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
	011133	A. BUILDING: ______ B. WING ______	08/19/2008

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
CLINIC FOR WOMEN	**3607 W 16TH ST STE 2B INDIANAPOLIS, IN 46222**

(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 standard licensure survey. Facility Number: 011133 Survey Date: 8-18-08 / 8-19-08 Surveyors: Jack I. Cohen, MHA Medical Surveyor John Lee, RN Public Health Nurse Surveyor QA: claughlin 08/22/08	T 000		
T 026	410 IAC 26-4-1 GOVERNING BODY 410 IAC 26-4-1(c)(3) (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. This RULE is not met as evidenced by:	T 026		

Indiana State Department of Health
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

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T 026	Continued From page 1 Based on document review and interview, the governing board did not review reports of the quality assessment and improvement (QA&I) program at least every 6 months in year 2007. Findings: 1. On 8-19-08 at 2:15 pm, review of governing board minutes for the year 2007 dated 12-21-07 indicated the governing board did not review any reports of the QA&I program. 2. On 8-19-08 at 2:15 pm, employee #A1 was requested to provide documentation of any other governing board meetings held in 2007 in which QA&I program results were reviewed by the governing board and none were provided prior to exit.	T 026		
T 062	410 IAC 26-4-2 GOVERNING BODY 410 IAC 26-4-2(d)(4) (d) In appointing or contracting with medical staff, the governing body shall do the following: (4) Maintain a reasonably accessible hard copy or electronic file for each member of the medical staff, which includes, but is not limited to, the following: (A) A completed, signed application. (B) The date and year of completion of all Accreditation Council for Graduate Medical Education (ACGME) accredited residency training programs, if applicable. (C) A current copy of the individual ' s credentials as follows: (i) An Indiana license showing date of licensure and number or available data provided	T 062		

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T 062	Continued From page 2	T 062		

by the
Indiana professional licensing agency. A copy of practice restrictions, if any, must be attached
to the license issued by the Indiana professional licensing agency through the appropriate
licensing board.
(ii) Indiana controlled substance registration showing number as applicable.
(iii) Drug Enforcement Agency registration showing number as applicable.
(iv) Documentation of experience in the practice of medicine.
(v) Documentation of specialty board certification as applicable.

This RULE is not met as evidenced by:
Based on document review, the facility failed to maintain a copy of the Indiana controlled substance registration for each medical staff member that ordered the use of controlled substances for 2 of 4 medical staff member files reviewed.

Findings include:

1. Review of patient #26's medical record (MR) indicated that MD #1 ordered Valium 10 mg, a schedule 4 substance, to be given on 12-20-07 and ordered Darvocet N 100 #10 tabs, a schedule 4 substance, to be dispensed to the on discharge on 12-20-07.

2. Review of patient #27's MR indicated that MD #3 ordered Valium 5 mg, a schedule 4 substance, to be given on 12-29-07.

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T 062	Continued From page 3 3. Review of MD #1 and #3's files indicated lack of documentation of an Indiana controlled substance registration.	T 062		
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 facility did not have an ongoing quality assessment and improvement (QA&I) program because several areas of review were only reported annually and not at least twice per year. Findings: 1. On 8-19-08 at 2:25 pm, review of facility QA&I documents indicated the services and functions of contracted biohazardous waste, internal housekeeping, internal lab, contracted lab, internal laundry, internal medical records, discharges, transfers, medication errors, response to patient emergencies, security and contracted maintenance were reviewed and reported annually.	T 094		

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T 094	Continued From page 4 2. On 8-19-08 at 2:25 pm, upon interview, employee #A1 indicated those services and functions were only reviewed and reported annually.	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; 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	T 104		

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T 104	Continued From page 5 (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. (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	T 104		

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T 104	Continued From page 6 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 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	T 104		

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T 104	Continued From page 7 (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. (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	T 104		

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T 104	Continued From page 8 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 facility failed to include serious adverse events in its quality assurance & improvement program (QA&I). Findings: 1. On 8-19-08 at 2:25 pm, review of the facility ' s QA&I program indicated it did not include serious adverse events. 2. On 8-19-08 at 2:25 pm, employee #A2 was	T 104		

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T 104	Continued From page 9	T 104		

requested to provide the above documentation and none was provided prior to exit.

T 222 | 410 IAC 26-11-1 INFECTION CONTROL PROGRAM | T 222

410 IAC 26-11-1(e)(1)(A,B,C&D)

(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.

(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.

This RULE is not met as evidenced by:
Based on document review, the facility failed to ensure that the infection control committee met at least quarterly and had a representative from the nursing staff (if the clinic employs a licensed nurse) for 1 infection control committee.

Findings include:

1. Review of facility staff personnel files indicated that staff #4 is a registered nurse and staff #6 is a

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T 222	Continued From page 10 licensed practical nurse. 2. Review of the Infection Control Committee minutes for the 2nd, 3rd and 4th quarter of 2007 and the 1st and 2nd quarter of 2008 indicated lack of documentation that a licensed nurse attended the Infection Control Committee meeting.	T 222		
T 340	410 IAC 26-17-1 PHYS. PLANT,MAINT.,EQUIP.,ENVIR.,SAFETY 410 IAC 26-17-1(a)(2) (2) The clinic must provide a physical plant and equipment that meets the statutory requirements and regulatory provisions of the fire prevention and building safety commission (IC 22, 675 IAC 22), Indiana fire prevention codes (675 IAC 22), and Indiana building codes (675 IAC 13). This RULE is not met as evidenced by: Based on document review and interview, the facility failed to monthly inspect 2 of 2 portable fire extinguishers. Findings: 1. Review of Section 906.2, 2008 Indiana Fire Code, General Requirements section, indicates portable fire extinguishers shall be selected, installed and maintained in accordance with this section and NFPA 10.	T 340		

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T 340	Continued From page 11 2. Review of NFPA 10, Section 4-3.4.2 indicates requirement of fire extinguisher inspections at least monthly with the date of inspection and the of the person performing be recorded. 3. On 8-19-08 at 9:30 am, review of the tag affixed to a portable fire extinguisher in a hallway indicated it had been inspected only in August, 2007. 4. On 8-19-08 at 9:45 am, review of the tag affixed to a portable fire extinguisher in the recovery area indicated it had been inspected only in August, 2007.	T 340		
T 416	410 IAC 26-17-4 PHYS. PLANT,MAINT.,EQUIP.,ENVIR.,SAFETY 410 IAC 26-17-4(2) All patient care equipment must be in good working order and regularly serviced and maintained as follows: (2) There must be evidence of preventive maintenance on all patient care equipment. This RULE is not met as evidenced by: Based on interview, the facility failed to provide evidence of preventive maintenance on 1 piece of patient care equipment. Findings: 1. On 8-19-08 at 1:45 pm, employee #A1 was asked to provide documentation of preventive maintenance on the speaker box for the nurse	T 416		

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T 416	Continued From page 12 call system. No documentation was provided prior to exit.	T 416		

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T 000	INITIAL COMMENTS Survey Type: Licensure Complaints IN00039763/20080453 Unsubstantiated, lack of sufficient evidence. IN00039986/20080504 Unsubstantiated, lack of sufficient evidence. Facility Number: 011133 Date: 08-19-08 Surveyors: John Lee, R.N. Public Health Nurse Surveyor Clinic for Women is in compliance with Indiana Abortion Clinic Licensure Rules 410 IAC 26-9-1, Medical Staff, 410 IAC 26-10-1, Patient care, and 410 IAC 26-10-2, Nursing services. QA: claughlin 08/28/08	T 000		

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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE