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T 000	INITIAL COMMENTS The visit was for a licensure survey. Facility Number: 011118 Survey Date: 11-12-14 to 11-13-14 Surveyors: Brian Montgomery, RN Public Health Nurse Surveyor Linda Plummer, RN Public Health Nurse Surveyor Marcia Anness, RN Public Health Nurse Surveyor Chris Greeney Life Safety Surveyor QA: claughlin 11/26/14	T 000		
T 056	410 IAC 26-4-2 GOVERNING BODY 410 IAC 26-4-2(d)(1) (d) In appointing or contracting with medical staff, the governing body shall do the following: (1) Ensure that appointments to or contracts with medical staff are acted upon with the advice and recommendation of the medical director. This RULE is not met as evidenced by: Based on document review and interview, the governing body failed to ensure that	T 056		

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T 056	Continued From page 1	T 056		

appointments to the medical staff were acted upon the advice and recommendation of the medical director for 3 of 3 medical staff files reviewed. (MD12, MD16 & MD17)

Findings:

1. The Medical Standards and Guidelines (revised 5-14) provided on 11-12-14 at 1130 hours and identified by the director of special projects A1 and regional director A2 as the abortion clinic medical staff bylaws indicated the following: "Clinician - such as physician (MD or DO)...all clinicians supervising or performing services are credentialed as required by ARMS [Affiliate Risk Management Services]....the following medical services require additional training and privileges...LEEP [Loop Electrosurgical Excision Procedure] (physician only)...Abortion (physician only)...Sterilization (physician only)..." The Medical Standards and Guidelines failed to ensure that the credential file for each candidate requesting appointment or reappointment included evidence of the privileges being requested to validate the governing body approval to perform such procedures.

2. The credential files for MD12, MD16 and MD17 lacked documentation of the most recent application for reappointment including the privileges being requested for approval by the governing body. Each credential file lacked documentation that MD11 (Medical Director) had reviewed and made recommendations to the Governing Body for MD12, MD16 and MD17's facility privileges. Each credential file lacked documentation that the governing body had approved privileges for MD12, MD16 or MD17.

3. On 11-13-14 at 1420 hours, the director of

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T 056	Continued From page 2 special projects A1 and quality assurance coordinator A4 were requested to provide documentation indicating the privileges requested by the clinical staff candidates for reappointment and none was provided prior to exit. 4. During an interview on 11-13-14 at 1630 hours, the quality assurance coordinator A4 confirmed that the credential files for MD12, MD16 and MD17 lacked documentation indicating the privileges requested for clinical staff reappointment, lacked documentation indicating that the medical director MD11 had reviewed and approved the privileges requested by each clinical staff candidate, and lacked documentation of the privileges granted by the governing body in response to a clinical staff request and medical director recommendation.	T 056		
T 076	410 IAC 26-4-2 GOVERNING BODY 410 IAC 26-4-2(g)(2) (g) The governing body is responsible for services delivered in the clinic by contractors for medical services. The governing body shall ensure the following: (2) That the services performed under a contract are: (A) provided in a safe and effective manner; and (B) included in the clinic ' s quality assessment and improvement program. This RULE is not met as evidenced by:	T 076		

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T 076	Continued From page 3 Based on document review and interview, the governing body failed to ensure that its contracted services were provided safely and effectively and evaluated through its quality assessment and improvement program. Findings: 1. The Manual of Medical Standards and Guidelines (approved 1-13) Clinical Program Structure: X. Risk and Quality Management failed to indicate a process for ensuring all contracted services at the clinic were evaluated and reviewed through its quality assessment and improvement (QA&I) program. 2. The 2014 Quality Improvement Work Plan failed to indicate a requirement for reviewing all contracted services through the clinic QA&I program. 3. The untitled document indicating 71 services under contract with the abortion clinic lacked an adequate description of the scope and nature of services provided to associate a vendor with the services reported by the Quarterly Vendor Review Form. 4. The Quarterly Vendor Review Form failed to indicate the name of the abortion clinic or the name of more than one of nine contracted services being reviewed by the tool. The anonymous provider form failed to ensure that each contracted service was evaluated for ongoing effectiveness at the clinic location. 5. The Quality Management and Infection Control committee meeting dated 6-02-14 failed to indicate a clinic location for the Vendor Review entry regarding a report of concern involving a	T 076		

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T 076	Continued From page 4 medical waste disposal service and failed to indicate documentation of a corrective action or committee recommendation in response. 6. During an interview on 11-13-14 at 0935 hours, quality assessment coordinator A4 confirmed that the Quarterly Vendor Review Form failed to ensure that all contracted services were provided in a safe and effective manner and reviewed through the QA&I program.	T 076		
T 078	410 IAC 26-4-2 GOVERNING BODY 410 IAC 26-4-2(g)(3) (g) The governing body is responsible for services delivered in the clinic by contractors for medical services. The governing body shall ensure the following: (3) That the clinic maintains a list of all contracted services, including the scope and nature of the services provided. This RULE is not met as evidenced by: Based on document review and interview, the center failed to maintain a list of all contracted services, including the scope and nature of services provided for 39 of 71 services. Findings: 1. A list of contracted services provided by quality assessment coordinator A4 failed to indicate the scope and nature of services provided for 13	T 078		

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T 078	Continued From page 5 services described as clinic supplies, 12 services described as maintenance / janitorial, 6 services described as equipment leasing & repair, 4 services described as lab fees, and 4 services described as telephone. 2. Review of center documentation indicated the following service providers: answering service by CS1, biomedical equipment service by CS2, environmental services provided by CS3, fire extinguisher service and fire alarm equipment certification by CS4, fire alarm monitoring service by CS5, fire sprinkler maintenance by CS6, generator service by CS7, heating and air conditioning service by CS8, mechanical engineering by CS9, medical gases by CS10, pathology services by CS11, pest control by CS12, pharmaceutical supply by CS13, trash disposal by CS14, and ultrasound equipment service by CS15. 3. During an interview on 11-13-14 at 0935 hours, quality assessment coordinator A4 confirmed that the list of contracted services had not been maintained.	T 078		
T 103	410 IAC 26-6-1 QUALITY ASSESSMENT AND IMPROVEMENT 410 IAC 26-6-1(b) (b) The clinic shall take appropriate action to address the opportunities for improvement found through the quality assessment and improvement program as follows: (1) The action must be documented. (2) The outcome of the action must be documented as to its effectiveness, continued follow-up, and impact on patient care.	T 103		

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This RULE is not met as evidenced by:
Based on document review and interview, the center failed to document an appropriate action or continued follow-up in response to opportunities for improvement identified through the quality assessment and improvement (QA&I) program.

Findings:

1. The Quality Management and Infection Control committee minutes dated 3-3-14 indicated the following: "Subject - Data Review / Audit Summary ...Discussion Summary ...Terminated Pregnancy Report...audits were reviewed." No QA&I committee meeting documentation indicated that the clinic associated with the licensing survey failed the Terminated Pregnancy Report audit completed in January or indicated a committee recommendation or action in response to the undocumented deficiency.

