

Virginia Women's Wellness
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Fax Transmittal Cover Sheet

Date: 4/11/13 Time: 12pm

Please deliver the following to:

Name: Kaylgen Creegan-Tedeschi
Company: VDH
Fax #: 804 367 2102

From: Michelle Nelson
Company: Virginia Women's Wellness
Fax #: 757 306 4710

Pages to Follow: 6

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APR 11 2013
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FORM APPROV

State of Virginia

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: FTAF-008	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 12/05/2012
NAME OF PROVIDER OR SUPPLIER VIRGINIA WOMEN'S WELLNESS		STREET ADDRESS, CITY, STATE, ZIP CODE 224 GROVELAND ROAD VIRGINIA BEACH, VA 23452	

(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
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T 000 12 VAC 5- 412 Initial comments

An unannounced Revisit to the initial Licensure survey conducted May 08, 2012 through May 09, 2012 was conducted at the above referenced facility December 5, 2012 by three (3) Medical Facilities Inspectors from the Virginia Department of Health's, Office of Licensure and Certification.

The following is a citation from the Initial survey, which was not corrected and therefore a repeat citation:
 12 VAC 5-412-260 - Administration, storage and dispensing of drugs
 The following citation is a new finding:
 12 VAC 5-412-210 C - Patient Rights
 The agency was not in compliance with 12 VAC-412 Regulations for the Licensure of Abortion Clinics. (Effective 12/29/2011)

T 000

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See Attachment #1

T 140 12 VAC 5-412-210 B Patients' rights

B. The facility shall establish and maintain complaint handling procedures which specify the:
 1. System for logging receipt, investigation and resolution of complaints; and
 2. Format of the written record of the findings of each complaint investigated.


This RULE: is not met as evidenced by:
 Based on observation and interview the facility failed to have a system for logging receipt of, investigation of and resolution of patient complaints.

The findings include:
 On 12/5/12 at approximately 4:00 P.M. the entrance conference was discussed with the administrator of the facility. It was explained the items we would need to review one of which was

T 140

A complaint log has been instituted. This log will be maintained by the Administrator

1313

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE 	TITLE ZRY611	(X6) DATE 2-2-13
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State of Virginia

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FORM APPROVE

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T 140	Continued From Page 1 the complaint log. At approximately 8 P.M. the administrator was reminded we would need the complaint log. The administrator stated, "We don't have a log. When we get a complaint we complete a progress note and file it in the patient's medical record." The administrator was asked if she could pull out the patients who registered a complaint and she stated, "No". The administrator could not provide information on who had filed a complaint; her investigation of the complaint or how the complaint was resolved or the findings of each complaint.	T 140	See attachment 2 & 3	
T 265	12 VAC 5-412-260 A Administration, storage and dispensing of dru A: Controlled substances, as defined in 54.1-3401 of the Drug Control Act of the Code of Virginia, shall be stored, administered and dispensed in accordance with federal and state laws. The dispensing of drugs, excluding manufacturers' samples, shall be in accordance with Chapter 33 of Title 54.1 of the Code of Virginia, Regulations Governing the Practice of Pharmacy (15 VAC 110-30). This RULE: is not met as evidenced by: Based on observation and interview it was determined the facility failed to store controlled substance(s) (medications) and other medications in a safe manner. Specifically, medications were drawn up in syringes and stored in a locked box for future use, those medications included Versed, Fentanyl, Lidocaine and Vasopressin. The facility's only procedure room also had a syringe with Romazicon in it that was attached to a butterfly (type of needle) dated 11/1/12 in a drawer.	T 265	The Administrator will continue to monitor the proper disposal of all medications. All single dose medications will be disposed of according to manufacturer suggested time of at the end of the procedure whichever comes first.	2-8-13

