This visit was for a State licensure survey.
Facility #: 011127
Survey Dates: 8-18-10/8-19-10

Surveyors:
Billie Jo Fritch, RN, BSN, MBA
Public Health Nurse Surveyor
Jacqueline Brown, RN
Public Health Nurse Surveyor
Linda Plummer, RN
Public Health Nurse

QA: claughlin 09/02/10 T 006 410 IAC 26-3-1 SURVEYS 410 IAC 26-3-1(a)

(a) The abortion clinic shall fully cooperate with surveys conducted by representatives of the department. Upon arrival of department surveyors at the clinic, the clinic may immediately contact the department to confirm the identity of the surveyors. Upon confirmation by the department of the survey and surveyors, the clinic shall:
(1) immediately admit the surveyors to the clinic; and
(2) not delay the survey.

Indiana State Department of Health
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE
STATE FORM 6899
Indiana State Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION
(X1) PROVIDER/SUPPLIER/CLIA

IDENTIFICATION NUMBER: 011127 08/19/2010
NAME OF PROVIDER OR SUPPLIER STREET ADDRESS, CITY, STATE, ZIP CODE
WOMEN'S PAVILION
2010 IRONWOOD CIR
SOUTH BEND, IN 46635

SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)
T 006 Continued From page 1 T 006
This RULE is not met as evidenced by: Based on policy and procedure review, observation, and staff interview, the facility failed to fully cooperate with survey conducted by representatives of the Indiana State Department of Health related to access to locked medication cabinet in one area toured (storage room).

Findings:
1. Policy titled, "Policy for Storage and Security of all On-Site Medications" was reviewed on 8/19/10 at 9:55 AM and indicated, "Narcotic agents, if on-site, will be kept in locked storage to which only [physician]/Medical Director has access."

2. While on tour of the facility on 8/19/10 at 10:45 AM, it was observed that the medication cabinet in the storage room was locked.

3. Personnel P7 was interviewed on 8/19/10 at 11:05 AM and confirmed the medication cabinet

in the storage room contained Stadol 10ml/2mg vials, was locked, and only the Medical Director has the key. A phone call was placed by P7 to the Medical Director on 8/19/10 at 11:38 AM and it was confirmed that they were the only personnel with access to the medication cabinet in the storage room and were not available to open it for the surveyors during the survey.

T 022 410 IAC 26-4-1 GOVERNING BODY 410 IAC 26-4-1(c)(1)

(c) The governing body shall do the following:

(1) Assume responsibility for:
(A) determining;
(B) implementing;
(C) monitoring; policies governing the clinic ' s operation.

This RULE is not met as evidenced by:
Based on document review and interview, the facility failed to ensure documentation to indicate that the governing body implements and monitors the policies which govern the clinic's operation.

Findings include:
1. Review of facility documents indicated lack of evidence that the governing body reviewed or approved the policies which govern the clinic's operation.

2. Interview with #S1 on 8-18-10 at 1230 hours confirmed there was no documentation to indicate the governing body reviewed or approved the policies which govern the clinic's operation. Additional documents were requested; none were provided prior to exit.

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:
Based on document review and interview, the facility failed to ensure documentation to indicate that the governing body had reviewed the reports of management operations for 2009 and 2010.

Findings include:
1. Review of facility documents indicated lack of evidence that the governing body had reviewed the reports of management operations for 2009 and 2010.

2. Interview with #S1 on 8-18-10 at 1230 hours confirmed there was no documentation indicating review of management operations for 2009 and 2010 by the governing body. Additional documents were requested; none were provided prior to exit.

T 028 410 IAC 26-4-1 GOVERNING BODY

410 IAC 26-4-1(c)(4)
(c) The governing body shall do the following:

(4) Maintain documents, registers, and reports that show the following:

(A) Ownership.
(B) Compliance with local, state, and federal laws and regulations.
(C) Adherence to clinic bylaws (if applicable) and clinic policies.

This RULE is not met as evidenced by:

Based on document review and interview, the facility failed to ensure maintenance of documents of ownership. Findings include:

1. Review of facility documents on 8-18-10 and 8-19-10 indicated lack of documents of ownership.

2. Interview with #S1 on 8-18-10 at 1410 hours indicated ownership documents were not available at the facility. Additional documents were requested; none were provided prior to exit.

T 034 410 IAC 26-4-1 GOVERNING BODY
410 IAC 26-4-1(c)(7)
(c) The governing body shall do the following:

(7) Ensure that clinic policies and procedures are:

(A) updated as needed; and
(B) reviewed at least triennially.

This RULE is not met as evidenced by:

Based on document review and interview, the governing body failed to ensure the clinic policies were reviewed at least triennially.

Findings include:

1. Review of facility documents indicated lack of evidence that policies were reviewed by the governing body at least triennially.

2. Interview with #S1 on 8-18-10 at 1230 hours confirmed that the governing body had not documented review of clinic policies at least triennially. Additional documents were requested; none were provided prior to exit.

T 084 410 IAC 26-5-1 ADMINISTRATION AND POLICIES
410 IAC 26-5-1(3)
The clinic administrator is responsible for day-to-day operations of the abortion clinic to include, but not be limited to, the following functions:

(3) Implementation of internal and external disaster and emergency preparedness plans with documentation of outcome.

This RULE is not met as evidenced by:
Based on document review and interview, the clinic administrator failed to implement internal and external disaster and emergency preparedness drills with documentation of outcomes during 2009 or 2010.

Findings include:

1. Review of facility documents on 8-18-10 indicated lack of evidence that the facility had conducted an internal or external disaster and emergency preparedness drill with documentation of outcome during 2009 or 2010.

2. Interview with #S1 on 8-18-10 at 1430 hours confirmed the facility had not conducted an internal or external disaster drill with documentation of outcome for 2009 or 2010.

Additional documents were requested; none were provided prior to exit.

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 failed to ensure an effective and comprehensive quality assessment and performance improvement program (QAPI) which includes all areas of the clinic involved in the provision of patient care.

Findings include:

1. Review of the facility QAPI program titled "Quality Assurance" on 8-18-10 indicated the program was designed to evaluate the testing process. The areas included were pretesting, testing, and post testing.

2. Review of the facility QAPI plan on 8-18-10 indicated lack of inclusion of all areas of the clinic involved in the provision of patient care.

3. Interview with #S1 on 8-18-10 at 1530 hours confirmed the document titled "Quality Assurance" is the QAPI program for the facility and that it does not include all areas of the clinic involved in the provision of patient care. Additional documents were requested; none were provided prior to exit.

T 096 410 IAC 26-6-1 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 26-6-1(a)(1)

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.

This RULE is not met as evidenced by:
Based on document review and interview, the facility failed to ensure the inclusion of all services in the facility quality assessment and performance improvement (QAPI) program including 1 of 6 contracted services and 4 of 4 direct services reviewed.

