

Indiana State Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>011128</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____  B. WING _____	(X3) DATE SURVEY COMPLETED  <b>09/05/2012</b>
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NAME OF PROVIDER OR SUPPLIER  <b>WOMEN'S MED GROUP PROFESSIONAL COR</b>	STREET ADDRESS, CITY, STATE, ZIP CODE <b>1201 N ARLINGTON AVE INDIANAPOLIS, IN 46219</b>
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T 000	<p><b>INITIAL COMMENTS</b></p> <p>This visit was for a standard licensure survey.</p> <p>Facility Number: 011128</p> <p>Survey Date: 9-4/5-12</p> <p>Surveyors: Jack I. Cohen, MHA Medical Surveyor</p> <p>John Lee, RN Public Health Nurse Surveyor</p> <p>QA: cloughlin 09/10/12</p> <p>10/24/12 revised due to IDR</p>	T 000		
T 026	<p><b>410 IAC 26-4-1 GOVERNING BODY</b></p> <p>410 IAC 26-4-1(c)(3)</p> <p>(c) The governing body shall do the following: (3) Review, at least every six (6) months, reports of management operations, including, but not limited to, the following: (A) Quality assessment and improvement program. (B) Patient services provided. (C) Results attained. (D) Recommendations made. (E) Actions taken. (F) Follow-up.</p>	T 026		

Indiana State Department of Health  
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

01/08/13

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T 026	<p>Continued From page 1</p> <p>This RULE is not met as evidenced by: Based on document review and interview, the governing authority (MD#1) failed to review the facility's quality assessment and improvement (QA&amp;I) program for 3 facility-provided services (activities) at least once every 6 months.</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>1. Review of the facility's QA&amp;I program indicated it did not include the facility-provided services of pharmacy, transfers and response to patient emergencies.</li> <li>2. In interview, on 9-5-12 at 4:05 pm, employee #A1 indicated the 3 above-stated facility provided services were not included in the facility's QA&amp;I program and no further documentation was provided prior to exit. Thus, there was no documentation MD#1 reviewed the facility-provided services of pharmacy, transfers and response to patient emergencies.</li> </ol>	T 026		
T 096	<p>410 IAC 26-6-1 QUALITY ASSESSMENT AND IMPROVEMENT</p> <p>410 IAC 26-6-1(a)(1)</p> <p>The program shall be ongoing and have a written plan of implementation that evaluates, but is not limited to, the following: (1) All services, including services furnished by a contractor.</p>	T 096		

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T 096	Continued From page 2  This RULE is not met as evidenced by: Based on document review and interview, the facility failed to include monitors and standards as part of its quality assessment and improvement (QA&I) program for 1 facility-provided service (pharmacy).  Findings:  1. Review of the facility's QA&I indicated it did not include monitors and standards for the facility-provided program of pharmacy.  2. In interview, on 9-5-12 at 4:05 pm, employee #A1 indicated the facility-provided pharmacy service was not included in the facility's QA&I program and no further documentation was provided prior to exit.	T 096		
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.	T 098		

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T 098	<p>Continued From page 3</p> <p>This RULE is not met as evidenced by: Based on document review and interview, the facility failed to include monitors and standards as part of its quality assessment and improvement (QA&amp;I) program for 2 facility-provided activities (transfers and response to patient emergencies).</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>1. Review of the facility's QA&amp;I indicated it did not include monitors and standards for the facility-provided activities of transfers and response to patient emergencies.</li> <li>2. In interview, on 9-5-12 at 4:05 pm, employee #A1 indicated the facility-provided services of transfers and response to patient emergencies was not included in the facility's QA&amp;I program and no further documentation was provided prior to exit.</li> </ol>	T 098		
T 134	<p>410 IAC 26-7-2 MEDICAL RECORDS</p> <p>410 IAC 26-7-2(c)</p> <p>(c) Patient records for surgical abortions must document and contain, at a minimum, the following:</p> <ol style="list-style-type: none"> <li>(1) Patient identification.</li> <li>(2) Appropriate medical history.</li> <li>(3) Results of the following:               <ol style="list-style-type: none"> <li>(A) A physical examination.</li> <li>(B) Diagnostic or laboratory studies, or both</li> </ol> </li> </ol>	T 134		

