Indiana State Department of Health

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 _____	04/04/2018

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

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T 000	INITIAL COMMENTS This visit was for a state licensure survey. Facility Number: 011128 Survey Date: 04-02-2018 to 04-04-2018 QA: 4/12/18	T 000		
T 098	410 IAC 26-6-1 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 26-6-1(a)(2) The program shall be ongoing and have a written plan of implementation that evaluates, but is not limited to, the following: (2) All functions, including, but not limited to, the following: (A) Discharge. (B) Transfer. (C) Infection control. (D) Response to patient emergencies. This RULE is not met as evidenced by: Based on document review and interview, the facility failed to include response to patient emergencies in its quality assurance and performance improvement program (QAPI) for calendar year 2017. Findings include:	T 098		

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T 098	Continued From page 1 1. Review of the clinic's QAPI program for calendar year 2017 indicated it did not include response to patient emergencies 2. In interview on 04-04-2018 at 5:15 pm, employee #A1, Assistant Director, confirmed the above and no other documentation was provided prior to exit.	T 098		
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. (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.	T 134		

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T 134	Continued From page 2 (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 a copy of the terminated pregnancy report was in the medical record (MR) in 25 of 25 medical records reviewed (1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24 and 25). Findings include: 1. Review of patients 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24 and 25's medical records lacked documentation of a terminated pregancy report state form 56114. 2. Interview on 4/4/2018, at approximately 12:30 pm with N1 (Registered Nurse, Assistant Director) confirmed facility had not included a state form 56114 in the medical records.	T 134		
T 140	410 IAC 26-8-1 PERSONNEL POLICIES AND RECORDS 410 IAC 26-8-1(a)(2)	T 140		

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T 140	Continued From page 3 (a) The abortion clinic shall maintain current and accurate personnel records for all employees. Personnel records shall: (2) Include personal data to include: (A) education; (B) experience; (C) date of employment; (D) a copy of current license when required; (E) evidence of participation in job-related educational and training activities; and (F) health records of employees that relate to post offer and subsequent: (i) physical examinations; (ii) tests; and (iii) immunizations. This RULE is not met as evidenced by: Based on document review and interview, the facility failed to ensure physical examination for 2 (S1, and S5) personnel files of 6 personnel files reviewed. Finding include: 1. Review of facility policy, Safety, revised 3/1/2018, indicated the following, the record contains the following on each employee, name and social security number, a copy of the hepatitis vaccination series status including dates and information relative to the employee's ability to receive the vaccination, copies of annual immunizations and TB testing or exam, a copy of employee accidents reports, a copy of all occupational examination results, medical testing	T 140		

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T 140	Continued From page 4 and follow-up procedures, the employer's copy of the healthcare professional's written opinion, a copy of information provided to the healthcare professional, records of occupational exposure monitoring, records of occupational safety training and records of any other occupational medicine intervention. 2. Review of personnel files indicated the following, S1 (Medical Assistant) and S5 (Licensed Practical Nurse), lacked documentation of Physical Examination. 3. Interview on 4/3/2018, at approximately 9:50 am, with N1 (Registered Nurse, Assistant Director) confirmed the above.	T 140		
T 168	410 IAC 26-8-3 PERSONNEL POLICIES AND RECORDS 410 IAC 26-8-3(b) (b) The clinic shall ensure cardiopulmonary resuscitation (CPR) competence in accordance with current standards of practice and clinic policy for all health care workers including contract and agency personnel who provide direct patient care. This RULE is not met as evidenced by: Based on document review and interview, the facility failed to follow its policy to ensure cardiopulmonary resuscitation (CPR) competence in accordance with clinic policy for 1 of 2 physician credential files reviewed and 2 of 6 employee files reviewed.	T 168		