Findings include:

1. Review of facility documents on 8-18-10 indicated an agreement with a heating and cooling company to service, clean and change filters on the furnaces and air conditioners twice a year. Facility documents reviewed on 8-18-10 lacked evidence that the contracted service was included in the facility QAPI program.

2. Review of QAPI program documents lacked evidence that the direct services of medical records, maintenance, nursing, and pharmacy were included in the facility QAPI program.

3. Interview with #S1 on 8-18-10 at 1530 hours indicated the services above are not included in the facility QAPI program. Additional documents were requested; none were provided prior to exit.

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 ensure the inclusion of discharges, transfers, and response to patient emergencies in the facility quality assessment and performance improvement (QAPI) program.

Findings include: Review of facility documents on 8-19-10 indicated lack of documentation that discharges, transfers, and response to patient emergencies were included in the facility QAPI program.

2. Interview with #S1 on 8-19-10 at 1145 hours confirmed that discharges, transfers, and response to patient emergencies were not included in the facility QAPI program. Additional documents were requested; none were provided prior to exit.

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
(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 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 edministration of a medication to which a patient has a known allergy and drug-drug interactions or 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 (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 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's quality assessment and performance improvement (QAPI) program failed to ensure a process to determine the occurrence of reportable events within the clinic.

Findings include:

1. Review of facility documents on 8-18-10 indicated lack of evidence that the clinic's QAPI program had a process in place to determine the occurrence of reportable events within the clinic.

2. Interview with #S1 on 8-19-10 at 1145 hours indicated the clinic's QAPI program did not have a process in place to determine the occurrence of reportable events within the clinic. Additional documents were requested; none were provided prior to exit.

T 105 410 IAC 26-6-2 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 26-6-2(a)(2)

(2) A process for reporting to the department each reportable event listed in subdivision (1) that is determined by the clinic's quality assessment and improvement program to have occurred within the clinic.
(b) Subject to subsection (e), the process for determining the occurrence of the reportable events listed in subsection (a)(1) by the clinic's quality assessment and improvement program shall be designed by the clinic to accurately determine the occurrence of any of the reportable events listed in subsection (a)(1) within the clinic in a timely manner.
(c) Subject to subsection (e), the process for reporting the occurrence of a reportable event listed in subsection (a)(1) shall comply with the following:

(1) The report shall:
(A) be made to the department;
(B) be submitted not later than fifteen (15) working days after the reportable event is determined to have occurred by the clinic's quality assessment and improvement program;
C) be submitted not later than four (4) months after the potential reportable event is brought to the program's attention; and (D) identify the reportable event, the quarter of occurrence, and the clinic, but shall not include any identifying information for any:
(i) patient;
(ii) individual licensed under IC 25; or
(iii) clinic employee involved;
or any other information.

(2) A potential reportable event may be identified by a clinic that:
(A) receives a patient as a transfer; or
(B) admits a patient subsequent to discharge; from another health care facility subject to a reportable event requirement. In the event that a clinic identifies a potential reportable event originating from another health care facility subject to a serious reportable event requirement, the identifying clinic shall notify the originating health care facility as soon as they determine an

event has potentially occurred for consideration by the originating health care facility's quality assessment and improvement program.

(3) The report, and any documents permitted under this section to accompany the report, shall be submitted in an electronic format, including a format for electronically affixed signatures.

(4) A quality assessment and improvement program may refrain from making a determination about the occurrence of a reportable event that involves a possible criminal act until criminal charges are filed in the applicable court of law.

(d) The clinic's report of a reportable event listed in subsection (a)(1) shall be used by the department for purposes of publicly reporting the type and number of reportable events occurring within each clinic. The department's public report will be issued not less frequently than annually.

(e) Any reportable event listed in subsection (a)(1) that:

(1) is determined to have occurred within the clinic between:
(A) January 1, 2009; and
(B) the effective date of this rule; and

(2) has not been previously reported; must be reported within five (5) days of the effective date of this rule. (Indiana State Department of Health; 410 IAC 26-6-2)

This RULE is not met as evidenced by:

Based on document review and interview, the facility's quality assessment and performance improvement (QAPI) program did not have a process in place to report reportable events to the Indiana State Department of Health (ISDH).

Findings include:

1. Review of facility documents on 8-19-10 indicated lack of evidence that the facility's QAPI program had a process in place to report reportable events to the ISDH.

2. Interview with #S1 on 8-19-10 at 1145 hours confirmed that the facility QAPI program does not have a process in place to report reportable events to the ISDH. Additional documents were requested; none were provided prior to exit.

T 110 410 IAC 26-7-1 MEDICAL RECORDS 410 IAC 26-7-1(a)(2)(B)

(a) The abortion clinic must do the following:
(2) Have a written policy that ensures responsibility for and maintenance of surgical abortion records as follows:

(B) The policy must provide safeguards to assure protection of the medical records from the following:
(i) Fire.
(ii) Water.
(iii) Other sources of damage.

This RULE is not met as evidenced by:

Based on document review and interview, the facility failed to ensure a written policy to provide protection of the medical records from fire, water, or other damage.

Findings include:

1. Review of facility documents on 8-18-10 indicated lack of evidence of a policy related to the protection of medical records.

2. Interview with #S1 on 8-18-10 at 1510 hours confirmed that the facility does not have a policy related to the protection of medical records from fire, water, or other damage. Additional documents were requested; none were provided prior to exit.

T 118 410 IAC 26-7-1 MEDICAL RECORDS T 118 410 IAC 26-7-1(b)(3)

(b) A medical record must be maintained with documentation of service rendered for each surgical abortion patient of the clinic as follows:
(3) The clinic shall use a system of author identification and record maintenance that:
(A) ensures the integrity of the authentication; and
(B) protects the security of all record entries. Each entry must be authenticated in accordance with the clinic and medical staff policies.

This RULE is not met as evidenced by:

Based on patient medical record review and interview, the facility failed to ensure that all entries in the medical record were authenticated by the author in 30 out of 30 records reviewed and failed to create a policy related to entry authentication (Pts. #1 through #30).

Findings:

1. Review of closed patient medical records, through out the survey process of 8/18/10 and 8/19/10, indicated nursing staff were documenting vital signs during the "Recovery Period" and Discharge Notes", but were not authenticating these written notes

2. At 3:45 PM on 8/18/10, interview with staff member NA indicated:
a. there is no facility policy related to entry authentication in the medical record
b. medical records #1 through #30 are lacking authentication by the recovery room nurse of their patient notes
c. the recovery nurse should be signing/authenticating their recovery and discharge information that is documented in the patient medical record

T 122 410 IAC 26-7-1 MEDICAL RECORDS 410 IAC 26-7-1(b)(5)

(b) A medical record must be maintained with documentation of service rendered for each surgical abortion patient of the clinic as follows:

(5) Plain paper facsimile orders, reports, and documents are acceptable for inclusion in the medical record if allowed by the clinic policies.

