

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: AB0031	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING: _____	(X3) DATE SURVEY COMPLETED 06/22/2016
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NAME OF PROVIDER OR SUPPLIER A PREFERRED WOMEN'S HEALTH CTR	STREET ADDRESS, CITY, STATE, ZIP CODE 1604 JONES FRANKLIN ROAD RALEIGH, NC 27606
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E 000 Initial Comments

An unannounced on site recertification survey was conducted on June 22, 2016 to review the NC Rules Governing the Certification of Clinics for Abortions. Deficiencies were found in the areas of .0311(a) Surgical Services, .0311(b)(1) Tissue Examination and .0314(a) Cleaning of Equipment.

E 000

E 157 .0311(A) Surgical Services

10A-14E .0311(a) The procedure room shall be maintained exclusively for surgical procedures and shall be so designed and maintained to provide an atmosphere free of contamination by pathogenic organisms. The clinic shall establish procedures for infection control and universal precautions.

This Rule is not met as evidenced by:
Based on review of the facility's policy and procedures, observation and staff interview, the facility staff failed to discard expired medication and supplies.

The findings included:

Review on June 22, 2016 of the policy and procedure "Emergency Back-Up Services" revealed, "... Each month the Emergency Supply Checklist is to be performed jointly by the Clinic Manager and Registered Nurse to check expirations dates, order supplies and discard expired medications. ..." Further review revealed no policy for checking expiration dates on medications and supplies outside of the Banyan Kit (emergency supply case).

E 157

6/23/16
 Medications and Medical
 Supplies will be checked
 monthly and as needed by
 RN supervisor and site
 administrator.
 See Exhibit I

Division of Health Service Regulation LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE 	TITLE Administrator	(X6) DATE 8/3/16
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E 157	<p>Continued From page 1</p> <p>1. Observation on June 22, 2016 at 1100 in the nurses station revealed 3 boxes of 25 5/8 inch needles with an expiration date of 9/15 (September 2015) in a cabinet. Observation revealed each box contained 100 (one hundred) needles for a total of 300 needles.</p> <p>Interview with staff #1 on June 22, 2016 during tour revealed the expiration dates were not checked. Interview revealed the syringes should not be used and needed to be discarded. The interview confirmed the observation finding.</p> <p>2. Observation on June 22, 2016 at 1100 in the nurses station revealed 4 boxes of 25 5/8 inch needles with an expiration date of 7/15 (July 2015) in a cabinet. Observation revealed each box contained 100 (one hundred) needles for a total of 400 needles.</p> <p>Interview with staff #1 on June 22, 2016 during tour revealed the expiration dates were not checked. Interview revealed the syringes should not be used and needed to be discarded. The interview confirmed the observation finding.</p> <p>3. Observation on June 22, 2016 at 1100 in the nurses station revealed a Flat of 25 vials of 1% Lidocaine (numbing medicine) with an expiration date of January 1, 2016 in a cabinet. Observation revealed the staff failed to check medications for expiration dates.</p> <p>Interview with staff #1 on June 22, 2016 during tour revealed the expiration dates were not checked. Interview revealed the medication should not be used and needed to be discarded. The interview confirmed the observation finding.</p>	E 157		

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E 158	Continued From page 2	E 158		
E 158	<p>.0311(B) Surgical Services</p> <p>10A-14E .0311(b) Tissue Examination:</p> <p>(1) The physician performing the abortion is responsible for examination of all products of conception (P.O.C.) prior to patient discharge. Such examination shall note specifically the presence or absence of chorionic villi and fetal parts, or the amniotic sac. The results of the examination shall be recorded in the patient's medical record.</p> <p>(2) If adequate tissue is not obtained based on the gestational age, ectopic pregnancy or an incomplete procedure shall be considered and evaluated by the physician performing the procedure.</p> <p>(3) The clinic shall establish procedures for obtaining, identifying, storing, and transporting specimens</p> <p>This Rule is not met as evidenced by: Based on review of the facility's policy and procedures, Closed medical record review and staff interview, the facility physician failed to document a pathology report in 4 of 16 charts reviewed. (Charts #1, #4, #17 and #20)</p> <p>The findings included:</p> <p>Review on June 22, 2016 of the policy and procedure "XI Surgical Services" revealed, "... 2. Tissue Examination a. The physican performing the abortion shall examine the products of conception prior to discharging the patient from the clinic. ..."</p> <p>1. Closed medical record review on June 22,</p>	E 158	<p style="text-align: right;">6/23/16</p> <p>APWHC Physician Pathology Review Policy memo reviewed and signed off by physicians. See Exhibit II completion will be monitored through weekly and quarterly chart reviews by management.</p>	

