

Indiana State Department of Health

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>011117</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____  B. WING _____	(X3) DATE SURVEY COMPLETED  <b>01/24/2017</b>
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NAME OF PROVIDER OR SUPPLIER  <b>PLANNED PARENTHOOD OF INDIANA AND KENTUCKY</b>	STREET ADDRESS, CITY, STATE, ZIP CODE <b>421 S COLLEGE AVE BLOOMINGTON, IN 47403</b>
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T 000	<p>INITIAL COMMENTS</p> <p>This visit was for a State licensure survey.</p> <p>Dates of survey: 1/23/17 to 1/24/17</p> <p>Facility #011117</p> <p>QA: 2/1/17 jlh</p>	T 000		
T 038	<p>410 IAC 26-4-1 GOVERNING BODY</p> <p>410 IAC 26-4-1(c)(8)(B)</p> <p>(c) The governing body shall do the following: (8) Establish the following: (B) A process for the following: (i) Reporting licensed health professionals who fail to comply with state professional licensing requirements as found in IC 25-22.5. (ii) Documenting actions against licensed health professionals who fail to comply with the clinic policies and procedures. (iii) Reporting information that statute requires the abortion clinic to report to a state agency or law enforcement agency.</p> <p>This RULE is not met as evidenced by: Based on document review and interview, the governing body (GB) failed to establish a process for reporting licensed health professional (LHP)</p>	T 038		

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

TITLE

(X6) DATE

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T 038	Continued From page 1  who fail to comply with state professional licensing requirements or clinic policies and procedures (P&P) for one clinic.  Findings:  1. Review of GB Bylaws, clinic P&Ps and facility documents, lacked documentation of a process for reporting licensed health professional who fail to comply with state professional licensing requirements.  2. On 1/23/17 at 10:30am, A3, Vice President of Patient Services, indicated he/she did not believe the clinic had a policy for reporting LHPs who fail to comply with state professional licensing requirements. On 1/24/17 at 4:15pm, A3 verified that the clinic did not have documentation of a process for reporting LHPs.	T 038		
T 096	410 IAC 26-6-1 QUALITY ASSESSMENT AND IMPROVEMENT  410 IAC 26-6-1(a)(1)  The program shall be ongoing and have a written plan of implementation that evaluates, but is not limited to, the following: (1) All services, including services furnished by a contractor.          This RULE is not met as evidenced by: Based on document review and interview, the	T 096		

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T 096	<p>Continued From page 2</p> <p>quality assessment and performance improvement (QAPI) program failed to include 3 of 6 directly provided services (nursing, laundry, medical record review services) and 2 of 4 contracted services (maintenance and laboratory) in the plan or evaluation of services for fiscal year (FY) 2017.</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>1. Review of the document titled Administrative Chapter 2: Clinical Services, Revised June 2016, indicated in 2.6, Clinical Quality Improvement (CQI): Affiliates should have a CQI program in place to track, trend and improve clinical quality outcomes on a continuous basis. They should also set goals for at least one clinical quality measure and implement changes to improve performance.</li> <li>2. Review of the spreadsheet titled FY 2017 Risk and Quality Management Work Plan lacked documentation of review or evaluation of nursing services, laundry services, medical record review services, maintenance services or laboratory services.</li> <li>3. Review of FY 2017 vendor audits lacked documentation of review or evaluation of contracted services for maintenance or laboratory.</li> <li>4. On 1/24/17 at 12:30pm, A2, Risk and Quality Manager, indicated the FY 2017 spreadsheet was the written plan for the clinic's QAPI program and that the FY ran from July 2016 to June 2017. A2 verified lack of documentation for review or evaluation of nursing services, laundry services, medical record review services, maintenance services or laboratory services.</li> </ol>	T 096		