This RULE is not met as evidenced by:

Based on document review and interview, the facility failed to ensure a policy related to plain paper facsimile.

Findings include:

1. Review of facility documents on 8-18-10 indicated lack of evidence of a policy related to plain paper fax.

2. Interview with #S1 on 8-18-10 at 1510 hours confirmed that the facility does not have a policy regarding plain paper fax. Additional documents were requested; none were provided prior to exit.

T 126 410 IAC 26-7-1 MEDICAL RECORDS 410 IAC 26-7-1(b)(7)
(b) A medical record must be maintained with documentation of service rendered for each surgical abortion patient of the clinic as follows:

(7) The clinic shall ensure the confidentiality of patient records. The clinic must develop, implement, and maintain the following:
(A) A procedure for releasing information or copies of records only to authorized individuals in accordance with federal and state laws.
(B) A procedure that ensures that unauthorized individuals cannot gain access to medical records.

This ELEMENT is not met as evidenced by:

Based on document review, observation, and interview, the facility failed to ensure a policy and procedure for releasing information or copies of records only to authorized individuals in accordance with federal and state laws.

Findings include:

1. Review of facility documents on 8-18-10 indicated lack of evidence of a policy and procedure for releasing information or copies of records only to authorized individuals.

2. When entering the facility on 8-19-10 at 0900 hours with #S2, it was observed that the sliding file doors to the medical record storage cabinets in the registration area were open. This could allow access to patient records and not protect the records from fire or water.

2. While touring the facility on 8-19-10 at 0930 hours with #S2 present, it was observed that the door to the medical record storage room was open and the file cabinets were unlocked, allowing access to patient records.

2. Interview with #S1 on 8-18-10 at 1510 hours confirmed the facility does not have a policy and procedure for releasing information or copies of records only to authorized individuals. Additional documents were requested; none were provided prior to exit.

5. Interview with #S1 and #S2 on 8-19-10 at 0930 hours confirmed the sliding doors to the medical record storage cabinets in the registration were open and cannot be locked because they do not have access to the key; #S1 and #S2 confirmed the file cabinets in the medical record storage room are unlocked and the door was open on 8-18-10 and 8-19-10.

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.
(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 patient medical record review, policy and procedure review, and interview, the facility failed to: ensure an appropriate medical history was performed for 30 out of 30 patients (#1 through #30);

failed to document patient reactions to drugs listed as "allergic" to in 4 of 30 medical records (#2, #7, #11, and #13);

failed to provide evidence of appropriate consent for procedures as required by IC-34-2-1.1 for 4 of 4 patients presenting for a repeat surgical abortion (#8, #19, #23 and #24);

and failed to document discharge vital signs for 3 of 30 patients (#8, #10 and #21).

Findings:

1. Review of closed patient medical records, through out the survey process of 8/18/10 and 8/19/10, indicated:

a. patient medical records #1 through #30 had patient self reported health/medical history information noted on the "Medical History" form

b. patient medical records #1 through #30 were lacking a medical history performed by a qualified practitioner

c. patients #2, #7, #11 and #13 listed allergies to: "All cillins" for #2 and #7; "sensitive to Codeine" for #11 and "Penicillin and Singulair"--"allergic to penicillin, Singulair--occasional yeast infection when taking antibiotics" for #13

d. patient #8 had a surgical abortion on 6/15/10 and signed the 18 hour consent form "Required components of Abortion Consent Documentation" on the day of the procedure, not at least 18 hours prior to the procedure (pt. had a previous abortion procedure done 6/08)

e. pt. #19 had a surgical abortion on 5/11/10 and signed the 18 hour consent form "Required components of Abortion Consent Documentation" on the day of the procedure, not at least 18 hours prior to the procedure (pt. had a previous abortion procedure done 1/09)

f. pt. #23 had a surgical abortion on 3/12/10 and signed the 18 hour consent form "Required components of Abortion Consent Documentation" on the day of the procedure, not at least 18 hours prior to the procedure (pt. had a previous abortion procedure done 5/09)

g. pt. #24 had a surgical abortion on 3/12/10 and signed the 18 hour consent form "Required components of Abortion Consent Documentation" on the day of the procedure, not at least 18 hours prior to the procedure (pt. had a previous abortion procedure done 8/08)

h. pts. #8, #10 and #21 were lacking documentation of B/P and pulse at the time of discharge in the "Discharge Notes" section of the chart

2. At 2:00 PM on 8/18/10, review of policy and procedure, "Policy for History and Physical for New and Established Patients" (without a date or policy number), indicated:

a. "All patients, regardless of procedure or patient status (new or established) will be screened for following parameters/conditions during their in-take process: Name-Address-Age-...Known Drug Allergies (including level of sensitivity to med)..."

3. Interview with staff member NA at 12:40 PM and 3:30 PM on 8/18/10 indicated:
a. the patient's medical history is captured on both the "intake form" (face sheet) and "Medical History" form
b. a patient's medical history is self reported and checked over by a facility staff member
c. there is no medical history performed by a physician, or medical practitioner qualified by profession or licensing as per standards of practice
d. staff are to question patients related to allergy documentation and to note the type of reaction a patient had to a particular medication--this was absent for patients #2, #7, #11 and #13
e. pts # 8, #19, #23 and #24 all had previous abortions and the facility does not feel they need a repeat of information related to choices/options per IC-34-2-1.1 for a repeat procedure to be performed
f. pts. #8, #10 and #21 are lacking documentation by nursing of B/P and pulse in the discharge notes section of the chart

T 136 410 IAC 26-7-2 MEDICAL RECORDS

(d) An appropriate history and physical examination report must be in the patient ' s chart before a surgical abortion. The report shall include, but is not limited to, the following:

T 136 Continued From page 25 T 136
(1) Vital signs.
(2) Allergies.
(3) Any significant risk factors.
(4) The date written.

This RULE is not met as evidenced by:

Based on patient medical record review, policy and procedure review, and interview, the medical staff failed to ensure an appropriate medical history was performed for 30 out of 30 patients (#1 through #30 that would include any significant risk factors related to the surgical procedure.