2. The Report of Management Operations for the period 1-01-14 to 3-31-14 indicated that the survey clinic failed the Terminated Pregnancy Report audit completed in January and no documentation indicated a corrective action in response to the identified deficiency. The management report indicated that a re-audit would occur in April and indicated that the report was submitted to the Board of Directors on 4-05-14.

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T 103	Continued From page 7 3. The Governing Board meeting minutes dated 4-05-14 indicated the following: "Did have an audit issue with terminated pregnancy reports. 3 of 4 centers didn't pass audit. Will be re-auditing ..." The governing board minutes failed to indicate a corrective action in response to the identified deficiency. 4. The Quality Management and Infection Control committee minutes dated 6-02-14 failed to indicate that a Terminated Pregnancy Report audit was repeated for the survey clinic or the two other centers that didn't pass the initial audit. 5. The Report of Management Operations for the period 4-01-14 to 6-30-14 failed to indicate that the Terminated Pregnancy Report audit was repeated for the survey clinic. 6. The Quality Management and Infection Control committee minutes dated 6-02-14 indicated the following: "...two complications at [the survey clinic] that may have been a result of incorrect ultrasound imaging. This has been rectified ..." The documentation failed to indicate the corrective action or indicate a committee recommendation including ongoing monitoring of the action for its effectiveness. 7. The Report of Management Operations for the period 4-01-14 to 6-30-14 failed to indicate documentation related to ultrasound issues. 8. The Governing Board meeting minutes dated 8-23-14 indicated the following: "A Report of Management Operations handout was given to the board ...It includes ultrasound issues ..." The board minutes failed to indicate a specific clinic management report associated with the ultrasound issues and failed to indicate an action	T 103		

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T 103	Continued From page 8 or governing board recommendation including ongoing monitoring of an action for its effectiveness 9. During an interview on 11-13-14 at 1020 hours, quality assessment coordinator A4 confirmed that the QA&I committee minutes and the survey clinic reports of management operations lacked documentation of actions or committee recommendations in response to deficiencies.	T 103		
T 132	410 IAC 26-7-2 MEDICAL RECORDS 410 IAC 26-7-2(b) (b) Entries in the medical record must be as follows: (1) Legible. (2) Complete. (3) Made by authorized individuals as specified in clinic and medical staff policies. (4) Authenticated and dated in accordance with this article. This RULE is not met as evidenced by: Based on policy and procedure review, medical record review, and staff interview, the facility failed to ensure the implementation of its policy related to complete medical records for 26 of 30 patient record. (Pts. #1 through #19, #23, #24, #25, #26, #27, #29, and #30.); and failed to ensure the authentication of 27 of 30 records reviewed. (Pts. #1 through #10, #12, #13, #14, #15, #17 through #27, #29, and #30.) Findings:	T 132		

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T 132	Continued From page 9 1. Review of the policy and procedure "Clinical Program Structure", I-A-1, PPINK revised May 2014, indicated: a. On page 11, under section "VI. Maintaining Affiliate Medical Records", it reads; "...Records must be 1. factual, complete, concise, and professional...". b. On page 12, it reads in item 9.: "...records are completely and accurately documented by only those staff who are authenticated on the signature cards maintained by the Human Resources. Department...". 2. Review of medical records indicated: a. Pt. #1: A. Lacked completion in the: I. "Procedure" portion of the medical record in the area: "Abortion performed under ultrasound--no/yes" (provider failed to check one of the boxes). II. "Plan" portion of the chart for "Discharge pt. from recovery room per protocol..." - the practitioner failed to check the box giving an order for discharge from the recovery area. III. "Sedation Management" portion of the chart for "VS (vital signs) stable throughout procedure" and "Ready for transport/transfer to recovery room". B. Lacked authentication in the "Provider signoff" areas of the "History" and "Abortion (surgical)" sections of the chart. b. Pt. #2: A. Lacked completion in the: I. "Abortion History" section related to "Drug/alcohol use in the last 24 hrs. - yes/no" (One of the boxes not checked.) II. "Procedure" portion of the medical record in the area: "Abortion performed under ultrasound--no/yes". Provider failed to check one	T 132		

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of the boxes.)
B. Lacked authentication in the "Provider signoff" areas of the "History" and "Abortion (surgical)" sections of the chart.

c. Pt. #3:
A. Lacked completion in the:
I. "Procedure" portion of the medical record in the area: "Abortion performed under ultrasound--no/yes". (Provider failed to check one of the boxes.)
II. "Plan" portion of the chart for "Discharge pt. from recovery room per protocol...". (The practitioner failed to check the box giving an order for discharge from the recovery area.)
B. Lacked authentication in the "Provider signoff" areas of the "History" and "Abortion (surgical)" sections of the chart.

d. Pt. #4:
A. Lacked completion in the:
I. "Physical Exam" portion of the chart related to "airway adequate - no/yes". (Box not checked for this patient who received IV sedation.)
II. "Plan" portion of the chart for "Discharge pt. from recovery room per protocol...". (The practitioner failed to check the box giving an order for discharge from the recovery area.)
B. Lacked authentication in the "Provider signoff" areas of the "History" and "Abortion (surgical)" sections of the chart.

e. Pt. #5:
A. Lacked completion in the:
I. "POC (product of conception) portion of the chart for: "Tissue exam consistent with documented gestational age". (Box not checked.)
II. "Plan" portion of the chart for "Discharge pt. from recovery room per protocol...". (The

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practitioner failed to check the box giving an order for discharge from the recovery area.)
B. Lacked authentication in the "Provider signoff" areas of the "History" and "Abortion (surgical)" sections of the chart.

f. Pt. #6:
A. Lacked completion in the:
I. "Physical Exam" portion of the chart related to "airway adequate - no/yes". (Box not checked for this patient who received IV sedation.)
II. "Plan" portion of the chart for "Discharge pt. from recovery room per protocol...". (The practitioner failed to check the box giving an order for discharge from the recovery area.)
B. Lacked authentication in the "Provider signoff" areas of the "History" and "Abortion (surgical)" sections of the chart.

g. Pt. #7:
A. Lacked completion in the:
I. "Plan" portion of the chart for "Discharge pt. from recovery room per protocol...". (The practitioner failed to check the box giving an order for discharge from the recovery area.)
B. Lacked authentication in the "Provider signoff" areas of the "History" and "Abortion (surgical)" sections of the chart.

h. Pt. #8:
A. Lacked completion in the:
I. "Abortion History" section related to "Drug/alcohol use in the last 24 hrs. - yes/no". (One of the boxes not checked.)
II. "Plan" portion of the chart for "Discharge pt. from recovery room per protocol...". (The practitioner failed to check the box giving an order for discharge from the recovery area.)
B. Lacked authentication in the "Provider signoff" areas of the "History" and "Abortion

