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 _____	02/08/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WOMEN'S MED GROUP PROFESSIONAL COR	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 This visit was for a state licensure survey. Facility Number: 011128 Survey Date: 02-06-2017 to 02-08-2017 QA: 3/2/17 jlh IDR Committee met on 04-12-17. Tags T066 & T098 deleted. JL	T 000	Revision 2 May 2017	
T 004	410 IAC 26-2-7 LICENSE REQUIREMENTS 410 IAC 26-2-7 A license issued under this article must be conspicuously posted on the premises in an area open to patients. This RULE is not met as evidenced by: Based on observation, the facility failed to conspicuously post its license in an area open to patients in 1 instance. Findings include: 1. On 02-07-2017 at 11:00 am, in the presence of employee #A1, Head Nurse, it was observed in the facility's reception office the facility's license was on a side wall that was not conspicuous to patients.	T 004	The office manager moved the license to the wall next to the check-in window facing into the waiting room. The office manager is responsible for ensuring that it remains conspicuously displayed.	03/14/17

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T 092	Continued From page 1	T 092		
T 092	410 IAC 26-5-2 REQUIRED POLICIES AND PROCEDURES 410 IAC 26-5-2(c)(2) (2) A written policy to address the internal review of unusual occurrences and disasters. This policy must include, but not be limited to, the following: (A) Patient injuries or marked deterioration of patient condition occurring under unanticipated or unexpected circumstances. (B) Unexplained loss of or theft of a controlled substance. (C) Deaths occurring within the clinic. This RULE is not met as evidenced by: Based on document review and interview, the facility failed to have a policy (ies) that addressed deaths within the clinic in 1 instance. Findings include: 1. Review of facility policies indicated there were none that addressed deaths within the clinic. 2. In interview on 02-08-2017 at 10:30 am, employee #A1 confirmed the above and no other documentation was provided prior to exit.	T 092	The Medical Director wrote a policy for deaths and published it in the Medical Manual (attachment B). Now that the policy exists, there is not likely to be a recurrence.	03/14/17
T 140	410 IAC 26-8-1 PERSONNEL POLICIES AND RECORDS	T 140		

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T 140	Continued From page 2 410 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 maintain personnel files which documented evidence of job related educational and training activities and physical exam in 3 of 10 employee files reviewed, and failed to have documentation of immunization status for 7 of 10 employee files reviewed. 1. Facility Safety policy ES 80, last updated 12/10/2015, indicated The Safety Manager provides annual retraining in this program to all employees. She records annual retraining in each Employee Health Folder. 2. Staff members #P8, P9 and P10's (all 3 are nurse practioners (NP) files lacked documentation of any type of educational activities since hire, all over at least a year ago,	T 140	The Office Manager requested the effected employees to obtain their childhood immunization records from their high schools at a staff meeting on 3/15/17. The Office Manager is responsible for following up to insure that the records are obtained and placed in the employees' personnel files. The Office Manager is responsible for insuring that these records are obtained within 30 days of hire for new employees. Disputed in part REVISED The additional information requested in response to the IDR of this tag is provided as attachments H1-H4 (collaborative practice agreements). The Nurse Practitioners are a part of the Medical Staff (like the physicians) and are independent contractors. They are paid through the professional corporation not by the management company. As such, ----cont'd	04/10/17