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T 134	<p>Continued From page 4</p> <p>(if performed).</p> <p>(4) Any allergies and abnormal drug reactions.</p> <p>(5) Entries related to anesthesia administration.</p> <p>(6) Evidence of appropriate informed consent for procedures and treatments as required by IC 16-34-2-1.1.</p> <p>(7) A report describing techniques, findings, and tissue removed or altered.</p> <p>(8) Authentication of entries by the physician or physicians and health care workers who treated or cared for the patient.</p> <p>(9) Condition on discharge, disposition of the patient, and time of discharge.</p> <p>(10) Discharge entry to include instructions to the patient or patient ' s legal representative.</p> <p>(11) A copy of the following:</p> <p>(A) The transfer form if the patient was referred to a hospital or other facility.</p> <p>(B) The terminated pregnancy report filed with the department.</p> <p>(12) Any report filed with a state agency or law enforcement agency pursuant to a statutory reporting requirement.</p> <p>This RULE is not met as evidenced by: Based on document review and interview, the facility failed to ensure that medical records (MR) documented and contained any report filed with a state agency or law enforcement agency pursuant to a statutory reporting requirement for 1 of 2 minor patient MRs reviewed (Patient #29).</p> <p>Findings include:</p>	T 134		

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T 134	Continued From page 5  1. Review of patient #29's MR indicated that the patient was a 15-year old who had an abortion and the MR lacked documentation that a report was filed with either a state agency or law enforcement agency.  2. On 09-05-12 at 1345 hours, staff #2 confirmed that the Minor Sexual Contact Report lacked documentation of being reported for patient #29.	T 134		
T 140	410 IAC 26-8-1 PERSONNEL POLICIES AND RECORDS  410 IAC 26-8-1(a)(2)  (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 that personnel records contained documentation of health records of employees that relate to post offer physical	T 140		

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T 140	<p>Continued From page 6</p> <p>examinations for 7 of 8 personnel files reviewed (Staff #2, 3, 4, 6, 7, 8 &amp; 9).</p> <p>Findings include:</p> <ol style="list-style-type: none"> <li>1. Review of policy/procedure Pre-employment Physical Examination indicated the following: "A physical examination may be required periodically or individually in cases where there is reason to believe that an individual's physical condition may significantly increase the occupational hazards affecting the employee, other employees, the general public or the facilities in which the work is to be performed, or where the employee's job may require the undertaking of any task which may substantially or inherently impaired by that physical condition." This policy/procedure was last reviewed/ revised on 02-23-12.</li> <li>2. Review of staff #2, 3, 4, 6, 7, 8 &amp; 9's personnel files lacked documentation of pre-employment physicals and or documentation indicating if a pre-employment physical was required.</li> <li>3. On 09-04-12 at 1400 hours, staff #1 confirmed that there was no documentation of pre-employment physicals for staff #2, 3, 4, 6, 7, 8 &amp; 9.</li> </ol>	T 140		
T 152	<p>410 IAC 26-8-2 PERSONNEL POLICIES AND RECORDS</p> <p>410 IAC 26-8-2(3)(A)</p> <p>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</p>	T 152		

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T 152	<p>Continued From page 7</p> <p>follows:</p> <p>(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 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.</p> <p>This RULE is not met as evidenced by: Based on document review and interview, the facility failed to ensure that all new employees, staff members, and contractors who have a negative history of tuberculosis or a negative test result having direct patient contact must have a baseline two step tuberculin skin test using the Mantoux method or a quantiferon-TB assay unless the individual has documentation that a tuberculin skin test had been applied at any time during the previous 12 months and the result was negative for 9 of 10 employee files reviewed (Staff #AH 1, AH 2, 2, 3, 4, 6, 7, 8 &amp; 9).</p> <p>Findings include:</p> <p>1. Review of policy/procedure TB Testing indicated the following: "1. Procedure Within two weeks of employment, the safety Manager performs a two-step TB test on new employees. This consist of an initial PPD read at 48-72 hours followed by a second PPD within 14</p>	T 152		



