; and - Dirt and debris on the floor behind the cabinet. 32. During an interview on 03/07/18 at 1:20 PM, Staff H stated that: - The housekeeper cleaned but everyone was responsible to clean their own areas including counters and cabinets; - The person responsible for the area was responsible to clean the emergency boxes including inside the boxes; - Staff L and the housekeeper were responsible to dust the shelving in the supply room; and - She did not agree that the supply room shelves were uncleanable.	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.	L1136		5/18/18

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L1136	Continued From page 16 This regulation is not met as evidenced by: Based on record review, observation, and interview, the facility failed to ensure patients were given "medically accurate information that a reasonable patient would consider material to the decision of whether or not to undergo the abortion" with respect to the medical risks of "harm to subsequent pregnancies or the ability to carry a subsequent child to term, and possible adverse psychological effects associated with the abortion" for a patient (#22) observed as required by law (Section 188.027.1(1), RSMO). The Abortion Facility does an average of 315 cases per month. On the first day of the survey, there were no procedures. Findings included: 1. Review of Missouri law 188.027.1(1) RSMo, showed: - The physician who is to perform or induce the abortion, a qualified professional, or the referring physician has informed the woman orally, or reduced to writing, and in person, of the following: --(b) Medically accurate information that a reasonable patient would consider material to the decision of whether or not to undergo the abortion, including: --b. The immediate and long-term medical risks to the woman associated with the proposed abortion method including, but not limited to, infection,hemorrhage, cervical tear or uterine perforation, harm to subsequent pregnancies or the ability to carry a subsequent child to term, and possible adverse psychological effects associated with the abortion. 2. Observation on 03/06/18 at 10:45 AM showed Staff GG, Physician, spoke with Patient #22 and	L1136		

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L1136	Continued From page 17 stated that: - She would provide the immediate and long-term risks; - There were known medical risks that she would tell the patient about and then there were medical risks that the state of Missouri would like the patient to believe, but there was "no medical evidence to support" (what the state of Missouri would like the patient to believe); - Patient #22 would be almost 14 weeks gestational age at the time of the (surgical abortion) procedure; - There was a risk of infection, bleeding, and injury to the cervix or uterus; - The medication (to dilate the uterus) given prior to the procedure would cause cramping and bleeding; and - The state of Missouri would like you to believe that the procedure will affect your ability to get pregnant, carry a pregnancy to term, and put you at risk of psychological problems, but there was "no medical evidence to support" (what the state of Missouri would like the patient to believe). During an interview immediately after the observation, Staff GG stated that she had 70 clients with whom to complete the informed consent process that day (03/06/18). 3. During an interview on 03/07/18 at 8:52 AM, Staff FF, Physician, stated that: - What the abortion facility physicians told the clients was based on studies that they had from all over, particularly European countries; - For most women, the range of emotions was normal and most women could handle those emotions; - Staff FF's thought was to base it on medical evidence and that it felt dishonest if there was no medical evidence; and	L1136		

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L1136	Continued From page 18 - While there were studies that showed a link (to the risks described in 188.027 and the written informed consent documentation published by the Department), as physicians they went by the preponderance of evidence. 4. During an interview on 03/07/18 at 4:34 PM, during the survey exit conference, Staff CC, Physician, Medical Director, stated that: - He agreed with Staff GG and Staff FF; and - There was no compelling medical evidence to support all of the risks (as described in 188.027 and in the written informed consent documentation published by the Department). 5. Note: It is medically inaccurate for the physicians to state that there is no medical evidence to support that an abortion poses a risk of harm to subsequent pregnancies or the ability to carry a subsequent child to term, and possible adverse psychological effects associated with the abortion. For some examples of published evidence, see below: -Swingle HM, Colaizy TT, Zimmerman MB, Morriss FH Jr. Abortion and the risk of subsequent preterm birth: a systematic review with meta-analyses. J. Reprod. Med 2009 Feb; 54: 95-108; -PS Shah, a, b, J Zaoa on behalf of Knowledge Synthesis Group of Determinants of preterm/LBW. Induced termination of pregnancy and low birth weight and preterm birth: a systematic review and meta-analyses births*BJOG 2009; 116: 1425-1442; -Oliver-Williams C, Fleming M, Monteath K, Wood AM, Smith GC. Changes in association between previous therapeutic abortion and	L1136		

