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	AB0028	A. BUILDING: _____ B. WING _____	11/12/2020

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

1/19/21 DM

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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; (4) minutes of the clinic's professional and administrative staff meetings; (5) a current copy of the rules of this Subchapter; (6) reports of inspections, reviews, and corrective actions taken related to licensure; and (7) contracts and agreements related to licensure to which the clinic is a party. (b) All operating licenses, permits, and certificates shall be displayed on the licensed premises. (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: (1) patient selection and exclusion criteria; and clinical discharge criteria; (2) policy and procedure for validating the full and true name of the patient; (3) policy and procedure for each type of abortion procedure performed at the clinic; (4) policy and procedure for the provision of patient privacy in the recovery area of the clinic; (5) protocol for determining gestational age	E 132	E132 AWCR failed to ensure Patients Privacy in the Recovery Room. The clinic manager purchased indoor room dividers on 11/13/2020 to ensure patient privacy in the recovery room. All patients receiving the surgical procedure will have a room divider between them and the next patient chair in recovery to ensure their privacy. The Registered Nurse on duty will set up the Recovery Room every morning before clinic, placing a divider between each patient chair. The Reg. Nurse will take down the divider after clinic daily to clean and sterilize. 11/16/2020	11/13/2020

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E 132	Continued From page 1 as defined in Rule .0101(5) of this Subchapter; (6) protocol for referral of patients for whom services have been declined; and (7) protocol for discharge instructions that informs patients who to contact for post-procedural problems and questions. This Rule is not met as evidenced by: Based on facility policy review, observation and staff interview, the facility staff failed to ensure patient privacy was provided to patients in the recovery room. The findings include: Review of the facility's "Patient's Rights Policy" (not dated) revealed "Patients have a right to: ...Security and safety, personal privacy, and confidentiality of information. ..." Observation during tour of the recovery room on 11/12/2020 at 0945 revealed six chairs for patients to sit after procedures were completed. Observation revealed no privacy screens or barriers between the chairs. Observation on 11/12/2020 at 1405 revealed three patients sitting in chairs in the recovery room. Observation revealed there was no barrier to separate patients to promote privacy in the recovery room. Observation revealed a nurse in the recovery room discussed the patient's pain level and management of pain with one of the three patients sitting in a chair in the recovery room. Observation revealed the other two paints in the recovery room were able to hear the conversation. Interview on 11/12/2020 at 1420 with the Clinic	E 132	The clinic manager will do random checks once weekly for 6 weeks to ensure the dividers are used and clean daily. 11/16/2020-12/18/2020 The Quality Assurance process will be utilized to maintain and substain compliance.	

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E 132	Continued From page 2 Manager revealed the facility did not use a barrier between patients in the recovery room to provide privacy. Interview confirmed there are times when all six chairs are occupied by patients in the recovery room.	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; (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	E 137	E137 Medical Records The physcians at AWCR failed to ensure history and physcial exams were documented 11/16/202 The physcians at AWCR will indicate a physcial exam and patient history has been done on patients having a surgical procedure or medical procedure. The Director of Nursing will do chart audits for six weeks to ensure the patients medical history and physcial exams are done	

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E 137	Continued From page 3 interview, the facility staff failed to ensure a history and physical examination was documented for 7 of 7 patients undergoing a medical abortion (#13, #15, #16, #17, #18, #19, #20). The findings include: 1. Review of a closed medical record on 11/12/2020 revealed Patient #13 was a 17 year-old who underwent a medical abortion on 10/26/2020. Medical record review failed to reveal documentation of a physical exam by the treating physician. Interview on 11/12/2020 at 1615 with the Clinic Manager revealed there was no facility policy for the physician to perform and document a physical exam prior to a patient undergoing a medical abortion. Interview revealed the physicians perform and document a history & physical exam prior to surgical abortions, but the physicians do not believe it to be necessary prior to medical abortions. 2. Review of a closed medical record on 11/12/2020 revealed Patient #15 was a 24 year-old who underwent a medical abortion on 02/06/2020. Medical record review failed to reveal documentation of a physical exam by the treating physician. Interview on 11/12/2020 at 1615 with the Clinic Manager revealed there was no facility policy for the physician to perform and document a physical exam prior to a patient undergoing a medical abortion. Interview revealed the physicians perform and document a history & physical exam prior to surgical abortions, but the physicians do not believe it to be necessary prior to medical	E 137	Any reoccurring patterns will be presented to the Quality Control Committee. 01/14/2021 The Quality Control Committee edited AWCR medical charts ommitted the physcial exam for cervix, uterus, size and adnexa,	