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T 098	<p>410 IAC 26-6-1 QUALITY ASSESSMENT AND IMPROVEMENT</p> <p>410 IAC 26-6-1(a)(2)</p> <p>The program shall be ongoing and have a written plan of implementation that evaluates, but is not limited to, the following: (2) All functions, including, but not limited to, the following: (A) Discharge. (B) Transfer. (C) Infection control. (D) Response to patient emergencies.</p> <p>This RULE is not met as evidenced by: Based on document review and interview, the quality assessment and performance improvement (QAPI) program failed to include 2 of 4 functions (discharge and response to patient emergencies) in the plan or evaluation of services for fiscal year (FY) 2017.</p> <p>Findings:</p> <p>1. Review of the policy document titled Administrative Chapter 2: Clinical Services, Revised June 2016, indicated in 2.6, Clinical Quality Improvement (CQI): Affiliates should have a CQI program in place to track, trend and improve clinical quality outcomes on a continuous bases. They should also set goals for at least one clinical quality measure and implement changes to improve performance.</p>	T 098		

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T 098	Continued From page 4  2. Review of the spreadsheet titled FY 2017 Risk and Quality Management Work Plan lacked documentation of review or evaluation for the functions of discharge and response to patient emergencies.  3. On 1/24/17 at 12:30pm, A2, Risk and Quality Manager, indicated the FY 2017 spreadsheet was the written plan for the clinic's QAPI program and that the FY ran from July 2016 to June 2017. A2 verified lack of documentation for review or evaluation of discharge and response to patient emergencies.	T 098		
T 110	410 IAC 26-7-1 MEDICAL RECORDS  410 IAC 26-7-1(a)(2)(B)  (a) The abortion clinic must do the following: (2) Have a written policy that ensures responsibility for and maintenance of surgical abortion records as follows: (B) The policy must provide safeguards to assure protection of the medical records from the following: (i) Fire. (ii) Water. (iii) Other sources of damage.  This RULE is not met as evidenced by: Based on document review and interview, the clinic failed to have a written policy to provide safeguards and assure protection of the medical	T 110		

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T 110	Continued From page 5  records from fire, water and other sources of damage for one facility.  Findings:  1. Review of clinic policies lacked documentation of a policy to provide safeguards and assure protection of the medical records from fire, water and other sources of damage.  2. On 1/24/17 at 10:00am, A1, Director of Abortion Operations, verified that the clinic did not have a policy for provision of safeguards to assure protection of the medical records from fire, water and other sources of damage.	T 110		
T 128	410 IAC 26-7-1 MEDICAL RECORDS  410 IAC 26-7-1(c)  (c) A written or electronic register must be kept of all patients treated that provides the following: (1) Identification data. (2) Treatment rendered. (3) Attending physician. (4) Condition on discharge. (5) Transfers to hospital facility. (6) Other data deemed necessary by the clinic.  This RULE is not met as evidenced by: Based on document review and interview, the facility failed to maintain a completed register with all required components in 2 instances.  Findings include;	T 128		

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T 128	Continued From page 6  1. Review of the paper version of the patient register/log used on surgery days indicated it lacked documentation of the attending physician.  2. An electronic log was then provided by staff member #N1 (Vice President of Patient Services) which lacked documentation of the condition on discharge.  3. Staff member #N1 verified the logs did not contain the required components at 11:50 a.m. on 1/23/17.	T 128		
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.	T 152		

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T 152	<p>Continued From page 7</p> <p>This RULE is not met as evidenced by: Based on document review and interview, the infection control committee failed to ensure the screening of employees for mycobacterium tuberculosis (TB) in 7 (N1, N2, N3, N4, N5, N6, N7) of 7 personnel files reviewed.</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>Infection Control Manual and OSHA Risk Exposure Plan, revised 11/2016, indicated on page 54: "All new health care workers (HCW) are required to provide negative baseline testing for M. tuberculosis infection prior to beginning work at PPINK."</li> <li>Review of personnel files confirmed personnel: <ul style="list-style-type: none"> <li>A. N1 (Healthcare Assistant [HCA]) hired on 4/27/15 lacked documentation of negative baseline testing prior to beginning work.</li> <li>B. N2 (HCA) hired on 8/1/16 lacked documentation of negative baseline testing prior to beginning work.</li> <li>C. N3 (Licensed Practical Nurse [LPN]) hired on 7/14/14 lacked documentation of negative baseline testing prior to beginning work.</li> <li>D. N4 (HCA) hired on 4/27/15 lacked documentation of negative baseline testing prior to beginning work.</li> <li>E. N6 (HCA) hired on 12/7/15 lacked documentation of negative baseline testing prior to beginning work.</li> <li>F. N7 (Registered Nurse [RN]) hired on 8/1/16 lacked documentation of negative baseline testing prior to beginning work.</li> </ul> </li> <li>Staff P1 (Director of Abortion Operations) was interviewed on 1/24/17 at approximately 1500</li> </ol>	T 152		



