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Robin M. Pelland RN, MA

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FORM APPROVED

04/04/2016

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: AB0004	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____ B. WING _____	(X3) DATE SURVEY COMPLETED 02/25/2016
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NAME OF PROVIDER OR SUPPLIER CAROLINA WOMEN'S CLINIC	STREET ADDRESS, CITY, STATE, ZIP CODE 421 WENDOVER ROAD CHARLOTTE, NC 28211
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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
E 156	<p>.0310 Emergency Back-Up Services</p> <p>10a NCAC 14E .0310</p> <p>(a) Each clinic shall have a written plan for the transfer of emergency cases from the clinic to a nearby hospital when hospitalization becomes necessary.</p> <p>(b) The clinic shall have procedures, personnel, and suitable equipment to handle medical emergencies which may arise in connection with services provided by the clinic.</p> <p>(c) The clinic shall have a written agreement between the clinic and a hospital to facilitate the transfer of patients who are in need of emergency care. A clinic that has documentation of its efforts to establish such a transfer agreement with a hospital that provides emergency services and has been unable to secure such an agreement shall be considered to be in compliance with this Rule.</p> <p>(d) The clinic shall provide intervention for emergency situations. These provisions shall include:</p> <p>(1) basic cardio-pulmonary life support;</p> <p>(2) emergency protocols for:</p> <p>(A) administration of intravenous fluids;</p> <p>(B) establishing and maintaining airway support;</p> <p>(C) oxygen administration;</p> <p>(D) utilizing a bag-valve-mask resuscitator with oxygen reservoir;</p> <p>(E) utilizing a suction machine; and</p> <p>(F) utilizing an automated external defibrillator;</p> <p>(3) emergency lighting available in the procedure room as set forth in Rule .0206 of this Subchapter; and</p> <p>(4) ultrasound equipment.</p>	E 156	<p><i>Please see attached</i></p>	

Division of Health Service Regulation
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

Robin M. Pelland

TITLE

Clinical Coordinator

(X8) DATE

3-21-16

Division of Health Service Regulation

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E 156	Continued From page 1 This Rule is not met as evidenced by: Based on facility tour, observation and staff interview the facility failed to provide an automatic external defibrillator (AED) and emergency protocol for utilizing an automatic external defibrillator (AED) in emergency situations. Findings include: Observation on 02/24/2016 at 1300-1515 of entire facility revealed no AED was on the premises for use in emergency situation and no protocol for utilizing an AED. Interview with Clinical Coordinator on 02/24/2016 at 1600 revealed that no AED was on the premises and no protocol was available for utilization of an AED. The interview further revealed the CEO (Chief Executive Officer) would be contacted regarding this requirement.	E 156		
E 165	.0314 Cleaning of Materials and Equipment 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. This Rule is not met as evidenced by: Based on review of facility Policy and Procedure, observation and staff interview the facility failed to ensure suction bottles and tubing were cleaned to prevent the transmission of infection. Findings include:	E 165		

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E 165	Continued From page 2 Review of facility Policy "Cleaning POC (products of conception) and Tubing Between Patients and at the End of the Day" no date included, "After each patient ...will clean the bottle thoroughly assuring there is no visible blood, or tissue...a scrubbing brush will be used for this process. A mixture of Terga-zyne (sic) (EPA registered cleanser enzyme for presoaking proteinaceous (blood is an example) soils and hard-to-remove stains.) and water will be placed in the bottle and left soaking for 5 minutes. The external portion will be sprayed with Sanizide (Surface Disinfectant Spray is a convenient, fast-acting, multi-purpose, broad-spectrum disinfectant/deodorizer for environmental surfaces).and will remain soaking for 5 minutes...at the end of the day the POC bottle will be cleansed as above and then soaked with a bleach solution of 10:1 for 20 minutes. The jar will then be rinsed, dried and stored in a clean area. At the end of each surgery day the tubing will be thoroughly internally and externally rinsed. The instrument person will assure there is no visible blood or tissue internally and externally. The tubing will be filled with a 10:1 bleach solution and submerged in a 10:1 bleach solution. The tubing will remain in the solution for 20 minutes. The tubing will then be rinsed thoroughly internally and externally and stored in a clean area." Observation on 02/24/2016 at 1400-1500 in the instrument cleaning areas at the end of the surgery day, revealed the bottles did not receive the bleach solution soak step required. Interview on 02/24/2016 at 1445 with the Instrument person performing bottle cleaning revealed the end of surgery day cleaning process described and demonstrated did not include the bleach solution step. Interview with the Clinical Coordinator on 02/25/2016 at 1200 revealed that it was her	E 165		