Findings:
1. Review of closed patient medical records, through out the survey process of 8/18/10 and 8/19/10, indicated:
a. patient medical records #1 through #30 had patient self reported health/medical history information noted on the "Medical History" form b. patient medical records #1 through #30 were lacking a medical history performed by a qualified practitioner as per standards of practice

d. pt. #1 signed a "Diabetic Risk Form"

e. pt. #14 signed a "Pre existing Condition" form

f. pt. #19 listed 8 pregnancies with 3 previous abortions

g. pt. #20 listed 8 pregnancies with 4 "miscarriages"

2. At 2:00 PM on 8/18/10, review of policy and procedure, "Policy for History and Physical for New and Established Patients" (without a date or policy number), indicated:
a. "All patients, regardless of procedure or patient status (new or established) will be screened for following parameters/conditions during their in-take process: Name-Address-Age-...Pre-existing Conditions (including, but not limited to) diabetes, high bp, cardiac conditions, respiratory conditions, seizures, Hepatitis A-D, sickle cell, TB, gynecological conditions, various anemia's)..."

3. Interview with staff member NA at 12:40 PM and 3:30 PM on 8/18/10 indicated:
a. the patient's medical history is captured on both the "intake form" (face sheet) and "Medical History" form
b. a patient's medical history is self reported and checked over by a facility staff member with request for patients to sign the medical risk form, if they deem it necessary
c. there is no medical history performed by a physician, or medical practitioner qualified by profession or licensing as per standards of practice
d. there is no guidance, or policy and procedure, that indicates what criteria indicate a patient may be at risk for a surgical abortion procedure
e. there is no documentation by the physician of having reviewed the patient's self reported medical history
f. there is no documentation by the physician of whether or not a patient has significant risk for the surgical procedure to be performed annual performance evaluations, based on the job description, for each employee and contract and agency personnel.

This RULE is not met as evidenced by: Based on policy and procedure review, personnel record review, and staff interview, the facility failed to ensure annual performance evaluations, based on the job description, for 7 of 7 (P1 through P7) personnel records reviewed.

Findings:
1. Policy titled "Annual Competency for Nursing and Other Para Professional Personnel", reviewed on 8/19/10 at 10:34 AM, indicated on pg. 1, "The Medical Director and/or Advanced Practice Nurse will evaluate all para-professional personnel for competency per annum...The results of these exams will be placed in the personnel section of employee ' s chart and be directly correlated to the employee ' s job description, which they will be read and signed by employee. "

2. Review of personnel records on 8/18/10 at 12:20 PM, indicated:

a. P1 had a hire date of 8/2009 and was lacking documentation of current annual evaluation.

b. P2 had a hire date of 2/2007 and was lacking documentation of current annual evaluation.
c. P3 had a hire date of 9/1982 and was lacking documentation of current annual evaluation.
d. P4 had a hire date of 9/2004 and was lacking documentation of current annual evaluation.
e. P5 had a hire date of 4/2005 and was lacking documentation of current annual evaluation.
f. P6 had a hire date of 8/2003 and was lacking documentation of current annual evaluation.
g. P7 had a hire date of 9/2004 and was lacking documentation of current annual evaluation.

3. Personnel P7 was interviewed on 8/18/10 at 1:56 PM and indicated the above mentioned personnel records were lacking documentation of current annual evaluation as required per facility policy and procedure.

T 152 410 IAC 26-8-2 PERSONNEL POLICIES AND RECORDS 410 IAC 26-8-2(3)(A)
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 follows:
(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.

This RULE is not met as evidenced by: Based on policy and procedure review, personnel record review, and staff interview, the facility failed to ensure documentation of 2-step Mantoux testing for 2 of 2 (P3 and P7) personnel records reviewed.

Findings:
1. Policy titled "Infection Control Committee Membership", reviewed on 8/19/10 at 10:07 AM, indicated on pg. 1, "The Infection Control Committee will regulate employees for vaccinations, titers and TB (Tuberculosis) testing ...All employees must be current for TB testing. "

2. Review of personnel records on 8/18/10 at 12:20 PM, indicated:
a. P3 had a hire date of 9/1982 and was lacking current documentation of 2-step Mantoux testing.
b. P7 had a hire date of 9/2004 and was lacking current documentation of 2-step Mantoux testing.

3. Personnel P7 was interviewed on 8/18/10 at 1:56 PM and indicated the above mentioned personnel records were lacking documentation of current 2-step Mantoux testing as required per facility policy and procedure.

T 166 410 IAC 26-8-3 PERSONNEL POLICIES AND RECORDS 410 IAC 26-8-3(a)(2)

(a) The clinic must do the following:

(2) Orientate all new employees, including contract and agency personnel, to applicable clinic and personnel policies.

This RULE is not met as evidenced by: Based on policy and procedure review, personnel record review, and staff interview, the facility failed to orientate all new employees to applicable clinic and personnel policies for 7 of 7 (P1 through P7) personnel records reviewed.

Findings:

1. Policy titled "New Employee Orientation", reviewed on 8/19/10 at 10:26 AM, indicated on pg. 1, "All new employees will be oriented through their preliminary employment period of 90 days, through verbal and written instruction. "

2. Review of personnel records on 8/18/10 at 12:20 PM, indicated:
a. P1 had a hire date of 8/2009 and was lacking documentation of orientation to the facility.
b. P2 had a hire date of 2/2007 and was lacking documentation of orientation to the facility.
c. P3 had a hire date of 9/1982 and was lacking documentation of orientation to the facility.
d. P4 had a hire date of 9/2004 and was lacking documentation of orientation to the facility.
e. P5 had a hire date of 4/2005 and was lacking documentation of orientation to the facility.
f. P6 had a hire date of 8/2003 and was lacking documentation of orientation to the facility.
g. P7 had a hire date of 9/2004 and was lacking documentation of orientation to the facility.

3. Personnel P7 was interviewed on 8/18/10 at 1:56 PM and indicated the above mentioned personnel records were lacking documentation of orientation to the facility as required per facility policy and procedure.

T 178 410 IAC 26-9-1 MEDICAL STAFF 410 IAC 26-9-1(c)(1)

The policies must provide for and the medical staff must ensure the following:

(1) An appropriate and timely medical history and physical examination is performed.

This RULE is not met as evidenced by: Based on patient medical record review, policy and procedure review, and interview, the medical director failed to ensure an appropriate medical history was performed for 30 out of 30 patients (#1 through #30).

Findings:
1. Review of closed patient medical records, through out the survey process of 8/18/10 and 8/19/10, indicated:
a. patient medical records #1 through #30 had patient self reported health/medical history information noted on the "Medical History" form
b. patient medical records #1 through #30 were lacking a medical history performed by a qualified practitioner

2. At 2:00 PM on 8/18/10, review of policy and procedure, "Policy for History and Physical for New and Established Patients" (without a date or policy number), indicated:

a. "All patients, regardless of procedure or patient status (new or established) will be screened for following parameters/conditions during their in-take process:
Name-Address-Age-...Known Drug Allergies (including level of sensitivity to med)..."

