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T 000	INITIAL COMMENTS The visit was for a licensure survey. Facility Number: 011117 Survey Date: 12-17/18-14 Surveyors: Brian Montgomery, RN Public Health Nurse Surveyor Linda Plummer, RN Public Health Nurse Surveyor Chris Greeney Life Safety Surveyor QA: claughlin 12/23/14	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 develop and maintain its policies governing the clinic's operation and failed to ensure that the credentialed clinical staff files included documentation of the privileges being	T 056		

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T 056	Continued From page 1	T 056		

requested and granted to each clinical staff for 1 (MD17) of 2 credential file reviewed.

Findings:

1. The Governing Board Bylaws Resolution (approved 5-08) indicated the following: "The procedures which may be performed at Georgetown at 86th, Merrillville or Bloomington by any of the physician members of the medical staff are the following: Surgical abortion-first trimester, Medical Abortion, Cryotherapy, Loop Electrosurgical Excision Procedure (LEEP), Colposcopy, Ultrasound, Family planning services including testing for sexually transmitted diseases, [and] vaccinations."

2. The Governing Board Bylaws Resolution (approved 8-10) indicated the following: "Clinical privileges will be granted in accordance with the PPIN Medical Standards and Guidelines Manual."

3. The Medical Standards and Guidelines (revised 5-14) identified as the abortion clinic medical staff bylaws indicated the following: "The following terms are used throughout the Manual to describe various categories of clinical staff: [1.] Clinician - such as physician (MD or DO) ... [4.] all clinicians supervising or performing services are credentialed as required by ARMS [Affiliate Risk Management Services] ....PPINK policy for granting clinical privileges: PPINK provides certain medical services that require additional specialized training and the grant of privileges. The following medical services require additional training and privileges ...LEEP [Loop Electrosurgical Excision Procedure] (physician only), Abortion (physician only), Moderate sedation, Sterilization (physician only). Granting privileges will be done by the Medical Director or

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may be delegated by the Medical Director to Lead Clinician." The Medical Standards and Guidelines failed to specify an effective period of time for each appointment and reappointment and failed to ensure that the credential file for each candidate requesting appointment/reappointment included documentation of specific privileges being requested to validate a Medical Director recommendation for approval as requested (or with modifications) prior to approval by the governing body.

4. The Governing Board minutes dated 8-23-14 indicated the following: "Appointment/Reappointment of Medical Staff ...MD11 recommends the reappointment of MD15, MD12, MD16, MD18, MD17. Motion to reappoint medical staff. It was MSP [motion sustained and passed]" The board minutes lacked documentation indicating a medical director recommendation for reappointment with privileges as requested to validate the board approval to perform specific procedures by each medical staff.

5. The credential file for MD17 indicated an application for reappointment dated 12-31-12 and no documentation indicated the privileges currently being requested, the privileges granted by the governing body or the effective period for which privileges were granted. Documentation signed on 2-04-10 by MD17 indicated that clinical privileges to perform one clinical procedure was initially granted 12-2002 and no documentation indicated that a review was performed by the medical director MD11 for the non-specific privilege(s) recommended to the governing body for approval on 8-23-14.

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T 056	Continued From page 3 6. During an interview on 12-18-14 at 1245 hours, the quality assurance coordinator A3 confirmed that the credential file for MD17 lacked documentation of the privileges requested for clinical staff reappointment, lacked documentation of a review and recommendation by the medical director MD11, and lacked documentation of the privileges granted by the governing board including the time period for which the privileges were effective.	T 056		
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 upon document review, observation and interview, the facility failed to follow their policy/procedure ensuring that medical records (MR) were protected from fire, water, and other sources of damage.	T 110		