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T 152	Continued From page 8  hours and confirmed the above-mentioned personnel lacked documentation of completion of TB screening prior to beginning work.	T 152		
T 178	<p>410 IAC 26-9-1 MEDICAL STAFF</p> <p>410 IAC 26-9-1(c)(1)</p> <p>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.</p> <p>This RULE is not met as evidenced by: Based on document review and interview, the medical director failed to develop and maintain a policy to ensure timeliness of medical history and physical (H&amp;P) examinations for one facility.</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>1. Review of the document titled Administrative Chapter 6: Personnel, Revised June 2016, indicated in 6.1.3, Medical Director Responsibilities, that the medical director is responsible for overseeing the development and implementation of affiliate medical policies and protocols in accordance with...state and local regulations.</li> <li>2. Review of clinic policies lacked documentation of a policy to ensure timeliness of medical history and physical examinations for one facility.</li> <li>3. Review of Medical Standards and Guidelines,</li> </ol>	T 178		

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T 178	Continued From page 9  Revised 10/16, implemented 12/16, indicated what should be included in an H&P, but lacked documentation of policy to ensure timeliness and gave no time protocol for completion.  4. On 1/23/17 at 10:10am, A2, Risk and Quality Manager, verified lack of documentation of a policy to ensure timeliness of medical history and physical H&P) examinations.	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: Based on document review and interview, the facility failed to follow their policy/procedure for recovery area assessment criteria for 22 of 22 closed medical records (MR) reviewed.  Findings:  1. Policy/procedure 18.1.2, Recovery Area Assessment Criteria, revised/reapproved 6/2016 indicated on page 2 point 1. A., "Patients receiving minimal or no sedation who are post surgical abortion....must assess the following at initiation of recovery and then at least every 15 minutes during the recovery process until discharge. Blood pressure, respiratory rate, pulse (a minimum of 2 sets)."	T 184		

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T 184	<p>Continued From page 10</p> <p>2. Review of patient 5's MR on 1/23/17 at approximately 1400 hours indicated: A. Recovery Room Grid: 10/20/16 at 1204 hours: Blood Pressure (BP) 102/80. B. Recovery Room Grid: 10/20/16 at 1219 hours: BP 118/76. Respirations 16. The record lacked documentation of pulse and respiratory rate at 1204 hours and a pulse at 1219 hours.</p> <p>3. Review of patient 6's MR on 1/23/17 at approximately 1400 hours indicated: A. Recovery Room Grid: 9/22/16 at 1548 hours: BP 118/78. Pulse 80. B. Recovery Room Grid: 9/22/16 at 1603 hours: BP 110/76. Pulse 78. C. Both sets of vital signs lacked a respiratory rate.</p> <p>4. Review of patient 7's MR on 1/23/17 at approximately 1400 hours indicated: A. Recovery Room Grid: 9/15/16 at 1128 hours: BP 96/52. B. Recovery Room Grid: 9/15/16 at 1143 hours: BP 102/60. C. Both sets of vitals lacked a respiratory rate and pulse.</p> <p>5. Review of patient 8's MR on 1/23/17 at approximately 1400 hours indicated: A. Recovery Room Grid: 9/8/16 at 1142 hours: BP 184/113. B. Recovery Room Grid: 9/8/16 at 1157 hours: BP 166/90. C. Both sets of vitals lacked a respiratory rate and pulse.</p> <p>6. Review of patient 9's MR on 1/23/17 at approximately 1400 hours indicated: A. Recovery Room Grid: 9/1/16 at 1109</p>	T 184		

