STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	011128	A. BUILDING: _____ B. WING _____	03/06/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WOMEN'S MED GROUP PROFESSIONAL CORPORAT	1201 N ARLINGTON AVE INDIANAPOLIS, IN 46219

(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
T 000	INITIAL COMMENTS The visit was for a State licensure survey. Facility Number: 011128 Survey Date: 3/5-6/19 QA: 3/12/19	T 000		
T 034	410 IAC 26-4-1 GOVERNING BODY 410 IAC 26-4-1(c)(7) (c) The governing body shall do the following: (7) Ensure that clinic policies and procedures are: (A) updated as needed; and (B) reviewed at least triennially. This RULE is not met as evidenced by: Based on document review and interview, the facility failed to ensure its policy/procedures were updated as needed and reviewed at least annually per policy for one occurrence. Findings include: 1. Review of the policy/procedure manual titled Quality Assurance and Risk Management (revised 10-29-14) indicated the following: "This manual is under the authority of MD 11, the Medical Director...[who]...annually reviews this manual." 2. On 3-5-19 at 1700 hours, the Operations	T 034		

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T 034	Continued From page 1 Manager A1 confirmed the Quality Assurance and Risk Management manual and policy/procedures lacked documentation of an annual review since 2014.	T 034		
T 078	410 IAC 26-4-2 GOVERNING BODY 410 IAC 26-4-2(g)(3) (g) The governing body is responsible for services delivered in the clinic by contractors for medical services. The governing body shall ensure the following: (3) That the clinic maintains a list of all contracted services, including the scope and nature of the services provided. This RULE is not met as evidenced by: Based on document review and interview, the center failed to maintain a list of all contracted services, including the scope and nature of services provided for 2 of 22 services (medical gases and tissue pathology). Findings include: 1. Review of a list of contracted services provided on request lacked documentation indicating a category description and provider name for medical gases and tissue pathology services. 2. Review of center documentation indicated the following service providers: medical gas services	T 078		

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T 078	Continued From page 2 by CS2 and tissue pathology services by CS3. 3. On 3-5-19 at 1200 hours, the Operations Manager A1 confirmed the list of contracted services had not been maintained.	T 078		
T 094	410 IAC 26-6-1 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 26-6-1(a) (a) The abortion clinic must develop or adopt, implement, and maintain an effective, organized, clinic-wide, comprehensive quality assessment and improvement program in which all areas of the clinic involved in the provision of surgical abortion participate. This RULE is not met as evidenced by: Based on document review and interview, the quality assessment and improvement (QA&I) program failed to follow its policy/procedures and maintain documentation including the participation of all committee members and clinic areas involved with the provision of abortion services for 3 of 4 quarters in 2018 (1st, 2nd & 3rd Quarter 2018). Findings include: 1. Review of the Quality Assurance and Risk Management (QA/RM) Manual (revised 10-29-14) indicated the following: "The QA/RM Committee meets twice a year...The Quality Assurance/Risk Management Committee (QA/RM Committee) is	T 094		

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T 094	Continued From page 3 composed of the Center's Medical Director, Center Director, [sic] Head Nurse. The QA/RM Committee maintains a record of its meetings using the Risk Management and Quality Assurance Checklist...The QA Team reviews the available quality indicators to assure that standards are being met and to identify areas for improvement. It also serves as the Center's Infection Control Committee. The Team has three members: The Head Nurse, the Center Director or Customer Service Manager, and a floating member. The Head Nurse serves as the Team's facilitator and coordinator. Each team member attends each Team meeting. The Quality Assurance Team meets quarterly...The Quality Assurance Team records its review on the Quality Assurance Team Checklist...They report their findings at the next staff meeting...The Medical Director reviews and signs off on each report within 30 days of its completion..." 2. Review of the 11-9-17 Risk Management and Quality Assurance Checklist indicated a review of the 1st half 2017 was performed by the Medical Director MD11 and the Head Nurse A11 and no documentation provided for review indicated two (2) biennial reviews were conducted in 2018 for the 2nd half 2017 and/or 1st half 2018. 3. Review of the 4-26-18 Quality Assurance Team Checklist indicated it was completed by A11 and lacked documentation indicating at least one other member was present, or any quality assessment studies were being conducted, or any opportunities for improvement were identified and/or addressed. 4. Review of the 4-26-18 Quality Assurance Staff Review lacked documentation of a review by MD11 within 30 days.	T 094		