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T 132	Continued From page 12 (surgical)" sections of the chart. i. Pt. #9: A. Lacked completion in the: I. "Abortion History" section related to "Drug/alcohol use in the last 24 hrs. - yes/no". (One of the boxes not checked for a pt. receiving IV sedation.) II. "POC portion of the chart for: "Tissue exam consistent with documented gestational age". (Box not checked.) III. "Plan" portion of the chart for "Discharge pt. from recovery room per protocol...". (The practitioner failed to check the box giving an order for discharge from the recovery area.) B. Lacked authentication in the "Provider signoff" areas of the "History" and "Abortion (surgical)" sections of the chart. j. Pt. #10: A. Lacked completion in the: I. "Sedation Management" portion of the chart for "VS (vital signs) stable throughout procedure" and "Ready for transport/transfer to recovery room". II. "Plan" portion of the chart for "Discharge pt. from recovery room per protocol...". (The practitioner failed to check the box giving an order for discharge from the recovery area.) B. Lacked authentication in the "Provider signoff" areas of the "History" and "Abortion (surgical)" sections of the chart. k. Pt. #11: A. Lacked completion in the: I. "Procedure" portion of the medical record in the area: "Abortion performed under ultrasound--no/yes". (Provider failed to check one of the boxes.) II. "Sedation Management" portion of the chart	T 132		

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T 132	Continued From page 13 for "VS (vital signs) stable throughout procedure" and "Ready for transport/transfer to recovery room". l. Pt. #12: A. Lacked completion in the: I. "Procedure" portion of the medical record in the area: "Abortion performed under ultrasound--no/yes". (Provider failed to check one of the boxes.) II. "Procedure" portion of the medical record in the area of "Start Time" and "Stop Time" of the procedure. B. Lacked authentication in the "Provider signoff" areas of the "History" and "Abortion (surgical)" sections of the chart. m. Pt. #13: A. Lacked completion in the: I. "Procedure" portion of the medical record in the area: "Abortion performed under ultrasound--no/yes". (Provider failed to check one of the boxes.) II. "Sedation Management" portion of the chart for "VS (vital signs) stable throughout procedure" and "Ready for transport/transfer to recovery room". B. Lacked authentication in the "Provider signoff" areas of the "History" and "Abortion (surgical)" sections of the chart. n. Pt. #14: A. Lacked completion in the: I. "Abortion History" section related to "Drug/alcohol use in the last 24 hrs. - yes/no". (One of the boxes not checked for a pt. receiving IV sedation.) II. "Abortion History" section related to: "Currently ill or sick - no/yes; Pulmonary embolus - no/yes; and Cerebrovascular accident no/yes"	T 132		

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not marked on the history form.
III. "POC portion of the chart for: "Tissue exam consistent with documented gestational age". (Box not checked.)
IV. "Plan" portion of the chart for "Discharge pt. from recovery room per protocol...". (The practitioner failed to check the box giving an order for discharge from the recovery area.)
V. "Recovery Management" section of the chart, the "Intake Assessment Time" (arrival to the recovery room) was blank and the "arrived via" area was blank.
VI. "Sedation Management" portion of the chart for "VS (vital signs) stable throughout procedure" and "Ready for transport/transfer to recovery room".
B. Lacked authentication in the "Provider signoff" areas of the "History" and "Abortion (surgical)" sections of the chart.

o. Pt. #15:
A. Lacked completion in the:
I. "Plan" portion of the chart for "Discharge pt. from recovery room per protocol...". (The practitioner failed to check the box giving an order for discharge from the recovery area.)
II. "Sedation Management" portion of the chart for "VS (vital signs) stable throughout procedure" and "Ready for transport/transfer to recovery room".
B. Lacked authentication in the "Provider signoff" areas of the "History" and "Abortion (surgical)" sections of the chart.

p. Pt. #16:
A. Lacked completion in the:
I. "Plan" portion of the chart for "Discharge pt. from recovery room per protocol...". (The practitioner failed to check the box giving an order for discharge from the recovery area.)

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T 132	Continued From page 15 II. "Recovery Management" section of the chart, the "Intake Assessment Time" (arrival to the recovery room) was blank and the "arrived via" area was blank. q. Pt. #17: A. Lacked completion in the: I. "Abortion History" section related to "Drug/alcohol use in the last 24 hrs. - yes/no". (One of the boxes not checked for a pt. receiving IV sedation.) II. "Abortion History" section related to: "Currently ill or sick - no/yes; Pulmonary embolus - no/yes; and Cerebrovascular accident no/yes" not marked on the history form. III. "Plan" portion of the chart for "Discharge pt. from recovery room per protocol...". (The practitioner failed to check the box giving an order for discharge from the recovery area.) IV. "Discharge Details" section, the "Patient released to" was blank--staff did not document that a driver was available for this IV sedated patient upon discharge. B. Lacked authentication in the "Provider signoff" areas of the "History" and "Abortion (surgical)" sections of the chart. r. Pt. #18: A. Lacked completion in the: I. "Abortion History" section related to "Drug/alcohol use in the last 24 hrs. - yes/no". (One of the boxes not checked for a pt. receiving IV sedation.) II. "Abortion History" section related to: "Currently ill or sick - no/yes; Pulmonary embolus - no/yes; and Cerebrovascular accident no/yes" not marked on the history form. III. "Plan" portion of the chart for "Discharge pt. from recovery room per protocol...". (The practitioner failed to check the box giving an	T 132		

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order for discharge from the recovery area.)
B. Lacked authentication in the "Provider signoff" areas of the "History" and "Abortion (surgical)" sections of the chart.

s. Pt. #19:
A. Lacked completion in the:
I. "Abortion History" section related to "Drug/alcohol use in the last 24 hrs. - yes/no". (One of the boxes not checked for a pt. receiving IV sedation.)
II. "POC portion of the chart for: "Tissue exam consistent with documented gestational age". (Box not checked.)
III. "Plan" portion of the chart for "Discharge pt. from recovery room per protocol...". (The practitioner failed to check the box giving an order for discharge from the recovery area.)
IV. "Recovery Management" section of the chart, the "Intake Assessment Time" (arrival to the recovery room) was blank and the "arrived via" was blank.
B. Lacked authentication in the "Provider signoff" areas of the "History" and "Abortion (surgical)" sections of the chart.

t. Pt. #20, #21, and #22:
A. Lacked authentication in the "Provider signoff" areas of the "History" and "Abortion (surgical)" sections of the chart.

u. Pt. #23:
A. Lacked completion in the:
I. "Sedation Management" portion of the chart for "VS (vital signs) stable throughout procedure" and "Ready for transport/transfer to recovery room".
B. Lacked authentication in the "Provider signoff" areas of the "History" and "Abortion (surgical)" sections of the chart.

