

Indiana State Department of Health

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 011117 | (X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____ | (X3) DATE SURVEY COMPLETED 03/15/2018 |
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| NAME OF PROVIDER OR SUPPLIER PLANNED PARENTHOOD OF INDIANA AND KENTUCKY | STREET ADDRESS, CITY, STATE, ZIP CODE 421 S COLLEGE AVE BLOOMINGTON, IN 47403 |
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| T 000 | INITIAL COMMENTS This visit was for a State licensure survey. Dates of survey: 3/14/18 to 3/15/18 Facility #011117 QA: 3/21/18 | T 000 | | |
| T 026 | 410 IAC 26-4-1 GOVERNING BODY 410 IAC 26-4-1(c)(3) (c) The governing body shall do the following: (3) Review, at least every six (6) months, reports of management operations, including, but not limited to, the following: (A) Quality assessment and improvement program. (B) Patient services provided. (C) Results attained. (D) Recommendations made. (E) Actions taken. (F) Follow-up. This RULE is not met as evidenced by: Based on document review and interview, the governing body (GB) failed to review quality assessment and performance improvement (QAPI) program reports at least every 6 months during 4 quarters of calendar year 2017. Findings include: 1. Review of GB Board Meeting minutes dated | T 026 | | |

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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

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| T 028 | Continued From page 1 11/28/2017, 8/26/2017, 5/31/2017, 3/22//2017 and 1/25/2017 lacked documentation of review of QAPI reports by the GB. 2. On 3/15/18 at approximately 3:00pm, A1, Vice President of Patient Services, indicated review of QAPI program reports did not show in GB meeting minutes and the facility had no other documentation of the GB having reviewed QAPI reports within the 4 quarters of the 2017 calendar year. | T 026 | | |
| T 118 | 410 IAC 26-7-1 MEDICAL RECORDS 410 IAC 26-7-1(b)(3) (b) A medical record must be maintained with documentation of service rendered for each surgical abortion patient of the clinic as follows: (3) The clinic shall use a system of author identification and record maintenance that: (A) ensures the integrity of the authentication; and (B) protects the security of all record entries. Each entry must be authenticated in accordance with the clinic and medical staff policies. This RULE is not met as evidenced by: Based on document review and interview, the facility failed to follow their policy/procedure for medical record documentation for 20 of 30 closed medical records (MR) reviewed. Findings: | T 118 | | |

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| T 118 | Continued From page 2 1. Policy/procedure 5.2, Administrative Chapter 5: Medical Records, Documentation, and Reporting Requirements, revised/reapproved 3/2017 indicated on page 3-4: "III. Documentation must be performed in accordance with accepted professional standards and any applicable laws/regulations. It must...F. Be signed with the full name of the signer including credentials for licensed staff and titles for non-licensed staff". 2. Review of patient 1's MR lacked documentation of authentication signature of medical staff D1 for Visit Summary note dated 3/8/18 at 0750 hours. 3. Review of patient 2's MR lacked documentation of authentication signature of medical staff D1 for Visit Summary note dated 3/8/18 at 0740 hours. 4. Review of patient 3's MR lacked documentation of authentication signature of medical staff D1 for Visit Summary note dated 3/8/18 at 0940 hours. 5. Review of patient 4's MR lacked documentation of authentication signature of medical staff D1 for Visit Summary note dated 2/22/18 at 0730 hours. 6. Review of patient 5's MR lacked documentation of authentication signature of medical staff D1 for Visit Summary note dated 2/22/18 at 0900 hours. 7. Review of patient 6's MR lacked documentation of authentication signature of medical staff D1 for Visit Summary note dated 2/08/18 at 0820 hours. | T 118 | | |

Indiana State Department of Health

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| T 118 | <p>Continued From page 3</p> <p>8. Review of patient 7's MR lacked documentation of authentication signature of medical staff D1 for Visit Summary note dated 2/08/18 at 1000 hours.</p> <p>9. Review of patient 9's MR lacked documentation of authentication signature of medical staff D1 for Visit Summary note dated 2/01/18 at 1000 hours.</p> <p>10. Review of patient 10's MR lacked documentation of authentication signature of medical staff D1 for Visit Summary note dated 1/25/18 at 1000 hours.</p> <p>11. Review of patient 14's MR lacked documentation of authentication signature of medical staff D1 for Visit Summary note dated 12/14/17 at 1330 hours.</p> <p>12. Review of patient 16's MR lacked documentation of authentication signature of medical staff D1 for Visit Summary note dated 12/07/17 at 1330 hours.</p> <p>13. Review of patient 17's MR lacked documentation of authentication signature of medical staff D1 for Visit Summary note dated 11/30/17 at 0730 hours.</p> <p>14. Review of patient 18's MR lacked documentation of authentication signature of medical staff D1 for Visit Summary note dated 11/16/17 at 1230 hours.</p> <p>15. Review of patient 19's MR lacked documentation of authentication signature of medical staff D1 for Visit Summary note dated 09/21/17 at 1028 hours.</p> | T 118 | | |