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T 110	Continued From page 4 Findings: 1. The Manual of Medical Standards and Guidelines (revised 5-14) section VI Maintaining Affiliate Medical Records indicated the following: " Affiliates must have policies that ensure medical record safety and that are in compliance with HIPAA ...PPINK records will be stored in file cabinets ... " 2. During a tour of the clinic basement on 12-17-14 at 1535 hours, the following condition was observed: cardboard banker boxes containing MRs in storage on top of metal 4 drawer file cabinets. It was observed that the area was under the protection of fire sprinklers in the event of a fire. 3. During an interview on 12-17-14 at 1535 hours, clinic manager A2 confirmed that the MRs were unprotected from water damage or damage from rodents when stored in the manner described above.	T 110		
T 114	410 IAC 26-7-1 MEDICAL RECORDS 410 IAC 26-7-1(b)(1) (b) A medical record must be maintained with documentation of service rendered for each surgical abortion patient of the clinic as follows: (1) Medical records: (A) are documented accurately and in a timely manner; (B) are readily accessible; and (C) permit prompt retrieval of information.	T 114		

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This RULE is not met as evidenced by:
Based on policy and procedure review, medical record review, and interview, the facility failed to ensure the accuracy of medical records for 8 of 30 patients (Patients #7, 8, 16, 18, 21, 22, 23, and 27).

Findings:
1. Review of the policy "Clinical Program Structure", I-A-1, last revised May 2014, indicated:
a. In section "VI. Maintaining Affiliate Medical Records", it read: "...Records must be 1. factual, complete, concise, and professional 2. legible...".

2. Review of medical records indicated:
a. Pt. #7 was discharged from the RR (recovery room) at 1:34 PM on 12/4/14 and had VS (vital signs) documented as taken at 1:46 PM.
b. Pt. #8 was discharged from the RR at 2:11 PM on 11/20/14 and had VS documented as taken at 2:23 PM.
c. Pt. #16 was discharged from the RR at 11:33 AM on 10/23/14 and had VS documented as taken at 11:39 AM.
d. Pt. #18 was discharged from the RR at 3:25 PM on 10/23/14 and had VS documented as taken at 3:34 PM.
e. Pt. #21 was discharged from the RR at 2:55 PM on 10/02/14 and had VS documented as taken at 3:08 PM.
f. Pt. #22 had a TPR (terminated pregnancy report) that indicated the patient had a "Medical (non-surgical) Mifepristone/Misoprostol" abortion, when a surgical abortion was performed on 10/2/14.
g. Pt. #23 was discharged from the RR at 5:15

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T 114	Continued From page 6 PM on 10/02/14 and had VS documented as taken at 5:25 PM. h. Pt. #27 was discharged from the RR at 11:20 AM on 9/25/14 and had VS documented as taken at 11:33 AM. 3. At 11:00 AM on 12/17/14, interview with staff member #40, the quality director, indicated: a. The medical records, as listed in 2. above, are inaccurate. b. It is thought that staff may have taken VS before patients were discharged, but entered them at a later time and did not change the time to the actual time taken. c. There may be a system problem with computer times, as well.	T 114		
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 upon document review, observation and	T 126		

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T 126	Continued From page 7 interview, the facility failed to follow their policy/procedure ensuring that medical records (MR) were protected from access by unauthorized persons. Findings: 1. The Manual of Medical Standards and Guidelines (revised 5-14) section VI Maintaining Affiliate Medical Records indicated the following: " Safeguards against loss and use by unauthorized persons must be maintained ...PPINK records will be stored in file cabinets ...Paper charts must be secured by lock when unattended by personnel ... " 2. During a tour of the clinic basement on 12-17-14 at 1535 hours, the following condition was observed: cardboard banker boxes containing MR in storage on top of metal 4 drawer file cabinets. It was identified that the MR storage area was accessible to entry through two unlocked doors on the basement level and no restriction to basement access from the first floor clinical areas was observed. 3. During an interview on 12-17-14 at 1535 hours, clinic manager A2 confirmed that the MR were not protected from access by unauthorized persons.	T 126		
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.	T 132		