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T 152	<p>Continued From page 8</p> <p>days." This policy/procedure was last reviewed/revise on 11-07-07.</p> <p>2. Review of the following personnel files indicated the following: Staff AH #1 was hired on 04-2012 and lacked documentation of 2 step PPD. Staff AH #2 was hired on 01-2010 and lacked documentation of 2 step PPD. Staff #2 was hired on 05-10-2012 and had documentation of a PPD on 05-14-12 and lacked documentation of a second PPD. Staff #3 was hired on 08-16-2012 and had documentation of a PPD on 08-31-12 and lacked documentation of a second PPD. Staff #4 was hired on 07-02-2012 and had documentation of a PPD on 06-28-12 and lacked documentation of a second PPD. Staff #6 was hired on 07-31-2012 and had documentation of a PPD on 05-09-12 and lacked documentation of a second PPD. Staff #7 was hired on 08-16-2012 and had documentation of a PPD on 08-23-12 and lacked documentation of a second PPD. Staff #8 was hired on 03-02-2012 and had documentation of a PPD on 03-21-12 and lacked documentation of a second PPD. Staff #9 was hired on 04-06-2012 and had documentation of a PPD on 04-02-12 and lacked documentation of a second PPD.</p> <p>3. On 09-04-12 at 1400 hours, staff #1 confirmed that 2 step PPDs were not being done.</p>	T 152		
T 168	<p>410 IAC 26-8-3 PERSONNEL POLICIES AND RECORDS</p> <p>410 IAC 26-8-3(b)</p>	T 168		

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T 168	<p>Continued From page 9</p> <p>(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.</p> <p>This RULE is not met as evidenced by: Based on document review and interview, the facility failed to follow established policy/procedures for Advanced Cardiac Life Support (ACLS) for 1 of 2 licensed practical nurse (LPN) personnel files reviewed (Staff #2) and 1 of 1 medical staff files (MD#1) reviewed.</p> <p>Findings include:</p> <ol style="list-style-type: none"> <li>1. Review of policy/procedure Cardiopulmonary Resuscitation (CPR) indicated the following: "2. Advanced Cardiac Life Support (ACLS) The Safety Manager will ensure that all nurses (LPNs, RNs) maintain biannual currency in Provider ACLS." This policy/procedure was last reviewed/ revised on 11-07-07.</li> <li>2. Review of staff #2's personnel file indicated that he/she was a LPN and had no documentation of having ACLS.</li> <li>3. On 09-04-12 at 1420 hours, staff #2 confirmed that he/she did not have ACLS.</li> </ol>	T 168		
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T 206	Continued From page 10	T 206		
T 206	<p>410 IAC 26-11-1 INFECTION CONTROL PROGRAM</p> <p>410 IAC 26-11-1(a)(1)</p> <p>(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.</p> <p>This RULE is not met as evidenced by: Based on document review and interview, the facility failed to provide a safe and healthful environment that minimizes infection exposure and risk to patients.</p> <p>Findings include:</p> <ol style="list-style-type: none"> <li>Review of the manufacturer's recommendations for Metriclean 2 enzymatic cleaner indicated the following: use 1 ounce per gallon of water.</li> <li>On 09-04-12 at 1020 hours, staff #5 confirmed that he/she is not sure how much Metriclean 2 is mixed with water to clean dirty procedure instruments.</li> <li>Review of Mr. Clean with Febreze floor cleaner lacked documentation of being a healthcare facility disinfectant.</li> <li>On 09-04-12 at 1035 hours, staff #4 confirmed that the facility uses Mr. Clean with Febreze floor cleaner to clean the procedure room floors.</li> </ol>	T 206		