T 178 Continued From page 32 T 178

3. Interview with staff member NA at 12:40 PM and 3:30 PM on 8/18/10 indicated:

a. the patient's medical history is captured on both the "intake form" (face sheet) and "Medical History" form
b. a patient's medical history is self reported and checked over by a facility staff member
c. there is no medical history performed by a physician, or medical practitioner qualified by profession or licensing, as per standards of practice
d. the facility policy and procedure, as stated in

2. above, does not indicate that a qualified medical professional/practitioner must perform an

appropriate and timely medical history

T 180 410 IAC 26-9-1 MEDICAL STAFF 410 IAC 26-9-1(c)(2)

The policies must provide for and the medical staff must ensure the following:

(2) All physician orders:
(A) are in writing or acceptable computerized form;
(B) must be authenticated by a responsible physician as allowed by clinic policies not to exceed thirty (30) days.

This RULE is not met as evidenced by: Based on document review and interview, the facility failed to ensure a policy to ensure that physician orders must be authenticated by a physician within thirty days.

Findings include:

1. Review of facility documents on 8-18-10 indicated lack of evidence of a policy ensuring that physician orders are authenticated by a physician within thirty days.

2. Interview with #S1 on 8-18-10 at 1500 hours confirmed that the facility does not have a policy related to authentication of orders by a physician. Additional documents were requested; none were provided prior to exit.

T 194 410 IAC 26-10-1 PATIENT CARE AND NURSING SERVICES 410 IAC 26-10-1(b)(2)

(b) Written patient care policies and procedures must be available to personnel and must include, but not be limited to, the following:

(2) A provision for instruction or instructions to be given to the patient or the patient ' s legal representative regarding follow-up care and transportation needed by the patient on discharge following a surgical abortion to include at least the following:
(A) Signs and symptoms of possible complications.
(B) Activities allowed and to be avoided.
(C) Hygienic and other postdischarge procedures to be followed.
(D) Clinic emergency phone numbers available on a twenty-four (24) hour basis.
(E) Follow-up appointment, if indicated.
(F) Counseling regarding Rh typing.
(G) Administration of Rh immune globulin, if indicated, unless:
(i) the patient signs a waiver refusing the administration; or
(ii) other arrangements for administration are documented.

This RULE is not met as evidenced by: Based on patient medical record review and interview, the facility failed to ensure that counseling for patients occurred, related to Rh typing and Rho Gam administration, and was documented for 3 of 3 Rh negative patients (Pts. #7, #12 and #29).
Findings:
1. Review of closed patient medical records through out the survey process of 8/18/10 and 8/19/10, indicated patients #7, #12, and #29 were Rh negative and required administration of Rho Gam, but all lacked any documentation of counseling related to the Rho Gam need and process

2. Interview with staff member NA at 3:15 PM on 8/18/10 indicated:

a. there is "no counseling done" with patients related to the Rh typing and need for Rho Gam, if negative
b. the process is "explained if needed", but not documented anywhere

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 observation and interview, the facility failed to ensure a safe and healthful environment that minimizes infection exposure to patients, health care workers and persons who accompany patients.

Findings include:

1. While touring the facility on 8-19-10 at 0955 hours, the following was observed in the central sterile room which poses the risk for infection exposure to patients:
a.) The dirty area for cleaning instruments was next to the clean wrapping area for instruments.
b.) The sterile wrapped instruments are in the same room on shelves next to the red-bagged biohazardous waste container, dirty instruments, and two (2) bags of dirty towels.
c.) The clean linens are in the same room on shelves next to the red-bagged biohazardous waste container, dirty instruments, and two (2) bags of dirty towels.
d.) Two bags of dirty towels were observed, one bag in a plastic container, and the second bag on the floor.

2. On 8-19-10 at 0955 hours, #S2 indicated one bag of dirty towels was one week old, the 2nd bag was two weeks old; waiting for laundry pick up.
#S2 confirmed the above findings.

T 214 410 IAC 26-11-1 INFECTION CONTROL PROGRAM410 IAC 26-11-1(c)

(c) The clinic must designate a person qualified by training or experience as responsible for the following:

(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 medical staff record review and staff interview, the facility failed to designate a person qualified by training or experience as responsible for ongoing infection control activities and the development and implementation of policies related to infection control.

Findings:
1. Review of medical staff records on 8/18/10 at 12:30 PM indicated S3 lacked documentation of training or experience in infection control.

2. Personnel P7 was interviewed on 8/18/10 at 1:56 PM and confirmed the above mentioned medical staff record was lacking documentation of training or experience in infection control.

T 248 410 IAC 26-11-2 INFECTION CONTROL PROGRAM 410 IAC 26-11-2(a)(3)

(3) Records of results must be maintained and evaluated periodically to include, but not be limited to, the following:

(A) Records of recording thermometers or a daily record of the sterilizing cycle:

(i) date;
(ii) time;
(iii) temperature;
(iv) pressure; and
(v) contents; for each sterilizer load.

(B) Results of biological indicators used in testing the sterilizing processes.

This RULE is not met as evidenced by: Based on policy and procedure review, observation, and staff interview, the facility failed to maintain a daily record of the sterilizing cycle that includes: date, time, temperature, pressure, and contents for each sterilizer load; and the results of biological indicators used in testing the sterilizing processes.

Findings:

1. Policy titled, "Policy for Sterilization Cycles and Results of Biological Indicators" was reviewed on 8/19/10 at 9:45 AM and indicated, "The Instrument Technician will keep accurate and up to date records of all sterilization cycles, including date, time, temperature, pressure and contents. The Instrument Technician will also keep accurate and up to date records of all biological indicators and or spore testing in regards to equipment used for sterilization."

2. While on tour of the facility on 8/19/10 at 10:45 AM, it was observed that a daily record of the sterilizing cycle had not been maintained. The last entries in the log were on 9/27/06 and 7/6/07.

3. Personnel P7 was interviewed on 8/19/10 at 11:05 AM and confirmed a daily record of the sterilizing cycle had not been maintained and kept up-to-date.

T 296 Continued From page 38 T 296 410 IAC 26-13-3 ANESTHESIA AND SURGICAL 410 IAC 26-13-3(b)

(b) The following equipment and supplies must be available to the procedure and recovery areas:

(1) Emergency call system.
(2) Oxygen.
(3) Resuscitation equipment.

This RULE is not met as evidenced by: Based on observation and staff interview, the facility failed to ensure resuscitation equipment related to oral suction was available to the procedure and recovery areas.

Findings:

1. While on tour of the facility on 8/19/10 at 10:45 AM, it was observed that no oral suction resuscitation equipment was available in the procedure or recovery areas.

2. Personnel P7 was interviewed on 8/19/10 at 11:05 AM and confirmed there was no resuscitation equipment related to oral suction available to the procedure and recovery areas.

T 322 410 IAC 26-16-1 PHARMECEUTICAL SERVICES410 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;
(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 patient medical record review, policy and procedure review, and interview, the facility failed to implement its policy related to standing orders for 30 out of 30 patients for take home Doxycycline and failed to require the authentication of medication administration to ensure that only licensed/qualified staff are giving patient medications in 30 of 30 patient records (pts. #1 through #30).