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T 094	Continued From page 4 5. Review of the 7-10-18 Quality Assurance Team Checklist indicated a review by the newly appointed Assistant Director AHP21, A11 and Head Nurse A9 and lacked documentation (i.e., a Quality Assurance Staff Review) indicating it was presented at a staff meeting, or reviewed by MD11 within 30 days. 6. No documentation indicated a 3rd quarter QA Team meeting (i.e., a Quality Assurance Team Checklist) or a Quality Assurance Staff Review was completed during the remainder of 2018. 7. On 3-6-19 at 1715 hours, the Operations Manager A1 confirmed the above.	T 094		
T 104	410 IAC 26-6-2 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 26-6-2 (a) Reportable events Sec. 2. (a) The clinic's quality assessment and improvement program under section 1 of this rule shall include the following: (1) A process for determining the occurrence of the following reportable events within the clinic: (A) The following surgical events: (i) Surgery performed on the wrong body part, defined as any surgery performed on a body part that is not consistent with the documented informed consent for that patient. Excluded are emergent situations: (AA) that occur in the course of surgery; or (BB) whose exigency precludes obtaining informed consent;	T 104		

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T 104	Continued From page 5 or both. (II) Surgery performed on the wrong patient, defined as any surgery on a patient that is not consistent with the documented informed consent for that patient. (III) Wrong surgical procedure performed on a patient, defined as any procedure performed on a patient that is not consistent with the documented informed consent for that patient. Excluded are emergent situations: (AA) that occur in the course of surgery; or (BB) whose exigency precludes obtaining informed consent; or both. (iv) Retention of a foreign object in a patient after surgery or other invasive procedure. The following are excluded: (AA) Objects intentionally implanted as part of a planned intervention. (BB) Objects present before surgery that were intentionally retained. (CC) Objects not present prior to surgery that are intentionally left in when the risk of removal exceeds the risk of retention, such as microneedles or broken screws. (v) Intraoperative or immediately postoperative death in an ASA Class I patient. Included are all ASA Class I patient deaths in situations where anesthesia was administered; the planned surgical procedure may or may not have been carried out. (B) The following product or device events: (i) Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the clinic. Included are generally detectable contaminants in drugs, devices, or biologics regardless of the source of contamination or product.	T 104		

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T 104	Continued From page 6 (ii) Patient death or serious disability associated with the use or function of a device in patient care in which the device is used or functions other than as intended. Included are, but not limited to, the following: (AA) Catheters. (BB) Drains and other specialized tubes. (CC) Infusion pumps. (DD) Ventilators. (iii) Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in the clinic. Excluded are deaths or serious disability associated with neurosurgical procedures known to present a high risk of intravascular air embolism. (C) The following patient protection events: (i) Infants discharged to the wrong person. (ii) Patient death or serious disability associated with patient elopement. (iii) Patient suicide or attempted suicide resulting in serious disability, while being cared for in the clinic, defined as events that result from patient actions after admission to the clinic. Excluded are deaths resulting from self inflicted injuries that were the reason for admission to the clinic. (D) The following care management events: (i) Patient death or serious disability associated with a medication error, for example, errors involving the wrong: (AA) drug; (BB) dose; (CC) patient; (DD) time; (EE) rate; (FF) preparation; or (GG) route of administration. Excluded are reasonable differences in clinical judgment on drug selection and dose. Includes administration of a medication to which a patient	T 104		

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T 104	Continued From page 7 has a known allergy and drug-drug interactions for which there is known potential for death or serious disability. (ii) Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA incompatible blood or blood products. (iii) Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in the clinic. Included are events that occur within forty-two (42) days post-delivery. Excluded are deaths from any of the following: (AA) Pulmonary or amniotic fluid embolism. (BB) Acute fatty liver of pregnancy. (CC) Cardiomyopathy. (iv) Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in the clinic. (v) Death or serious disability (kernicterus) associated with the failure to identify and treat hyperbilirubinemia in neonates. (vi) Stage 3 or 4 pressure ulcers acquired after admission to the clinic. Excluded is progression from Stage 2 or Stage 3 if the Stage 2 or Stage 3 pressure ulcer was recognized upon admission or unstageable bacause of the presence of eschar. (vii) Patient death or serious disability resulting from joint movement therapy performed in the clinic. (viii) Artificial insemination with the wrong donor sperm or wrong egg. (E) The following environmental events: (i) Patient death or serious disability associated with an electric shock while being cared for in the clinic. Excluded are events involving planned treatment, such as electrical countershock or elective cardioversion.	T 104		