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T 132	Continued From page 8 (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 interview, the facility failed to ensure the completeness of medical records for 16 of 30 patients (Patients #3, 6, 10, 11, 13, 14, 16, 17, 18, 21, 22, 23, 26, 27, 29, and 30). Findings: 1. Review of the policy "Clinical Program Structure", I-A-1, last revised May 2014, indicated: a. In section "VI. Maintaining Affiliate Medical Records", it read: "...Records must be 1. factual, complete, concise, and professional 2. legible...". 2. Review of the policy "Surgical Abortion Services", VII-A-1, last revised August 2014, indicated: a. In the section "PPINK Medical records", it read: "...2. A copy of the State Mandated Information Consent (PL-187) must be scanned into the patient's electronic chart...". 3. Review of patient medical records indicated: a. Pt. #3 lacked: A. Completion on the form 55321 ("Abortion Fetal Ultrasound and Heart Tone Certification", whether or not the patient wanted to view the fetal ultrasound and whether or not the patient wished to hear the fetal heart tone prior to the abortion procedure. B. The form 55320, the state's form for	T 132		

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abortion consent.

b. Pt. #6 had a surgical abortion and lacked documentation of "Tissue exam consistent with documented gestational age" in the "Procedure" portion of the chart.

c. Pt. #10 lacked documentation of the time of discharge from the recovery room, and lacked indication that a "Local" was used (Lidocaine 1% noted in chart) in the "Sedation Preference" section of the chart.

d. Pt. #11 lacked documentation of the time the patient arrived in the recovery room, and lacked documentation of "Tissue exam consistent with documented gestational age" in the "Procedure" portion of the chart.

e. Pt. #13 lacked documentation in the "Procedure" portion of the chart for "Discharge pt. from recovery room per protocol...", and lacked documentation of the time the patient arrived in the recovery room.

f. Pt. #14 had a surgical abortion and lacked history indication for: "Bleeding disorder (yes or no); Breast feeding (yes/no); Diabetes (yes/no); Heart disease (yes/no); Hypertension (yes/no); Kidney failure (yes/no); Liver disease/tumor (yes/no)"; and "Drug/alcohol use in last 24 hrs (yes/no)", and lacked documentation in the "Procedure" portion of the chart for "Discharge pt. from recovery room per protocol...".

g. Pt. #16 had a surgical abortion and lacked documentation in the "Procedure" portion of the chart for "Discharge pt. from recovery room per protocol...", and lacked documentation in the Recovery room portion of the chart that the patient was: "...discharged in good condition (yes/no); Sedation complications (yes/no); Patient ambulatory (yes/no); and Driver/support person aware of reason for visit (yes/no)".

h. Pts. #17 and #18 had surgical abortions and lacked documentation in the "Procedure" portion

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of the chart for "Discharge pt. from recovery room per protocol...".
i. Pts. #21, #22, #26, and #27 had surgical abortions and lacked documentation of "Tissue exam consistent with documented gestational age" in the "Procedure" portion of the chart, and lacked documentation in the "Procedure" portion of the chart for "Discharge pt. from recovery room per protocol...".
j. Pt. #23 had a surgical abortion and lacked documentation in the "Procedure" portion of the chart for "Discharge pt. from recovery room per protocol...".
k. Pt. #29 lacked indication that a "Local" was used (Lidocaine 1% noted in chart) in the "Sedation Preference" section of the chart, and lacked documentation in the "Procedure" portion of the chart for "Discharge pt. from recovery room per protocol...".
l. Pt. #30 had a surgical abortion and lacked indication that a "Local" was used (Lidocaine 1% noted in chart) in the "Sedation Preference" section of the chart, lacked documentation in the "Procedure" portion of the chart for "Discharge pt. from recovery room per protocol...", and lacked documentation of the time the patient was discharged from the recovery room.

4. At 11:05 AM on 12/18/14, interview with staff member #40, the quality director, indicated:
a. Portions of patient medical records are incomplete and lacking documentation, as listed in 2 above, as required per facility policy.

5. At 11:50 AM on 12/17/14, interview with staff member #41, the clinic director, indicated:
a. The state mandated form (55320) cannot be found for pt. #3.
b. The state mandated form (55321) is not complete for pt. #3.