Indiana State Department of Health

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| T 118 | <p>Continued From page 4</p> <p>16. Review of patient 20's MR lacked documentation of authentication signature of medical staff D1 for Visit Summary note dated 08/31/17 at 0822 hours.</p> <p>17. Review of patient 21's MR lacked documentation of authentication signature of medical staff D1 for Visit Summary note dated 08/24/17 at 1120 hours.</p> <p>18. Review of patient 22's MR lacked documentation of authentication signature of medical staff D1 for Visit Summary note dated 08/10/17 at 1033 hours.</p> <p>19. Review of patient 28's MR lacked documentation of authentication signature of medical staff D1 for Visit Summary note dated 04/20/17 at 0820 hours.</p> <p>20. Review of patient 29's MR lacked documentation of authentication signature of medical staff D1 for Visit Summary note dated 04/12/17 at 1410 hours.</p> <p>21. Review of patient 30's MR lacked documentation of authentication signature of medical staff D1 for Visit Summary note dated 03/30/17 at 0842 hours</p> <p>22. On 3/15/18 at approximately 1200 hours, staff N1 (Director of Clinical Operations) was interviewed and confirmed patient 1, 2, 3, 4, 5, 6, 7, 9, 10, 14, 16, 17, 18, 19, 20, 21, 22, 28, 29 and 30's MR lacked documentation of a medical staff provider's signature and confirmed the medical staff provider is required to authenticate medical record documentation per his/her signature. Staff N1 confirmed staff should follow policy/procedure for medical records documentation.</p> | T 118 | | |

Indiana State Department of Health

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| T 184 | <p>410 IAC 26-10-1 PATIENT CARE AND NURSING SERVICES</p> <p>410 IAC 26-10-1(a)(1)</p> <p>(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;</p> <p>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 6 of 22 closed medical records (MR) reviewed.</p> <p>Findings:</p> <ol style="list-style-type: none"> 1. Policy/procedure 18.1.2, Recovery Area Assessment Criteria, revised/reapproved 6/2016 indicated on page 2 indicated: "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)." 2. Review of patient 5, 6, 7, 18, 19 and 22's MR lacked documentation of assessment of 2 complete sets of vital signs to include blood pressure, respiratory rate and pulse at initiation of recovery. 3. On 3/14/18 at approximately 1430 hours, staff N1 (Director of Clinical Operations) was interviewed and confirmed patient 5, 6, 7, 18, 19 and 22's MR lacked documentation of | T 184 | | |

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| T 184 | Continued From page 6 assessment of 2 complete sets of vital signs to include blood pressure, respiratory rate and pulse. Staff N1 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 include: 1. Review of PPINK (Planned Parenthood Indiana Kentucky) Infection Control Manual & OSHA Risk Exposure Plan, revised/reviewed 04/2017 indicated: A. page 19: "Standard precautions are OSHA's required method of control to protect staff from exposure to all human blood, certain human body fluids and other potentially infectious material (OPIM). In using Standard Precautions, | T 206 | | |

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| T 206 | <p>Continued From page 7</p> <p>we assume that all human blood and OPIM be treated as if known to be infectious for hepatitis B virus, HIV, or other blood borne pathogens regardless of the perceived "low risk" of a patient. In the health care setting, standard precautions apply to all patients regardless if you suspect or do not suspect they may be contagious".</p> <p>B. page 20: "Soiled patient care equipment: Handle in a manner that prevents transfer of microorganisms to others and to the environment".</p> <p>2. While on tour of facility on 3/15/18 at approximately 1400 hours, accompanied by staff N2 (Center Manager), 4 bottles of medications including 1 bottle of Ibuprofen 800 mg 100 tablets, 1 bottle of metronidazole 500 mg 50 tablets and 2 bottles of azithrozyclin 250 mg 30 tablets, were found on the countertop in the lab room along with supplies for specimen processing of labs including Rh and pregnancy testing.</p> <p>3. Staff N2 (Center Manager) was interviewed on 3/16/18 at approximately 1415 hours and confirmed staff set the above-mentioned medication bottles on the countertop for easy access to administer to patients. Staff N2 confirmed the countertop is also used as workspace for processing lab specimens including urine and blood for Rh and pregnancy testing. Staff N2 confirmed staff should observe standard precautions. Staff N2 confirmed processing lab specimens utilizing urine and blood samples on the same countertop which patient medications are placed may result in exposure to potentially infectious material.</p> | T 206 | | |

