

*J. Spence*  
8/17/15

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FORM APPROVED

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  AB0020	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____  B. WING _____	(X3) DATE SURVEY COMPLETED  06/17/2015
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NAME OF PROVIDER OR SUPPLIER  
**PLANNED PARENTHOOD OF WILMINGTON**

STREET ADDRESS, CITY, STATE, ZIP CODE  
**1925 TRADD COURT  
WILMINGTON, NC 28401**

(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
E 137	<p><b>.0305(A) MEDICAL RECORDS</b></p> <p>10A-14E .0305 (a) A complete and permanent record shall be maintained for all patients including the date and time of admission and discharge; the full and true name; address; date of birth; nearest of kin; diagnoses; duration of pregnancy; condition on admission and discharge; referring and attending physician; a witnessed, voluntarily-signed consent for each surgery or procedure and signature of the physician performing the procedure; and the physician's authenticated history and physical examination including identification of pre- existing or current illnesses, drug sensitivities or other idiosyncrasies having a bearing on the operative procedure or anesthetic to be administered.</p> <p>This Rule is not met as evidenced by: Based on closed medical record review and staff interview, the facility failed to maintain a complete medical record that includes a physician signature on the voluntarily-signed surgery consent form in the patient's permanent medical record for 4 of 10 records reviewed (Patients #6, 7, 8, &amp; 10).</p> <p>1. Closed medical record review of Patient #6 revealed a 31 year-old who had a surgical abortion on 4/10/15. Review of the voluntarily-signed consent form revealed no physician signature. Interview on 6/17/15 at 2:30pm with employee Regional Director revealed that agency policy is to follow all State laws, including to obtain physician signature on all surgery consent forms. Interview confirmed that no physician signature</p>	E 137	<p>10A-14E .0305(A) At Planned Parenthood South Atlantic (PPSAT), patient signatures on consents for surgical and medication abortions require a witness by trained staff members. Prior to and after each procedure, physicians review and sign off on the patient's medical record to ensure histories are reviewed, required examinations are performed, voluntary consents are obtained, and patient consent process is witnessed as per NCDHHS regulations.</p> <p>As of 5/11/15, PPSAT revised abortion consent procedures to include physician signature on abortion consent forms (see attached CIIC-022 and CIIC-027). PPSAT provided a thorough training for all staff, including physicians providing abortions, 6/18/2015.</p> <p>The health center manager will review all charts at the end of each clinic day to ensure compliance with physician signatures on CIIC-022 and CIIC-027 forms. Daily monitoring will continue until consistent compliance is demonstrated.</p> <p>Regional Lead Clinician will conduct an audit of 10 charts at the end of three months to ensure compliance. Quarterly monitoring will continue until consistent compliance is demonstrated.</p>	6.18.2015

Division of Health Service Regulation

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE  
*[Signature]*

TITLE  
*Vice President of Patient Services*

(X6) DATE  
*8/3/15*

Division of Health Service Regulation

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NAME OF PROVIDER OR SUPPLIER  PLANNED PARENTHOOD OF WILMINGTON	STREET ADDRESS, CITY, STATE, ZIP CODE 1925 TRADD COURT WILMINGTON, NC 28401
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E 137	Continued From page 1  was obtained. 2. Closed medical record review of Patient #7 revealed a 24 year-old who had a surgical abortion on 4/17/15. Review of the voluntarily-signed consent form revealed no physician signature. Interview on 6/17/15 at 2:30pm with employee Regional Director revealed that agency policy is to follow all State laws, including to obtain physician signature on all surgery consent forms. Interview confirmed that no physician signature was obtained. 3. Closed medical record review of Patient #8 revealed a 22 year-old who had a surgical abortion on 4/18/15. Review of the voluntarily-signed consent form revealed no physician signature. Interview on 6/17/15 at 2:30pm with employee Regional Director revealed that agency policy is to follow all State laws, including to obtain physician signature on all surgery consent forms. Interview confirmed that no physician signature was obtained. 4. Closed medical record review of Patient #10 revealed a 24 year-old who had a surgical abortion on 3/17/15. Review of the voluntarily-signed consent form revealed no physician signature. Interview on 6/17/15 at 2:30pm with employee Regional Director revealed that agency policy is to follow all State laws, including to obtain physician signature on all surgery consent forms. Interview confirmed that no physician signature was obtained.	E 137		
E 165	.0314 CLEANING OF MATERIALS AND EQUIPMENT  10A-14E .0314 (a) All supplies and	E 165	10A-14E .0314 On June 18, 2015 a new refrigerator was purchased for Wilmington, NC health center.	6.18.15

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E 165	<p>Continued From page 2</p> <p>equipment used in patient care shall be properly cleaned or sterilized between use for different patients.</p> <p>(b) Methods of cleaning, handling, and storing all supplies and equipment shall be such as to prevent the transmission of infection through their use.</p> <p>This Rule is not met as evidenced by: Based on observation during tour, the facility failed to properly store medications in a manner to prevent possible cross contamination with biohazardous material.</p> <p>The findings include:</p> <p>Tour of the facility on June 17, 2015 at 1000 revealed the medication refrigerator also housed a cardboard box in the door which stored patient blood samples waiting to be sent out for laboratory results. The tour also revealed there is a biohazard refrigerator where products of conception (POC) are kept post procedure waiting for disposal.</p> <p>Interview with the Regional Director on June 17, 2015 at 1430 revealed she was aware of how the medication refrigerator was being used and understands the contamination issue. Interview confirmed the medication refrigerator was also being used to store patient blood samples waiting to be sent out for laboratory testing.</p>	E 165	<p>Health center staff has reviewed PPSAT Infection Prevention Policy and Procedures mandating medications and blood products, including blood samples, must be stored in separate refrigerators. The health center now has 2 separate refrigerators: one for the storage of medications and one for the storage of blood products including blood samples.</p> <p>In addition, appropriate storage of POC was reviewed with health center staff. As per PPSAT Infection Prevention Policies and Procedures, staff will continue storing POC in a separate freezer that is used solely for this purpose.</p> <p>Health Center Manager will monitor the correct, separate storage of medications and blood products, including POC, during monthly health center Infection Prevention checks. Regional Lead Clinician will monitor when performing quarterly site visits.</p> <p>The following statement, as found in E 165 is a statement of fact that on site reviewers observed: "the tour also revealed there is a biohazard refrigerator where products of conception (POC) are stored post procedure waiting for disposal." Reviewers did not find inappropriate storage of POC during their site visit.</p>	Reviewed June 4, 2015 during staff meeting.