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E 137	Continued From page 4 abortions. 3. Review of a closed medical record on 11/12/2020 revealed Patient #16 was a 33 year-old who underwent a medical abortion on 03/24/2020. Medical record review failed to reveal documentation of a physical exam by the treating physician. Interview on 11/12/2020 at 1615 with the Clinic Manager revealed there was no facility policy for the physician to perform and document a physical exam prior to a patient undergoing a medical abortion. Interview revealed the physicians perform and document a history & physical exam prior to surgical abortions, but the physicians do not believe it to be necessary prior to medical abortions. 4. Review of a closed medical record on 11/12/2020 revealed Patient #17 was a 37 year-old who underwent a medical abortion on 08/31/2020. Medical record review failed to reveal documentation of a physical exam by the treating physician. Interview on 11/12/2020 at 1615 with the Clinic Manager revealed there was no facility policy for the physician to perform and document a physical exam prior to a patient undergoing a medical abortion. Interview revealed the physicians perform and document a history & physical exam prior to surgical abortions, but the physicians do not believe it to be necessary prior to medical abortions. 5. Review of a closed medical record on 11/12/2020 revealed Patient #18 was a 31 year-old who underwent a medical abortion on 06/27/2020. Medical record review failed to reveal	E 137		

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E 137	Continued From page 5 documentation of a physical exam by the treating physician. Interview on 11/12/2020 at 1615 with the Clinic Manager revealed there was no facility policy for the physician to perform and document a physical exam prior to a patient undergoing a medical abortion. Interview revealed the physicians perform and document a history & physical exam prior to surgical abortions, but the physicians do not believe it to be necessary prior to medical abortions. 6. Review of a closed medical record on 11/12/2020 revealed Patient #19 was a 17 year-old who underwent a medical abortion on 08/29/2020. Medical record review failed to reveal documentation of a physical exam by the treating physician. Interview on 11/12/2020 at 1615 with the Clinic Manager revealed there was no facility policy for the physician to perform and document a physical exam prior to a patient undergoing a medical abortion. Interview revealed the physicians perform and document a history & physical exam prior to surgical abortions, but the physicians do not believe it to be necessary prior to medical abortions. 7. Review of a closed medical record on 11/12/2020 revealed Patient #20 was an 18 year-old who underwent a medical abortion on 07/02/2020. Medical record review failed to reveal documentation of a physical exam by the treating physician. Interview on 11/12/2020 at 1615 with the Clinic Manager revealed there was no facility policy for the physician to perform and document a physical	E 137		

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E 137	Continued From page 6 exam prior to a patient undergoing a medical abortion. Interview revealed the physicians perform and document a history & physical exam prior to surgical abortions, but the physicians do not believe it to be necessary prior to medical abortions.	E 137		
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, review of the manufacturer's guidelines for sterilization monitoring, clinic's autoclave testing log and staff interview, the clinic staff failed to prevent the possibility transmission of infection by failing to perform biological testing according to manufacturers' recommendation for 1 of 2 autoclaves used for steam sterilization of the surgical instruments; failing to test high level disinfectant solution as per manufacturers' recommendations used for suction tubing; and failing to disinfect vaginal ultrasound probes according to the facility policy. The findings include: 1. Review of the manufacturers'	E 165	E 165 Cleaning of Materials and Equipment 11/13/2020 The clinic manager at AWCR trained staff on AWCR Policy and Protocol for Biological testing according to manufactures recommendation. On 11/12/2020 the clinic manager did a Pro Sure test on the new autoclave. The test on 11/13/2020 passed. The results were logged in the auto clave log for the need cont	