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| T 214 | Continued From page 8 | T 214 | | |
| T 214 | 410 IAC 26-11-1 INFECTION CONTROL PROGRAM 410 IAC 26-11-1(c) (c) The clinic must designate a person qualified by training or experience as responsible for the following: (1) Ongoing infection control activities. (2) The development and implementation of policies governing control of infections and communicable diseases. This RULE is not met as evidenced by: Based on document interview the facility failed to designate a person qualified by training or experience as responsible for facility infection control activities. Findings include: 1. Staff N3 (Director of Clinical Services) was interviewed on 3/15/18 at approximately 1300 hours and confirmed the facility did not have a person designated responsible for facility infection control activities. | T 214 | | |
| 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 | T 232 | | |

Indiana State Department of Health

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| T 232 | <p>Continued From page 9</p> <p>to, the following:</p> <p>(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:</p> <p>(i) Sanitation, including proper disposal of removed tissue.</p> <p>(ii) Universal precautions, including infectious waste management.</p> <p>(iii) Cleaning, disinfection, and sterilization.</p> <p>(iv) Aseptic technique, invasive procedures, and equipment usage.</p> <p>(v) Reuse of disposables.</p> <p>(vi) A system for handling patients with communicable diseases.</p> <p>(vii) A system, which complies with state and federal law, to monitor the immune status of health care workers exposed to communicable diseases.</p> <p>(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.</p> <p>(ix) Requirements for personal hygiene and attire that meet acceptable standards of practice.</p> <p>(x) A program of linen management.</p> <p>This RULE is not met as evidenced by: Based on document review and interview, the facility failed to follow the facility's infection control</p> | T 232 | | |

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| T 232 | <p>Continued From page 10</p> <p>policies and procedures (P&P) for housekeeping services for 5 of 7 personnel files reviewed (S1, S2, S3, S4 and S6).</p> <p>Findings include:</p> <ol style="list-style-type: none"> Review of facility policies and procedures of the Infection Control Manual & OSHA (Occupational Safety and Health Administration) Risk Exposure Plan, Revised 04/2017, indicated the following: Housekeeping Services. In all health centers daily cleaning and decontamination of the exam rooms, labs and equipment is done by trained staff... Review of personnel files for S1, S2, S3, S4 and S6 lacked documentation of daily cleaning and decontamination training. On 3/15/18 at approximately 2:00pm, A1, Vice President of Patient Services, indicated that the contracted housekeeping service did not clean or decontaminate exam rooms, laboratories or equipment. A1 further indicated that those processes are performed by staff members and that any staff member, including S1, S2, S3, S4, S5, S6 and S7, could perform those duties. A1 verified lack of documentation of housekeeping/cleaning and decontamination training for S1, S2, S3, S4 and S6 and indicated that S5, date of hire 11/6/17, was still in orientation. | T 232 | | |
| T 322 | <p>410 IAC 26-16-1 PHARMECEUTICAL SERVICES</p> <p>410 IAC 26-16-1(3)(A)</p> <p>The clinic must provide drugs and biologicals in a</p> | T 322 | | |

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| T 322 | <p>Continued From page 11</p> <p>safe and effective manner in accordance with accepted professional practice. The clinic must have the following:</p> <p>(3) Written policies and procedures developed, implemented, maintained, and made available to personnel, including, but not limited to, the following:</p> <p>(A) Drug:</p> <p>(i) handling;</p> <p>(ii) storing;</p> <p>(iii) labeling;</p> <p>(iv) dispensing; and</p> <p>(v) administration according to established clinic policies and acceptable standards of practice.</p> <p>This RULE is not met as evidenced by: Based on document review, observation and interview, the facility failed to follow its policy/procedure for expired medications & unauthorized access to medications for 1 facility.</p> <p>Findings include:</p> <p>1. Review of policy/procedure PS_16, Pharmaceuticals in the Health Centers, revised/reviewed 2/15/18 indicated the following: All medications, except controlled substances, will be stored in locked areas away from patient access; only licensed staff may access medications unless under the direct supervision of a licensed provider.</p> <p>All expired medication must be tracked on the Expired Medication Log - the log is available on</p> | T 322 | | |

