

Indiana State Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 011133	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED 12/10/2014
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NAME OF PROVIDER OR SUPPLIER CLINIC FOR WOMEN	STREET ADDRESS, CITY, STATE, ZIP CODE 3607 W 16TH ST STE 2B INDIANAPOLIS, IN 46222
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T 000	<p>INITIAL COMMENTS</p> <p>This visit was for a State licensure survey.</p> <p>Facility Number: 011133</p> <p>Survey Date: 12-9/10-14</p> <p>Surveyors: Jack I. Cohen, MHA Medical Surveyor</p> <p>Linda Plummer, RN Public Health Nurse Surveyor</p> <p>William C. Greeney Life Safety Code Surveyor</p> <p>QA: claughlin 12/16/14</p>	T 000		
T 114	<p>410 IAC 26-7-1 MEDICAL RECORDS</p> <p>410 IAC 26-7-1(b)(1)</p> <p>(b) A medical record must be maintained with documentation of service rendered for each surgical abortion patient of the clinic as follows: (1) Medical records: (A) are documented accurately and in a timely manner; (B) are readily accessible; and (C) permit prompt retrieval of information.</p> <p>This RULE is not met as evidenced by: Based on policy review and medical record review, the facility failed to ensure the accuracy of</p>	T 114		

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

TITLE

(X6) DATE

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T 114	<p>Continued From page 1</p> <p>patient records for 6 of 30 medical records reviewed (Patients #13, # 21, #22, #25, #27 and #29).</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. Review of the policy "T 114, 116, 120 and 122", last approved on 12/10/13, (No title), indicated: "It is the policy of Clinic for Women that medical records will be maintained with documentation of service rendered...1. Medical records are documented accurately and in a timely manner..." 2. Review of patient medical records indicated: <ol style="list-style-type: none"> a. Pt. #13 lacked documentation of the time the consent for an abortion procedure was signed by the patient on form 55320. b. Pt. #21 had documentation of having been given Naproxen at 8:15 AM on 10/3/14 on the "Surgery Report" form and the "Recovery Notes" form, but had a "Conscious Sedation Behavior Assessment" form indicating the patient had Valium 10 mg administered at 8:15 AM with monitoring done at almost 15 minute intervals until 10:15 AM. c. Pt. #25 had documentation on the "Surgery Report" form that Valium 10 mg and Motrin 800 mg was given pre procedure, but lacked documentation of the Valium administration on the "Recovery Notes" form. d. Pt. #27 lacked documentation of AM or PM on the the consent for an abortion procedure that was signed by the patient (form 55320). The procedure was the next day, so that the 18 hour wait could have been in question. e. Pt. #29 lacked documentation of the time the consent for an abortion procedure was signed by the patient on form 55320. 	T 114		

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T 206	Continued From page 2	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 observation and interview, the clinic failed to ensure a safe and healthful environment was maintained that would minimize the risk to patients, health care workers, or others, in two (2) areas of the facility that were toured (exam room and procedure room #1).</p> <p>Findings: 1. While on tour of the facility on 12/9/14 at 3:05 PM in the company of staff member #40, the clinic director, it was observed that the ultrasound machine in the exam room had dust on several surfaces of the machine.</p> <p>2. While on tour of the facility on 12/9/14 at 3:22 PM in the company of staff member #40, it was observed in procedure room #1 that: a. The window blinds were excessively dusty. b. There was a quarter sized tear in the leather covering of the exam table, which allowed an almost golf ball size of foam padding to protrude (in the lower center portion of the exam table pad where patients' vaginal area is exposed for</p>	T 206		

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T 206	Continued From page 3 procedures). 3. At 4:15 PM on 12/10/14, interview with staff member #43, the infection control practitioner, indicated: a. It was agreed that the areas listed in 1. and 2. above were not cleaned as expected and presented possible infection problems. b. The clinic staff clean the facility. c. The last quarterly cleaning day was "the end of September".	T 206		
T 232	410 IAC 26-11-1 INFECTION CONTROL PROGRAM 410 IAC 26-11-1(e)(2)(E) (e) The clinic must establish a committee to monitor and guide the infection control program in the clinic as follows: (2) The infection control committee responsibilities must include, but are not limited to, the following: (E) Reviewing and recommending changes in procedures, policies, and programs that are pertinent to infection control. These include, but are not limited to, the following: (i) Sanitation, including proper disposal of removed tissue. (ii) Universal precautions, including infectious waste management. (iii) Cleaning, disinfection, and sterilization. (iv) Aseptic technique, invasive procedures, and equipment usage. (v) Reuse of disposables. (vi) A system for handling patients with communicable diseases.	T 232		

