

Division of Health Service Regulation

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>AB0004</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING: _____  B. WING _____	(X3) DATE SURVEY COMPLETED  <b>06/15/2023</b>
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NAME OF PROVIDER OR SUPPLIER  <b>A WOMAN'S CHOICE OF CHARLOTTE</b>	STREET ADDRESS, CITY, STATE, ZIP CODE <b>421 WENDOVER ROAD CHARLOTTE, NC 28211</b>
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*DM  
10/26/23*

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E 000	Initial Comments  An onsite complaint investigation and licensure survey was conducted on June 15, 2023 to determine compliance with the North Carolina Rules Governing the Certifications of Clinics for Abortion. Deficiencies were identified with respect to 10A NCAC 14E .0302 Governing Authority, 10A NCAC 14E .0307 Nursing Services and 10A NCAC 14E .0312 Medications and Anesthesia NC00199498	E 000		
E 131	.0302 Governing Authority  10A NCAC 14E .0302 (a) The governing authority, as defined in Rule .0101(6) of this Subchapter, shall appoint a chief executive officer or a designee of the clinic to represent the governing authority and shall define his or her authority and duties in writing. This person shall be responsible for the management of the clinic, implementation of the policies of the governing authority and authorized and empowered to carry out the provisions of these Rules. (b) The chief executive officer or designee shall designate, in writing, a person to act on his or her behalf during his or her absence. In the absence of the chief executive officer or designee, the person on the grounds of the clinic who is designated by the chief executive officer or designee to be in charge of the clinic shall have access to all areas in the clinic related to patient care and to the operation of the physical plant. (c) When there is a planned change in ownership or in the chief executive officer, the governing authority of the clinic shall notify the Division in writing of the change. (d) The clinic's governing authority shall adopt operating policies and procedures that shall: (1) specify the individual to whom	E 131	<p><i>AWCC Registered Nurse and Clinic Manager 10/15/23 have been retrained by the Nurse Supervisor on AWCC medication storage policy and how to properly log patient medication</i></p> <p><i>The clinic manager and/or Registered Nurse will email the medication log once a week for a month and bi weekly for two months to the Regional Director to ensure the logs are done correctly.</i></p> <p><i>Correction completed by October 15, 2023.</i></p>	

Division of Health Service Regulation LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE <i>Drenda Spence</i>	TITLE <i>NC Regional Clinic Director</i>	(X6) DATE <i>7/13/2023</i>
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E 131	<p>Continued From page 1</p> <p>responsibility for operation and maintenance of the clinic is delegated and methods established by the governing authority for holding such individuals responsible;</p> <p>(2) provide for at least annual meetings of the governing authority, for which minutes shall be maintained; and</p> <p>(3) maintain a policies and procedures manual designed to ensure professional and safe care for the patients which shall be reviewed, and revised when necessary, at least annually, and shall include provisions for administration and use of the clinic, compliance, personnel quality assurance, procurement of outside services and consultations, patient care policies, and services offered.</p> <p>(e) When the clinic contracts with outside vendors to provide services such as laundry, or therapy services, the governing authority shall be responsible to assure the supplier meets the same local and state standards the clinic would have to meet if it were providing those services itself using its own staff.</p> <p>(f) The governing authority shall provide for the selection and appointment of the professional staff and the granting of clinical privileges and shall be responsible for the professional conduct of these persons.</p> <p>(g) The governing authority shall be responsible for ensuring the availability of supporting personnel to meet patient needs and to provide safe patient care.</p> <p>This Rule is not met as evidenced by: Based on review of facility policies and procedures, Patient Medication Administration Log, Medication Count Log and staff interviews the governing authority failed to provide oversight for controlled substance medication counts for 1</p>	E 131		

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E 131	<p>Continued From page 2</p> <p>of 3 controlled substance medications.</p> <p>Findings include:</p> <p>Review of the policy titled Medication Storage Policy dated 5/2023 revealed "... Medication that is pre drawn must be labeled, capped and stored in appropriate area. *Lidocaine is per (sic) drawn per patient each day. Lidocaine syringe is dated and capped. If a multi-dose has been opened or accessed, the vial should be dated and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial ... Registered Nurse is responsible for all medications. She has to count medication daily with medical staff and/or Director of Patient Services. The Registered Nurse is responsible for medication logs and making sure medications are not expired."</p> <p>Review of the "Patient Medication Administration Log" for Diazepam 10 mg (milligram)/tab (tablet) for dates 5/12/2023 to current (6/15/2023) revealed Diazepam was administered on 05/12/2023, 05/15/2023, 05/16/2023, 06/08/2023, 06/09/2023, and on 06/10/2023.</p> <p>Review of the "Medication Count Log" for Diazepam 10 mg/tab revealed a count of the Diazepam was not performed on 05/12/2023, 05/15/2023, 05/16/2023, 06/08/2023, 06/09/2023, and 06/10/2023, the dates the Medication Administration Log revealed the medication was administered.</p> <p>Interview on 06/15/2023 at 1003 with RN #1 revealed she was the primary nurse for the facility. Interview revealed RN #1 had been off for a few days and was just returning to work. Interview revealed RN #1 counts the narcotic</p>	E 131		