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T 184	<p>Continued From page 11</p> <p>hours: BP 110/60. B. Recovery Room Grid: 9/1/16 at 1124 hours: BP 108/62. C. Both sets of vitals lacked a respiratory rate and pulse.</p> <p>7. Review of patient 10's MR on 1/23/17 at approximately 1400 hours indicated: A. Recovery Room Grid: 9/1/16 at 1445 hours: BP 155/88. B. Recovery Room Grid: 9/1/16 at 1500 hours: BP 122/68. C. Both sets of vitals lacked a respiratory rate and pulse.</p> <p>8. Review of patient 11's MR on 1/23/17 at approximately 1400 hours indicated: A. Recovery Room Grid: 9/1/16 at 1517 hours: BP 100/60. B. Recovery Room Grid: 9/1/16 at 1526 hours: BP 102/62. C. Both sets of vitals lacked a respiratory rate and pulse.</p> <p>9. Review of patient 12's MR on 1/23/17 at approximately 1400 hours indicated: A. Recovery Room Grid: 8/25/16 at 1605 hours: BP 122/77. B. Recovery Room Grid: 8/25/16 at 1622 hours: BP 110/64. C. Both sets of vitals lacked a respiratory rate and pulse.</p> <p>10. Review of patient 13's MR on 1/23/17 at approximately 1400 hours indicated: A. Recovery Room Grid: 8/25/16 at 1326 hours: BP 90/60. B. Recovery Room Grid: 8/25/16 at 1322 hours: BP 96/62. C. Recovery Room Grid: 8/25/16 at 1340</p>	T 184		

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T 184	<p>Continued From page 12</p> <p>hours: BP 94/60. D. The vitals lacked a respiratory rate and pulse.</p> <p>11. Review of patient 14's MR on 1/23/17 at approximately 1400 hours indicated: A. Recovery Room Grid: 8/11/16 at 1332 hours: BP 90/60. The vitals lacked a pulse or respiratory rate. B. Recovery Room Grid: 8/25/16 at 1347 hours: BP 102/70, Respirations 16. The vitals lacked a pulse.</p> <p>12. Review of patient 15's MR on 1/23/17 at approximately 1400 hours indicated: A. Recovery Room Grid: 8/17/16 at 1201 hours: BP 100/60. B. Recovery Room Grid: 8/17/16 at 1216 hours: BP 102/58. C. Recovery Room Grid: 8/17/16 at 1231 hours: BP 98/62. D. The vitals lacked a respiratory rate and pulse.</p> <p>13. Review of patient 16's MR on 1/23/17 at approximately 1400 hours indicated: A. Recovery Room Grid: 7/28/16 at 1315 hours: BP 120/60. The vitals lacked respiratory rate and pulse. B. Recovery Room Grid: 7/28/16 at 1330 hours: BP 110/76, Pulse 80. The vitals lacked respiratory rate.</p> <p>14. Review of patient 18's MR on 1/23/17 at approximately 1400 hours indicated: A. Recovery Room Grid: 7/21/16 at 1009 hours: BP 100/72. The vitals lacked a pulse and respiratory rate.</p>	T 184		

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T 184	<p>Continued From page 13</p> <p>15. Review of patient 19's MR on 1/23/17 at approximately 1400 hours indicated: A. Recovery Room Grid: 7/28/16 at 1545 hours: BP 80/50. The vitals lacked a pulse and respiratory rate. B. Recovery Room Grid: 7/28/16 at 1600 hours: BP 101/61, Pulse 73. The vitals lacked a respiratory rate.</p> <p>16. Review of patient 20's MR on 1/23/17 at approximately 1400 hours indicated: A. Recovery Room Grid: 7/14/16 at 1511 hours: BP 98/74, Pulse 86. The vitals lacked a respiratory rate.</p> <p>17. Review of patient 21's MR on 1/23/17 at approximately 1400 hours indicated: A. Recovery Room Grid: 7/7/16 at 1253 hours: BP 120/78. The vitals lacked a respiratory rate and pulse. B. Recovery Room Grid: 7/7/16 at 1310 hours: BP 122/68, Pulse 72. The vitals lacked a respiratory rate.</p> <p>18. Review of patient 22's MR on 1/23/17 at approximately 1400 hours indicated: A. Recovery Room Grid: 1/19/17 at 1248 hours: BP 120/60, Respirations 16. B. Recovery Room Grid: 1/19/17 at 1303 hours: BP 122/64, Respirations 16. C. The vitals lacked a pulse rate.</p> <p>19. Review of patient 23's MR on 1/23/17 at approximately 1400 hours indicated: A. Recovery Room Grid: 11/3/16 at 1349 hours: BP 98/60, Respirations 18. B. Recovery Room Grid: 11/3/16 at 1404 hours: BP 118/70, Respirations 18. C. The vitals lacked a pulse rate.</p>	T 184		