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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, employee file review, and staff interview, the facility failed to implement its policy related to two step TB (tuberculosis) testing for 2 of 2 staff members hired in 2014 (N4 and N7). Findings: 1. Review of the policy and procedure for "PPINK Infection Control Manual and OSHA Exposure Control Plan", in Chapter 5 - Occupational Health, adopted 07/2013, indicated: a. "...All new health care workers (HCW) are required to provide negative baseline testing for	T 152		

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T 152	Continued From page 12 M, tuberculosis infection prior to beginning work at PPIN...Newly hired HCW: NO Tuberculosis test within 12 months of start date. The HCW may choose to do either a BAMT (blood assay for mycobacterium tuberculosis) or a two step TST (tuberculin skin test)...The first test must be done before their first day of work. The second TST should be administered 1 - 3 weeks after the first TST result is read...Newly hired HCW: Tuberculosis test within 12 months of start date. If the HCW can produce documentation of a prior negative TST or BAMT within the past 12 months, the HCW will not need a TB test...". 2. Review of personnel files indicated: a. Staff member N4 was hired 10/13/14 and had only one TB test documented: given on 11/21/14 and read on 11/24/14. b. Staff member N7 was hired 3/31/14 and had a TB test documented as given on 3/31/14 and read on 4/3/14. 3. At 10:15 AM on 12/18/14, interview with staff member #40, the quality director, indicated: a. Staff members N4 and N7 should have had either proof of having had a negative TB test prior to hire, or a second TB test after hire to complete the two step process required per facility policy.	T 152		
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.	T 178		

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T 178	Continued From page 13 This RULE is not met as evidenced by: Based on policy and procedure review, medical record review, and interview, the facility failed to ensure that history and physical examinations were performed by practitioners for 8 of 10 patients who had medical abortions, and 13 of 20 patients who had surgical abortions (Medical abortion patients #9, 12, 15, 19, 20, 24, 25, and #28 and surgical abortion patients #11, 13, 14, 16, 17, 18, 21, 22, 23, 26, 27, 29, and #30). Findings: 1. Review of the policy "Mifepristone Medication Abortion", VII-B-1, last revised August 2014, indicated: a. "Medical Screening and Evaluation Medical History - A targeted medical history that includes screening to identify possible contraindications and/or special conditions must be completed. Physical Examination - must be done before administering medications and must include 1. blood pressure 2. bimanual exam when indicated (e.g., vaginal bleeding or abdominal/pelvic pain). 3. additional examination as indicated by history or laboratory findings...". 2. Review of the policy "Surgical Abortion Services", VII-A-1, last revised August 2014, indicated: a. "Medical Screening and Evaluation Medical History 1. A targeted medical history that includes screening to identify possible contraindications and/or special conditions must be completed. 2. Special attention must be given to reported allergies to medications, antiseptic solutions, and latex. Physical Examination - must include 1. temperature, if	T 178		

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T 178	Continued From page 14 symptomatic of infection 2. blood pressure 3. cardiac auscultation...". 3. Review of medical records indicated: a. Regarding those patients having medical abortions: A. Pts. #9, 12, 15, 19, 20, 24, 25, and #28 lacked authentication by the physician of the "Abortion History (Surgical and MAB)" (medical abortion) sections of the chart. b. Regarding those patients having surgical abortions: A. Pts. #11, 13, 14, 16, 17, 18, 21, 22, 23, 26, 27, 29, and #30 lacked authentication by the physician of the "Abortion History (Surgical and MAB)" sections of the chart. 4. At 1:59 PM and 2:30 PM on 12/17/14, and at 11:05 AM on 12/18/14, interview with staff member #40, the quality director, indicated: a. The medical and surgical abortion charts, as listed in 2. a. and 2. b. above were lacking authentication by the physician responsible that would indicate performing or reviewing the data present in the records.	T 178		
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:	T 184		