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E 131	Continued From page 3  medications every morning she works. Interview revealed sometimes the nurse covering when she is off does not do the counts.  Interview on 06/15/2023 at 1750 with Clinic Manager #2 revealed when she became the Clinic Manager in February of 2023, she did not realize she was supposed to count the medications with the nurse so there was a period of time no counts were being performed. Interviewed revealed they recognized and corrected that problem. Interview revealed it was recognized that the nurse filling in when the primary nurse was off was not performing the count and a fix was put in place beginning of May 2023. Clinic Manager #2 while reviewing the medication administration log and the medication count sheet recognized there continues to be a problem.	E 131		
E 151	.0307 Nursing Service  10A NCAC 14E .0307 (a) The clinic shall have an organized nursing staff under the supervision of a nursing supervisor who is currently licensed as a Registered Nurse and who has responsibility and accountability for all nursing services. (b) The nursing supervisor shall be responsible and accountable to the chief executive officer or designee for: (1) provision of nursing services to patients; and (2) developing a nursing policy and procedure manual and written job descriptions for nursing personnel. (c) The clinic shall have the number of licensed and ancillary nursing personnel on duty to assure that staffing levels meet the total nursing needs of	E 151		

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E 151	<p>Continued From page 4</p> <p>patients based on the number of patients in the clinic and their individual nursing care needs. (d) There shall be at least one Registered Nurse with experience in post-operative or post-partum care who is currently licensed to practice professional nursing in North Carolina on duty in the clinic at all times patients are in the clinic.</p> <p>This Rule is not met as evidenced by: Based on policy review, medical record review and staff interview, facility nursing staff failed to document administration of anti-D immune globulin or refusal of the medication for 1 of 5 sampled patients with Rh negative results (Patient #17).</p> <p>The findings included:</p> <p>Review of facility policy revealed a reference to the "National Abortion Federation (NAF) 2022 Clinical Policy Guidelines for Abortion Care." Review of the NAF guidelines revealed ... 4. Laboratory Practice Policy Statement: Rh alloimmunization may jeopardize the health of a subsequent pregnancy. (1) There is no evidence that providing anti-D immunoglobulin in early pregnancy prevents alloimmunization and poor outcome in a subsequent pregnancy, however, it is recommended later in pregnancy.(2) Standard 4.1.</p> <p>Rh status testing must be offered to all people with unknown Rh status over 12 weeks from the last menstrual period and anti-D immune globulin must be offered to patients over 12 weeks who are Rh negative. ... Recommendation 4.1.3 A person who is over 12 weeks LMP (last menstrual period) and declines Rh testing or anti-D immune globulin should sign an informed waiver. ..."</p>	E 151	<p><i>AWCC STAFF have been retrained on AWC Anti-D policy.</i></p> <p><i>The clinic manager will observe staff once weekly for a month and bi weekly for two months to ensure staff is following AWC Anti-D policy.</i></p> <p><i>Completed by October 15, 2023</i></p>	10/15/23

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E 151	Continued From page 5  Review on 06/15/2023 of Patient #17 revealed a 23 year-old female that arrived to the clinic at 0828 and had a surgical abortion procedure performed on 06/10/2023. Review of the medical record revealed the patient had an ultrasound completed with results showing the patient was 12 weeks and 3 days pregnant. Review of the patient's laboratory testing revealed the patient tested Rh negative. Review of the medical record revealed no evidence that the patient was offered or declined the anti-D immune globulin. Review revealed the patient departed the clinic at 1518.  Interview on 06/15/2023 at 1600 with the Clinic Manager revealed Patient #17 was not administered the anti-D immune globulin. Interview revealed there was no documentation that the patient was offered, explained risks and benefits of receipt of the medication, or that the patient declined the medication. Interview revealed the nurse should have documented that the medication was administered or that the patient declined the medication after risks and benefits were explained. Interview revealed the nurse failed to follow the facility policy.	E 151		
E 159	.0312(A) Medications and Anesthesia  10A-14E .0312 (a) Medication (1) No medication or treatment shall be given except on written order of a physician. (2) Medications must be administered in accordance with the Nurse Practice Act of the State of North Carolina, and must be recorded in the patient's permanent record.	E 159		