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	011126	A. BUILDING: _____ B. WING _____	03/06/2019

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T 104	Continued From page 8 (ii) Any incident in which a line designated for oxygen or other gas to be delivered to a patient: (AA) contains the wrong gas; or (BB) is contaminated by toxic substances. (iii) Patient death or serious disability associated with a burn incurred from any source while being cared for in the clinic. (iv) Patient death or serious disaability associated with a fall while being cared for in the clinic. (v) Patient death or serious disability associated with the use of restraints or bedrails while being cared for in the clinic. (F) The following criminal events: (i) Any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider. (ii) Abduction of a patient of any age. (iii) Sexual assault on a patient within or on the grounds of the clinic. (iv) Death or significant injury of a patient or staff member resulting from a physical assault, that is, battery, that occurs within or on the grounds of the clinic. This RULE is not met as evidenced by: Based on document review and interview, the	T 104		

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T 104	Continued From page 9 facility failed to ensure its quality assessment and improvement (QA&I) program included a process to determine the occurrence of all reportable events at the clinic for one occurrence. Findings include: 1. On 3-5-19 at 1015 hours, the Operations Manager A1 was requested to provide documentation indicating a process for determining all serious adverse events that must be reported to the ISDH (Indiana State Department of Health) and none was provided prior to exit. 2. Review of the 160 page Medical Policy and Procedure Manual (revised 12-8-18) and the 25 page Quality Assurance and Risk Management Manual (revised 10-29-14) lacked documentation indicating a process to determine the occurrence of all serious adverse events as defined by State law 410 IAC 26-6-2 Reportable Events. 3. On 3-6-19 at 1655 hours, staff A1 confirmed no documentation indicating a process to determine the occurrence of all reportable events to be reported to the ISDH was available.	T 104		
T 134	410 IAC 26-7-2 MEDICAL RECORDS 410 IAC 26-7-2(c) (c) Patient records for surgical abortions must document and contain, at a minimum, the following: (1) Patient identification. (2) Appropriate medical history. (3) Results of the following: (A) A physical examination.	T 134		

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T 134	Continued From page 10 (B) Diagnostic or laboratory studies, or both (if performed). (4) Any allergies and abnormal drug reactions. (5) Entries related to anesthesia administration. (6) Evidence of appropriate informed consent for procedures and treatments as required by IC 16-34-2- 1.1. (7) A report describing techniques, findings, and tissue removed or altered. (8) Authentication of entries by the physician or physicians and health care workers who treated or cared for the patient. (9) Condition on discharge, disposition of the patient, and time of discharge. (10) Discharge entry to include instructions to the patient or patient ' s legal representative. (11) A copy of the following: (A) The transfer form if the patient was referred to a hospital or other facility. (B) The terminated pregnancy report filed with the department. (12) Any report filed with a state agency or law enforcement agency pursuant to a statutory reporting requirement. This RULE is not met as evidenced by: Based on document review and interview, the facility failed to ensure in 30 medical records reviewed that a copy of a transfer form was completed for 1 of 1 transfer (patient #7). Findings include: 1. Review of patient #7's MR indicated 9/21/2018,	T 134		