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T 184	Continued From page 15 Based on policy and procedure review, medical record review, and staff interview, the facility failed to ensure the implementation of policy and standards of care, related to the checking of VS (vital signs) in the procedure/surgery suite, for 18 of 20 patients of those having surgical abortions (Pts. #1, 6, 7, 8, 10, 11, 13, 14, 16, 17, 18, 21, 22, 23, 26, 27, 29, and #30) and failed to ensure interpretive services for 1 of 1 patient who listed a language other than English as their primary language (Pt. #3). 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 21, it read in the "Client Discharge Criteria" section: "...4. PPINK recovery room a. Monitoring: 1. Blood pressure is to be taken one time prior to the patient leaving the surgical exam room,...2. Blood pressure and pulse are to be taken one time prior to the patient leaving the recovery room...". 2. Review of medical records indicated: a. Pts. #1, 6, 7, 8, 10, 11, 13, 14, 16, 17, 18, 21, 22, 23, 26, 27, 29, and #30 had VS taken prior to their procedures and in the RR (recovery room), but lacked any documentation of VS taken while in the surgical exam room. 3. At 11:00 AM on 12/17/14, interview with staff member #40, the quality director, indicated: a. Patients (as listed in 2. a. above) were lacking documentation of having their VS taken in the surgical suite. b. It was thought that the computer system is timed incorrectly.	T 184		

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T 184	Continued From page 16 4. Review of the policy "Clinical Program Structure", I-A-1, revised May 2014, indicated: a. On page 9 under "Interpreters...Language line may be used for interpreters", it read: "1. Affiliates must assess and ensure the training and competency of individuals who deliver interpreting and translation services. 2. Bilingual staff that communicate directly with clients in their preferred language must demonstrate a command of both English and the target language...". 5. Review of medical records indicated that patient #3 listed on one document in their medical record that their "primary language" was "Hispanic", and on another form, listed their "language" as "Spanish". 6. At 3:50 PM on 12/17/14, interview with staff member #41, the clinic manager, indicated: a. This staff person remembered pt. #3 and that the clinic staff provided the phone language line for interpretation to the Spanish speaking patient. b. It was agreed that there was no documentation in the medical record that interpretive services were provided. 7. At 10:15 AM on 12/18/14, interview with staff member #40, the quality director, indicated: a. The facility has documents in Spanish for those patients who are not competent in English. b. The medical record for patient #3 had English consents and documents. c. It cannot be determined, due to lack of documentation, that the patient could read/understand the English consents and documents provided.	T 184		

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T 194	Continued From page 17	T 194		
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 document review, medical record review, and staff interview, the facility failed to document patients' post procedure instructions regarding hygiene for 20 of 20 patients who had surgical abortion procedures (Patients#1, #3, #6, #7, #8. #10, #11, #13, #14, #16, #17, #18, #21,	T 194		

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T 194	Continued From page 18 #22, #23, #26, #27, #29 and #30). Findings: 1. Review of handouts, educational materials, and discharge instructions indicated Hygiene instructions were not addressed in any of the written materials given to patients. 2. Review of patient medical records #1, #3, #6, #7, #8. #10, #11, #13, #14, #16, #17, #18, #21, #22, #23, #26, #27, #29 and #30 indicated that all were lacking documentation of education/instructions regarding hygiene post procedure. 3. At 11:05 AM on 12/18/14, interview with staff member #40, the quality 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		
T 218	410 IAC 26-11-1 INFECTION CONTROL PROGRAM 410 IAC 26-11-1(d)(2) (d) The clinic administrator must do the following: (2) Provide for appropriate infection control input into plans for renovation and new construction to ensure awareness of federal, state, and local rules that affect infection control practices as well as plan for appropriate protection of patients and employees during construction or renovation.	T 218		

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T 218	Continued From page 19 This RULE is not met as evidenced by: Based on document review, observation and interview, the Infection Control (IC) committee failed to provide effective input regarding plans for renovation and ensure a safe environment that minimized infection exposure and risk for patients and personnel in 1 of 2 procedure rooms (north room) of the clinic. Findings: 1. During a tour on 12-17-14 at 1615 hours, the following condition was observed in the north procedure room of the clinic: a glass block window with an incomplete return of mortar for the upper right margin of the window opening that allowed dust, dirt and insects to freely enter the procedure room from the inner wall space. 2. During an interview on 12-17-14 at 1615 hours, clinic manager A2 confirmed that the incomplete window mortar failed to prevent contamination from entering the procedure room when patients were present.	T 218		
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:	T 232		

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T 232	Continued From page 20 (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 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, employee file review, and staff interview, the infection control committee failed to implement its policy	T 232		

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related to the immune status of staff for rubella, rubeola, and varicella for 1 of 2 newly hired (2014) employees (N4) and related to Hepatitis B for 1 staff member who requested to receive the series of injections at the time of hire (N4) and failed to maintain and follow its policy/procedure regarding the periodic review of all IC-related policies and procedures.