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T 184	<p>Continued From page 14</p> <p>20. Review of patient 24's MR on 1/23/17 at approximately 1400 hours indicated: A. Recovery Room Grid: 12/15/16 at 1130 hours: BP 114/72. The vitals lacked a pulse or respiratory rate. B. Recovery Room Grid: 12/15/16 at 1145 hours: BP 110/68, Respirations 18. The vitals lacked a pulse rate.</p> <p>21. Review of patient 25's MR on 1/23/17 at approximately 1400 hours indicated: A. Recovery Room Grid: 12/15/16 at 1251 hours: BP 100/70, Respirations 16. B. Recovery Room Grid: 12/15/16 at 1304 hours: BP 118/74, Respirations 16. C. The vitals lacked a pulse rate.</p> <p>22. Review of patient 26's MR on 1/23/17 at approximately 1400 hours indicated: A. Recovery Room Grid: 12/8/16 at 1042 hours: BP 126/74. The vitals lacked a pulse or respiratory rate. B. Recovery Room Grid: 12/8/16 at 1058 hours: BP 122/76, Respirations 16. The vitals lacked a pulse rate.</p> <p>23. Review of patient 27's MR on 1/23/17 at approximately 1400 hours indicated: A. Recovery Room Grid: 12/8/16 at 1417 hours: BP 124/72, Respirations 16. B. Recovery Room Grid: 12/8/16 at 1432 hours: BP 110/72, Respirations 16. C. The vitals lacked a pulse rate.</p> <p>24. Review of patient 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 18, 19, 20, 21, 22, 23, 24, 25, 26 and 27's MR lacked documentation of assessment of</p>	T 184		

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T 184	Continued From page 15  2 complete sets of vital signs to include blood pressure, respiratory rate and pulse at initiation of recovery as indicated per facility policy/procedure 18.1.2, Recovery Area Assessment Criteria.  25. On 1/23/17 at approximately 1430 hours, staff P4 (Center Manager) was interviewed and confirmed patient 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 18, 19, 20, 21, 22, 23, 24, 25, 26 and 27's MR lacked documentation of assessment of 2 complete sets of vital signs to include blood pressure, respiratory rate and pulse. Staff P4 confirmed staff failed to complete assessment at initiation of recovery as written per facility policy.	T 184		
T 206	410 IAC 26-11-1 INFECTION CONTROL PROGRAM  410 IAC 26-11-1(a)(1)  (a) The clinic must do the following: (1) Provide a safe and healthful environment that minimizes infection exposure and risk to the following: (A) Patients. (B) Health care workers. (C) Persons who accompany patients.  This RULE is not met as evidenced by: Based on document review, observation and interview the facility failed to provide a safe and healthful environment that minimizes infection exposure and risk to patients and health care workers for 1 of 3 (Lab) areas toured.  Findings:	T 206		



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T 206	<p>Continued From page 16</p> <ol style="list-style-type: none"> <li>Review of Certificates of Analysis dated 1/18/17 for Human Whole Blood (Rh Positive) product, Lot numbers: BRH1268997 and BRH1268996, purchase order number 45616, 1 individual donor of 6 mL of human whole blood (Rh Positive) indicated: Biohazard information: This material should be handled as if capable of transmitting infectious agents. Please use universal precautions. No test method can provide total assurance that hepatitis B virus, hepatitis C virus, human immunodeficiency virus, or other infectious agents are absent. Thus, all biological products that we provide should be handled at the bio-safety level 2 as recommended by the CDC/NIH manual "Biosafety in microbiological and biomedical laboratories, from potentially infectious human serum or blood specimens".</li> <li>Review of Instructions for Use of Eldoncard No. 4304 indicated: 3. With a pipette, apply blood onto each of the circular fields. 4. Stir the blood in the Anti-D field with an Eldonstick until the reagent is completely dissolved. 5. To develop a possible agglutinate, the card must be tilted for at least 40 seconds. Tilt the Eldoncard to an almost upright position and wait 10 seconds. A wave of blood will move the red cells slowly to the bottom of the fields.</li> <li>While on tour of facility on 1/24/17 at approximately 1145 hours, in the presence of staff P1 and P4, 2 vials of Human Whole Blood (Rh positive) used for Rh quality control testing were found in the refrigerator located in the lab along with other medications such as vaccines, RhO immune globulin, pregnancy test controls and Nuvarings. In addition, 6 Eldoncards which would be use for 6 different patients were observed on the countertop of the lab for use of</li> </ol>	T 206		