Findings:

1. At 2:00 PM on 8/18/10, review of the policy and procedure, "Policy for Verbal Orders", (lacking a policy number), with a hand written date at the top right of the page as: 7/24/08, read:
a. "Only Medical Director Authorized employees are allowed to take verbal orders and call in prescriptions. The Employee allowed to take verbal orders is Valerie Miller (L.P.N.)."

2. At 3:15 PM on 8/18/10, review of the policy and procedure (from the "Protocol Manual, page 64), titled "Medications Standing Orders", indicated:
a. "Staff may administer the following medications...Post-Operative Medications"
A. "A. Antibiotics: Doxycycline 100 mg. or tetracycline 500 mg to be taken twice a day until gone (10 tablets for 5 days)..."
B. "B. Ergotrate: 0.2 mg to be given following the procedure if pregnancy is over 12 weeks. 0.2 mg. IM or IV may be ordered in certain cases at the physician's discretion. Methergine may be substituted if ergotrate is not available."
C. "C. Non-steroidal anti-inflammatory medications Patient instructed to use if needed for pain or cramps..."
D. "D. Acetaminophen: 1 - 2 extra strength tablets may be given in Ready Room or recovery if allergic to aspirin family of drugs..."

3. At 11:45 AM on 8/19/10, review of policy and procedure "Policy for Distributing and Charting Medications" (lacking a date or policy number), indicated:
a. "All support staff (nurses, medical assistants etc.) that distribute prescription medication to patients for immediate or later ingestion will chart date and time medication is given, with lot #'s and expiration dates, dosage and route..."

4. Review of closed patient medical records, through out the survey process of 8/18/10 and 8/19/10, indicated:
a. patients #1 through #30 received "Doxycycline Hyclate 100 mg #15 tablets Sig: i q 12 Hrs." as per stamped documentation in the"Discharge Notes" section of the patient charts
b. time given and authentication by the staff member who dispensed the Doxycycline to patients #1 through #30 is lacking
c. the lot number and expiration date of the Doxycycline is lacking on all 30 patient records

d. patients #1, #5, #6, #8, #9, #10, #11, #13, #15, #16, #18, #20, #23, #28, were given "iv 200 mg Ibuprofen", but are lacking the time this medication was given, the lot number and expiration date are not documented, and there is no authentication by the staff member who gave the medication

e. patients #2, #22, #25, #26 and # 29 were given "ii acetaminophen ES", but are lacking the time this medication was given, the lot number and expiration date are not documented, and there is no authentication by the staff member who gave the medication

f. pts. #7 and #30 had documentation that reads: "gave ii 200 mg Ibuprofen...", but are lacking the time this medication was given, the lot number and expiration date are not documented, and there is no authentication by the staff member who gave the medication

g. patient #14 had the following documentation in the "Discharge Notes" section of the chart:

A. was given "iv 200 mg Ibuprofen", but is lacking the time this medication was given, the lot number and expiration date are not documented, and there is no authentication by the staff member who gave the medication

B. was given a "Rx (prescription) for Vicoprofen 75/200 #6"

C. "Methergine 0.2 mg gave i tab now--Methergine 0..2 mg x 5 tabs take i hs ac then tid ac."

h. pt. #17 was given "...Methergine 0.2 mg i tab now--Methergine 0.2 mg x 9 tabs take i hs ac then TID ac.", but is lacking the time this medication was given, the lot number and expiration date are not documented, and there is no authentication by the staff member who gave the medication

i. pts. #19 and #24 were given: "...iii 200 mg Ibuprofen...", but are lacking the time this medication was given, the lot number and expiration date are not documented, and there is no authentication by the staff member who gave the medication

j. pt. #27 was given: "...i 800 mg Ibuprofen...", but is lacking the time this medication was given, the lot number and expiration date are not documented, and there is no authentication by the staff member who gave the medication

k. patient #9 had a surgical abortion on 6/22/10 and was documented on 6/25/20 at 4:36 PM related to:

A. "...c/o fever (101.0) x 12 hours,..."

B. instructions given: "Pt was advised to start NSAID and to go to pharmacy for Rx...CVS...Ampicillin 500 mg...Cleocin...spoke to pharmacist", but is lacking documentation of this being a verbal order with a date and time of the order and is lacking authentication by the staff member who took the order

5. Interview with staff member NA at 3:30 PM on 8/18/10 indicated:

a. the facility has another LPN (licensed practical nurse) working in the recovery, giving patient medications, and is documenting in the medical record--discharge notes section, but is not authenticating the documentation so that it can be determined that a licensed professional is administering meds as per standards of practice

b. the standing orders policy for Doxycycline indicate dispensing 10 tables for 5 days, when documentation indicates 15 tabs are being sent with patients (all 30 patients received 15 tablets)

c. the standing orders policy does not given a number of 0.2 mg Methergine to dispense--patient # 14 was given 5 tabs; pt. #17 was given 9 tabs and no "verbal order" was written

d. the staff person dispensing/administering medications is not writing that some are verbal orders, if that is the situation

e. at this time, per facility policy, only staff member NA is allowed to take a verbal order, even though another LPN is now working at the facility and dispensing medications

f. the notes for pt. #9 are lacking documentation that the medications ordered at CVS were a verbal order from the physician, and are lacking a date and time of the verbal order and authentication by the nurse accepting that order

g. it is unclear in the standing orders policy, how many Ibuprofen are to be administered and patients were given two, three and four 200 mg tablets without the standing order being defined or a written verbal order being written

h. medications given are lacking documentation of lot numbers, time given and expiration dates for the medications given (as per policy in 3. above)

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 controlled drugs listed in Schedule II of the Comprehensive of 1976 and other drugs subject to abuse must be separately locked.

drugs as designated in item

(ii) must be securely affixed Drug Abuse Prevention and Control Act permanently affixed compartments that are

(iii) Drug carts, if used, with controlled when not in use.

This RULE is not met as evidenced by:

This RULE is not met as evidenced by: Based on observation and staff interview, the facility failed to ensure resuscitation equipment related to oral suction was available to the procedure and recovery areas.

Findings:

1. While on tour of the facility on 8/19/10 at 10:45 AM, it was observed that no oral suction resuscitation equipment was available in the procedure or recovery areas.

2. Personnel P7 was interviewed on 8/19/10 at 11:05 AM and confirmed there was no resuscitation equipment related to oral suction available to the procedure and recovery areas.

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 personnel, including, but not limited to, the

(A) Drug:

(i) handling;

(ii) storing;

(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 patient medical record review, policy and procedure review, and interview, the facility failed to implement its policy related to standing orders for 30 out of 30 patients for take home Doxycycline and failed to require the authentication of medication administration to ensure that only licensed/qualified staff are giving patient medications in 30 of 30 patient records (pts. #1 through #30).