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T 134	Continued From page 11 at 12:26 pm, pelvic examination then procedure started. 9/21/2018 Provider Orders indicated D&C (dilation and curettage) attempted under US (Ultra Sound) guidance uterus posterior. Will give Misoprostol 800 mcg (micrograms) and recheck in 1-2 hours. Patient refused Misoprostol. 14:37 pm, Called ambulance. Ambulance at 14:52 pm. Transfer to an acute care facility. MR lacked a copy of the transfer form. 2. Interview on 3/6/2019, at approximately 4:54 pm, with N1 (Operations Manager) confirmed the above.	T 134		
T 144	410 IAC 26-8-1 PERSONNEL POLICIES AND RECORDS 410 IAC 26-8-1(c)(1) (c) The clinic must do the following: (1) Maintain current job descriptions with reporting responsibilities for all personnel and annual performance evaluations, based on the job description, for each employee and contract and agency personnel. This RULE is not met as evidenced by: Based on document review and interview, the facility failed to ensure evaluations were completed per policy on 3 of 9 (S1, S3 and S9's) employee personnel files reviewed.	T 144		

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T 144	Continued From page 12 Findings Include: 1. Facility policy, Employee Progress Report, last approved 5/24/2018, indicated the Employee Progress Report is completed by both the employee and the manager at three months of employment, again at six months and then every year thereafter. 2. Review of facility email from N1 (Operations Manager) on 1/8/2019, at 4:15 pm, indicated all of the girls are due or over due to staff reviews in (facility). At this point I am requesting to put this off till (until) April is (if) okay with you. 3. Review of S1's personnel file indicated, hire date of 4/10/14, last evaluation 11/17.Review of S3's personnel file indicated hire date 9/11/13, last evaluation 11/17. Review of S9's employee personnel file indicated, hire date 4/15/02 last evaluation 7/17. 4. Interview on 3/6/2019, at approximately 11:30 am, with N1 confirmed the above.	T 144		
T 152	410 IAC 26-8-2 PERSONNEL POLICIES AND RECORDS 410 IAC 26-8-2(3)(A) The clinic shall do the following: (3) Ensure that all employees, staff members, and contractors having direct patient contact are evaluated at least annually for tuberculosis as follows: (A) Any person with a negative history of tuberculosis or a negative test result must have a baseline two step tuberculin skin test using the Mantoux method or a quantiferon-TB assay	T 152		

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T 152	Continued From page 13 unless the individual has documentation that a tuberculin skin test has been applied at any time during the previous twelve (12) months and the result was negative. This RULE is not met as evidenced by: Based on document review and interview, the facility failed to ensure employees having direct patient contact are evaluated at least annually for tuberculosis (TB) 2 of 9 (S4 and S7's) personnel files reviewed. Findings include: 1. Review of facility policy, Employee Health and First Aid, last approved 5/24/2018, indicated the record contains the following information on each employee...copies of annual immunizations and TB testing or exam... 2. Review of S4's personnel file lacked documentation of current TB testing or exam. Review of S7's personnel file lacked documentation of current TB testing or exam. 3. Interview on 3/6/2019, at approximately 4:44 pm, with N1 (Operations Manager) confirmed the above.	T 152		
T 206	410 IAC 26-11-1 INFECTION CONTROL PROGRAM	T 206		

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T 206	Continued From page 14 410 IAC 26-11-1(a)(1) (a) The clinic must do the following: (1) Provide a safe and healthful environment that minimizes infection exposure and risk to the following: (A) Patients. (B) Health care workers. (C) Persons who accompany patients. This RULE is not met as evidenced by: Based on document review, observation and interview, the facility failed to ensure ready to use electric heating pads were clean for 3 of 4 heating pads (Recovery Room) and ensure food items were not stored in a patient care areas. (Ultrasound Room) Findings include; 1. Facility policy titled "...V. Blood-borne Pathogens Exposure Control Plan" last reviewed/revised 5/24/18 indicated the following: "...Methods of Compliance...9. Eating and Drinking Areas: Eating, drinking...are prohibited in work areas where there may be occupational exposure to a blood-borne pathogen or potentially infectious material (such as examination rooms...)...15. Housekeeping: a. Housekeeping of Patient Care Areas: Nursing staff performs specialized cleaning of furnishing, equipment and walls in patient care areas daily...At the end of the day, patient care areas will be clean and stocked, ready for use the following day; furniture, equipment, walls and floors will be free of dust, dirt, splatters, spills and stains...The Head Nurse supervises this activity..."	T 206		

Indiana State Department of Health

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	011128	A. BUILDING: _____ B. WING _____	03/06/2019