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E 158	<p>Continued From page 3</p> <p>2016 revealed Chart #1, a 23 year old admitted for a surgical abortion (SAB) performed by Staff #4 in April 7, 2016. Review revealed no documentation of the products of conception indicating the presence of chorionic villi and fetal parts or amniotic sac.</p> <p>Interview on June 22, 2016 1700 with staff #1 revealed the pathology was not completed and should have been. Interview revealed today (June 22, 2016), "We made a notice that all pathology will be documented and signed in all charts." The interview confirmed the observation finding.</p> <p>2. Closed medical record review on June 22, 2016 revealed Chart #4, a 38 year old admitted for a surgical abortion (SAB) performed by Staff #4 in April 15, 2016. Review revealed no documentation of the products of conception indicating the presence of chorionic villi and fetal parts or amniotic sac.</p> <p>Interview on June 22, 2016 1700 with staff #1 revealed the pathology was not completed and should have been. Interview revealed today (June 22, 2016), "We made a notice that all pathology will be documented and signed in all charts." The interview confirmed the observation finding.</p> <p>3. Closed medical record review on June 22, 2016 revealed Chart #17, a 25 year old admitted for a surgical abortion (SAB) performed by Staff #4 in June 11, 2016. Review revealed no documentation of the products of conception indicating the presence of chorionic villi and fetal parts or amniotic sac.</p> <p>Interview on June 22, 2016 1700 with staff #1 revealed the pathology was not completed and should have been. Interview revealed today (June</p>	E 158		
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E 158	<p>Continued From page 4</p> <p>22, 2016), "We made a notice that all pathology will be documented and signed in all charts." The interview confirmed the observation finding</p> <p>4. Closed medical record review on June 22, 2016 revealed Chart #20, a 18 year old admitted for a surgical abortion (SAB) performed by Staff #5 in June 21, 2016. Review revealed no documentation of the products of conception indicating the presence of chorionic villi and fetal parts or amniotic sac.</p> <p>Interview on June 22, 2016 1700 with staff #1 revealed the pathology was not completed and should have been. Interview revealed today (June 22, 2016), "We made a notice that all pathology will be documented and signed in all charts." The interview confirmed the observation finding</p>	E 158		
E 165	<p>.0314 Cleaning of Materials and Equipment</p> <p>10A-14E .0314 (a) All supplies and equipment used in patient care shall be properly cleaned or sterilized between use for different patients. (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 review of the facility's policy and procedures, observation during tour, and staff interview, the facility failed to prevent the transmission of infection by failing to clean the ultrasound (U/S) probe prior to bringing a patient</p>	E 165	<p>6/23/16 Cleaning protocols of ultrasound probe after each use on each patient reviewed and demonstrated by staff. Evaluation of compliance will be monitored by direct observation of probe cleaning annually and as indicated by RN supervisor as well as physician.</p>	

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E 165	<p>Continued From page 5 to the examination room.</p> <p>The findings included:</p> <p>Review on June 22, 2016 of the policy and procedure "Cleaning of Materials and Equipment" revealed, " All supplies and equipment used in patient care shall be properly cleaned or sterilized between uses for different patients. Whenever possible, disposable supplies/equipment will be used in this facility.</p> <p>Observation during tour on June 22, 2016 at 1130 revealed Staff #6 escorted a patient out of the exam room. Observation revealed the exam table appeared clean (disposable sheet was torn off revealed vinyl table) no used supplies on counters, counters dry and unsoiled. Observation revealed residual gel on a vaginal probe for the U/S machine. Observation revealed Staff #6 escorted a patient into the examination room. Observation revealed staff failed to prevent potential cross-contamination by failing to properly clean equipment prior to a patient entering the examination room.</p> <p>Interview with Staff #1 during tour at 1130 revealed there was still gel on the probe. Interview revealed gel is placed on the probe and then a protective sleeve is placed over the gelled probe for the examination. Interview revealed this was a follow-up day and some patients received an U/S as follow up from their procedures. Interview revealed the patient escorted out of the room received an U/S. Interview revealed that Staff #6 had not finished cleaning the room (U/S machine). Interview revealed the room should have been completely cleaned prior to escorting the next patient into the examination room. The Interview confirmed the observation finding.</p>	E 165	<p><u>Note:</u> Staff member responsible for performing ultrasounds and cleaning probe between patients on 6/22/16 was interviewed and stated she always cleaned probe after each patient, however when the surveyor and site administrator entered the ultrasound room during their building tour, the employee thought she was supposed to promptly leave as not to interrupt.</p>	
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XII

Medications and Anesthesia

1. Medications

a. Only medications or treatments that have been written as an order for that patient shall be given by the nursing staff.

b. Medications may only be given in accordance with the nurse practice act. Each medication or treatment must be noted on the patient's medical record.

c. Each patient (in absence of an allergy to medication or class of medications) (unless otherwise indicated by written protocol of the physician) shall receive:

1. 800mg Ibuprofen PO, preoperatively

2. 25/50 mg of Vistaril PO, preoperatively (Hydroxyzine)

3. 10cc's of intracervical 1% lidocaine, immediately pre-procedure

4. Other medications, antibiotics as may be ordered by the physician

5. Patient may receive at their request or the physician's discretion additional preoperative sedation, consisting of 10-20mg of Nubain IM and 25mg of Phenergan IM.

d. Medications and supplies will be inspected monthly and as needed by the RN Supervisor and Site Administrator.

2. No flammable anesthetics shall be used in this clinic.



PLEASE REVIEW WITH ALL PHYSICIANS IMMEDIATELY.

Daily chart audits to be done by manager to ensure pathology section is completed by physicians until issue is remedied. From then on, charts will be reviewed quarterly and as indicated.

The physician performing the abortion is responsible for examination of all products of conception (P.O.C.) prior to patient discharge. **Such examination shall note specifically the presence or absence of chorionic villi and fetal parts or the amniotic sac. The results of the examination shall be recorded in the patient's medical record.**

The facility has written procedures, supplies, and equipment available for gross and microscopic evaluation of abortion specimens. If placental or fetal tissue is not identified by gross examination, a microscopic examination must be done on the P.O.C. In cases where the microscopic evaluation is negative for chorionic villi and fetal parts, or the weight of the P.O.C. falls substantially below the appropriate weight range for fetal age, a microscopic examination by a board certified or board eligible pathologist shall be done on the P.O.C. Please consult APWHC P.O.C. Pathology Handling Procedure for further assistance.

Failure to comply with this policy will result in counseling of the appropriate physician and/or staff member, and possible administrative action.