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 read: "...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 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

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duties. Employee Group One...Nurses...Health Center Assistants...".

3. Review of the policy "Clinical Program Structure, I-A-1, last revised May 2014, indicated:
a. In section "m. Personnel", it read: "1. Employee records are kept for the following:...h. Health status and immunity to rubella, Hepatitis B and other communicable diseases per applicable policies...".

4. Review of employee files indicated:
a. Staff member N4, a health care assistant, was hired 10/13/14 and:
A. Had a document signed by the employee indicating that they "...cannot produce proof of immunity..." to "Measles/Mumps/Rubella" or "Varicella".
B. Had a form signed on 10/13/14 requesting the Hepatitis B series.

5. At 9:35 AM on 12/18/14, interview with staff member #40, the quality director, indicated:
a. The policy related to the requirement for immunity history for communicable diseases was not implemented for staff member N4.
b. The Hepatitis B series has not yet begun for staff member N4, as required within 10 days of hire, per policy.
6. The policy/procedure Infection Control Plan (approved 7-13) indicated the following: "Continuous monitoring of the Infection Prevention Program is an essential component of all Risk and Quality Management programs. 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 by the Risk and Quality Management (RQM) Committee on an annual

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T 232	Continued From page 23 basis or whenever new mandates are required." 7. The Quality Management and Infection Control Meeting minutes dated 12-01-14 indicated the following: "Approval of Infection Control Manual: approved by committee members present." 8. On 12-18-14 at 1005 hours, the quality Assurance Coordinator A3 was requested to provide RQM committee meeting minutes including documentation indicating that an annual review of the IC program policies and procedures had been performed and no documentation was provided prior to exit. 9. During an interview on 12-18-14 at 1225 hours, the quality Assurance Coordinator A3 confirmed that the 2014 RQM committee minutes failed to indicate that an annual review of the IC program policies and procedures was performed and confirmed that no additional documentation was available.	T 232		
T 258	410 IAC 26-11-3 INFECTION CONTROL PROGRAM 410 IAC 26-11-3(3)(B) The clinic, whether it operates its own laundry or uses outside laundry service, must ensure that the laundry process complies with a recognized laundry standard as follows: (3) Central clean linen storage space must be provided as follows: (B) If laundry is processed in the clinic: (i) a laundry processing area must be provided; (ii) clean linen storage and mending	T 258		

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T 258	Continued From page 24 must be separated from soiled linen handling and storage; and (iii) employee hand washing facilities must be available in each room where clean or soiled linen is processed and handled. This RULE is not met as evidenced by: Based on document review, observation, and interview, the clinic failed to ensure that its laundry process complied with recognized laundry standards and protected its employees from exposure to potentially infectious organisms. Findings: 1. The clinic Infection Control Manual Chapter 2: Cleaning, Disinfection and Sterilization section heading titled Laundry Services (revised 10-14) indicated the following: "All laundry must be washed in HOT water (140o F or above)." 2. Clinic documentation titled 2014 Washing Machine Log indicated the following: "Please document temperature in appropriate boxes ..." for the row titled Hot water temperature 140o F or > and the log indicated a checkmark entry in the corresponding monthly column space for the months of August, September, October and December 3. During a clinic tour on 12-17-14 at 1540 hours,	T 258		

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T 258	Continued From page 25 in the 2nd floor locker room area, a washer and dryer unit were observed with no thermometer or other instrumentation to observe and monitor hot water temperature and no point-of -use inline hot water heater with a temperature display was present in the alcove. 4. During an interview on 12-18-12 at 1025 hours, clinic manager A2 confirmed that they (A2) had made the monthly entries and confirmed that no temperature monitoring had been performed.	T 258		
T 314	410 IAC 26-15-1 LABORATORY SERVICES 410 IAC 26-15-1(e) (e) All nursing and other clinic personnel performing laboratory testing must have competency assessed annually with documentation of assessment maintained in the employee file for the procedures performed. 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 annual competency documentation for two of 3 HCAs (health care assistants) approved to do in house lab testing/point of care testing (N5 and N7). Findings: 1. Review of the policy "Clinical Program Structure" I-A-1, last revised May 2014, indicated: a. In section 2. "In-House laboratory", it read: "...b. Competency testing is performed based on CLIA guidelines for in-house testing...".	T 314		