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T 206	Continued From page 15 2. During facility tour beginning at 9:39 a.m. on 3/6/19 with A1 (Operations Manager) the following was observed: (A) On 3/6/19 at 1/16/18 at 9:50 a.m., a 16 ounce jar of peanut butter with the seal broken and an individually wrapped Reese's cup was observed in the top drawer of a cabinet. (Ultrasound Room) (B) On 3/6/19 at 10:30 a.m., three electric heating pads without the covers on were located on three separate chairs and had an accumulation of dirt/debris located on the cord, pad and controller. (Recovery Room) 3. During an interview with A2 (Licensed Practical Nurse) on 3/6/19 at 10:35 a.m., he/she verified there was a total of four electric heating pads and that there were not enough heating pad covers to change in between each patient. A2 verified that he/she does not wipe down the heating pads or cords between each patient and that he/she would wipe down the heating pad controllers at the end of the day if he/she remembered to do so. 4. During an interview with A1 on 3/6/19 at 9:50 a.m., he/she verified there should not be any food stored in the patient care areas including the ultrasound room or cabinets. 5. During an interview with A1 on 3/6/19 at 5:08 p.m., he/she verified the electric heating pads, cords and controller should be cleaned daily.	T 206		
T 220	410 IAC 26-11-1 INFECTION CONTROL PROGRAM 410 IAC 26-11-1(e)(1)	T 220		

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T 220	Continued From page 16 (e) The clinic must establish a committee to monitor and guide the infection control program in the clinic as follows: (1) The infection control committee must meet at least quarterly. This RULE is not met as evidenced by: Based on document review and interview, the Infection Control committee (ICC) failed to conduct quarterly meetings in accordance with committee meeting requirements for 3 of 4 quarterly meetings in 2018 (1st, 2nd & 3rd Quarter 2018). Findings include: 1. Review of the Infection Control Policy (approved 10-29-14) indicated the following: "Responsibilities: The Infection Control Committee meets quarterly to oversee the implementation and operation of infection control activities." 2. Review of ICC meeting documentation indicated on 3-15-18 a review of 4th quarter 2017 infection control monitors was performed and no other ICC meeting documentation indicated a review of the 1st, 2nd or 3rd quarter infection control monitors was completed during the remainder of 2018. 3. On 3-6-19 at 1715 hours, the Operations Manager A1 confirmed the above.	T 220		

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T 258	Continued From page 17	T 258		
T 258	410 IAC 26-11-3 INFECTION CONTROL PROGRAM 410 IAC 26-11-3(3)(B) The clinic, whether it operates its own laundry or uses outside laundry service, must ensure that the laundry process complies with a recognized laundry standard as follows: (3) Central clean linen storage space must be provided as follows: (B) If laundry is processed in the clinic: (i) a laundry processing area must be provided; (ii) clean linen storage and mending must be separated from soiled linen handling and storage; and (iii) employee hand washing facilities must be available in each room where clean or soiled linen is processed and handled. This RULE is not met as evidenced by: Based on document review, observation, and interview, the clinic failed to follow its laundry policy/procedures, ensure that its laundry process complied with recognized laundry standards, and hand washing facilities were available in each room where clean or soiled laundry was handled and processed for one occurrence. Findings include:	T 258		

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T 258	Continued From page 18 1. Review of the 2003 Guidelines for Environmental Infection Control in Health-Care Facilities: Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC) recommendations for (G) Laundry and Bedding indicated the following: "A laundry facility is usually partitioned into two separate areas - a "dirty" area for receiving and handling the soiled laundry and a "clean" area for processing the washed items...Laundry areas should have handwashing facilities readily available to workers...A temperature of at least 160 degrees F (Fahrenheit)[71 degrees Celsius] for a minimum of 25 minutes is commonly recommended for hot-water washing...Low-temperature laundry cycles rely heavily on the presence of chlorine or oxygen-activated bleach to reduce the levels of microbial contamination...Chose chemicals suitable for low-temperature washing at proper use concentration if low-temperature (<160 degrees F)[<71 degrees C] laundry cycles are used..." 2. Review of the policy/procedure Laundry (approved 5-18) indicated the following: "Laundry personnel process soiled laundry in an area that is separate from the area where clean laundry is handled...Personnel use only all temperature detergents and a water temperature appropriate for the fabrics in each load. Liquid bleach is not to be used. Personnel performing laundry duties will complete the Laundry Log for each load of laundry. The Head Nurse inspects the laundry and reviews this log at least weekly...She records her observations on the log..." and no documentation indicated an approved laundry detergent to use when washing items at the clinic.	T 258		