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T 210	<p>410 IAC 26-11-1 INFECTION CONTROL PROGRAM</p> <p>410 IAC 26-11-1(a)(2)(A,B,C,D&amp;E)</p> <p>The policy must include a system designed for the:</p> <ul style="list-style-type: none"> <li>(A) identification;</li> <li>(B) surveillance;</li> <li>(C) investigation;</li> <li>(D) control; and</li> <li>(E) prevention;</li> </ul> <p>of infections and communicable diseases in patients and health care workers.</p> <p>This RULE is not met as evidenced by: Based on document review and interview, the facility failed to establish a written infection control policy that included a system designed for the identification, surveillance, investigation, control and prevention of infections and communicable diseases in patients and health care workers for 1 facility.</p> <p>Findings include;</p> <ol style="list-style-type: none"> <li>1. Review of the facility infection control policy &amp; procedure manual lacked documentation of a written infection control policy that included a system designed for the identification, surveillance, investigation, control and prevention of infections and communicable diseases in patients and health care workers.</li> <li>2. On 09-04-12 at 0935 hours and on 09-05-12 at 1400 hours, this surveyor requested from staff #2 to see the written infection control policy that included a system designed for the identification,</li> </ol>	T 210		
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T 210	Continued From page 12  surveillance, investigation, control and prevention of infections and communicable diseases in patients and health care workers and none was provided by exit on 09-05-12 at 1715 hours.	T 210		
T 214	<p>410 IAC 26-11-1 INFECTION CONTROL PROGRAM</p> <p>410 IAC 26-11-1(c)</p> <p>(c) The clinic must designate a person qualified by training or experience as responsible for the following:</p> <ul style="list-style-type: none"> <li>(1) Ongoing infection control activities.</li> <li>(2) The development and implementation of policies governing control of infections and communicable diseases.</li> </ul> <p>This RULE is not met as evidenced by: Based on document review and interview, the facility failed to ensure that the person designated as the person responsible for ongoing infection control activities and the development and implementation of policies governing control of infections and communicable diseases was qualified by training or experience.</p> <p>Findings include:</p> <ol style="list-style-type: none"> <li>1. Review of staff #2's personnel file lacked documentation of either experience or training for infection control activities and the development and implementation of policies governing control of infections and communicable diseases.</li> <li>2. On 09-04-12 at 1420 hours, staff #2 confirmed that he/she did not have documentation of either</li> </ol>	T 214		

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NAME OF PROVIDER OR SUPPLIER  <b>WOMEN'S MED GROUP PROFESSIONAL COR</b>	STREET ADDRESS, CITY, STATE, ZIP CODE <b>1201 N ARLINGTON AVE INDIANAPOLIS, IN 46219</b>
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T 214	Continued From page 13  experience or training in infection control activities.	T 214		
T 222	<p>410 IAC 26-11-1 INFECTION CONTROL PROGRAM</p> <p>410 IAC 26-11-1(e)(1)(A,B,C&amp;D)</p> <p>(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.</p> <p>(A) The person directly responsible for management of the infection surveillance, prevention, and control program as established in subsection (c). (B) The medical director. (C) A representative from the nursing staff (if the clinic employs a licensed nurse). (D) Representatives from other appropriate services within the clinic as needed.</p> <p>This RULE is not met as evidenced by: Based on document review and interview, the facility failed to ensure that the infection control committee meet at least quarterly with membership that includes the medical director for 1 infection control committee.</p> <p>Findings include:</p> <p>1. Review of the Quality Assurance Team Checklist meeting minutes that contains the</p>	T 222		