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T 140	Continued From page 3 and lacked documentation of a post offer physical exam. 3. Staff members # P1, P5, P6, P7, P8, P9 and P10's employee files lacked documentation of immunization status of those 7 nursing staff. 4. In interview on 02/6/2017 at 1330 hours, staff member #N1, nurse manager, indicated that he/she has been here only a few months and knew the personnel files needed work.	T 140	they are not subject to the same employment policies and procedures as the facility staff nor do they receive any of the benefits that regular employees receive (holiday pay, PTO, insurances, workmen's comp, unemployment, uniform allowance, etc.)	
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. This RULE is not met as evidenced by: Based on document review, observation and interview, the facility failed to provide an environment that minimizes the risk of infection exposure in two instances. 1. A. On 02/7/2017 at 1215 hours, while touring the facility instrument sterilization area, it was noted that an uncovered, unlabeled, red bucket, used for tissue disposal, was in close proximity to sterile areas. It is placed between the two autoclaves and the instrument pre-sterilization	T 206	The Head Nurse relocated the bucket for receiving tissue to an area under the sink where soiled instruments are received and cleansed prior to wrapping. The Head Nurse has established a procedure with the instrument techs that bucket will be disinfected after each use and stored in the biohazard room when not in use. The Head Nurse is responsible for insuring that this procedure is followed consistently. The Head Nurse developed a new procedure for processing and storing clean laundry. Clean laundry will be removed directly ---cont'd	03/14/17

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T 206	Continued From page 4 wrapping counter, risking contamination of the sterilized packages. B. On 02/7/2017 at 1215 hours, staff member # N1, nurse manager, indicated that there is a lid for the bucket and it was not known where else to put it. The disposable tissue, which is brought out at the same time as the dirty instruments, is in red biohazard bags. 2. Facility Safety Policy ES77, last updated on 12/10/2015, indicated laundry personnel process soiled laundry in an area that is separate from the area where clean laundry is handled. A. On 02/7/2017 at 1220 hours, while on tour of the facility, the laundry room was toured. It was noted that the floor and shelves in the rooms appeared to be dusty and there was debris on the floor. The floor appeared to be a rough, porous grout type base, from having tiles removed, untenable to thorough cleaning. It was also noted that clean laundry is stored unwrapped, on a shelf by the washer and dryer. B. On 02/7/2017 at 1220 hours, staff member #N1, nurse manager, indicated that the floor probably needs attention, to make it cleanable. Staff member #N1 also indicated that the only things washed here are blankets, the doctor's scrubs and white coats, but they are however, taken out of the dryer and stored on shelves right next to it.	T 206	from the dryer into clean laundry bins and transported to the room where drugs are stored in locked cabinets. Laundry will be sorted, folded and stored in this area where there is extra unused shelf space. The Head Nurse is responsible for insuring that this procedure is followed consistently. REVISION: The housekeeping log (attachment I) has been revised to include weekly vacuuming of the storage room floor and monthly vacuuming of the shelving. While the floor is rough from a very thin layer of old mastic, vacuuming will remove all surface dust and the floor will be cleaner than a carpeted floor. The Director will be responsible that this new procedure is followed.	
T 214	410 IAC 26-11-1 INFECTION CONTROL PROGRAM 410 IAC 26-11-1(c) (c) The clinic must designate a person qualified by training or experience as responsible for the following:	T 214		

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T 214	Continued From page 5 (1) Ongoing infection control activities. (2) The development and implementation of policies governing control of infections and communicable diseases. This RULE is not met as evidenced by: Based on document review and interview, the facility failed to have a person qualified by training or experience to be responsible for infection control (IC) activities. 1. Based on personnel file review, staff member #1 (nursing manager) file lacked documentation of any training in infection control. 2. In interview on 02/7/2017 at 1400 hours, staff member #1 indicated that he/she had no formal training in infection prevention since college nursing classes.	T 214	The Head Nurse has registered for two courses offered by Association of Professionals in Infection Control and Epidemiology and accredited by the American Nurses Credentialing Center. They are "Disinfection and Sterilization: Best Practices in Reprocessing Surgical Instruments" for 1.5 CNE hours and "Basics of Infection Prevention from the Association of Professionals in Infection Control and Epidemiology" for 7 CNE hours. The Head Nurse will be responsible for maintaining proficiency in infection control so that the issue does not recur.	04/20/17
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 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	T 326	The Betadine bottles were labeled and dated on 3/12/17. The Head Nurse will be responsible that this problem does not recur.	03/12/17