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| T 322 | <p>Continued From page 12</p> <p>the Health Center Resources Drive; expired medications should be disposed of immediately in each health center's expired medication bin; this must be stored in a locked area away from patient access.</p> <p>2. On 3/15/18 between 11:00am and 12:00pm, during facility tour, in the presence of A6, Facility Manager, in room #8, the recovery room, inside the medication storage refrigerator were 2 vials Promethazine 25mg/ml observed with a manufacturer expiration date of 10/2017.</p> <p>3. On 3/15/18 at approximately 11:45am, A6 indicated the expired Promethazine should have been discarded and should not be in the patient medication refrigerator.</p> <p>4. While on tour of facility on 3/15/18 at approximately 1400 hours, accompanied by staff N2 (Center Manager), 4 bottles of medications including 1 bottle of Ibuprofen 800 mg 100 tablets, 1 bottle of metronidazole 500 mg 50 tablets and 2 bottles of azithrozyclin 250 mg 30 tablets, were found unsecured located on the countertop in the lab room.</p> <p>5. While on tour of facility on 3/15/18 at approximately 1430 hours, accompanied by staff N2, a medication refrigerator was observed to be unlocked and contained medications for patient administration that unauthorized individuals could have access to.</p> <p>6. Staff N2 (Center Manager) was interviewed on 3/15/18 at approximately 1430 hours and confirmed staff placed the above-mentioned medication bottles on the countertop in the lab room for ease of access to administer to patients. Staff N2 confirmed the medications located on</p> | T 322 | | |

Indiana State Department of Health

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| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: 011117 | (X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____ | (X3) DATE SURVEY COMPLETED 03/15/2018 |
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| NAME OF PROVIDER OR SUPPLIER PLANNED PARENTHOOD OF INDIANA AND KENTUCKY | STREET ADDRESS, CITY, STATE, ZIP CODE 421 S. COLLEGE AVE BLOOMINGTON, IN 47403 |
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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 |
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| T 322 | Continued From page 13 the countertop of the lab room were unsecured and potentially accessible to unauthorized individuals. Staff N2 confirmed the medication refrigerator located in the recovery area was unlocked and contained medications for administration to patients. | T 322 | | |
| T 404 | 410 IAC 26-17-3 PHYS. PLANT, MAINT., EQUIP., ENVIR., SAFETY 410 IAC 26-17-3(2) The condition of the physical plant and the overall clinic environment must be developed and maintained in such a manner that the safety and well-being of patients is assured as follows: (2) No condition may be created or maintained that may result in a hazard to: (A) patients; (B) authorized visitors; or (C) employees. This RULE is not met as evidenced by: Based on observation and interview, the facility created a condition that may have resulted in a hazard to patients, visitors or employees in 1 instance for 1 facility. Findings include: 1. On 3/15/18 at approximately 12:00pm, during facility tour, in the presence of A6, Facility Manager, and A1, Vice President of Patient Services, the following was observed: In an office (indicated to be the area of medical gas storage), on the floor, leaned up against a desk was an | T 404 | | |

Indiana State Department of Health

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| T 404 | Continued From page 14 unsecured green oxygen cylinder tank. 2. On 3/15/18 at approximately 12:00pm, A1 verified that the oxygen tank was unsecured, could create a source of potential hazard to patients, visitors or employees and should be stored in a secured manner and location. | T 404 | | |
| T 414 | 410 IAC 26-17-4 PHYS. PLANT,MAINT.,EQUIP.,ENVIR.,SAFETY 410 IAC 26-17-4(1) All patient care equipment must be in good working order and regularly serviced and maintained as follows: (1) All patient care equipment must be on a documented maintenance schedule of appropriate frequency in accordance with one (1) of the following: (A) Acceptable standards of practice. (B) The manufacturer ' s recommended maintenance schedule. This RULE is not met as evidenced by: Based on document review and interview, the facility failed to ensure 6 of 8 pieces/types of patient care equipment (defibrillator, emergency call system, recovery chairs, vacuum units, examine tables, and procedure tables) were on a documented maintenance schedule in accordance with acceptable standards or the manufacturer's recommendations. Findings include: | T 414 | | |