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T 168	Continued From page 5 1. Review of a facility document titled Employee Safety Handbook, approved 03/01/18, indicated the Safety Manager maintains a record of each employee's training in basic CPR and BLS [basic life safety]. Further review of the document indicated the Safety Manager ensures that physicians maintain currency (sic) in Provider ACLS [advanced cardiac life support]. 2. Review of 2 physician credential files indicated file MD#2, Gynecologist, had documentation of ACLS that expired 3/20/2016, not current per facility policy. 3. Review of employee files indicated file S1, Medical Assistant, and S5, Licensed Practical Nurse, lacked documentation of CPR competence per facility policy. 3. In interview on 04-04-2018 at approximately 5:15 pm, employee #A1, Assistant Director, confirmed all the above and no other documentation was provided prior to exit.	T 168		
T 206	410 IAC 26-11-1 INFECTION CONTROL PROGRAM 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.	T 206		

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T 206	Continued From page 6 This RULE is not met as evidenced by: Based on document review, observation and interview, the facility failed to ensure a safe and healthful environment that minimizes infection exposure and risk in patients in three instances. Findings include: 1. Review of Hemocue Operating Manual indicated the following, the cover may be cleaned with alcohol or a mild soap solution. 2. On observation 4/2/2018, at approximately 2:27 pm with N1 (Registered Nurse, Assistant Director) the following was observed, a cardboard note with brownish colored droplets taped on hemocue cover. 3. Interview on 4/2/2018, at approximately 2:47 pm, with N1, confirmed there was brownish colored droplets on cardboard note taped to hemocue cover. 4. On observation 4/2/2018, at approximately 3:15 pm, with N1 (Registered Nurse, Assistant Director) the following was observed washer and dryer in back of storage room. Floor of room with sticky lines of material (appears to be old flooring glue) which could not be properly cleaned. Dirt and debris under shelves with sterile supplies including, gloves, cytology brushes and cotton tip applicators stored on the shelves. 5. Interview on 4/2/2018, at approximately 3:15 pm with N1, confirmed the dirty laundry was bought into storage room and loaded into machines, the floor was covered in sticky lines and sterile supplies were stored on shelves.	T 206		

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T 206	Continued From page 7 6. Review of facility policy, Women's Med, revised 12/6/2017, indicated the following, Inventory Management, ensures items do not expire before being used. 7. On observation 4/2/2018, at approximately 3:27 pm, with N1 (Registered Nurse, Assistant Director) the following was observed 1 box of 23G needles expired in 2001-08, containing 22 needles. 8. Interview on 4/2/2018, at approximately 3:27 pm with N1, confirmed the expired needles.	T 206		
T 234	410 IAC 26-11-2 INFECTION CONTROL PROGRAM 410 IAC 26-11-2(a) (a) Sterilization of equipment and supplies must be provided, within the scope of the service offered, in accordance with acceptable standards of practice or manufacturer ' s recommendations and applicable state laws and rules (to include 410 IAC 1-4, Universal Precautions). This RULE is not met as evidenced by: Based on document review, interview and observation, the facility failed to ensure facility policy was followed regarding cleaning of instruments in one facility. Findings include:	T 234		

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T 234	Continued From page 8 1. Review of facility policy, Safety, revised 3/1/2017, indicated the following, Immerse instruments in a enzymatic cleaner/lubricant (such as Metri Clean) for 5 minutes following the manufacturer's directions for preparation and use. 2. Observation on 4/2/2018, at approximately 4:25 pm with N1 (Registered Nurse, Assistant Director) the following was observed. Metri Clean 2 in Instrument processing area. Review of the Metri Clean 2 label indicated it was not an enzymatic cleaner. 3. Interview with on 4/2/2018, at approximately 4:25 pm, with N2 (Medical Assistant) confirmed Metri Clean 2 was used to clean instruments. 4. Interview on 4/2/2018, at approximately 4:34 pm, with N1 confirmed Metri Clean 2 Instrument cleaner was not enzymatic.	T 234		
T 322	410 IAC 26-16-1 PHARMECEUTICAL SERVICES 410 IAC 26-16-1(3)(A) 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: (3) Written policies and procedures developed, implemented, maintained, and made available to personnel, including, but not limited to, the following: (A) Drug: (i) handling; (ii) storing;	T 322		