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E 159	<p>Continued From page 6</p> <p>This Rule is not met as evidenced by: Based on policy and procedure review, observation and staff interviews, the facility staff failed to ensure 57 of 57 medications with no labeled expirations dates were not available for use.</p> <p>Findings included:</p> <p>Review of the policy titled Medication Storage Policy dated 5/2023 revealed "... Medication that is pre drawn must be labeled, capped and stored in appropriate area. *Lidocaine is per (sic) drawn per patient each day. Lidocaine syringe is dated and capped. If a multi-dose has been opened or accessed, the vial should be dated and discarded within 28 days unless the manufacturer specifies a different (shorter or longer) date for that opened vial ... Registered Nurse is responsible for all medications. She has to count medication daily with medical staff and/or Director of Patient Services. The Registered Nurse is responsible for medication logs and making sure medications are not expired."</p> <p>Observation of the RN and Clinic Manager performing the medication count of controlled substance medications during tour on 06/15/2023 at 0915 revealed:</p> <p>(a) a clear plastic zippered baggie with three syringes with 2 mL (milliliters) of clear fluid inside each syringe. There was a blue sticker with Fentanyl preprinted on the label. The dosage was not filled out, there was no date, time, or initials of who prepared the syringe.</p> <p>(b) a clear plastic zippered baggie with six syringes containing 2 mL of clear liquid, with a clear sticker with preprinted in pink Fentanyl 100 mcg (micrograms)/2 mL. There was no date,</p>	E 159	<p>AWCC manager and Registered Nurse have been retrained by AWC Nurse Supervisor on medication storage policy. The Nurse Supervisor trained the Registered Nurse how to properly label medication, date, time and name of Reg. Nurse prepared initials. The clinic manager will observe Reg. Nurse once weekly for a month and bi weekly for two months to ensure Reg. Nurse is following AWC medication storage policy. Completed by October 15, 2023</p>	10/15/23

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E 159	<p>Continued From page 7</p> <p>time, or initials of who prepared the syringe.</p> <p>(c) two bottles of Midazolam 10 mg (milligrams)/10 mL (1 mg/1 mL) opened. One bottle contained about 1/4 liquid. The bottle was not labeled with the open date, time, or initials of who opened/accessed the bottle. The second bottle of Midazolam was half full of liquid. The bottle was not labeled with the open date, time, or initials of who opened/accessed the second bottle.</p> <p>(d) two syringes with clear liquid not labeled with what was in the syringes. The syringes were not labeled with medication, dosage, date, time, or who prepared the syringe.</p> <p>(e) five syringes containing 2 mL per syringe of clear fluid. Fentanyl preprinted on a pink sticker was attached to the syringes. The sticker did not contain the dosage/strength of the medication. The syringes were not labeled with the date, time, or initials of who prepared the syringes.</p> <p>(f) five vials Fentanyl Citrate 100 mcg/2 mL with an expiration date of February 1, 2004.</p> <p>(g) a large clear plastic zippered baggie contained five syringes labeled with clear sticker with Midazolam 1 mg/mL written in green. Two of the syringes contained 5 mLs of clear liquid and three of the syringes contained 1 mL of clear liquid. The five syringes were not labeled with date, time, or initials of who prepared the solution. The large baggie also contained fifteen syringes with an orange label with Versed preprinted on the label. The fifteen syringes contained 5 mL of clear liquid. The syringes were not labeled with the date, time or initials of who prepared the syringes.</p> <p>(h) five opened bottles of Diazepam not labeled with date opened, time, or initials of who opened the bottle. The bottles were labeled 1 through 5. Bottle #1 had handwritten "#47" on the bottle, and it contained 47 tablets. Bottle #2 had handwritten "#90" on the bottle, and it contained 91 tablets.</p>	E 159		



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E 159	<p>Continued From page 8</p> <p>Bottle #3 had handwritten "#82" on the bottle, and it contained 82 tablets. Bottle #4 had handwritten "#98" on the bottle, and it contained 96 tablets. Bottle #5 had handwritten "#24.5" and it contained 24.5 pills.</p> <p>(i) a basket containing fourteen syringes labeled Lidocaine. Each syringe contained 10 mL of clear liquid. The syringes were not labeled with the date, time, or initials of who prepared the syringes.</p> <p>(j) a clear plastic zippered baggie with a syringe with 7 mL of clear liquid. The baggie was labeled "7 cc Lidocaine". There syringe was not labeled with the date, time or who prepared the syringe.</p> <p>(k) one box containing nine ampules of Methylergonovine Maleate 0.2 mg/mL with an expiration date 4/2023.</p> <p>Interview on 06/15/2023 at 1003 with RN #1 revealed she was the primary nurse for the facility. Interview revealed RN #1 had been off for a few days and was just returning to work. Interview revealed RN #1 counted the narcotic medications every morning she works. Interview revealed the Lidocaine was usually drawn up a day or two prior. Interview revealed the Lidocaine was used quickly. Interview revealed RN #1 did not know who prepared the medication or when it was prepared.</p> <p>NC00199498</p>	E 159		