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T 206	Continued From page 17  quality control testing using blood contained in the vials observed in the refrigerator.  4. Staff P4 (Center Manager) was interviewed on 1/25/17 at approximately 1145 hours and confirmed 2 vials of blood, along with medications were being stored together in the refrigerator located in the lab. Staff P4 confirmed staff perform Rh quality control testing utilizing Eldoncards placed on the countertop of the lab. Staff P4 confirmed the 2 blood vials stored in the refrigerator are used in performing the Rh quality control testing by placing drops of blood on the Eldoncards. Staff P4 confirmed staff prepare medications and other lab tests, such as pregnancy tests, on the same countertop used to perform the Rh quality control tests. Staff P1 (Director of Abortion Operations) was interviewed on 1/25/17 at approximately 1145 hours and confirmed facility staff should not be storing blood vials in the refrigerator along with medications and Rh quality control testing should not be performed on the same countertop used to prepare medications and/or other lab tests due to potential for transmitting infectious agents.	T 206		
T 258	410 IAC 26-11-3 INFECTION CONTROL PROGRAM  410 IAC 26-11-3(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	T 258		

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T 258	<p>Continued From page 18</p> <p>provided;</p> <p>(ii) clean linen storage and mending must be separated from soiled linen handling and storage; and</p> <p>(iii) employee hand washing facilities must be available in each room where clean or soiled linen is processed and handled.</p> <p>This RULE is not met as evidenced by: Based on observation and interview, the clinic failed to ensure that an employee hand washing facility was available in the room where clean or soiled linen is processed and handled for one facility.</p> <p>Findings:</p> <p>1. On 1/24/17 at approximately 1:45 pm, during facility tour, in the presence of A4, Center Manager, and A1, Director of Abortion Operations, the following was observed: Upstairs on the second floor was a room with lockers and a closet area with the washer and dryer (W/D). No sink or hand washing facility was available in that room.</p> <p>2. On 1/24/17 at approximately 1:45 pm, A1 indicated the locker room with the W/D was the area used to launder/process both soiled and clean linens from the clinic. A1 indicated the facility followed "CMS" guidelines as laundry</p>	T 258		

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T 258	Continued From page 19 standards.  3. On 1/24/17 at 2:00 pm A5, LPN (licensed practical nurse), indicated he/she does do laundry for the clinic and does so in the locker room W/D area. A5 indicated soiled physician scrubs, blankets, pillow cases, wash clothes, etc. are laundered in the facility. A5 indicated hand washing is done in the restroom.	T 258		
T 406	410 IAC 26-17-3 PHYS. PLANT,MAINT.,EQUIP.,ENVIR.,SAFETY  410 IAC 26-17-3(3)(A)  The condition of the physical plant and the overall clinic environment must be developed and maintained in such a manner that the safety and well-being of patients is assured as follows: (3) Provision must be made for the periodic inspection, preventive maintenance, and repair of the physical plant and equipment by qualified personnel as follows: (A) Operation, maintenance, and spare parts manuals must be available, along with training or instruction, or both, of the appropriate clinic personnel, in the maintenance and operation of fixed and movable equipment.  This RULE is not met as evidenced by: Based on document review and interview, the clinic failed to ensure availability of the operation and maintenance manual of the back-up	T 406		