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L1136	Continued From page 19 preterm birth in Scotland, 1980 to 2008: a historical cohort study. PLoS Med 2013; 10(7): e1001481.doi.10.1371/journal. Pmed 1001481. Epub 2013 July 9; and -Thorp JM Jr, Harmann KE, Shadigan E. Long-term physical and psychological health consequences of induced abortion: review of the evidence. Obstet Gynecol Surv. 2003 Jan; 58(1): 67-79	L1136		
L1163	19 CSR 30-30.060(3)(C) A medical history shall be obtained A medical history shall be obtained and a health assessment including a pelvic examination shall be performed. There must be confirmation of pregnancy by clinical evidence and laboratory tests. The findings shall be used in determining the duration of gestation, identifying preexisting medical or other complications, and detecting any factors which could influence the choice of the procedure, anesthesia or preoperative and postoperative management. If the physician determines gestation is beyond the first trimester, an ultrasound examination shall be performed and results shall be recorded in the patient's chart. This regulation is not met as evidenced by: Based on policy review, record review, observation, and interview, the facility failed to: - Ensure a pelvic examination (visual and physical examination of a woman's reproductive organs [the vagina, cervix, fallopian tubes, vulva, ovaries, and uterus] for any abnormalities) was completed prior to the procedure for one (#25) of one patient observed and five (#1, #2, #6, #9, and #12) of	L1163		5/18/18

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L1163	Continued From page 20	L1163		

sixteen patients' medical records reviewed; and
- Ensure a physical examination was completed immediately prior to the procedure, in order to evaluate the procedural risks for one (#25) of one patient observed and four (#2, #6, #9, and #12) of sixteen patients' medical records reviewed.
The Abortion Facility does an average of 315 procedures per month. On the first day of the survey, there were no procedures.

Findings included:

1. Review of the facility's policy titled, "Abortion," dated 09/29/17, showed:
- 1.1 Medication Abortion:
 * Physical Examination must include blood pressure and additional examination as indicated by history or laboratory findings; and
 * Bimanual exam (two fingers of one hand are inserted in the vagina and the other hand gently palpates the uterus, cervix and adnexae [the ovaries, fallopian tubes, and the ligaments that hold the uterus in place] to evaluate pregnancy, cysts and/or masses in the ovaries) when indicated (e.g., vaginal bleeding or abdominal/pelvic pain).
(Note: The policy did not address completing a physical examination to detect any factors which could influence the choice of the procedure to be performed.)

2. Review of the facility's policy titled, "Abortion," dated 09/29/17, showed:
- 1.2 Surgical Abortion:
 * Physical examination must include a visual exam of the vulva, vagina, and cervix, and a bimanual exam, including estimation of uterine size and position and palpation of the adnexa.

3. Review of Patient #1's medical record, with an

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L1163	Continued From page 21 admission date of 02/28/18, for a surgical abortion procedure showed the facility failed to document a pelvic examination had been completed. 4. During an interview on 03/06/18 at 9:30 AM, Staff H, Health Center Manager, stated that Patient #1 should have had a pelvic examination but she was not sure why it was not documented in the medical record. 5. Review of Patient #2's medical record, with an admission date of 02/20/18, for a medication abortion (a type of non-surgical procedure in which medication is used to bring about an abortion to end a pregnancy) procedure showed: - The facility failed to document a pelvic examination had been completed; and - The facility failed to ensure a physical examination to evaluate any factors which could influence the choice of the procedure to be performed was documented prior to the procedure performed. 6. During an interview on 03/06/18 at 11:08 AM, Staff H stated that: - No pelvic examinations were completed for patients that received a medication abortion procedure; - They completed a physical examination that included a heart and lung assessment on patients that received a surgical abortion procedure; - The facility took vital signs (clinical measurements, specifically pulse rate, temperature, respiration rate, and blood pressure, that indicate the state of a patient's essential body functions) but did not complete physical examinations that included a heart and lung assessment on patients that received a medication abortion procedure; and	L1163		