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T 232	<p>Continued From page 4</p> <p>(vii) A system, which complies with state and federal law, to monitor the immune status of health care workers exposed to communicable diseases.</p> <p>(viii) An employee health program to determine the communicable disease history of new personnel as well as an ongoing program for current personnel as required by state and federal agencies.</p> <p>(ix) Requirements for personal hygiene and attire that meet acceptable standards of practice.</p> <p>(x) A program of linen management.</p> <p>This RULE is not met as evidenced by: Based on policy review, employee file review, and staff interview, the infection control committee failed to ensure that the employee health program determined the communicable disease history of new employees, for 6 of 6 staff members (Staff members N1 through N6).</p> <p>Findings: 1. Review of the policy "Policy for Orientation/Training of New Employee and Contract Personnel", T164 & 166 & 168, last approved 12/10/13, indicated: The policy read: "...All new employees and contract personnel must have the following: a complete physical and TB (tuberculosis) information on file prior to start date of employment appropriate licenses job application provide a record of CPR (cardio pulmonary resuscitation) training and annual competency.</p>	T 232		

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T 232	Continued From page 5 verification of current Hepatitis B vaccine or sign a waiver to decline HBV (hepatitis B vaccine)...". 2. Review of the policy "Policy for Communicable Disease", T 148, last approved 12/10/13, indicated: The policy read: "All employees of Clinic for Women shall have their health monitored in accordance with the clinics infectious control program. All employees, staff members and contractors having direct patient contact are evaluated at least annually for Tuberculosis...". 3. Review of employee files indicated: a. Staff member N1 was a recovery room assistant who was hired 6/6/14 and lacked any documentation of communicable disease history for Rubella, Rubeola, or Varicella. b. Staff members N2 through N6 were hired between 2000 and 2007, were lab techs, patient educators, one RN (registered nurse), and surgical assistants, who lacked any documentation of communicable disease history for Rubella, Rubeola, or Varicella. 4. Interview with staff member #43, the infection preventionist, at 12:00 PM on 12/9/14, indicated: a. The policies, as listed in 1., and 2., fail to address communicable diseases such as Rubella, Rubeola, and Varicella. b. The facility has no testing requirements, such as titers, for communicable diseases, nor does it require newly hired staff to provide communicable disease history.	T 232		
T 322	410 IAC 26-16-1 PHARMECEUTICAL SERVICES 410 IAC 26-16-1(3)(A)	T 322		

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T 322	<p>Continued From page 6</p> <p>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:</p> <p>(3) Written policies and procedures developed, implemented, maintained, and made available to personnel, including, but not limited to, the following:</p> <p>(A) Drug:</p> <p>(i) handling;</p> <p>(ii) storing;</p> <p>(iii) labeling;</p> <p>(iv) dispensing; and</p> <p>(v) administration according to established clinic policies and acceptable standards of practice.</p> <p>This RULE is not met as evidenced by: Based on document review, medical record review, and staff interview, the clinic failed to ensure medications given, prior to procedures, were given as per policy for 30 of 30 medical records reviewed (Patients #1 through #30).</p> <p>Findings:</p> <p>1. Review of the policy "Valium/diazepam, Motrin/ibuprofen and Naproxen", T318a, last approved 12/10/13, indicated: The policy read: "...Wait time for patients that receive oral sedation (valium...and motrin) must wait a minimum of 45 minutes prior to abortion procedure. Wait time for patient (sic) that receive (sic) naproxen is 30 minutes prior to abortion procedure is 30 minutes" (sic).</p>	T 322		