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E 165	Continued From page 7 recommendations for the "ProSpore" (biological autoclave testing) revealed "... Biological Indicators: The Centers for Disease Control and Prevention recommended regular use of mechanical, chemical and biological indicators to ensure the effectiveness of sterilization processes. ... EZTest Steam vials contain a liquid culture of Geobacillus sterathermophilus spores, and are designed for monitoring the efficacy of steam sterilization cycles... Perform in-office testing at least weekly to monitor steam sterilizers ... results in 24 hours. ..." Review of the biological testing log revealed no biological testing for one of two autoclaves from 10/14/2020 through 11/12/2020. Interview on 11/12/2020 at 1145 with the Clinic Manager revealed a new autoclave was obtained on 10/14/2020 and no biological testing had been done since the new autoclave was purchased. The Clinic Manager state, "I thought we didn't have to do it (biological testing) when we got the new autoclave. I just found out when you asked for it that we should have been doing the ProSpore testing. I have missed five weeks. We have already run a test today. I will not use the new autoclave until I get results back." 2. Review of the facility's "Policy and Procedure for using Cidex OPA test strips" (not dated) revealed "Policy: To ensure Cidex OPA solution destroys 100% of Mycobacterium tuberculosis the minimum effective concentration (MEC) required for high level disinfection should be tested with the appropriate CIDEX solution test strips prior to usage. For optimal results, follow the instructions carefully. ... Procedure: 10 Completely submerge indicating pad of the strip into the CIDEX solution. Hold for 1 second and remove. DO NOT shake	E 165	autoclave machine; and will continue to be done weekly by the clinic manager and/or team lead. The Clinic manager/ Director/Nurse will report any findings to the Quality control Committee.	

A Woman's CHOICE OF RALEIGH INC

A Woman's Choice of Raleigh, Inc

Prosure Test Biological Monitoring Service

Contents of the Maxi Test Biological Monitoring Service

The Maxi Test contains test envelops. With each envelop are one (1) or two (2) test strips and one (1) control strip.

Instruction for Use

1. Remove one or two test strips from pocket marked "test strips" (DO NOT remove test strips from blue blassin pouch, as this will invalidate the test. (DO NOT REMOVE TEST CONTROL STRIP)
2. Place One (1) test in center of the autoclave to be sterile and the other test strip in the most difficult place in the autoclave. Run a normal sterilization cycle. DO NOT PROCESS THE CONTROL STRIP
3. Upon completion of the sterilization cycle, remove the test strips and return to the packet marked "Test strip" Seal the flap closed. Let the strip dry completely before returning to the envelop.
4. Complete all information requested on envelop and mall
5. Test results will be mailed or faxed to your office quarterly. Test failure will be reported immediately by phone. Test failure reported by phone will receive conformation by fax, mail or email.

[redacted]

Hachment 1 (E165)

Prosure Test Biological Test Log (Weekly)

Date	Results	Tech Signature

Hachment 2 (E165)

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E 165	Continued From page 8 strip. 20 Remove excess solution by standing the strip upright on a paper towel. 30 Read results in 90 seconds. Do NOT read past 90 seconds. IF ANY BLUE remains on the pad part from the top line, solution is ineffective and must be discarded." Review of the manufacturers' recommendations for "CIDEX OPA Solution Test Strips" revealed "... F. Directions for Use ... 4. Remove one test strip from the bottle and replace bottle cap immediately. 5. Use a watch or timer to monitor the following steps. 6. Timing control is critical to accurate reading. 7. Completely submerge indicating pad at the end of the test strip into the container of solution being tested. Hold for one second and remove. Do not leave the strip in the test solution for longer than one second or 'stir' the test strip in the solution. ... 8. Remove excess solution from the indicating pad by standing the strip upright on a paper towel. 9. Read the test results of the color reaction present on the indicating pad at 90 seconds after the test strip is removed from the solution. If read in less than 90 seconds, the color change may be incomplete and may be interpreted incorrectly. ... To indicate an effective concentration of the solution, the indicating pad will be completely purple. Any shade of purple is acceptable. ... If any blue appears on the indicating pad apart from the top line, the solution is below the MEC of 0.3% and should be discarded. ..." Observation on 11/12/2020 at 1010 during tour of the sterile processing area revealed a container of solution that contained suction tubing submerged in the solution. Interview during the tour with a staff member that was responsible for disinfecting and sterilizing instruments and equipment revealed the solution was CIDEX OPA	E 165	The clinic manager 11/13/2020 retrained staff at AWCR on the Policy and Procedure for Using Cidex opa test strips per the manufacture instruction ensuring correct timing and effective concentration of the solution. The Director of Nursing will observe the staff once a week for 6 week to ensure staff is using the test strips accurately. 11/16/2020 - 12/18/2020 The clinic manager or Director of Nursing will report any findings to the Quality Control Committee	

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E 165	Continued From page 9	E 165		

that was used for disinfecting the suction machine tubing used during abortion procedures. The staff member presented a log of testing for the CIDEX OPA solution that revealed daily testing was completed and review of the October and November 2020 results showed all tests "passed." The staff member was asked to perform a test to check the concentration of the solution. The staff member removed a test strip from the bottle and submerged the indicating pad in the solution for one second, then laid the strip on a towel and immediately announced it passed because it was purple. The staff member failed to wait 90 seconds to read the strip. The surveyor asked the staff member to repeat the test and use a timer and read the results after 90 seconds. Observation revealed when the repeat test was conducted and the strip was read at 90 seconds, the strip turned blue and failed. The staff member stated "I have not been waiting 90 seconds to read the results. I have been reading it immediately after I remove it from the solution."