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T 406	<p>Continued From page 20</p> <p>generator and training or instruction of appropriate clinic personnel in the maintenance and operation of fixed and movable equipment for one facility.</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>1. Review of facility documents, policies and procedures and equipment manuals lacked documentation of an operation and maintenance manual for the back-up generator.</li> <li>2. Review of the personnel list lacked documentation of clinic person(s) responsible for maintenance or operation of fixed and moveable equipment.</li> <li>3. On 1/23/17 at 11:00am, documentation of who is responsible for facility maintenance along with documentation of their training was requested of A3, Vice President of Patient Services.</li> <li>4. Review of generator manuals lacked documentation the operation and maintenance manual.</li> <li>5. Review of personnel files SA1, SA2, SA3 and SA4 lacked documentation of training or instruction for maintenance and operation of the generator.</li> <li>6. On 1/24/17 at 4:15 pm, A3 verified no other generator manuals were available nor was documentation of clinic personnel responsible for maintenance of facility equipment.</li> </ol>	T 406		
T 408	410 IAC 26-17-3 PHYS. PLANT,MAINT.,EQUIP.,ENVIR.,SAFETY	T 408		

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T 408	<p>Continued From page 21</p> <p>410 IAC 26-17-3(3)(B)</p> <p>The condition of the physical plant and the overall clinic environment must be developed and maintained in such a manner that the safety and well-being of patients is assured as follows:</p> <p>(B) All mechanical equipment (pneumatic, electric, sterilizing, or other) must be on a documented maintenance schedule of appropriate frequency in accordance with one (1) of the following:</p> <p>(i) Acceptable standards of practice.</p> <p>(ii) The manufacturer ' s recommended maintenance schedule.</p> <p>This RULE is not met as evidenced by: Based on document review and interview, it could not be determined that the back-up generator was on a maintenance schedule of appropriate frequency for one back up generator of one facility.</p> <p>Findings:</p> <ol style="list-style-type: none"> <li>1. Review of facility documents, policies and manuals lacked documentation of a maintenance schedule or procedures for maintenance for the back up-generator.</li> <li>2. Review of preventive maintenance (PM) documentation indicated the back-up generator was last serviced for PM on 1/15/16.</li> <li>3. On 1/24/17 at 3:40pm, A4, Center Manager, indicated the back-up generator is serviced annually by an outside provider, the most recent</li> </ol>	T 408		

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T 408	Continued From page 22  PM was 1/15/16 and manufacturer recommendations for the generator detailing frequency of checks was not available.	T 408		
T 418	410 IAC 26-17-4 PHYS. PLANT, MAINT., EQUIP., ENVIR., SAFETY  410 IAC 26-17-4(3)  All patient care equipment must be in good working order and regularly serviced and maintained as follows: (3) Appropriate records must be: (A) kept pertaining to: (i) equipment maintenance; (ii) repairs; and (iii) electrical current leakage checks; and (B) analyzed at least triennially.  This RULE is not met as evidenced by: Based on document review, observation and interview the clinic failed to ensure electrical current leakage checks were done for 6 of 6 pieces of patient care equipment (2 autoclaves, 2 exam lights and 2 exam tables).  Findings:  1. Review of the policy titled Equipment Management, Revised 01/2017, indicated the following: Autoclave: Control - Inspect the power supply line and ensure proper grounding. Exam lights: Control - Make sure cord is not frayed along the length. Exam table: Control - Make	T 418		

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T 418	<p>Continued From page 23</p> <p>sure cord is not frayed.</p> <p>2. On 1/24/17 between 1:30pm and 2:00 pm, during facility tour, in the presence of A4, Center Manager, the following pieces of corded electrical equipment were observed: 2 autoclave units, 2 exam lights and 2 exam tables.</p> <p>3. Review of Equipment Maintenance Checks dated Year 2016: 4/30, 7/25, 9/17 and 1/19 and the document titled K&amp;R Annual Preventative Maintenance dated 5/11/16 lacked documentation of electrical current leakage checks of the 2 autoclaves, 2 exam lights or the 2 exam tables.</p> <p>4. On 1/24/17 at 4:15 pm, A3, Vice President of Patient Services, verified that the clinic lacked documentation of electrical current leakage checks for the autoclaves, exam lights and exam tables.</p>	T 418		