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T 314	Continued From page 26 2. Review of employee files indicated: a. Staff member N5, a HCA hired 6/22/09, lacked documentation of annual competency check for Hemoglobin testing of patients. b. Staff member N7, a HCA hired 3/31/14, had a UPT (urine pregnancy test) competency form that was not dated to indicate when the competency was checked. 3. At 10:15 AM on 12/18/14, interview with staff member #40, the quality director, indicated: a. Annual competency is required for Rh testing, Hemoglobin testing, UPTs and other in-house labs. b. No competency for Hemoglobin testing can be found for staff member N5, c. The document indicating staff member N7 was checked off to do UPTs was not dated.	T 314		
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	T 322		

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T 322	Continued From page 27 established clinic policies and acceptable standards of practice. This RULE is not met as evidenced by: Based on policy and procedure review, observation, and interview, the facility failed to implement its policy related to multi dose vials. Findings: 1. Review of the policy "Pharmaceutical Services" 1-A-2, last revised March 2014, indicated: a. On page 5 under "Other", it read: "...If a multi-dose vial has been opened or accessed (e.g., needle-punctured) the vial must be dated and discarded in accordance with manufacturer's instructions and state/local regulations. If no specific guidelines are provided, CDC recommends discarding the vial within 28 days (CDC 2011)...". 2. While on tour of the facility on 12/1714 at 4:12 PM in the "Clean lab" area, in the company of staff member #41, the clinic manager, it was observed that the Lidocaine 1% 50 ml vial was opened and not dated. 3. Interview with staff member #41 at 4:12 PM on 12/17/14 indicated the vial of Lidocaine should have been dated when opened and destroyed after 28 days, as per facility policy. 4. While on tour of the facility in the company of staff member #41, on 12/17/14 at 4:20 PM, it was observed in the "Clean lab" that in the locked medication box, the Diazepam 10 ml vial was	T 322		

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	011117	A. BUILDING: _____ B. WING _____	12/18/2014

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T 322	Continued From page 28 opened and dated on 9/25/14. 5. Interview with staff member #41 at 4:20 PM on 12/17/14 indicated the vial of Diazepam should have been destroyed as it was beyond the 28 days allowed after first opening/accessing it on 9/25/14.	T 322		
T 398	410 IAC 26-17-2 PHYS. PLANT,MAINT.,EQUIP.,ENVIR.,SAFETY 410 IAC 26-17-2(e)(8) (e) Requirements for design standards are as follows: (8) An approved antiscald device shall be provided on the hot water supply to all hand washing facilities limiting the water temperature to a maximum of one hundred ten (110) degrees Fahrenheit (forty-three (43) degrees Celsius). This RULE is not met as evidenced by: Based on observation and interview, the facility failed to install an anti-scald devices on the hot water supply to all hand washing facilities. This finding could affect any staff, visitors or patients using hand washing stations in the facility. The findings include: 1. During observation on 12/17/2014 between 9:35 and 10:05 A.M., hot water temperature in the recovery room bathroom measured at 122.3	T 398		

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T 398	Continued From page 29 degrees Fahrenheit. The hot water temperature in the sink of the family planning hallway bathroom measured 125.5 degrees Fahrenheit. An installed anti-scald device was not observed on the hot water supply. 2. Interview with CM#1, the clinic manager, on 12/17/14 at 11:30 A.M. indicated the facility did not have an anti-scald device installed on its hot water supply.	T 398		
T 424	410 IAC 26-17-5 PHYS. PLANT,MAINT.,EQUIP.,ENVIR.,SAFETY 410 IAC 26-17-5(1) The building or buildings, including fixtures, walls, floors, ceiling, and furnishings throughout, must be kept clean and orderly in accordance with current standards of practice, including the following: (1) Environmental services must be provided in such a way as to guard against transmission of disease to patients, health care workers, the public, and visitors by using the current principles of the following: (A) Asepsis. (B) Cross-contamination prevention. (C) Safe practice. This RULE is not met as evidenced by: Based on observation, document review and interview, the facility failed to ensure that environmental services were provided as required to guard against cross contamination and	T 424		

