REC'D APR 19 2017 Jaye Spruchia 4/24/17

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FORM APPROVED

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0028	A. BUILDING: _____ B. WING _____	02/16/2017

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
A WOMAN'S CHOICE OF RALEIGH, INC	3305 DRAKE CIRCLE RALEIGH, NC 27607

(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 127	.0206(4) Elements and Equipment 10A NCAC 14E .0206 The physical plant shall provide equipment to carry out the functions of the clinic with the following minimum requirements: (4) Buildings systems and medical equipment shall have preventative maintenance conducted as recommended by the equipment manufacturers' or installers' literature to assure operation in compliance with manufacturer's instructions This Rule is not met as evidenced by: Based on observation during tour of the clinic and staff interview, the facility failed to ensure annual preventative maintenance was completed on an Ultraound Machine (Model # 149296YM6) and 2 suction machines (serial #s 7167 and 7168). The findings include: Tour of the facility on 02/15/2017 at 1330 revealed an ultrsound machine (Model # 149296YM6) and two (2) suction machines (serial #s 7167 and 7168) used for current patient care. Review of facility documents revealed the most current preventative maintance performed on the ultrasound machine was 05/29/2014. Documentation of preventative maintance on the two suction machines was not available for review. Interview on 02/16/2017 at 1030 AS #1 revealed there is no current contract to conduct preventative maintance on the patient care equipment. Interview revealed if any of the equipment does not work correctly they send it off to be serviced. Interview revealed she can not find someone to service the suction machines due to the age of the equipment.	E 127	E127 The facility has found a contractor to maintence the ultrasound machine yearly and another contractor to maintence the auto clave yearly to ensure annual preventative maintence.	3/11/17 ultrasound 4/14/17 auto clave

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LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Sheila Spence — TITLE: Regional Manager — (X6) DATE: 4/18/17

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E 137	.0305(A) Medical Records 10A NCAC 14E .0305 MEDICAL RECORDS (a) A complete and permanent record shall be maintained for all patients including: (1) the date and time of admission and discharge; (2) the patient's full and true name; (3) the patient's address; (4) the patient's date of birth; (5) the patient's emergency contact information; (6) the patient's diagnoses; (7) the patient's duration of pregnancy; (8) the patient's condition on admission and discharge; (9) a voluntarily-signed consent for each surgery or procedure and signature of the physician performing the procedure witnessed by a family member, other patient representative, or facility staff member; (10) the patient's history and physical examination including identification of pre-existing or current illnesses, drug sensitivities or other idiosyncrasies having a bearing on the procedure or anesthetic to be administered; and (11) documentation that indicates all items listed in Rule .0304(d) of this Section were provided to the patient. This Rule is not met as evidenced by: Based on medical record reviews and staff and physician interviews, the clinic failed to obtain a signed consent for a repeat surgery for 1 of 1 surgical patients needing a repeat surgical procedure (# 11). The findings include:	E 137	The Regional Manager retrained all medical staff (RN's, RMA's and CNA's) on how to obtain a signed consent for a repeat surgical patient needing a repeat surgical procedure.	2/20/17

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E 137	Continued From page 2 Medical record review of Patient # 11 revealed the patient underwent a surgical abortion on 11/22/2016. Review revealed Patient # 11 returned to the clinic on 12/06/2016 with complaints of pain and bleeding and was examined by the physician who decided to perform another D&E (dilation and evacuation) procedure, after which the physician recorded the D&E was performed without complications with no villi noted. Record review revealed a consent for the abortion procedure on 11/22/2016, but did not reveal another consent for the D&E procedure on 12/06/2017. Interview with MD #1, on 02/16/2017 at 1130, revealed another consent was not obtained as the MD considered it as part of the followup care needed. Interview with Administrative Staff # 1, on 02/16/2017 at 1150, revealed that when a patient returns and needs a follow-up procedure, a new consent should be obtained. Interview revealed it was not acceptable to use the previous consent.	E 137		
E 138	.0305(B) Medical Records 10A-14E .0305 (b) All other pertinent information such as pre- and post-procedure instructions, laboratory report, drugs administered, report of abortion procedure, and follow-up instruction, including family planning advice, shall be recorded and authenticated by signature, date, and time. This Rule is not met as evidenced by: Based on medical record review and staff and	E 138	E138 Medical Record 4/20/17 Regional Manager retrained medical staff on how to document specific drugs administred to patients during a repeat surgical procedure. The Quality Control	

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E 138	Continued From page 3 physician interviews, the clinic failed to document specific drugs administered for 1 of 1 patients during a repeat surgical proceddure. (# 11) The findings include: Medical record review of Patient # 11 revealed the patient underwent a surgical abortion on 11/22/2016. Review revealed Patient # 11 returned to the clinic on 12/06/2016 with complaints of pain and clots, was examined by the physician who decided to perform another D&E (dilation and evacuation) procedure, and after which the physician recorded the D&E was performed under sedation without complications. Record review did not indicate the names of medications given in the follow-up procedure. Interview with MD # 1, on 02/16/2017 at 1130, revealed the physician did not start a new record or write a complete operative note after the procedure. Interview revealed the MD considered it part of follow-up care and did a progress note without recording all details. Interview with Administrative Staff # 1, on 02/16/2017 at 1150, revealed a new chart should have been started and complete documentation, including medications administered should have been recorded. Interview revealed the charting was not acceptable.	E 138	Committee advised the Physcian to use detailed process note for patients with complaints and concerns after surgical or medical procedures.	
E 156	.0310 Emergency Back-Up Services 10a NCAC 14E .0310 (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.	E 156		

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E 156	Continued From page 4 (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. (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. (d) The clinic shall provide intervention for emergency situations. These provisions shall include: (1) basic cardio-pulmonary life support; (2) emergency protocols for: (A) administration of intravenous fluids; (B) establishing and maintaining airway support; (C) oxygen administration; (D) utilizing a bag-valve-mask resuscitator with oxygen reservoir; (E) utilizing a suction machine; and (F) utilizing an automated external defibrillator; (3) emergency lighting available in the procedure room as set forth in Rule .0206 of this Subchapter; and (4) ultrasound equipment. This Rule is not met as evidenced by: Based on observation and staff interview, the clinic failed to provide functioning emergency lighting in the procedure rooms for 2 of 2 procedure rooms observed.	E 156	E 156 The facility shall provide interventions for emergency situations. They have a contractor that will provide yearly maintence. The Regional Manager has trained staff on the emergency back up light protocol.	2/20/17

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E 156	Continued From page 5 The findings include: Observation of emergency lighting in both procedure rooms on 02/15/2017 at 1430 revealed the emergency lighting did not work when tested. Interview with Administrative Staff # 1 on 02/16/2017 at 1150 confirmed the emergency lights did not work.	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 observation during tour and staff interview, the facility failed to properly store medications in a manner to prevent possible cross contamination with biohazardous material. The findings include: Tour of the facility on 02/15/2017 at 1330 revealed the laboratory refrigerator which contained blood tubes used for RH (Rhesus) factor controls also housed refrigerated medications such as Rhogam, NuvaRing and TB (tuberculin) vaccine. Tour also revealed the	E 165	The Regional Manager has retrained medical staff the proper way to store medications in a manner to prevent possible cross contamination with biohazardous material.	2/20/17

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E 165	Continued From page 6 laboratory refrigerator displayed a biohazard sign on the door. Interview with CMA #1 during tour on 02/15/2017 at 1330 revealed there is only one refrigerator available in the facility. Interview revealed the medications and laboratory controls have always been stored together. Interview revealed she understands the contamination possibilities.	E 165		