

5/11/2023
9/13/24
Approved POE
Jung H. Kelly

PRINTED: 10/05/2022
FORM APPROVED

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 09/09/2022
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NAME OF PROVIDER OR SUPPLIER
A WOMAN'S CHOICE OF CHARLOTTE

STREET ADDRESS, CITY, STATE, ZIP CODE
**421 WENDOVER ROAD
CHARLOTTE, NC 28211**

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E 000	Initial Comments An unannounced survey was conducted on September 8, 2022 through September 9, 2022 to determine compliance with the North Carolina Rules Governing the Certifications of Clinics for Abortion. Survey findings revealed an Imminent Threat to the health and safety of patients was identified on September 09, 2022 at 1237. Pursuant to 10 NCAC 14E .0314 Cleaning of Material and Equipment, the clinic staff failed to clean vaginal speculums in a manner to ensure the safety and prevention of the transmission of infections. The Imminent Threat was communicated to the Clinic Manager on September 09, 2022 at 1237. The facility took immediate actions to include removing all speculums that were not autoclaved out of circulation and recleaned, packaged, and autoclaved all speculums prior to use. The Clinic Manager re-educated all the clinical staff on 09/08/2022 at 1630 on the protocol for sterilizing speculums. The Imminent Threat was removed based on the immediate actions taken and verification of the actions.	E 000		
E 132	.0303 Policies & Procedures & Administratives Recor 10A NCAC 14E .0303 (a) The following essential documents and references shall be on file in the administrative office of the clinic: (1) documents evidencing control and ownerships, such as deeds, leases, or incorporation or partnership papers; (2) policies and procedures of the governing authority, as required by Rule .0302 of this Section; (3) minutes of the governing authority meetings;	E 132		

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

Drenda Spencer NC Regional Clinic Director

TITLE

(X6) DATE

10/10/2022

STATE FORM

6899

X9BL11

If continuation sheet 1 of 9

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E 132	<p>Continued From page 1</p> <p>(4) minutes of the clinic's professional and administrative staff meetings;</p> <p>(5) a current copy of the rules of this Subchapter;</p> <p>(6) reports of inspections, reviews, and corrective actions taken related to licensure; and</p> <p>(7) contracts and agreements related to licensure to which the clinic is a party.</p> <p>(b) All operating licenses, permits, and certificates shall be displayed on the licensed premises.</p> <p>(c) The governing authority shall prepare a manual of clinic policies and procedures for use by employees, medical staff, and contractual physicians to assist them in understanding their responsibilities within the organizational framework of the clinic. These shall include:</p> <p>(1) patient selection and exclusion criteria; and clinical discharge criteria;</p> <p>(2) policy and procedure for validating the full and true name of the patient;</p> <p>(3) policy and procedure for each type of abortion procedure performed at the clinic;</p> <p>(4) policy and procedure for the provision of patient privacy in the recovery area of the clinic;</p> <p>(5) protocol for determining gestational age as defined in Rule .0101(5) of this Subchapter;</p> <p>(6) protocol for referral of patients for whom services have been declined; and</p> <p>(7) protocol for discharge instructions that informs patients who to contact for post-procedural problems and questions.</p> <p>This Rule is not met as evidenced by: Based on facility policy and procedure, observation during tour, and staff interviews, the facility failed to ensure patient privacy was provided to patients in the recovery room.</p>	E 132	<p>9/9/2023</p> <p>AWCC STAFF WAS reeducated by the clinic manager on AWCC Patient Privacy. The clinic manager purchase screen protector and installed curtains to go in between chairs in the recovery room to ensure patient privacy.</p> <p>Clinic manager will observe twice weekly for a month and once weekly for 2 months.</p> <p>Correction completed by 1-9-2023.</p>	1-9-23
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E 132	Continued From page 2 The findings included: Review of the facility's policy and procedure titled "Policy for the provision of patient privacy in the recovery area of the clinic" not dated revealed "if a patient request to speak to a staff member in private during their recover stay, (clinic name) staff will provide portable privacy screens to be placed on each side of the patient's recliner." Observation during tour of the recovery room on 09/08/2022 at 1519 revealed seven chairs for patients to sit after procedures were completed. Observation revealed there were six patients sitting in the recovery room chairs. Observation revealed there were no privacy screens or barriers between the chairs. Observation revealed a nurse in the recovery room discussed the patient's discharge instructions with one of the six patients sitting in a chair in the recovery room. Observation revealed the other five patients were able to hear the conversation. Interview on 09/08/2022 at 1520 with the Clinic Manager (CM) #3 revealed she was only aware of the one privacy screen. Interview confirmed there were no privacy screens being used and there were six patients in the recovery room during the observation.	E 132		
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;	E 137		