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T 222	Continued From page 14  Infection Control Committee indicated the following: the 08-29-12, 02-29-12, 01-31-12, 12-28-11, 11-29-11, 10-28-11, 09-30-11 and 08-31-11 Quality Assurance Team Checklist meeting minutes lacked documentation that the medical director attended the meetings.  2. On 09-05-12 at 1400 hours, staff #2 confirmed that the Quality Assurance Team Checklist meeting minutes lacked documentation that the medical director attended.	T 222		
T 252	410 IAC 26-11-3 INFECTION CONTROL PROGRAM  410 IAC 26-11-3(1)  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: (1) Clean linen must be separated from soiled linen at all times.  This RULE is not met as evidenced by: Based on observation, it could not be determined the clean linen was separated from the soiled linen in the laundry room.  Findings:  1. On 9-4-12 at 10:10 am, in the presence of employees #A1 and #A2, it was observed in the laundry room that the clean linen and dirty linen were in the same room. The room size was approximately 10 feet by 15 feet. It was also	T 252		

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T 252	Continued From page 15  observed the washer and dryer were next to each other and the clean and dirty linen were next to each other with no barrier for separation. Thus, there could have been cross contamination due to the closeness of the clean and dirty linen.	T 252		
T 318	410 IAC 26-16-1 PHARMACEUTICAL SERVICES  410 IAC 26-16-1(1)  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: (1) A: (A) designated professional person with prescriptive authority; or (B) pharmacist; who is responsible for the control of drug stocks in the clinic.  This RULE is not met as evidenced by: Based on document review and interview, the facility failed to designate who is responsible for the control of drug stocks in the clinic other than controlled drugs.  Findings:  1. Review of a document entitled Women's Med Group, pages MM 71 and 72, Section E. Controlled Substances, subsection 5. Inventory Verification, indicated the Medical Director performs independent inventory	T 318		



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T 318	Continued From page 16  verification biannually or when a discrepancy is reported to him.  2. In interview, on 9-5-12 at 10:15 am, employee #A1 indicated there was no other documentation which indicated who was designated as responsible for the control of drug stocks in the clinic other than controlled drugs. No other documentation was provided prior to exit.	T 318		
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, the facility created 1 condition that could result in a hazard to patients, visitors and employees.  Findings:  1. On 9-4-12 at 10:15 am, in the presence of employees #A1 and #A2, it was observed in the biohazard waste room there were 3 small nitrous oxide tanks standing upright on the floor and not	T 404		

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T 404	Continued From page 17  secured by chain or holder.  2. If any of the above tanks were knocked over and broke the head off the compressed cylinder, it could result in harm to people and/or property.	T 404		
T 414	410 IAC 26-17-4 PHYS. PLANT,MAINT.,EQUIP.,ENVIR.,SAFETY  410 IAC 26-17-4(1)  All patient care equipment must be in good working order and regularly serviced and maintained as follows: (1) All patient care equipment must be on a documented maintenance schedule of appropriate frequency in accordance with one (1) of the following: (A) Acceptable standards of practice. (B) The manufacturer ' s recommended maintenance schedule.  This RULE is not met as evidenced by: Based on document review and interview, the facility failed to maintain 1 Automated External Defibrillator (AED) according to the manufacturer's recommendation.  Findings:  1. Review of the 2006 Cardiac Science Corp. manual for the facility's AED, page 43, Section 6, entitled SCHEDULED MAINTENANCE, subtitled MONTHLY MAINTENANCE, indicated:	T 414		

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T 414	<p>Continued From page 18</p> <p>Open the AED lid. Wait for the AED to indicate status: Observe the change of the STATUS INDICATOR to RED. After approximately 5 seconds, verify that the STATUS INDICATOR returns to GREEN. Check the expiration dates on the electrodes. Listen for the voice prompts. Close the lid and confirm that STATUS INDICATOR remains GREEN.</p> <p>2. In interview, on 9-5-12 at 3:30 pm, employee #A1 indicated there was no documentation of the above-stated monthly maintenance for the facility's AED and no further documentation was provided by exit.</p>	T 414		