Findings:

1. At 2:00 PM on 8/18/10, review of the policy and procedure, "Policy for Verbal Orders",

(lacking a policy number), with a hand written date at the top right of the page as: 7/24/08, read:
a. "Only Medical Director Authorized employees are allowed to take verbal orders and call in prescriptions. The Employee allowed to take verbal orders is Valerie Miller (L.P.N.)."

2. At 3:15 PM on 8/18/10, review of the policy and procedure (from the "Protocol Manual, page 64), titled "Medications Standing Orders", indicated:

a. "Staff may administer the following medications...Post-Operative Medications"

A. "A. Antibiotics: Doxycycline 100 mg. or tetracycline 500 mg to be taken twice a day until gone (10 tablets for 5 days)..."
B. "B. Ergotrate: 0.2 mg to be given following the procedure if pregnancy is over 12 weeks. 0.2 mg. IM or IV may be ordered in certain cases at the physician's discretion. Methergine may be substituted if ergotrate is not available."
C. "C. Non-steroidal anti-inflammatory medications Patient instructed to use if needed for pain or cramps..."
D. "D. Acetaminophen: 1 - 2 extra strength tablets may be given in Ready Room or recovery if allergic to aspirin family of drugs..."

3. At 11:45 AM on 8/19/10, review of policy and procedure "Policy for Distributing and Charting Medications" (lacking a date or policy number), indicated:
a. "All support staff (nurses, medical assistants etc.) that distribute prescription medication to patients for immediate or later ingestion will chart date and time medication is given, with lot #'s and expiration dates, dosage and route..."

4. Review of closed patient medical records, through out the survey process of 8/18/10 and 8/19/10, indicated:
a. patients #1 through #30 received "Doxycycline Hyclate 100 mg #15 tablets Sig: i q 12 Hrs." as per stamped documentation in the "Discharge Notes" section of the patient charts
b. time given and authentication by the staff member who dispensed the Doxycycline to patients #1 through #30 is lacking
c. the lot number and expiration date of the Doxycycline is lacking on all 30 patient records
d. patients #1, #5, #6, #8, #9, #10, #11, #13, #15, #16, #18, #20, #23, #28, were given "iv 200 mg Ibuprofen", but are lacking the time this medication was given, the lot number and expiration date are not documented, and there is no authentication by the staff member who gave the medication
e. patients #2, #22, #25, #26 and # 29 were given "ii acetaminophen ES", but are lacking the time this medication was given, the lot number and expiration date are not documented, and there is no authentication by the staff member who gave the medication
f. pts. #7 and #30 had documentation that reads: "gave ii 200 mg Ibuprofen...", but are lacking the time this medication was given, the lot number and expiration date are not documented, and there is no authentication by the staff member who gave the medication
g. patient #14 had the following documentation in the "Discharge Notes" section of the chart:
A. was given "iv 200 mg Ibuprofen", but is lacking the time this medication was given, the lot number and expiration date are not documented, and there is no authentication by the staff member who gave the medication
B. was given a "Rx (prescription) for Vicoprofen 75/200 #6"
C. "Methergine 0.2 mg gave i tab now--Methergine 0..2 mg x 5 tabs take i hs ac then tid ac."
h. pt. #17 was given "...Methergine 0.2 mg i tab now--Methergine 0.2 mg x 9 tabs take i hs ac then TID ac.", but is lacking the time this medication was given, the lot number and expiration date are not documented, and there is no authentication by the staff member who gave the medication
i. pts. #19 and #24 were given: "...iii 200 mg Ibuprofen...", but are lacking the time this

ii. medication was given, the lot number and expiration date are not documented, and there is no authentication by the staff member who gave the medication

j. pt. #27 was given: "...i 800 mg Ibuprofen...", but is lacking the time this medication was given, the lot number and expiration date are not documented, and there is no authentication by the staff member who gave the medication

k. patient #9 had a surgical abortion on 6/22/10 and was documented on 6/25/20 at 4:36 PM related to:

A. "...c/o fever (101.0) x 12 hours,..."

B. instructions given: "Pt was advised to start NSAID and to go to pharmacy for Rx...CVS...Ampicillin 500 mg...Cleocin...spoke to pharmacist", but is lacking documentation of this being a verbal order with a date and time of the order and is lacking authentication by the staff member who took the order

5. Interview with staff member NA at 3:30 PM on 8/18/10 indicated:

a. the facility has another LPN (licensed practical nurse) working in the recovery, giving patient medications, and is documenting in the medical record--discharge notes section, but is not authenticating the documentation so that it can be determined that a licensed professional is administering meds as per standards of practice

b. the standing orders policy for Doxycycline indicate dispensing 10 tables for 5 days, when documentation indicates 15 tabs are being sent with patients (all 30 patients received 15 tablets)

c. the standing orders policy does not given a number of 0.2 mg Methergine to dispense--patient # 14 was given 5 tabs; pt. #17 was given 9 tabs and no "verbal order" was written

d. the staff person dispensing/administering medications is not writing that some are verbal orders, if that is the situation

e. at this time, per facility policy, only staff member NA is allowed to take a verbal order, even though another LPN is now working at the facility and dispensing medications

f. the notes for pt. #9 are lacking documentation that the medications ordered at CVS were a verbal order from the physician, and are lacking a date and time of the verbal order and authentication by the nurse accepting that order

g. it is unclear in the standing orders policy, how many Ibuprofen are to be administered and patients were given two, three and four 200 mg tablets without the standing order being defined or a written verbal order being written

h. medications given are lacking documentation of lot numbers, time given and expiration dates for the medications given (as per policy in 3. above)

T 326 410 IAC 26-16-1 PHARMACEUTICAL T 326 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 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 ensure storage of drugs and biologicals in a safe and effective manner in accordance with accepted standards of practice.

Findings include:
1. While touring the facility on 8-19-10 at 0930 hours in the presence of #S2, 25 vials of Lidocaine were observed unsecured on top of a file cabinet in the medical records storage room. The door to the room was observed open on 8-18-10 and 8-19-10.

2. While touring the facility on 8-19-10 at 0955 hours in the presence of #S2, 2 vials of Lidocaine, one of which was open, were observed on a shelf above the dirty instrument cleaning area in the central sterile room.

3. On 8-19-10 at 0930 hours and 0955 hours, #S2 confirmed the vials of Lidocaine were unsecured.

T 396 410 IAC 26-17-2 PHYS. T 396 PLANT,MAINT.,EQUIP.,ENVIR.,SAFETY410 IAC 26-17-2(e)(7)

(e) Requirements for design standards are as follows:
(7) Each building shall have a [sic., at] least two (2) exits that are remote from each other.

