State of Virginia

STATEMENT OF DEFICIENC ES AND PLAN OF CORRECTION	(X1) PROV DER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULT PLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AF-0020	A. BUILDING _____ B. WING _____	02/21/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
WHOLE WOMAN'S HEALTH OF CHARLOTTESVILLE	**2321 COMMONWEALTH DRIVE CHARLOTTESVILLE, VA 22901**

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFIC ENCIES (EACH DEFIC ENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENT FY NG INFORMATION)	D PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFIC ENCY)	(X5) COMPLETE DATE
T 000	Initial Comments - 4 An unannounced second Licensure Revisit inspection to the revisit inspection conducted 1/3/19, was completed on 2/21/19 by two (2) Medical Facilities Inspectors from the Office of Licensure and Certification, Virginia Department of Health. The unannounced Biennial Licensure inspection was conducted 6/4/18 through 6/5/18 and 6/7/18. The facility was in compliance with the State Board of Health 12 VAC 5-412, Regulations for Abortion Facilities (Rev. 2017). All previous citations were found to have been cleared. No new concerns were identified.	T 000		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

State of Virginia

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	AF-0020	A. BUILDING _____ B. WING _____	01/03/2019

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WHOLE WOMAN'S HEALTH OF CHARLOTTESVILLE	2321 COMMONWEALTH DRIVE CHARLOTTESVILLE, VA 22901

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{T 000}	Initial Comments An unannounced Licensure Revisit Inspection to the Biennial Licensure Inspection which was completed on June 4 through June 5, 2018 and June 7, 2018, was conducted January 3, 2019, by two (2) Medical Facilities Inspectors from the Virginia Department of Health, Office of Licensure and Certification. The facility was not in compliance with 12 VAC 5-412, Regulations for the Licensure of Abortion Facilities (Rev. 2017) in the area of Infection Prevention and for Administration, Storage and Dispensing of Drugs. Corrections are required. Other areas previously cited (Administration, Medical Testing and Laboratory Services, Anesthesia Services, and Health Information Records) were cleared.	{T 000}	The leadership team of Whole Woman's Health of Charlottesville is responsible for the operation of the facility, including compliance with Virginia state regulations. Please see the specific plan of correction for each alleged deficiency under the appropriate tag below. The Clinic Director and Medical Director of Whole Woman's Health of Charlottesville are responsible for ensuring the implementation of this plan of correction.	
{T 195}	12 VAC5-412-220 B Infection Prevention Written infection prevention policies and procedures shall include, but not be limited to: 1. Procedures for screening incoming patients and visitors for acute infectious illnesses and applying appropriate measures to prevent transmission of community-acquired infection within the facility; 2. Training of all personnel in proper infection prevention techniques; 3. Correct hand-washing technique, including indications for use of soap and water and use of alcohol-based hand rubs;	{T 195}	RECEIVED JAN 28 2019 VDH/OLC	

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE

Clinic Director 1/23/2019

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
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(T 195)	Continued From Page 1 4. Use of standard precautions; 5. Compliance with blood-borne pathogen requirements of the U.S. Occupational Safety & Health Administration; 6. Use of personal protective equipment; 7. Use of safe injection practices; 8. Plans for annual retraining of all personnel in infection prevention methods; 9. Procedures for monitoring staff adherence to recommended infection prevention practices; and 10. Procedures for documenting annual retraining of all staff in recommended infection prevention practices. This RULE: is not met as evidenced by: Based on interview and document review, it was determined facility staff failed to ensure that single use vials were used one time for one patient only. Findings included: On January 3, 2019 at 2:30 p.m., an interview was conducted with Staff Member (SM) #2, related to carrying IV (intravenous) medications for sedation pre-drawn in a syringe in a fanny pack around his/her waist. SM #2 stated "I look at the schedule for the day, and draw up what I expect to use, place it in the fanny pack, which I keep on me the rest of the day. I use medications from the fanny pack as needed for sedation." SM #2 also stated, "Medications not used are discarded at the end of the day, and that is recorded in the log". The surveyor inspected the pre-drawn syringes,	(T 195)	12 VAC5-412-220 B Infection Prevention The Clinic Director is responsible to ensure that staff follow Whole Woman's Health written policy and procedures. The Medical Director will complete a peer led training with a fellow Whole Woman's Health Medical Director on/before February 8, 2018 to review Whole Woman's Health Procedure for Handling Controlled Medications. Additionally, the Clinic Director will also complete an in-service conducted by Director of Clinical Services to review Procedure for Handling Controlled Medications. In order to monitor compliance, an internal clinic audit will be conducted during the clinic's next quarterly quality assurance survey. The Clinic Director will continue to monitor Controlled Medication counts daily. Completion Date: February 8, 2019	