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T 132	Continued From page 17 v. Pt. #24: A. Lacked completion in the: I. "Plan" portion of the chart for "Discharge pt. from recovery room per protocol...". (The practitioner failed to check the box giving an order for discharge from the recovery area.) II. "Sedation Management" portion of the chart for "VS (vital signs) stable throughout procedure" and "Ready for transport/transfer to recovery room". B. Lacked authentication in the "Provider signoff" areas of the "History" and "Abortion (surgical)" sections of the chart. w. Pt. #25: A. Lacked completion in the: I. "Sedation Management" portion of the chart for "VS (vital signs) stable throughout procedure" and "Ready for transport/transfer to recovery room". B. Lacked authentication in the "Provider signoff" areas of the "History" and "Abortion (surgical)" sections of the chart. x. Pt. #26: A. Lacked completion in the: I. "Abortion History" section related to "Drug/alcohol use in the last 24 hrs. - yes/no". (One of the boxes not checked for a pt. receiving IV sedation.) II. "Procedure" portion of the medical record in the area: "Abortion performed under ultrasound--no/yes". (Provider failed to check one of the boxes.) B. Lacked authentication in the "Provider signoff" areas of the "History" and "Abortion (surgical)" sections of the chart. y. Pt. #27:	T 132		

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T 132	Continued From page 18 A. Lacked completion in the: I. "Sedation Preference" section--was blank-no documentation of "local only, IV sedation, moderate, PO (oral) narcotic", etc. II. B. Lacked authentication in the "Provider signoff" areas of the "History" and "Abortion (surgical)" sections of the chart. B. Lacked authentication in the "Provider signoff" areas of the "History" and "Abortion (surgical)" sections of the chart. z. Pt. #29: A. Lacked completion in the: I. "Sedation" section: lacked checking a box for either "IV sedation, "local anesthesia", or "General anesthesia". II. "Procedure" portion of the medical record in the area: "Abortion performed under ultrasound--no/yes". (Provider failed to check one of the boxes.) III. "Plan" portion of the chart for "Discharge pt. from recovery room per protocol...". (The practitioner failed to check the box giving an order for discharge from the recovery area.) B. Lacked authentication in the "Provider signoff" areas of the "History" and "Abortion (surgical)" sections of the chart. aa. Pt. #30: A. Lacked completion in the: I. "Procedure" portion of the medical record in the area: "Abortion performed under ultrasound--no/yes". (Provider failed to check one of the boxes.) II. "Discharge Details" section, "Sedation complications - no/yes" was not checked. B. Lacked authentication in the "Provider signoff" areas of the "History" and "Abortion (surgical)" sections of the chart.	T 132		

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T 132	Continued From page 19 3. At 4:15 PM on 11/12/14 and 12:00 PM on 11/13/14, interview with staff member #41, the regional director, indicated: a. Review of the on line medical records indicates that areas of the medical records are not being completed, as expected per facility policy, as listed in 2. above. 4. At 4:15 PM on 11/13/14, interview with staff member #43, the quality assurance coordinator, indicated: a. Physicians are to electronically "sign off" on the medical records in the areas of "provider sign off". 5. At 5:00 PM on 11/13/14, interview with staff member #40, the director of special projects, indicated: a. There is no policy, or medical staff rule/regulation, that addresses authentication of entries in the medical records, or related to the authentication of the history and physical portions of the medical record.	T 132		
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	T 134		

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T 134	Continued From page 20 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 policy and procedure review, medical record review, and staff interview, the facility failed to ensure that patients had a medical history and physical completed prior to abortion procedures for 7 of 30 patients (Pts. #20, #21, #22, #23, #24, #25, and #30); and failed to document the time of discharge for pt. #25. Findings: 1. Review of the policy and procedure "Analgesia and Sedation Services", I-F-1, with a	T 134		

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T 134	Continued From page 21 PPIN revised date of December 2012 and a PPINK adopted date of July 2013, indicated: a. On page 8, under "VI. Medical Screening And Evaluation For Minimal or Moderate Sedation", it reads: "...Medical History - A targeted medical history that includes screening to rule out possible contraindications must be completed...". b. On page 11, under "VI. Medical Screening And Evaluation For Minimal or Moderate Sedation", it reads: "Physical Examination - Focused physical examination must include 1. vital signs 2. oxygen saturation >95% prior to procedure (for moderate sedation) 3. auscultation of heart and lungs (for moderate sedation) 4. evaluation of the airway (for moderate sedation) 5. additional examination as indicated by history...". 2. Review of medical records indicated: a. Patients #20, #21, #22, and #30 received IV sedation of 100 mcg of Fentanyl and 1 or 2 mg of Versed and lacked the completion of a physical exam prior to sedation and surgical procedure. b. Patients #23, #24, and #25 had Valium (orally) given prior to their abortion procedure, and lacked completion of the physical portion of their history and physical examinations. c. Patient #25 lacked documentation of the time of discharge from the recovery room. 3. At 4:15 PM on 11/12/14 and 12:00 PM on 11/13/14, interview with staff member #41, the regional director, indicated: a. Review of the on line medical records indicates that physicals were not completed, per facility policy, as listed in 2. a. and b. above. b. It was confirmed that pt. #25 lacked documentation of the time of discharge from the recovery room.	T 134		

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T 158	410 IAC 26-8-2 PERSONNEL POLICIES AND RECORDS 410 IAC 26-8-2(3)(D) 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: (D) After baseline testing, tuberculosis screening must be completed annually and must include at a minimum a tuberculin skin test using the Mantoux method or a quantiferon-TB assay unless the individual was subject to subdivision " C " of this subsection [clause (C)]. This RULE is not met as evidenced by: Based on document review, employee health file review, and staff interview, the facility failed to ensure that an annual TB (tuberculosis) test was performed for 1 of 4 health care assistants (N3). Findings: 1. Review of the "Employee Handbook", page 7, indicated: "Health Screening/Immunizations", indicated: a. "Based on the Centers for Disease Control and Prevention (CDC) and/or Indiana Department of Health (IDH) recommendations, PPIN requires that all new health center employees provide negative baseline testing for tuberculosis infection prior to beginning work at PPIN. Annual testing for M. tuberculosis infection is required at some	T 158		

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T 158	Continued From page 23 locations...". 2. Review of employee health files indicated that N1 was hired 1/6/14 and had a negative TB test document provided that indicated their last TB test was read on 10/24/13, but lacked annual TB test documentation for October 2014. 3. At 12:04 PM on 11/12/14, interview with staff member #42, the health center manager, indicated: a. This facility requires annual TB testing. a. The annual TB test for staff member N1 should have occurred in October of this year, per facility policy requirements.	T 158		
T 168	410 IAC 26-8-3 PERSONNEL POLICIES AND RECORDS 410 IAC 26-8-3(b) (b) The clinic shall ensure cardiopulmonary resuscitation (CPR) competence in accordance with current standards of practice and clinic policy for all health care workers including contract and agency personnel who provide direct patient care. This RULE is not met as evidenced by: Based on policy and procedure review, employee file review, and staff interview, the facility failed to ensure CPR (cardio pulmonary) certification for 1 of 4 HCA (health care assistants). (Staff member #3.) Findings:	T 168		