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T 322	Continued From page 9 (iii) labeling; (iv) dispensing; and (v) administration according to established clinic policies and acceptable standards of practice. This RULE is not met as evidenced by: Based on document review, observation and interview the facility failed to implement policy related to medications in one facility. Findings include: 1. Review of facility policy, Medical, revised 12/7/2017, indicated the following, every staff member removes conditions that are unsafe to patients immediately, and then notifies their supervisor. Act first, communicate second. Such unsafe conditions include: expired drugs or laboratory reagents, improper staff actions, faulty equipment, etc... The Head Nurse oversees that all nursing staff adhere to best practices and standards of care in the handling, packaging, administering and handing out of medication. ...discards all drugs that will expire in the coming month. 2. On observation 4/2/2018, at approximately 3:27 pm, in the medication room, with N1 (Registered Nurse, Assistant Director) the following was observed. 4 vials of diazepam 5mg/ml, 10 ml, 2 expired 9/2017, and 2 expired 12/2017, not included in count. Inside a box marked needles was a plastic bag which contained blue paper taped shut which contained 5 vials of Gentamicin 80 mg/2ml, expired	T 322		

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T 322	Continued From page 10 3/1/2015. 3. Interview on 4/2/2018, at approximately 3:47 pm, with N1 confirmed the above.	T 322		
T 404	410 IAC 26-17-3 PHYS. PLANT,MAINT.,EQUIP.,ENVIR.,SAFETY 410 IAC 26-17-3(2) The condition of the physical plant and the overall clinic environment must be developed and maintained in such a manner that the safety and well-being of patients is assured as follows: (2) No condition may be created or maintained that may result in a hazard to: (A) patients; (B) authorized visitors; or (C) employees. This RULE is not met as evidenced by: Based on observation, interview, and document review, the facility failed to have appropriate equipment to use a caustic chemical substance according to manufacturer's instructions in 3 instances. Findings include: 1. On 04-02-2018 at approximately 4:35 pm, in the presence of employee #A1, Assistant Director), it was observed in the product of conception processing area a chemical, MetriClean 2, was stored. 2. In interview on the above date and time,	T 404		

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T 404	Continued From page 11 employee #A1 indicated the chemical was used when processing product of conception. 3. Review of the label on the bottle of MetriClean 2, a caustic chemical,indicated there were manufacturer's instructions which indicated First Aid Measures: EYES - Flush immediately with water for 20-30 minutes. 4. Review of the OSHA (Occupational and Safety Health Administration) hazard communication program indicated in general standard 1910.151 when necessary, facilities for drenching or flushing the eyes shall be provided within the work area for immediate emergency use. In applying these general terms, OSHA would consider the guidelines set by such sources as American National Standards Institute (ANSI) Z358.1 -1998, Emergency Eyewash and Shower Equipment, which indicated in section 7.4.4, that eyewash facilities are to be located to require no more than 10 seconds to reach but where a strong acid or a caustic chemical is used, the unit should be immediately adjacent to the hazard. 5. On the above-stated date, time, place, and presence of employee #A1, it was observed there was no eyewash facility immediately adjacent to the area where the caustic chemical was used. 6. On 04-02-2018 at approximately 4:40 pm, in the presence of employee #A1, Assistant Director, it was observed in Operating Room 1 there was an electrical outlet on a wall which had a broken plug receptacle. This posed an electrical hazard if an electrical plug was not properly seated in the receptacle. 7. On 04-02-2018 at approximately 4:40 pm, in the presence of employee #A1, it was observed	T 404		

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T 404	Continued From page 12 In Operating Room 1 on another wall, there was an alcohol-based hand sanitizer (ABHS) on the wall directly over an electrical outlet. This posed a fire hazard if the flammable alcohol in the sanitizer was sprayed or dropped into the electrical ignition source.	T 404		