Division of Health Service Regulation

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E 137	<p>Continued From page 3</p> <p>(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.</p> <p>This Rule is not met as evidenced by: Based on medical record review and staff interview, the facility failed to ensure a properly executed informed consent for a surgical abortion signed by the patient and/or the physician performing surgical abortion for 4 of 12 surgical patients (Patient #17, Patient #12, Patient #13 and Patient #18).</p> <p>Findings included:</p> <p>1. Review on 09/08/2022 of the closed medical record of Patient #17 revealed a 27-year-old female received a surgical abortion on 08/13/2022. Continued review revealed the consent for the abortion procedure was not signed by Patient #17 and was not signed by the Physician that performed the procedure.</p>	E 137	<p><i>Medical Records 1-9-23</i></p> <p><i>9-9-2022</i></p> <p><i>AWCC STAFF was re-educated on AWC medical record policy; informed consent by the patient and/or physician.</i></p> <p><i>Clinic manager and/or Registered Nurse will audit medical records once weekly for a month and bi-weekly for two months to ensure consent is done by patient and physician.</i></p> <p><i>Correction will be completed by 1-9-2023</i></p>	1-9-23
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E 137	Continued From page 4 Interview on 09/08/2022 at 1305 with Clinic Manager (CM) #3 revealed Patient #17 should have signed the consent. Interview revealed the Provider that performed the surgical procedure should have signed the consent prior to the procedure. 2. Review on 09/08/2022 of the closed medical record of Patient #12 revealed a 14-year-old female received a surgical abortion on 08/31/2022. Review revealed Patient #12's mother had signed the consent for the surgical abortion procedure. Review revealed the Physician that performed the surgical procedure had not signed the surgical abortion consent. Interview on 09/08/2022 at 1305 with the Clinic Manager (CM) #3 revealed the Provider that performed the surgical procedure should have signed the consent prior to the procedure. 3. Review on 09/08/2022 of the closed medical record of Patient #13 revealed a 27-year-old female received a surgical abortion on 08/22/2022. Review of the surgical abortion consent revealed Patient #13 and a witness had signed the consent. Continued review revealed the Physician that performed the surgical procedure had not signed the surgical abortion consent. Interview on 09/08/2022 at 1305 with the Clinic Manager (CM) #3 revealed the Provider that performed the surgical procedure should have signed the consent prior to the procedure. 4. Review on 09/08/2022 of the closed medical record of Patient #18 revealed a 36-year-old female received a surgical abortion on	E 137		