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T 168	Continued From page 24 1. Review of the policy "Clinical Program Structure", I-A-1, PPINK revised May 2014, indicated: a. On page 14, in section 3., it reads: "personnel who have documented current certification in basic cardiopulmonary resuscitation (CPR) in the immediate area while medical or surgical services are being provided. PPINK - staff who work in abortion sites (other than staff who only work the front desk or are PRN [as needed] staff), clinicians, or staff who give injections must have current CPR certification...". 2. Review of HCA employee files indicated that staff member #3 was a HCA hired 3/31/14 and was lacking any CPR certification documentation either expired, or current. 3. At 12:04 PM on 11/12/14, interview with staff member #42, the health center manager, it was indicated that staff member #3 had no CPR certification on file.	T 168		
T 184	410 IAC 26-10-1 PATIENT CARE AND NURSING SERVICES 410 IAC 26-10-1(a)(1) (a) All patient care services must: (1) meet the needs of the patient, within the scope of the service offered, in accordance with acceptable standards of practice; This RULE is not met as evidenced by: Based on policy and procedure review, medical record review, and staff interview, the facility	T 184		

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T 184	Continued From page 25 failed to ensure the implementation of policy, related to the checking of VS (vital signs) in the recovery room, for 18 of 30 patients, Pts. #1 through #6, #8, #9, #12, #17, #18, #20, #21, #22, #23, #24, #26, and #30; and failed to ensure the implementation of the policy related to oxygen saturation and the need for oxygen supplementation for 1 of 17 patients who received IV (intravenous) sedation. (Pt. #2.) Findings: 1. Review of the policy and procedure "Analgesia and Sedation Services", I-F-1, with a PPIN revised date of December 2012 and a PPINK adopted date of July 2013, indicated: a. On page 14, it reads in the section "Recovery Area": "...Vital signs must be taken at the initiation of recovery and then every 15 minutes during the recovery process until discharge...". 2. Review of patient medical records indicated: a. Pt. #1 received oral Valium 5 mg at 9:06 AM on 11/11/14, was received in the recovery room at 10:01 AM and only had one set of VS taken at 10:50 AM, prior to discharge at 10:52 AM. b. Pt. #2 received IV (intravenous) Fentanyl 100 mcg and Versed 1 mg at 9:42 AM on 11/11/14, arrived in the RR (recovery room) at 10:29 AM, had VS taken at 10:33 AM and 11:29 AM with discharge at 11:43 AM--VS were not every 15 minutes, as per policy. c. Pt. #3 received IV Fentanyl 100 mcg and Versed 1 mg at 10:27 AM on 10/17/14, arrived in the RR at 11:24 AM, had VS taken at 12:48 PM. Discharge was at 12:51 PM with VS not taken upon admission to the RR, or every 15 minutes in RR, as required by facility policy. d. Pt. #4 received IV Fentanyl 100 mcg and Versed 1 mg at 11:40 AM on 10/1/14, arrived in the RR at 12:20 PM, and had VS documented at	T 184		

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12:41 PM with discharge at 12:43 PM. No VS were taken upon arrival to the RR area.

e. Pt. #5 received IV Fentanyl 100 mcg and Versed 1 mg at 1:56 PM (this was the time documented in the MR--actual time given was unknown and not documented) on 10/1/14, arrived in the RR at 1:42 PM and had VS at 1:46 PM with DC (discharge) at 1:48 PM. (No arrival VS were taken.)

f. Pt. #6 received IV Fentanyl 100 mcg and Versed 1 mg at 1:51 PM on 10/1/14, arrived in the RR at 2:54 PM and had no VS noted between arrival and discharge at 3:14 PM.

g. Pt. #8 received IV Fentanyl 100 mcg and Versed 1 mg at 11:59 AM on 9/17/14, arrived in the RR at 2:06 PM and had VS documented at 2:31 PM prior to 2:33 PM DC. VS were not taken upon arrival to the RR and every 15 minutes, as per policy.

h. Pt. #9 received oral Valium 5 mg at 3:50 PM (time noted in chart-actual time given unknown) on 9/13/14, arrived in the RR at 2:48 PM with the only VS in RR at 3:50 PM prior to DC at 3:51 PM.

i. Pt. #12 received oral Valium 5 mg at 9:10 AM, arrived in the RR area at 10:15 AM and had VS taken at 10:28 AM prior to discharge, but lacked VS upon arrival to the RR.

j. Pt. #17 received 100 mcg Fentanyl and 1 mg Versed IV at 9:56 AM on 11/5/14, arrived in the RR at 10:33 AM, was discharged at 12:08 PM, and had VS at 10:36 AM and 12:06 PM, but not every 15 minutes as required per facility policy.

k. Pt. #18 received 100 mcg Fentanyl and 1 mg Versed IV at 11:29 AM on 11/5/14, arrived in the RR area at 1:33 PM, was discharged at 1:55 PM, and had one RR VS taken at 1:37 PM--none at DC.

l. Pt. #20 received 100 mcg Fentanyl and 1 mg Versed IV at 11:32 AM on 10/29/14, arrived in the RR at 12:05 PM, was discharged at 1:43 PM, and

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T 184	Continued From page 27	T 184		

only had one set of VS taken in the RR at 1:40 PM.

m. Pt. #21 received IV Fentanyl 100 mcg and Versed 1 mg at 10:26 AM on 10/29/14, arrived in the RR at 10:50 AM, was discharged at 11:50 AM, and had VS taken at 10:51 AM and 11:48 AM, but not every 15 minutes as required per facility policy.

n. Pt. #22 received IV Fentanyl 100 mcg and Versed 1 mg at 12:24 PM on 10/29/14, arrived in the RR at 1:10 PM, was discharged at 1:40 PM, and had VS taken at 1:36 PM, but not upon arrival to the RR.

o. Pt. #23 received oral Valium 5 mg on 10/29/14 at 10:56 AM, arrived in the RR at 11:40 AM, was discharged at 12:15 PM, and RR VS taken only at 12:13 PM.

p. Pt. #24 received oral Valium 5 mg on 10/29/14 at 12:08 PM, arrived in the RR at 1:15 PM, and was discharged at 2:02 PM with the only RR VS at 2:00 PM.

q. Pt. #26 received Fentanyl 100 mcg and Versed 2 mg IV at 10:56 AM on 7/11/14, arrived in the RR at 10:43 AM, was discharged at 11:08 AM, and had RR VS taken at 10:58 AM, but lacked VS upon arrival to the RR.

r. Pt. #30 received Fentanyl 100 mcg and Versed 2 mg IV at 10:21 AM on 7/10/14, arrived in the RR at 10:37 AM, was discharged at 11:16 AM, and had VS taken at 10:37 AM and 11:09 AM, but not every 15 minutes, as per policy.