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T 322	Continued From page 7 2. Review of patient medical records #1 through #30 indicated: a. Patients #1 through #7, #10, #11, #14, #16, #17, #19 through #24, #26, #27, #29 and #30 received Naproxen 550 mg prior to their abortion procedures, but lacked documentation of start time of the procedure, to assure that 30 minutes had elapsed between the receipt of medication and the beginning of the procedure. b. Patients #8, #9, #12, #13, #15, #18, #25, and #28 had Valium 10 mg and Motrin 800 mg given prior to their procedures, but lacked documentation of the start time of the procedure, to assure that 45 minutes had elapsed between the receipt of medication and the beginning of the procedure. 3. At 10:55 AM on 12/10/14, interview with staff member #40, the clinic director, indicated: The patient medical records fail to indicate what time the abortion procedure starts, so that it can't be determined if the Naproxen or Valium/Motrin given were given either 30 minutes, or 45 minutes, prior to the procedure, as stated in facility policy.	T 322		
T 334	410 IAC 26-17-1 PHYS. PLANT,MAINT.,EQUIP.,ENVIR.,SAFETY 410 IAC 26-17-1(a) (a) The clinic must be constructed, arranged, and maintained to ensure the safety of the patient and to provide facilities for services authorized under the clinic license as follows:	T 334		

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T 334	Continued From page 8 This RULE is not met as evidenced by: Based on observation, the clinic failed to ensure the safety of the patient in one (1) area of the facility that was toured (procedure room #2). Findings: 1. While on tour of the facility on 12/9/14 at 3:30 PM in the company of staff member #40, it was observed in procedure room #2 that: There was a V shaped tear in the linoleum in front of the ultrasound machine and within 2 1/2 feet of the exam table. (The tear was approximately 6 to 8 inches long with 2 inches of gap in the linoleum.)	T 334		
T 394	410 IAC 26-17-2 PHYS. PLANT,MAINT.,EQUIP.,ENVIR.,SAFETY 410 IAC 26-17-2(e)(6) (e) Requirements for design standards are as follows: (6) The minimum nominal door width for patient use shall be three (3) feet. This RULE is not met as evidenced by: Based on observation and interview, the facility failed for 3 of 4 bathroom doors observed to ensure the nominal width of each doorway was at least 36 inches. Findings include:	T 394		

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T 394	Continued From page 9 1. During observation on 12/10/2014 between 9:15 A.M. and 10:15 A.M., the doorway to the bathroom located in the waiting area and the bathroom door in the east end of the hall with the counseling rooms both measured to be 24 inches in width. Additionally, a bathroom next to the lab room had a doorway that measured 28 inches in width. 2. Interview with FD#1, the Facility Director, during the observation, indicated patients access all three of the bathrooms.	T 394		
T 398	410 IAC 26-17-2 PHYS. PLANT,MAINT.,EQUIP.,ENVIR.,SAFETY 410 IAC 26-17-2(e)(8) (e) Requirements for design standards are as follows: (8) An approved antiscald device shall be provided on the hot water supply to all hand washing facilities limiting the water temperature to a maximum of one hundred ten (110) degrees Fahrenheit (forty-three (43) degrees Celsius). This RULE is not met as evidenced by: Based on observation and interview, the facility failed to ensure an approved anti-scald device was installed on the facility's hot water supply. The findings include:	T 398		

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T 398	Continued From page 10 1. During observation on 12/10/2014 between 9:15 A.M. and 9:45 A.M. with the building's maintenance staff (MS#1), no anti-scald device was seen on the hot water supply. 2. Interview with MS#1 during the observation indicated no anti-scald device had been installed on the building's hot water supply.	T 398		
T 442	410 IAC 26-17-6 PHYS. PLANT,MAINT.,EQUIP.,ENVIR.,SAFETY 410 IAC 26-17-6(b) (b) The clinic must maintain adequate battery-powered lighting and sufficient equipment needed to provide for the: (1) completion of services; and (2) safety of patients and staff; in the event of a power loss. This RULE is not met as evidenced by: Based on observation and interview, the facility failed to ensure 2 of 4 installed battery-powered emergency lights functioned when tested. The findings include: 1. During observation on 12/10/2014 between 9:15 A.M. and 9:45 A.M. with the building's maintenance staff (MS#1), one installed emergency light located in the 2nd floor corridor near the elevator and a second one installed just	T 442		

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T 442	Continued From page 11 outside the entrance of the clinic on the second floor failed to illuminate when tested by MS#1. 2. Interview with MS#1 during the observation indicated the batteries in the lighting system needed to be replaced.	T 442		