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E 137	Continued From page 5 09/07/2022. Continued review revealed the consent for the abortion procedure was signed by Patient #18 and a witness. Continued review revealed the Physician that performed the surgical abortion had not signed the surgical abortion consent. Interview on 09/08/2022 at 1305 with the Clinic Manager (CM) #3 revealed the Provider that performed the surgical procedure should have signed the consent prior to the procedure.	E 137	Cleaning of material... 9/9/22 AWCC STAFF WAS re educated on Protocol for Sterilizing Speculums.	1-9-23
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 facility policy and procedure, observation during tour, and staff interviews, the facility failed to clean vaginal speculums in a manner to ensure the safety and prevention of the transmission of infections in 1 of 1 observation of vaginal speculum cleaning and reprocessing. The findings included: Review on 09/08/2022 of the facility policy and protocol titled "Scrub Room Protocol" not dated,	E 165	Clinic manager and/or Registered Nurse will observe staff cleaning and sterilizing equipment twice a week for a month and once weekly for two months to ensure staff is properly cleaning and sterilizing equipment Correction completed by 1-9-2023,	

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E 165	<p>Continued From page 6</p> <p>revealed "Scrubbing: ... 5. Put instruments in sink to soak in Enzyme solution ... 9. Rinse each instrument in clean water then towel or air dry instruments 10. Wrap instruments in sterile wrap (2 sheets) and seal with autoclave tape ... 11. Put any single instruments in clear bags and seal ... 13. Take wrapped/bagged items to autoclave ..."</p> <p>Observation on 09/08/2022 at 1538 during a facility tour revealed a soiled instrument cleaning room and a clean instrument cleaning room with a window with a ledge between the two rooms. Observation revealed instruments came into the soiled instrument cleaning room where they were washed and soaked in enzymatic detergent. Observation revealed instruments were then rinsed and placed on the ledge in the window. Observation revealed the instruments are visually inspected and if no residual is visible, the instrument was placed in a container with Microlube (lubricant to prevent rust and allow parts to move freely) to soak for two minutes. Observation revealed two towels on the counter space with speculums air drying. Observation revealed blue sterilization paper on the right side of the cabinet along with sterilizer indicator tape and strips. Observation revealed the adjacent room had a sterilizer on the cabinet with blue packets with sterilizer indicator tape sitting on the counter beside the sterilizer. Observation revealed the sterilizer door was partially opened. Observation revealed a bin with speculums that were not wrapped and were not in clear packs inside the bin. Continued tour in the Procedure room revealed observation of a smaller bin on a cart with a speculum that was not wrapped and was not in a pack inside the bin.</p> <p>Interview on 09/08/2022 at 1540 with Staff #1 revealed the speculums/dilators/instruments are</p>	E 165		

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E 165	<p>Continued From page 7</p> <p>cleaned on the dirty side and then put through the window to the clean side. Interview revealed Staff #1 then inspects them to ensure there is no residue or spots. Interview revealed the speculums are placed in the Microlube for two minutes to soak. Interview revealed the speculums are removed from the Microlube soak and placed on a towel to air dry. Interview revealed when the speculums are completely dry they are placed in the bin for use. Interview revealed the speculums do not get put in the autoclave. Interview revealed about two months ago the CEO #2 visited the facility and instructed the staff the speculums did not need to be autoclaved any longer. Interview revealed the speculums had not been autoclaved since that visit.</p> <p>Interview on 09/08/2022 at 1545 with Clinic Manager (CM) #3 revealed about two months ago, CEO #2 visited the clinic and instructed the staff that we no longer need to autoclave the speculums.</p> <p>Interview on 09/08/2022 at 1600 with MD #4 revealed he was not aware the speculums were not being sterilized.</p> <p>Telephone interview on 09/09/2022 at 0938 with CEO #2 revealed she "never ever told the clinic staff to not autoclave" the speculums. Interview revealed CEO #2 was going through training and told the staff to use "unwrap cycle" then to put the speculums in a container with a cover. Interview revealed "the staff must have gotten confused." Interview revealed CEO #2 knows North Carolina (NC) Laws and knows that the speculums have to be autoclaved. Interview revealed the speculums do not have to be wrapped but that the speculums do have to be autoclaved. Interview</p>	E 165		

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E 165	Continued From page 8 revealed if the staff cannot tell if a speculum has been autoclaved the staff need to wrap the speculum or put it in a clear bag for autoclaving.	E 165		