3. Interview with staff member #41, the regional director, at 4:00 PM on 11/13/14, indicated that VS were not being taken per facility policy for the 18 patients, as listed in 2. above.

4. Review of the policy and procedure "Analgesia and Sedation Services", I-F-1, with a PPIN revised date of December 2012 and a

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T 184	Continued From page 28 PPINK adopted date of July 2013, indicated: a. On page 14, in the middle of the page, it reads: "FYI (for your information) - Prevention and Management of Hypoxemia Supplemental oxygen should be considered for moderate sedation to reduce the frequency of hypoxemia and should be used if hypoxemia develops. If oxygen saturation drops below 93% a clinician must be informed. If oxygen saturation drops below 90% must initiate affiliate protocol for management of respiratory depression...". 5. Review of the medical record for pt. #2 indicated: a. The patient received 100 mcg of Fentanyl and 1 mg Versed at 9:42 AM on 11/11/14 and had an oxygen saturation % of 76 at 10:12 AM during the procedure (that started at 10:10 AM and ended at 10:22 AM, but lacked any documentation that oxygen was begun for this hypoxic patient. 6. Interview with staff member #41, the regional director, at 4:00 PM on 11/13/14, indicated it was unknown what was done about the 76% oxygen level for pt, #2 on 11/11/14 as documentation was lacking, as required per policy.	T 184		
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	T 194		

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T 194	Continued From page 29 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 policy and procedure review, document review, medical record review, and staff interview, the facility failed to ensure documentation of Rh counseling for 5 of 5 patients who were Rh negative (pts. #9, 11, 13, 15, and 28), and failed to ensure the documentation of instructions, regarding hygiene post procedure, for 30 of 30 patients (pts. #1 through #30). Findings: 1. Review of the policy and procedure "Surgical Abortion Services", policy number VII-A1, "adopted" July 2013 and "revised" August 2014, indicated: a. Under section "VII. Medical Screening and Evaluation", it reads: "Laboratory Testing - must include...3. Rh typing - must be	T 194		

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T 194	Continued From page 30 performed...Information regarding Rho (D) immune globulin must be given to the client in writing and must be documented in her medical record...". 2. Review of the medical records for patients #9, #11, #13, #15, and #28 indicated: A. All were Rh negative and required a dose of Rhogam post procedure. B. There was no documentation in the five records related to education and counseling being given to them regarding Rh typing, negativity, and Rhogam need. 3. At 2:30 PM on 11/13/14, interview with staff member #42, the regional director, indicated: A. Staff are providing Rh counseling, but the medical records, as listed in 2. above, lacked documentation of this education. 4. Review of handouts, educational materials, and discharge instructions indicated Hygiene instructions were not addressed in any of the written materials given to patients. 5. Review of the 30 medical records indicated that all were lacking documentation of education/instructions regarding hygiene post procedure. 6. At 4:15 PM on 11/12/14, interview with staff member #42, the regional director, indicated: a. There is nothing in writing regarding hygiene, other than not to douche. b. Staff instruct patients not to tub bathe for two weeks post procedure, but this is not on the written instructions given to patients, nor is it documented in the medical records that this education is being given.	T 194		

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T 208	Continued From page 31	T 208		
T 208	410 IAC 26-11-1 INFECTION CONTROL PROGRAM 410 IAC 26-11-1(a)(2) (a) The clinic must do the following: (2) Maintain a written infection control policy that provides for an active and effective clinic-wide infection control program. This RULE is not met as evidenced by: Based on review of the infection control plan/policy, and interview, the infection control committee/quality committee failed to approve its plan and policies on an annual basis. Findings: 1. Review of the document "Managing Infection Prevention in Health Centers", from the "PPINK Infection Control Manual & OSHA Risk Exposure Plan" binder, adopted 7/2013, indicated: a. On page 1-1, it reads: "...Ongoing Evaluation of Program...Therefore, all policies and procedures that compose the PPINK's Infection Prevention Program must be reviewed by the Quality Management and Infection Control (QMIC) Committee and the Risk and Quality Management (RQM) Committee on an annual basis or whenever new mandates are required." 2. At 4:25 PM on 11/13/14, interview with staff member #43, the quality assurance coordinator, indicated: a. It was thought that the Infection Prevention policies were reviewed/approved at the 12/2013 meeting of the quality/infection control committee,	T 208		

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T 208	Continued From page 32 but meeting minutes do not include any documentation regarding this. b. It cannot be determined the last time that the Infection Prevention policies were approved, so that the policy, as listed in 1. above, was not implemented.	T 208		
T 232	410 IAC 26-11-1 INFECTION CONTROL PROGRAM 410 IAC 26-11-1(e)(2)(E) (e) The clinic must establish a committee to monitor and guide the infection control program in the clinic as follows: (2) The infection control committee responsibilities must include, but are not limited to, the following: (E) Reviewing and recommending changes in procedures, policies, and programs that are pertinent to infection control. These include, but are not limited to, the following: (i) Sanitation, including proper disposal of removed tissue. (ii) Universal precautions, including infectious waste management. (iii) Cleaning, disinfection, and sterilization. (iv) Aseptic technique, invasive procedures, and equipment usage. (v) Reuse of disposables. (vi) A system for handling patients with communicable diseases. (vii) A system, which complies with state and federal law, to monitor the immune status of health care workers exposed to communicable diseases. (viii) An employee health program to	T 232		

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T 232	Continued From page 33 determine the communicable disease history of new personnel as well as an ongoing program for current personnel as required by state and federal agencies. (ix) Requirements for personal hygiene and attire that meet acceptable standards of practice. (x) A program of linen management. This RULE is not met as evidenced by: Based on policy and procedure review, document review, employee file review, and staff interview, the infection control committee failed to implement its policy related to the immune status of staff for rubella, rubeola, and varicella for 4 of 8 employees (N1, N21, N22 and N23) and related to Hepatitis B for 2 staff who requested to receive the series of injections. (N21 and N22) Findings: 1. Review of "Chapter 5 - Occupational Health", from the "PPINK Infection Control Manual and OSHA Exposure Control Plan", adopted 7/2013, indicated: a. Under "Guidelines for Initial - Employment Health Screening", it reads: "...Hepatitis B vaccine is recommended and will be offered to all employees and volunteers who are at risk of exposure to blood or body fluids (blood borne pathogens) within 10 days of onset of employment." b. Under "Recordkeeping", it reads: "...Personnel records for all staff must include a separate section of medical information	T 232		