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{T 195}	Continued From Page 2 and noted that they were labeled with medication name, strength, lot number; however, did not include the date the medication was withdrawn from the vial, or the initials of the person drawing up the medication. SM #2 stated, "Some patients do not need the full dose of the medication, so I will draw up half a dose for them. I use the other half for another patient". The surveyor followed up, and asked SM #2 if he/she used medication from a single dose vial for more than one patient, and he/she stated, "Yes, sometimes, the patient doesn't need but half a dose, so I use the other half for another patient". The surveyor reviewed the facility's policy entitled "Procedure for Handling Controlled Medications" with SM #2, specifically the section entitled "Drawing up IV Sedation", which stated in part the following: "5 ...Single-dose vials should be for single use only and used for one patient. SDVs [sic] are not to be used as MDVs [sic] under any circumstances. 6. Unless otherwise ordered by the physician, each patient will receive for sedation the medications ordered on the standing orders Nalbuphine 10 mg, Fentanyl 50 mcg-100 mcg Midazolam 1-2.5 mg ...8. Each syringe drawn up will be labeled with the medication quantities and strengths, date, and staff initials. SM #2 stated, "I was not aware that I couldn't use the medication from the vial for more than one patient. I was trying to keep from wasting the medication". According to facility documentation, SM #2 had attended an inservice on 7/9/18 regarding the facility policy and procedure for this practice evidenced by the staff members signature on the sign-in sheet.	{T 195}		

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{T 195}	Continued From Page 3 Concerns were discussed with SM #1, the Clinic Director, on 1/3/19 at 3:45 p.m., and with SM #2, the Medical Director, as noted above.	{T 195}		
{T 315}	12 VAC5-412-260 C Administration, Storage, Dispensing of Drugs Drugs maintained in the abortion facility for daily administration shall not be expired and shall be properly stored in enclosures of sufficient size with restricted access to authorized personnel only. Drugs shall be maintained at appropriate temperatures in accordance with definitions in 18 VAC 110-20-10. This RULE: is not met as evidenced by: Based on observation and staff interview, it was determined facility staff failed to ensure that medication syringes were labeled per the facility's policy and medication was stored per the manufacturer's recommendations. Findings included: On 1/3/19 at 2:30 p.m., an interview was conducted with Staff Member (SM) #2, the Medical Director, related to carrying IV (intravenous) medications for sedation pre drawn up in a syringe in a fanny pack around his/her waist. SM #2 stated "I look at the schedule for the day, and draw up what I expect to use, place it in the fanny pack, which I keep on me the rest of the day. I use medications from the fanny pack as needed for sedation". SM #2 also stated, "Medications not used are discarded at the end of the day, and that is recorded in the log." The surveyor inspected the pre-drawn syringes, and noted that they were labeled with medication name, strength, lot number; however, did not	{T 315}	12 VAC5-412-260 C Administration, Storage, Dispensing of Drugs The Clinic Director is responsible to ensure that staff follow Whole Woman's Health written policy and procedures. In order to ensure we continue to comply with manufacture recommendations, all Controlled Medications will remain in designated controlled secured area until needed for use. The Medical Director will complete a peer led training with a fellow Whole Woman's Health Medical Director on/before February 8, 2018 to review Whole Woman's Health Procedure for Handling Controlled Medications. Additionally, the Clinic Director will complete an in-service conducted by Director of Clinical Services to review Procedure for Handling Controlled Medications. The Clinic Director will continue to inspect all controlled medications labels for accuracy and document on the Controlled Medications Log on a daily basis. Completion Date: February 8, 2019	

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{T 315}	Continued From Page 4 include the date the medication was withdrawn from the vial, or the initials of the person drawing up the medication. The facility's policy entitled "Procedure for Handling Controlled Medications", which stated in part the following: " ...8. Each syringe drawn up will be labeled with the medication quantities and strengths, date, and staff initials ..." The surveyor reviewed the policy with SM #2, who stated, "I did not know I was to include the date/initials on the label". The surveyor reviewed the FDA prescribing information for Fentanyl Citrate Injection USP, and noted the following information , in part under the heading "Storage" included the following information: "Store at 20 degrees to 25 degrees C (68 degrees to 77 degrees F) [see USP Controlled Room Temperature}. PROTECT FROM LIGHT.". According to facility documentation, SM #2 had attended an inservice on 7/9/18 regarding the facility policy and procedure for this practice evidenced by the staff members signature on the sign-in sheet. Concerns were discussed on 1/3/19 at 2:20 p.m. with SM's #2, Medical Director, and #3, the Medical Assistant, at the time of the observation, and with SM #1, the Clinic Director, on 1/3/19 at 3:45 p.m.	{T 315}		