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T 424	Continued From page 30 regarding safe practices in 4 areas toured and failed to ensure that environmental surfaces were free of dust and particulate material including wall-mounted cabinets located over 1 of 2 tabletop sterilizer units at the clinic. Findings: 1. At 3:50 PM on 12/17/14, while on tour of the recovery room in the company of staff member #41, the clinic director, it was observed that the floor of the snack closet had an accumulation of dust and debris along with drywall dust particles. 2. Interview with staff member #41 at 3:50 PM on 12/17/14 indicated: a. The remodeling of the facility was completed the end of July 2014. (First patients seen after remodeling was completed were on 7/31/14.) b. Facility staff are responsible for cleaning the locked snack closet. c. It was agreed that the floor was dirty and had not been cleaned for quite some time. 3. At 3:55 PM on 12/17/14, while on tour of the East procedure room in the company of staff member #41, the clinic director, it was observed that: a. There was dust and dried splatters of ultrasound gel and/or other liquids on the ultrasound machine. b. The wall ventilation face plates had an accumulation of dust present. 4. At 3:55 PM on 12/17/14, interview with staff member #41 indicated agreement that the ultrasound machine and ventilation face plates had not been cleaned appropriately. 5. At 4:05 PM on 12/17/14, while on tour of the	T 424		

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T 424	Continued From page 31 North procedure room in the company of staff member #41, the clinic manager, it was observed that: a. The two wall mounted ventilation face plates had an accumulation of dust present. b. The window had a gap between the window and wall (right upper hand corner) that was 3 inches wide and approx. 6 inches long. c. There was a gap in the flooring tile approx 1/4 inch wide and several (6 +) inches long. 6. Interview with staff member #41 at 4:10 PM on 12/17/14 indicated agreement that the face plates were dusty and that appropriate cleaning of the surgical procedure room cannot be accomplished with gaps in the window and flooring. 7. At 4:20 PM on 12/17/14, while on tour of the family planning lab room in the company of staff member #41, the clinic manager, it was observed that there was a 1/2 to 3/4 inch gap in the flooring tile that measured 4 inches to 12 inches long in an L shape. 8. At 4:20 PM on 12/17/14 interview with staff member #41 indicated appropriate lab floor cleaning cannot be accomplished with gaps in the flooring. 9. The Infection Control Manual (revised 10-14) Chapter 2 heading titled Housekeeping Services indicated the following: "PPINK uses a professional cleaning service scheduled routinely ...to ensure that the workplace is maintained in a clean and sanitary condition ...daily cleaning and decontamination of the exam rooms, labs and equipment is done by trained staff ...following clinical days, routine housekeeping is done by staff ...at least yearly, a crew is retained to shampoo carpets and wipe down walls, baseboards and vents ..." No documentation	T 424		

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T 424	Continued From page 32 indicated a responsibility by either clinical staff or by the contracted cleaning service to maintain the tops of cabinets and door surfaces free of dust and particulate matter. 10. During a tour on 12-17-14 at 1340 hours, the following condition was observed in the clinical area: 2 privacy doors were observed with an accumulation of white dust and particulate material present on the large flat surfaces of the door . 11. During an interview on 12-17-14 at 1340 hours, the clinic manager A2 indicated that the clinic was extensively remodeled in June and July 2014 and indicated that the white dust was probably the result of drywall refinishing. 12. During a tour on 12-17-14 at 1420 hours, in the clean instrument sterilizing area of the clinic, the following condition was observed: a significant amount of accumulated dust and particulate matter was present on the top of a wall-mounted cabinet located directly over a countertop sterilizer unit. 13. During an interview on 12-17-14 at 1420 hours, the clinic manager A2 confirmed that the dirty cabinet tops were not being routinely cleaned and were unsanitary.	T 424		