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T 232	Continued From page 34 including:...Copy of any tests [sic] results relating to immunity of the following infections: Rubella, Mumps, Rubeola, Hepatitis B, Pertussis, and Varicella...". 2. Review of the Personnel Policies in the "PPINK Infection Control Manual and OSHA Exposure Control Plan", in chapter 4., indicated: a. Under "Employee Groups One and Two Employees in groups one and two whose licensing or job duties places them in patient care situations in health centers will be offered the Hepatitis B vaccine within 10 days of initial assignment and MUST receive complete infection control training prior to commencement of their duties. Employee Group One...Nurses...Health Center Assistants...". 3. Review of the welcome letters sent to employees N1, N21, N22, and N23 indicated: a. In the section "Work Safety", it reads: "Working in a PPINK health center requires you to bring some additional documentation for our records. On your first day of employment... you must bring:...Within 30 days of your start date, you must provide evidence of immunity to the following communicable diseases: Measles (Rubeola) Mumps German Measles (Rubella) Chickenpox (Varicella) Whooping cough (Pertussis) You can provide evidence of immunity by providing the Human Resources Department with copies of vaccination records or you can have your blood drawn to show serologic evidence of immunity (a titer). We can also accept a medical record if it shows that a laboratory confirmed you had the disease...". 4. Review of the document "Immunization, Health Care Workers January 2013 - Supplement to PPIN Infection Control Manual", indicated:	T 232		

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T 232	Continued From page 35 a. Under "Policy", it reads: "It is the policy of planned Parenthood of Indiana (PPIN) to minimize risks from communicable diseases and to ensure compliance with state and federal requirements regarding the health and safety of employees." b. Under section "C. Immunizations", it reads: "Rubeola/Rubella/Mumps/Varicella/Pertussis - New Hires 1. Within 30 days of hire, staff will provide evidence of immunity to the following communicable diseases. a. Measles (rubeola) b. Mumps c. German Measles (rubella) d. Chickenpox (varicella) e. Pertussis (whooping cough)...". 5. Review of employee health files indicated: a. N1, hired 1/6/14, signed on 3/12/14, a form indicating that regarding "Measles/Mumps/Rubella (MMR) Immunity Status Acknowledgement", this staff member "...cannot produce proof of immunity...at this time" and "...I understand that I may continue to be at risk of acquiring these diseases...Furthermore, I understand that in event of exposure to this communicable disease(s) I will be excluded from duty or assigned alternative work...". The same language was signed in regard to "Varicella (chicken Pox) Immunity Status Acknowledgement". b. N21, hired 2/17/14 lacked evidence of immunity to Rubella, Rubeola, and Varicella, as required per policy as stated in 3. above. c. N22, hired 9/29/14, signed the form listed in 4. a. above, on 11/11/14. d. N23 hired 9/2/14, signed the form listed in 4. a. above, on 10/10/14. 6. Review of employee health files indicated: a. Staff member N21 was hired 2/17/14 and signed the "Employee Consent to Hepatitis B	T 232		

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T 232	Continued From page 36 Vaccination" form, requesting the Hepatitis B series in February of 2014, but had no documentation that the series was begun. b. Staff member N22 was hired 9/29/14 and signed the "Employee Consent to Hepatitis B Vaccination" on 9/29/14, but had no documentation that the series was begun. 7. At 11:22 AM and 1:03 PM on 11/12/14, interview with staff member #42, the health center manager, indicated: a. Facility infection control policies require some sort of proof of immunity to Rubella, Rubeola, and Varicella, as per 1. b., 3., and 4.b., above and not a signed document stating that employees are unaware of their immunization status. b. Facility infection control policy, and OSHA regulations, indicate that staff requesting the Hepatitis B series are to begin this within 10 days of the written request. c. The facility is delinquent in beginning the Hepatitis B series for staff members N21 and N22, as they requested the series in February and September 2014, respectively.	T 232		
T 290	410 IAC 26-13-2 ANESTHESIA AND SURGICAL SERVICES 410 IAC 26-13-2(d) (d) The clinic must develop, implement, and maintain written policies governing surgical abortion services designed to assure the achievement and maintenance of appropriate standards of medical and patient care. This RULE is not met as evidenced by:	T 290		

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T 290	Continued From page 37 Based on policy and procedure review, medical record review, and staff interview, the facility failed to ensure that the policy/procedure for Analgesia & Sedation Services was followed for 9 of 30 patient, as per facility policy. (Pts. #2, 8, 9, 21, 25, 26, 27, 29, and 30.) Findings: 1. Review of the policy and procedure "Analgesia and Sedation Services", I-F-1, with a PPIN revised date of December 2013, and a PPINK adopted date of July 2013, indicated: a. Under section "VII. Provision of Minimal and Moderate Sedation" on page 12, it reads: "...Minimal and Moderate Sedation...2. prior to the provision of sedation, the team members must confirm the client identification, allergies to medication, and procedure. Client identification bands can help confirm client identification and identify allergies...". 2. Review of patient medical records indicated: a. Patients #2, #8, #9, #21, #26, #27, and #30 had IV (intravenous) sedation of Fentanyl 100 mcg and 1 or 2 mg of Versed prior to their surgical procedures, but lacked documentation of 1, 2 or 3 parts of the "Procedure" section of the medical record that included: "Patient's name and/or ID band checked; Required CIICs (consents and state signed forms) read/signed prior to procedure; Reviewed medical history, allergies, current medications, labs and ultrasound". b. Pts. #25 and #29 had oral Valium 5 mg given prior to their surgical procedure, but lacked documentation of 1, 2 or 3 parts of the "Procedure" section of the medical record that included: "Patient's name and/or ID band checked; Required CIICs (consents and state signed forms) read/signed prior to procedure;	T 290		

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T 290	Continued From page 38 Reviewed medical history, allergies, current medications, labs and ultrasound". 3. At 4:15 PM on 11/12/14 and 12:00 PM on 11/13/14, interview with staff member #41, the regional director, indicated: a. The area in the "Procedure" section of the medical records was not completed, as noted in 2. a. and b. above, as required by facility policy and standards of practice.	T 290		
T 316	410 IAC 26-15-1 LABORATORY SERVICES 410 IAC 26-15-1(f) (f) The clinic must develop, implement, and maintain written quality control and quality assurance policies and procedures for complexity of testing performed that are consistent with and include all standards found in 42 CFR 493. This RULE is not met as evidenced by: Based on policy and procedure review, document review, and interview, the facility failed to ensure that the lab refrigerator with Rh control solutions was monitored as per expectations. Findings: 1. Review of the "PPINK Laboratory Manual", adopted 11/2013, indicated: a. On page 55, it reads in the "Refrigerator" section: "...Control - Read and record temperature daily if used to store biological specimens. Read and record temperature twice daily if used to store vaccines or AB (abortion) lab controls. Temperature should read between 2 - 8	T 316		