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T 326	Continued From page 6 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 label 2 spray bottles of antiseptic skin solution. 1. On 02/7/2017 at 1230 hours, while touring facility procedure rooms, #1 and #2, it was observed that procedure carts both contained 12 ounce plastic spray bottles containing brown, clear solution. There were no labels on the bottles. 2. In interview on 02/7/2017 at 1230 hours, facility staff member #1, nursing manager, indicated that there should be labels on the bottles indicating dates and that it is Betadine.	T 326		
T 404	410 IAC 26-17-3 PHYS. PLANT,MAINT.,EQUIP.,ENVIR.,SAFETY 410 IAC 26-17-3(2)	T 404		

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T 404	Continued From page 7 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 failed to maintain the physical plant in such a manner to assure the safety of patients, authorized visitors, or employees in 8 instances. Findings: include: 1. On 02-07-2017 at 11:23 am in the presence of employee #A1, Head Nurse, it was observed in the product of conception room, which contained biohazardous material, there was no biohazard sticker on the outside of the room identifying the room as containing biohazardous material. 2. On 02-07-2017 at 11:23 am in the presence of employee #A1, Head Nurse, it was observed in the product of conception area there was an electrical switch on the wall that had no cover plate and an electrical wall outlet with no cover plate. 3. On 02-07-2017 at 11:25 am in the presence of employee #A1, it was observed in the nurse's locker room, there was an electrical wall outlet with no cover plate, and there was a toilet with a broken tank top.	T 404	The Head Nurse consolidated all biohazard material into one room and placed a biohazard sign on the door. The Head Nurse will be responsible that a sign is maintained on the door. The Head Nurse and Office Manager purchased and installed cover plates on all switches and outlets where they were missing. This omission occurred as a result of repainting of the area and the painter failed to replace them. This is a one time occurrence and is not likely to recur. The Office Manager oversaw the repair of the holes in the walls. She had backstops installed on the doors and the door closers adjusted to prevent a recurrence of this problem. --cont'd	03/15/17

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T 404	Continued From page 8 4. On 02-07-2017 at 11:28 am in the presence of employee #A1, it was observed in a storage room across from the nurse's locker room, there was an electrical switch on the wall with no cover plate. 5. On 02-07-2017 at 11:30 am in the presence of employee #A1, it was observed in the drug storage room there was a bathroom with an electrical switch on the wall with no cover plate. 6. On 02-07-2017 at 12:15 pm in the presence of employee #A1, it was observed in Procedure Room #2 there were 4 holes in the wall that were unpatched and a hole in the wall which appeared to have been caused by the door handle striking the wall. 7. On 02-07-2017 at 12:30 pm in the presence of employee #A1, it was observed in Operating Room #1 there was a hole in the wall which appeared to have been caused by the door handle striking the wall. 8 . On 02-07-2017 at 12:33 pm in the presence of employee #A1, it was observed in the trash dumpster area there was a considerable amount of miscellaneous trash strewn on the ground around the dumpster.	T 404	The small holes were left when the area was painted and a wall mounted hand sanitizer removed. The facility now uses counter top dispensers so this problem is not likely to recur. The Office Manager oversaw the replacement of the toilet with the broken top. This occurred as a result of construction damage and is not likely to recur. The Office Manager and staff cleaned dumpster area and the Office Manager added checking the dumpster area for cleanliness to the General Housekeeping log (attachment D). The Office Manager will be responsible for insuring that the new procedure is followed.	
T 408	410 IAC 26-17-3 PHYS. PLANT,MAINT.,EQUIP.,ENVIR.,SAFETY 410 IAC 26-17-3(3)(B) The condition of the physical plant and the overall clinic environment must be developed and maintained in such a manner that the safety and	T 408	The Medical Director has instructed the Office Manager of her responsibility for the general maintenance of the physical plant and to seek guidance when she is unsure as to how to proceed.	