Interview on 11/12/2020 at 1015 with the Clinic Manager revealed the facility policy and manufacturers' recommendation for testing the high level disinfectant was not followed. Interview revealed the staff member had not been reading and recording the results of the testing strips accurately.

3. Review of the facility's "Policy and Procedure for Transvaginal and Abdominal Ultrasound Probes" revised 03/15/19 revealed, "... Policy: Vaginal ultrasound probe must be cleaned and disinfected after each use. Probe must be disinfected with a high level disinfectant such as Cidex OPA Solution. Procedure: After use remove vaginal probe cover and wipe gel off using a clean dry 4 x 4 gauze. Unplug probe

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E 165	Continued From page 10 from the back of the machine. Place probe in Cidex OPA solution, set timer for 12 minutes and remove probe. Dry the probe with a clean 4 x 4. Place into distilled water for 1 minute. Dry with 4 x 4 gauze and replace into probe holder. ..." Observation during tour on 11/12/2020 at 0945 revealed an ultrasound machine that was used to perform abdominal and vaginal ultrasounds on patients prior to abortion procedures. Interview during tour with a staff member that performed the ultrasounds revealed she cleaned the ultrasound vaginal probe between patients using a Protex wipe. Interview on 11/12/2020 at 1215 with a staff member that performed ultrasounds revealed the staff member had been using the Protex wipes on the ultrasound probes instead of the Cidex OPA Solution since March. Interview on 11/12/2020 at 1240 with the Clinic Manager revealed she was not sure why the staff member was using the Protex wipe to disinfect the ultrasound probe. The Clinic Manager stated "Our policy is correct for cleaning the vaginal probes between patients. They should soak the probe for 12 minutes in CIDEX OPA. They are not doing that. they are using disinfectant spray. I will have to train my staff." Interview revealed the facility policy was not followed for disinfecting the ultrasound probe between patient use.	E 165		
E 166	.0315 Housekeeping 10A-14E .0315 Clinics that are certified by the Division to perform abortions shall meet the standards for sanitation as required by the Division of Public Health, Environmental Health	E 166		

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E 166	Continued From page 11 Section, in the rules and regulations governing the sanitation of hospitals, nursing homes, adult care homes, and other institutions, set forth in 15A NCAC 18A .1300, including subsequent amendments and editions, with special emphasis on the following: (1) the floors, walls, woodwork and windows must be cleaned, and accumulated waste material must be removed at least daily; (2) the premises must be kept free from rodents and insect infestation; (3) bath and toilet facilities must be maintained in a clean and sanitary condition at all times; and (4) linen that comes directly in contact with the patient shall be provided for each individual patient. No such linen shall be interchangeable from one patient to another before being cleaned, sterilized, or laundered. Copies of 15A NCAC 18A .1300 may be obtained at no charge from the Division of Public Health, Environmental Health Section, 1632 Mail Service Center, Raleigh, NC, 27699-1632, or accessed electronically free of charge from the Office of Administrative Hearings at <http://www.ncoah.com>. This Rule is not met as evidenced by: Based on observation and staff interview, facility staff failed to launder heating pad covers between patient use. The findings include: Observation during tour of the recovery room on 11/12/2020 at 1005 revealed six chairs used by patients after procedures were completed. Observation revealed a heating pad with a cover	E 166		

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E 166	Continued From page 12 placed in each of the six chairs. Observation on 11/12/2020 at 1405 revealed three patients sitting in chairs in the recovery room. Observation revealed all three patients were using a heating pad against their bodies. Interview with the registered nurse on 11/12/2020 at 1005 that was present in the recovery room revealed the heating pads were used by the patients during recovery to assist with pain management. The nurse reported that the heating pad covers were removed and cleaned at the end of each day. Interview revealed the heating pad covers were not disinfected or laundered between patient use.	E 166	E 166 House Keeping 11/12/2020 The clinic manager of AWCR trained staff on how to meet standard for sanitation with heating pads. AWCR has extra heating pad covers to change in between patients. 11/13/2020 The Registerd Nurse will change the heating pads cover in between patients or have a staff member change it between patients. The STAFF will wash the heating pad covers after clinic daily. A random visual valdation will be done	

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 _____	11/12/2020

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
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