This RULE is not met as evidenced by:

Based on observation and interview, the facility failed to have two (2) working exits which are remote from each other.
Findings include:
1. While touring the facility on 8-19-10 at 1015 hours, it was observed that the second exit, located in the recovery room, was not accessible for exit. The door was locked with a key, the opening was covered and taped, and there was no way to access the outside through this door in the case of a fire.
2. On 8-19-10 at 1015 hours, #S2 was requested to open the second exit, located in the recovery room. #S2 removed the covering from the key-lock area, and tried several keys from a cabinet in the recovery room; none of the keys available would unlock/open the door. #S2 confirmed that patients and staff would not be able to exit through the door in case of a fire, leaving the front door at the opposite end of the building as the only working exit.

T 404PLANT,MAINT.,EQUIP.,ENVIR.,SAFETY410 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 policy and procedure review, document review, observation, and staff interview, the facility failed to ensure that no condition was created or maintained that may result in a hazard to patients, visitors, or employees in four of four areas toured (Medication Refrigerator Storage, central sterile room, storage room, recovery room).

Findings include:
1. Policy titled, "Policy for Storage and Security of all On-Site Medications" was reviewed on 8/19/10 at 9:55 AM and indicated, "Medications that require storage at temperature lower than room temperature will be kept in a secure refrigerated area, which will have a thermometer whose levels are logged every day."

2. Review of the Protocol Manual indicated on page 26, point H., "Temperatures for the refrigerator and the Lab shall be monitored on a daily basis and recorded on a temperature log."

3. While on tour of the facility on 8/19/10 at 10:45 AM, it was observed that the a Daily Temperature Log lacked daily entries for recording the temperature of the fridge where medications were stored.

4. Personnel P7 was interviewed on 8/19/10 at 11:05 AM and confirmed temperatures of the medication refrigerator were not being recorded daily and were not up-to-date as required per facility policy and procedure.

5. While touring the facility on 8-19-10 at 0930 hours in the presence of #S2, the following was observed:
a.) Three (3) cardboard boxes were stored directly on the floor in the central sterile room.
b.) Seven (7) cardboard boxes were stored directly on the floor in the storage room.
c.) A light fixture was detached and hanging down in the storage room.
d.) An unsecured fire extinguisher was sitting on a box in the central sterile room.
e.) An unsecured fire extinguisher was sitting on the floor in the recovery room.
f.) A bag of dirty towels was laying directly on the floor in the central sterile room.

2. Interview with #S2 on 8-19-10 at 1015 hours, following the facility tour, confirmed the observation of the above findings during the facility tour.

T 408 410 IAC 26-17-3 PHYS. T 408PLANT,MAINT.,EQUIP.,ENVIR.,SAFETY410 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 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 ensure that the heating and air conditioning systems are maintained according to the written agreement with a heating and cooling company, #S4.

Findings include:

1. Review of facility documents on 8-18-10 indicated an agreement with a heating and cooling company (#S4) to service, clean and change filters on the furnaces and air conditioners twice yearly.

2. Review of facility documents on 8-18-10 indicated lack of evidence that the furnaces/air conditioners were serviced, cleaned, or filters changed in 2009 and 2010.

3. Interview with #S1 on 8-18-10 at 1530 hours confirmed that there is no documentation to indicate that the furnaces/air conditioners were serviced, cleaned, or had the filters changed in

2009 and 2010. Additional documents were requested; none were provided prior to exit.

T 436 410 IAC 26-17-6 PHYS. T 436 PLANT,MAINT.,EQUIP.,ENVIR.,SAFETY 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 facility failed to ensure a written fire control plan and failed to conduct fire drills for 2 of 4 quarters over the past 12 months.

Findings include:

1. Review of facility documents on 8-18-10 indicated lack of evidence of a written fire control plan.
2. Review of fire drills on 8-18-10 indicated drills were conducted 9-22-09 (3rd quarter of 2009), and 1-26-10 (1st quarter 2010). Documentation lacked evidence that drills were conducted during the 4th quarter of 2009 or 2nd quarter of 2010. Documentation of drills lacked the time the drill was conducted.
3. Interview with #S1 on 8-18-10 at 1450 hours confirmed that facility does not have a written fire control plan and that there was no documentation of fire drills being conducted during the 4th quarter of 2009 or the 2nd quarter of 2010.
Additional documents were requested; none were provided prior to exit.

T 438 410 IAC 26-17-6 PHYS. T 438PLANT,MAINT.,EQUIP.,ENVIR.,SAFETY410 IAC 26-17-6(a)(6)

(a) A safety management program must include, but not be limited to, the following:

(6) Maintenance of written evidence of regular inspection and approval by state or local fire control agencies in accordance with the following:
(A) Clinic policy.
(B) State and local regulations.

This RULE is not met as evidenced by: Based on document review and interview, the facility failed to ensure evidence of an inspection by the state or local fire control agency for 2009 or 2010.

Findings include:
1. Review of facility documents on 8-18-10 indicated the most recent fire inspection conducted by the local fire department was 5-15-08.

2. Interview with #S1 on 8-18-10 at 1530 hours indicated that the most recent fire inspection conducted by the local fire department was 5-15-08; #S1 indicated the facility has not

requested an inspection from the state or local fire control agencies. Additional documents were requested; none were provided prior to exit.

T 440 410 IAC 26-17-6 PHYS. T 440 PLANT,MAINT.,EQUIP.,ENVIR.,SAFETY 410 IAC 26-17-6(a)(7)

(a) A safety management program must include, but not be limited to, the following:

(7) Emergency and disaster preparedness coordinated with appropriate community, state, and federal agencies.410 IAC 26-17-6

This RULE is not met as evidenced by: Based on document review and interview, the facility failed to coordinate emergency and disaster preparedness with an appropriate community, state, or federal agency.

Findings include:
1. Review of facility documents on 8-18-10 indicated lack of evidence that the facility had coordinated emergency and disaster preparedness with an appropriate community, state, or federal agency.

2. Interview with #S1 on 8-18-10 at 1510 hours confirmed that the facility had not coordinated emergency and disaster preparedness with an appropriate community, state, or federal agency. Additional documents were requested; none were provided prior to exit.

T 442 410 IAC 26-17-6 PHYS. T 442PLANT,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 maintain any battery-powered lights or sufficient equipment needed to provide safety to employees and staff in the event of a power loss.

Findings include:

1. While touring the facility on 8-19-10 at 0930 hours, it was observed that the facility lacked battery-powered light or sufficient equipment needed to provide safety to employees and staff in the event of a power loss.
2. On 8-19-10 at 0930 hours while touring the facility, #S2 confirmed that the facility does not have any battery-operated lights or equipment needed to provide safety to employees and staff in the event of a power loss.