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| NAME OF PROVIDER OR SUPPLIER PLANNED PARENTHOOD OF INDIANA AND KENTUCKY | STREET ADDRESS, CITY, STATE, ZIP CODE 421 S COLLEGE AVE BLOOMINGTON, IN 47403 |
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| T 414 | <p>Continued From page 15</p> <p>1. Review of the policy titled Equipment Maintenance, March 24, 2017 (review/revise/approve/effective not noted), indicated the following: Ensure that required inspections, testing and maintenance is performed in accordance with the required Federal and State laws, regulations, guidelines, standards and manufacturer's recommendations.</p> <p>2. Review of the manufacturer manual recommendations for maintenance indicated the following:</p> <p>A. Zoll AED Plus Defibrillator/AED (automated external defibrillator): Inspect frequently, as necessary. Use the following maintenance checklist when you periodically check your AED. Check the following: (included, but was not limited to) Is the unit clean, undamaged, free of excessive wear? Are there any crack or loose parts? Batterles within expiration date. Replace if expired.</p> <p>B. No manuals for the emergency call code system or exam lights were provided. Unable to determine manufacturer recommendations or acceptable standards.</p> <p>C. Champlon "Passage" Recliner/recovery room chairs: General Maintenance and Care of Chairs, included the following: Periodically, check that the hinge fasteners, latch mount, release mount and back mount fasteners are secure. We suggest monthly, then tailor to our (sic) findings.</p> <p>D. Cabot Medical, Berkley Vacuum Curettage System: Maintenance. Check the float ball mechanism within the safety trap periodically. Replace filter when it becomes soiled or clogged.</p> <p>E. Midmark Ritter, exam table(s): Preventive Maintenance: Periodically inspect the following areas: Power cord. All fasteners. All mechanical functions. Periodically lubricate the following:</p> | T 414 | | |

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| T 414 | <p>Continued From page 16</p> <p>Back hinge. Footrest slide. Have an authorized service technician inspect your table every six month.</p> <p>F. Midmark Universal Procedures Table Procedure table: Scheduled Maintenance: Interval: Weekly: Visually inspect components for damage. Semi-Annually: Check all mechanical functions. Table shrouds should move smoothly. Replace any missing or illegible labels. All fasteners must be present and fastened securely. Inspect power cord and all wiring. Be sure all electrical connections are tight.</p> <p>3. Review of preventive maintenance (PM) documentation indicated the following for patient care equipment as follows:</p> <p>A. Defibrillator/AED: Maintenance Checks logs lacked documentation of what was checked or done. Unable to determine checks/maintenance was in accordance with manufacturer recommendations.</p> <p>B. Emergency call code system: Maintenance check logs indicated the following: Date Performed, 11/19 (2017), "Telephone Intercom System", "IT working on them". Date Performed 3/5/18, "Telephone Intercom System" - "Does not work".</p> <p>C. Biomedical engineering and internal PM documents lacked documentation of PM on the recliners/recovery room chairs.</p> <p>D. Biomedical engineering document dated 5/2/17, titled Annual Equipment Maintenance lacked documentation of PM for vacuum unit(s). Document of PM for a suction unit lacked documentation of what tasks were performed. Internal Equipment Maintenance Check logs lacked documentation of vacuum unit(s), listed Suction Machines, but lacked documentation of what tasks/checks were performed.</p> | T 414 | | |

Indiana State Department of Health

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| T 414 | Continued From page 17 E. Biomedical engineering document dated 5/2/17, titled Annual Equipment Maintenance lacked documentation of every 6 month PM and lacked documentation of tasks performed for PM of exam tables. F. Biomedical engineering document dated 5/2/17, titled Annual Equipment Maintenance lacked documentation of PM for procedure table(s). Internal Maintenance check logs lacked documentation of PM for procedure table(s). 4. A. On 3/14/18 between approximately 12:45pm and 2:00pm, the following was indicated in interview: A1, Vice President of Patient Services, indicated the clinic utilized a phone system as the emergency call code system. B. On 3/15/18 between approximately 12:30pm and 2:00pm, the following was indicated in interview: A3, Director of Clinical Operations, indicated any PM done on equipment in the clinic would be documented on the biomedical engineering form titled Annual Equipment Maintenance or the internal form titled Equipment Maintenance Checks. A3 verified that the forms lacked documentation of PM tasks were performed. | T 414 | | |