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T 316	Continued From page 39 degrees centigrade...". 2. Review of the lab refrigerator temperature checking log indicated: a. The June, July, and August logs read at the bottom of the page: "*Only use for VFC (vaccines for children), Surgical, or AB (abortion) sites. Contact QI (quality improvement) if temp falls outside range." and the other logs read: "*Only use for refrigerators with AB medications...Contact QAC (quality assurance coordinator) if temp falls out of range." b. No twice daily temps were documented for the PM of 7/10/14 and 7/23/14, and both AM and PM checks for 7/9/14, 7/24/14 and 7/25/14. (The days were not marked indicating the clinic was closed.) c. No twice daily temps were documented for June 2014 for 6/9/14 and the PM of 6/20/14 and 6/21/14. d. No PM temp check was documented for 9/10/14. e. No PM temp was noted for 10/4/14, and AM on 10/22/14, and 10/28/14. f. The temperature was noted as being out of range the AM of 10/20/14 and 10/21/14, but lacked any indication that the QAC was contacted. g. No PM temp was noted for 11/10/14 or 11/12/14. h. The temperature was noted as being out of range the AM and PM on 11/7/14, 11/8/14, 11/11/14, and 11/12/14, but lacked any indication that the QAC was contacted. 3. At 5:20 PM on 11/13/14, interview with staff member #43, the quality assurance coordinator, indicated: a. Staff calls this staff member when the refrigerator temperatures are not per the required	T 316		

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(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 316	Continued From page 40 2 to 8 degrees centigrade. b. Staff are then instructed to adjust the temperature controls of the refrigerator and to re check the temp in one hour to see if the adjustment brought the temp back into the expected range. c. There is no documentation that staff called the QAC regarding out of control temperatures, or that the temp was adjusted and re checked in one hour for correct temperature range. d. There are some dates, or times (AM or PM), that staff did not document refrigerator temperatures as listed in 2. above and the clinic was not noted as being closed at those times.	T 316		
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 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.	T 322		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	011118	A. BUILDING: _____ B. WING _____	11/13/2014

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T 322	Continued From page 41	T 322		

This RULE is not met as evidenced by:
Based on policy and procedure review, medical record review, and staff interview, the facility failed to ensure the implementation of its policy, related to the maximum amount of Fentanyl to be given per Kg (kilogram) of weight, for 17 of 18 patients who received IV sedation. (Pts. #2 through #9, #15, #17, #18, #19, #21, #22, #26, #27, #29 and #30.)

Findings:
1. Review of the policy and procedure "Analgesia and Sedation Services", I-F-1, with a PPIN revised date of December 2012 and a PPINK adopted date of July 2013, indicated:
a. On page 17, the "Maximum Recommended Dose (MRD) - single dose" for "Fentanyl Citrate" to be given IV (intravenous) was "0.5 - 1 mcg/kg".

2. Review of patient medical records, for those who received 100 mcg of Fentanyl, indicated that weights in kg (kilograms) were:
a. Pt. #2 = 79 kg.
b. Pt. #3 = 70 kg.
c. Pt. #4 = 57.61 kg.
d. Pt. #5 = 86 kg.
e. Pt. #6 = 56.7 kg.
f. Pt. #7 = 52 kg.
g. Pt. #8 = 62 kg.
h. Pt. #9 = 54 kg.
i. Pt. #17 = 68 kg.
j. Pt. #18 = 64 kg.
k. Pt. #19 = 79.83 kg.
l. Pt. #21 = 61 kg.
m. Pt. #22 = 92.99 kg.
n. Pt. #26 = 46.72 kg.
o. Pt. #27 = 63 kg.

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T 322	Continued From page 42 p. Pt. #29 = 50.8 kg. q. Pt. #30 = 83.91 kg. 3. At 2:15 PM on 11/13/14, interview with staff members #41, the regional director, and #40, the director of special projects, indicated: a. The practitioner always uses 100 mcg of Fentanyl for IV sedation. b. Facility policy for recommended maximum dose of Fentanyl is 1 mcg/kg. c. The patients listed in 2. above were all below 100 kg and, per facility policy, should not have received 100 mcg of Fentanyl.	T 322		
T 368	410 IAC 26-17-2 PHYS. PLANT,MAINT.,EQUIP.,ENVIR.,SAFETY 410 IAC 26-17-2(d)(1)(B) (d) Requirements for clinical facilities are as follows: (1) Procedure rooms shall be segregated and removed from general traffic flow and be a minimum of: (B) two hundred fifty (250) square feet, exclusive of vestibules, toilets, or closets for procedures that require conscious sedation. This RULE is not met as evidenced by: Based on observation and interview, the facility failed to ensure the procedure rooms were at least 250 square feet for 2 of 2 procedure rooms where conscious sedation is used.	T 368		

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T 368	Continued From page 43 Findings include: 1. During observation on 11/13/2014 at 9:30 A.M., two procedure rooms used in the facility both measured 12 feet by 11 feet 4 inches. The square footage of each individual procedure room was calculated at 136 square feet. 2. Interview with HCM#1, the Health Center Manager, on 11/13/2014 at 10:05 A.M. indicated the facility does provide conscious sedation services.	T 368		
T 432	410 IAC 26-17-6 PHYS. PLANT,MAINT.,EQUIP.,ENVIR.,SAFETY 410 IAC 26-17-6(a)(3) (a) A safety management program must include, but not be limited to, the following: (3) An ongoing clinic-wide process to evaluate and collect information about hazards and safety practices. This RULE is not met as evidenced by: Based upon document review and interview, the clinic failed to establish and maintain its safety program including an ongoing, center wide process to collect, evaluate and review information about hazards and safety practices. Findings: 1. The Manual of Medical Standards and Guidelines (approved 1-13) Clinical Program Structure X. Risk and Quality Management	T 432		

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T 432	Continued From page 44 indicated the following: "n. Environment 1. Site review - each clinic will be reviewed at least annually." 2. The 2014 Quality Improvement Work Plan indicated a requirement for conducting an annual clinic site review [safety inspection] by a regional manager and failed to indicate a process for reporting and reviewing the report through a safety program or committee. 3. On 11-12-14 at 0930 hours, the director of special projects A1, the regional director A2, and the health center manager were requested to provide documentation indicating that a safety inspection had been conducted at the clinic and reviewed through the safety program within the past year and none was provided prior to exit. 4. During an interview on 11-13-14 at 1345 hours, the quality assessment coordinator A4 confirmed that no documentation of an annual clinic safety inspection was available.	T 432		
T 440	410 IAC 26-17-6 PHYS. 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	T 440		

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T 440	Continued From page 45 This RULE is not met as evidenced by: Based on record review and interview, the facility failed to ensure evidence of a safety management program which included emergency and disaster preparedness coordination with appropriate community, state and federal agencies. Findings include: 1. A review on 11/13/2014 at 10:30 A.M. of the facility's "Safety and Security Manual", revised July 2011, indicated there was no documentation or instructions in the manual demonstrating coordination of emergency and disaster preparedness with any external agency. 2. During interview on 11/13/2014 at 10:55 A.M., QAC#1, Quality Assurance Coordinator, stated "we don't have a plan for (coordinating emergency and disaster prepardness with appropriate community, state and federal agencies)."	T 440		