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T 258	Continued From page 19 3. During a clinic tour on 3-6-19 at 1415 hours, in the presence of the Licensed Practical Nurse A8, in the back of a utility room used for clean storage of disposable and durable goods, an LG household clothes washer was observed immediately adjacent to a Westinghouse clothes dryer and no facilities for hand washing or means for hot water temperature monitoring was identified. 4. Review of clinic documentation titled Laundry Log indicated 'warm' water was used to wash each load of laundry on 1-4-19, 1-11-19, 1-18-19, 1-25-19, 2-1-19, 2-8-19, 2-15-19 and 2-22-19 and lacked documentation indicating weekly checks were performed by the Head Nurse. 5. On 3-6-19 at 1415 hours, staff A8 confirmed the washing machine and soiled laundry handling area was indistinguishable from the remainder of the clean utility room and/or clothes dryer, no facilities for hand washing were readily available in the area, and no hot water temperature monitoring was being performed for the soiled laundry being washed at the clinic. 6. On 3-6-19 at 1720 hours, the Operations Manager A1 confirmed the laundry policy/procedure lacked documentation indicating an approved laundry detergent for use at the clinic.	T 258		
T 326	410 IAC 26-16-1 PHARMACEUTICAL SERVICES 410 IAC 26-16-1(3)(C) The clinic must provide drugs and biologicals in a safe and effective manner in accordance with	T 326		

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T 326	Continued From page 20 accepted professional practice. The clinic must have the following: (C) Drugs must be accurately and clearly labeled and stored in specially designated, well-illuminated cabinets, closets, or storerooms and the following: (i) Drug cabinets must be accessible only to authorized personnel. (ii) Drug cabinets for storage of controlled drugs listed in Schedule II of the Comprehensive Drug Abuse Prevention and Control Act of 1976 and other drugs subject to abuse must be permanently affixed compartments that are separately locked. (iii) Drug carts, if used, with controlled drugs as designated in item (ii) must be securely affixed when not in use. This RULE is not met as evidenced by: Based on observation and interview, the facility failed to ensure medications individually packaged were labeled with an expiration date for 1 of 1 medication storage areas. Findings include; 1. Facility policy titled "VII. Medication Practices" last reviewed/revised 12/8/18 indicated the following: "...1. Responsibilities: The Head Nurse oversees that all nursing staff adhere to best practices and standards of care in the handling,	T 326		

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T 326	Continued From page 21 packaging, administering and handling out medication..." 1. During facility tour beginning at 9:39 a.m. on 3/6/19 with A1 (Operations Manager) the following was observed in the medication storage area: A total of 45 Azithromycin tablets individually packaged in re-sealable storage bags lacked an expiration date on either the back of the individual medication package or on the label on the re-sealable storage bags. During an interview on 3/6/19 at 5:15 p.m., A1 verified the lack of an expiration date on the 45 individually packaged Azithromycin tablets located in the medication storage area.	T 326		
T 330	410 IAC 26-16-1 PHARMACEUTICAL SERVICES 410 IAC 26-16-1(4) The clinic must provide drugs and biologicals in a safe and effective manner in accordance with accepted professional practice. The clinic must have the following: (4) A formulary. This RULE is not met as evidenced by: Based on observation and interview, the clinic failed to maintain its drug formulary for 1 of 47 medications at the clinic (Mifeprex/mifepristone/RU486).	T 330		

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T 330	Continued From page 22 Findings include: 1. Review of the Medical Policy and Procedure Manual (approved 12-8-18) section X.B. Medical Abortion Overview indicated the following: "Medical abortions are accomplished by providing the patient with a medication (Mifeprex also referred to as mifepristone or RU486) which interrupts the pregnancy or causes it to stop growing." 2. Review of the drug formulary (revised 12-20-18) lacked documentation of Mifeprex (mifepristone or RU486). 3. On 3-6-19 at 1550 hours, the Operations Manager A1 confirmed the above.	T 330		