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L1163	Continued From page 22 - There was no documentation in the medical record that Patient #2 received a pelvic examination or a physical examination that included a heart and lung assessment. 7. Review of Patient #6's medical record, with an admission date of 01/03/18, for a medication abortion procedure showed: - The facility failed to document a pelvic examination had been completed; and - The facility failed to document a physical examination had been completed prior to the procedure to be performed. 8. Review of Patient #12's medical record, with an admission date of 03/02/17, for a medication abortion procedure, showed: - The facility failed to document a pelvic examination had been completed; and - The facility failed to document a physical examination had been completed prior to the procedure to be performed. 9. During an interview on 03/07/18 at 9:02 AM, Staff H stated that Patient #12 did not have a heart and lung physical examination or a pelvic examination documented in the medical record. 10. Review of Patient #9's medical record, with an admission date of 11/22/17, for a medication abortion procedure, showed: - The facility failed to document a pelvic examination had been completed; and - The facility failed to document a physical examination had been completed prior to the procedure to be performed. 11. During an interview on 03/07/18 at 10:32 AM, Staff H stated that she agreed the medical record for Patient #9 did not contain a pelvic examination	L1163		

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L1163	Continued From page 23 or a physical examination. 12. Observation on 03/06/18 at 3:55 PM of Patient #25's medication abortion showed Staff FF, Physician, failed to perform a physical and pelvic examination on the patient. 13. During an interview on 03/06/18 at 4:00 PM, Staff CC, Physician, Medical Director, stated that: - They did not perform a pelvic examination on patients that received medication abortions; - It was not medically necessary to complete a pelvic examination on patients that received a medication abortion since those patients were given an ultrasound (machine that uses high-frequency sound waves to produce images of structures within the body) to confirm their pregnancy and that the gestation age (term used during pregnancy to describe how far along the pregnancy is. It is measured in weeks, from the first day of the woman's last menstrual cycle to the current date) was less than 10 weeks; - The medical necessity was not there to put anything in a women's vagina when they had the ultrasound confirming the pregnancy; and - There was no need to add the stress and discomfort of a pelvic examination to a patient that was terminating her pregnancy by a medication abortion. 14. During an interview on 03/06/18 at 4:05 PM, Staff FF stated that she did not perform physical or pelvic examinations on medical abortion patients as there was no indication to do so.	L1163		
L1170	19 CSR 30-30.060(3)(J) Each abortion facility shall develop Each abortion facility shall develop a quality	L1170		4/30/18

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L1170	Continued From page 24 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; 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 record review and interview, the facility failed to: - Hold quarterly quality assurance meetings; - Review the quality assurance meeting findings with the governing body quarterly; and - Develop a method to accurately track the in/out time of patients to ensure the time onsite was always less than 12 hours. The Abortion Facility does an average of 315 procedures per month. On the first day of the survey, there were no procedures. Findings included: 1. Review of the facility's policy titled "Patient Services Departmental Clinical Quality Assurance	L1170		

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L1170	Continued From page 25 Committee," dated 12/31/16 showed: - PPSLRSWMO (Planned Parenthood St. Louis Region South West Missouri) and Affiliated Corporations has a commitment to providing safe, quality care to patients and has a Clinical Quality Assurance (CQA) Committee that meets quarterly with the goal of improving clinical care and management by identifying, analyzing and monitoring patient service provision for compliance with Missouri and Illinois State Regulations, PPFA and Affiliate Standards and Guidelines and other governing bodies. - Agenda items include: * 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: - Completeness of clinical records; - Incidence of morbidity and mortality; - Intraoperative and postoperative complications; - All cases transferred to a hospital; - All cases that resulted in a length of stay of more than twelve (12) hours; - Errors in diagnosis; - Problems in compliance with state and local laws and regulations; - All cases in which the gestational age was determined to be beyond eighteen (18) weeks; and - The quality assurance program must show evidence of action taken as a result of identified problems. - The complication report results are reported at quarterly CQA meetings. 2. Review of the minutes from the CQA meetings for 2017 showed meetings were held on 01/23/17, 05/25/17, and 09/25/17. They failed to	L1170		

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L1170	Continued From page 26 meet during the fourth quarter (October, November, December) of the year. Review of the Board of Directors Meeting minutes for 2017 showed CQA meeting minutes were reviewed at the 02/01/17 and 10/11/17 meetings. They failed to review the quality assurance issues during the second quarter and the board did not meet during the third quarter of 2017. Review of the CQA minutes showed they did not address length of stay (if greater than 12 hours) during their meetings. 3. During an interview on 03/07/18 at 9:45 AM, Staff M, Quality Assurance Coordinator, stated that: - The CQA committee only met 3 times last year; - They had a complication report that addressed many of the issues they monitor in QA; - They were not open for over 12 hours a day in 2017; - Their "encounter sheets" document arrival time but not check out times; and - They did not have a system to track patients length of stay.	L1170		