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E 165	Continued From page 3 expectation that the policy would be followed by the Instrument cleaning (both tubing and bottles) staff members. Re-education would be performed immediately.	E 165		

Carolina Center for Women
421 N. Wendover Rd.
Charlotte, NC 28211

Deficiency:

E 156 0310 Emergency Back-Up Services
...the facility failed to provide an Automatic External Defibrillator (AED).

Provider's Plan of Correction

The owner and clinician are currently searching for an AED to suit Carolina Center for Women. Carolina Center for Women will have an AED on site by April 25, 2016.

Once, the AED is received a protocol will be written and an inservice conducted to the entire staff on safe and proper use of the AED. Utilization an AED will also be conducted during Healthcare Provider BLS training.

The protocol will be written and inservice conducted by Diana T. Ramas, PA-C. Diana T. Ramas, PA-C will assure all staff is properly trained on the AED. Diana, will also be responsible for assuring any new staff members are trained on use of the AED. Review of the protocol and use of the AED will be conducted by Diana annually.

Date by which the corrective action will be completed:

April 26, 2016

Carolina Center for Women
421 N. Wendover Rd.
Charlotte, NC 28211

Deficiency

E 165 0314 Cleaning of Material and Equipment
10A-10E

...person performing bottle cleaning revealed the ennf of surgery day cleaning process described and demonstration did not include the bleach solution step.

Plan of Correction

The protocol has been amended to remove the bleach soak of the tubing and POC jar. The new protocol includes a Terga-zyne soak of both the tubing and POC jars at the end of the surgery clinic.

The change to the protocol has been made and the new protocol has been placed in the Policy and Procedure Manual. Pamela Richardson, RMA and Diana T. Ramas, PA-C will ensure that the instrument cleaner will follow this protocol after each surgery clinic.

Date Correction will be implemented;

The correction has been made and the new protocol currently in use.

CAROLINA CENTER FOR WOMEN

Cleaning POC Bottles and Tubing Between Patients and at the End of the Day

Clean tubing and POC bottles will be used at the beginning of every surgery clinic. After each patient the tubing will be sprayed with Sanizide(TM) and will the solution will remain on the tubing for 5 minutes. After 5 minutes the tubing will be wiped off with a disposable paper towel.

After each patient the POC bottle will be brought into the cleaning area. The instrument person will clean the bottle thoroughly assuring there is no visible blood, or tissue remaining inside or outside of the bottle. A scrubbing brush will be used for this process. A mixture of a Terga-zyme and water will placed into the bottle and left soaking for 5 minutes. The external portion of the bottle will be sprayed with Sanizide and will remain soaking for 5 minutes. The jar will then be emptied and rinsed with warm water. The external portion of the jar will be wiped off with a disposable paper towel.

At the end of the day the POC bottle will be cleaned as above and then soaked with a Terga-zyme for 20 minutes. The jar will then be rinsed, dried and stored in a clean area.

At the end of each surgery day the tubing will be thoroughly internally and externally rinsed. The instrument person will assure there is no visible blood or tissue internally or externally. The tubing will be filled with Terga-zyme/water and submerged in a Terga-zyme/water solution. The tubing will remain in the solution for 20 minutes. The tubing will then be rinsed thoroughly internally and externally and stored in a clean area.