State of Virginia

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 FORM APPROV

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: FTAF-008	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____ B. WING _____	(X3) DATE SURVEY COMPLETED 12/05/2012
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T 265	Continued From Page 2	T 265	<p>An multi-dose vial will be disposed of after 28 days of opening</p> <p style="text-align: right;">2-5-13</p>	
	<p>The findings were:</p> <p>A tour of the facility's recovery room took place on December 5, 2012 beginning at 5:30 PM. The recovery room had a large locked metal cabinet that is used to store the facility's medications. The cabinet also houses another smaller locked box that is used to store vials of Versed and Fentanyl, which are medications used to sedate patients during their procedures. The locked box also had several plastic Ziploc bags with labeled syringes in them which contained the following:</p> <ul style="list-style-type: none"> 5 syringes labeled as, Vasopressin 4 units, expiration date 11/13, drawn up on 11/30/12 and initialed by the person who drew up the medication; 3 syringes labeled Lidocaine 1%, expiration date 11/14, drawn up 11/28/12 and initialed; 3 syringes labeled as Versed 2 mg, expiration date 4/14, drawn up 11/30/12 and initialed, and lastly 3 syringes labeled as Fentanyl 100 mcg, expiration date 4/15, drawn up 11/30/12 and also initialed. <p>The Administrator who was present during the tour was asked who prepared the medications in syringes. The Administrator stated she drew up and labeled all the medications and since several patients didn't come in for their procedures last week the syringes were saved for use this week.</p> <p>The facility's only procedure room was observed immediately after the recovery room by two (2) inspectors. In one of the drawers was a syringe attached to a butterfly (type of needle) with a clear liquid in it. The syringe was labeled, Romazicon 0.2 mg 11/1/12. Romazicon is a medication that may be used in emergency situations to reverse the effects of certain other medications.</p>			

W. Hachment #2

POLICY AND PROCEDURES MANUAL
Virginia facilities

- 5. Continuous electrocardiograph;
- 6. Devices for measuring blood pressure, heart rate and respiratory rate;
- 7. Defibrillator; and
- 8. Accepted methods of identifying and preventing the interchangeability of gases are not necessary because gases are not utilized to induce anesthesia in the Virginia Facilities.
- F. General Anesthesia, deep sedation, or a major conductive block shall not be administered in the facility.
- G. General Anesthesia, deep sedation, or a major conductive block shall not be administered in the facility.
- H. Discharge from anesthesia care is the responsibility of the health care practitioner providing the anesthesia care and shall occur only when the patient has met specific physician-defined criteria acceptable to the treating physician.
- I. Elective general anesthesia shall not be used.

XII. Administration, storage and dispensing of drugs.

- A. In the Virginia facilities, all controlled substances, as defined in § 54.1-3401 of the Drug Control Act of the Code of Virginia, shall be stored, administered and dispensed in accordance with federal and state laws. The dispensing of drugs, excluding manufacturers' samples, shall be in accordance with Chapter 33 of Title 54.1 of the Code of Virginia, Regulations Governing the Practice of Pharmacy (18VAC110-20), and Regulations for Practitioners of the Healing Arts to Sell Controlled Substances (18VAC110-30).
- B. Drugs, as defined in § 54.1-3401 of the Drug Control Act of the Code of Virginia, whose intended use is to induce a termination of pregnancy shall only be prescribed, dispensed or administered in the Virginia facilities by a Virginia licensed physician.
- C. In the Virginia facilities, all drugs maintained in the 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. All medications used for multiple Patients will be drawn from multi-use bottles. If a bottle or vial is labeled for single use, it will be used for only one Patient and any unused portions will be discarded as per the manufacturers suggested time or at the end of the

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POLICY AND PROCEDURES MANUAL
Virginia facilities

procedure or case, whichever comes first. When using multi-dose vials or bottles, the calculation of remaining medication left in the vial or bottle will be made by subtracting the amount drawn from the starting volume of unopened vial or bottle. Drugs shall be maintained at appropriate temperatures in accordance with definitions in 18VAC110-20-10. Multi dose vials shall be labeled with the date of opening or needle puncture and discarded after 28 days.

D. The mixing, diluting or reconstituting of drugs in the Virginia facilities for administration shall be in accordance with regulations of the Board of Medicine (18VAC85-20-400 et seq.). Mixing, diluting or reconstituting of drugs will be performed by a Physician, Registered Nurse or by a trained HCTM with a second check being performed by a Registered Nurse or Physician. This mixing, diluting or reconstituting shall take place on a designated sanitary work space.

E. Records of all drugs in Schedules I-V received, sold, administered, dispensed or otherwise disposed of shall be maintained in accordance with federal and state laws, to include the inventory and reporting requirements of a theft or loss of drugs found in § 54.1-3404 of the Drug Control Act of the Code of Virginia.

XIII. Equipment and Supplies.

The facility shall maintain medical equipment and supplies appropriate and adequate to care for patients based on the level, scope and intensity of services provided, including but not limited to:

1. A bed or recliner suitable for recovery;
2. Oxygen with flow meters and masks or equivalent;
3. Mechanical suction;
4. Resuscitation equipment to include, as a minimum, resuscitation bags and oral airways;
5. Emergency medications, intravenous fluids, and related supplies and equipment;
6. Sterile suturing equipment and supplies;
7. Adjustable examination light;
8. Containers for soiled linen and waste materials with covers; and
9. Refrigerator.

XIV. Emergency Equipment and Supplies

Revised: May 7, 2012