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T 408	Continued From page 9 well-being of patients is assured as follows: (B) All mechanical equipment (pneumatic, electric, sterilizing, or other) must be on a documented maintenance schedule of appropriate frequency in accordance with one (1) of the following: (i) Acceptable standards of practice. (ii) The manufacturer ' s recommended maintenance schedule. This RULE is not met as evidenced by: Based on document review and interview, the facility failed to document an appropriate schedule for preventive maintenance (PM) for 3 of 7 mechanical pieces of equipment/systems. Findings include: 1. Review of documents indicated there was no documented maintenance schedule for PM of mechanical equipment/systems according to acceptable standards of practice or the manufacturer's recommended maintenance schedule for an the emergency call system, emergency power source device and a smoke detector. 2. In interview on 02-07-2017 at 9:10 am, employee #A1, Head Nurse, confirmed the above and no documentation was provided prior to exit.	T 408	The Head Nurse has reviewed the manufacturers' literature for the emergency call system (phone system "all page") and emergency power source (APC UPSs). Neither manufacturer's literature contains information for a recommended maintenance schedule. The Head Nurse added operational checks of these systems to the monthly Safety Equipment Checklist (attachments E1 & E2). (Actually, the UPSs were already on the checklist). The Head Nurse also updated the monthly Safety Equipment Checklist to include the unlisted smoke detector(s). The Head Nurse will be responsible for following the new checklist to prevent a recurrence of these omissions.	03/20/17
T 410	410 IAC 26-17-3 PHYS. PLANT,MAINT.,EQUIP.,ENVIR.,SAFETY 410 IAC 26-17-3(3)(C)	T 410		

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T 410	Continued From page 10 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: (C) Operational and maintenance control records must be as follows: (i) Established and analyzed at least triennially. (ii) Readily available on the premises. This RULE is not met as evidenced by: Based on document review and interview, the facility failed to document operational and maintenance control records having been analyzed at least triennially for 7 of 7 mechanical pieces of equipment/systems. Findings include: 1. Review of facility documents indicated there was no documentation of operational and maintenance control records having been analyzed at least triennially for heating, ventilation, air conditioning, emergency call system, emergency power source device, fire alarm, and smoke detector. 2. In interview on 02-08-2017 at 1:00 pm, employee #A1, Head Nurse, confirmed there was no above-requested documentation. No other documentation was provided prior to exit.	T 410	The Medical Director added an item to the General Services review of the "Risk Management and Quality Assurance Checklist" to review preventive maintenance and service logs (attachment J). This review is semiannual. Doing a review of this nature on a continuing and rolling basis makes more sense to us. Incorporating this review formally in our QA process will insure that there is not a recurrence of this problem.	05/04/17
T 436	410 IAC 26-17-6 PHYS. PLANT,MAINT.,EQUIP.,ENVIR.,SAFETY	T 436		

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T 436	Continued From page 11 410 IAC 26-17-6(a)(5) (a) A safety management program must include, but not be limited to, the following: (5) A written fire control plan that contains provisions for the following: (A) Prompt reporting of fires. (B) Extinguishing of fires. (C) Protection of the following: (i) Patients. (ii) Personnel. (iii) Guests. (D) Evacuation. (E) Cooperation with firefighting authorities. (F) Fire drills. This RULE is not met as evidenced by: Based on document review and interview, the clinic failed to include in its fire control plan a provisions for prompt reporting of fires and cooperation with firefighting authorities in 1 instance. Findings include:: 1. Review of the facility's fire control plan entitled Fire Protocol, approved 07-20-2016, indicated it did not include provisions for prompt reporting of fires and cooperation with firefighting authorities. 2. In interview on 02-06-2017 at 3:10 pm, employee #A1, Head Nurse, confirmed all the above and no other documentation was provided prior to exit.	T 436	The Medical Director updated the Safety Manual and the Fire Protocol to include the prompt reporting of fires and cooperation with fire fighting authorities (attachments G1 & G2). The Head Nurse will be responsible for training staff in the new policy. Since this is a one time omission, the omission should not recur not that it is a part of a published document.	03/10/17